DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1120

[Docket No. FDA–2013–N–0227]

RIN 0910–AH91

Requirements for Tobacco Product Manufacturing Practice

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is proposing to establish tobacco product manufacturing practice requirements for manufacturers of finished and bulk tobacco products. This proposed rule, if finalized, would set forth the requirements with which finished and bulk tobacco product manufacturers must comply in the manufacture, preproduction design validation, packing, and storage of finished and bulk tobacco products, to assure that the public health is protected and that tobacco products are in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Either electronic or written comments on the proposed rule must be submitted by September 6, 2023. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 (PRA) by April 10, 2023 (see section ''VI. Paperwork Reduction Act of 1995'' of this document). See section V of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 6, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0227 for ''Requirements for Tobacco Product Manufacturing Practice.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

Submit comments on information collection issues to the Office of Management and Budget (OMB) in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title, ''Requirements for Tobacco Product Manufacturing Practice.''

FOR FURTHER INFORMATION CONTACT: Matthew Brenner, Office of Regulations, or Rear Admiral Emil Wang, Office of Compliance and Enforcement, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 877–287–1373, *AskCTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

This proposed regulation—proposed part 1120 (21 CFR part 1120)—sets forth requirements for tobacco product manufacturing practice (TPMP) and provides a framework for manufacturers of finished or bulk tobacco products to follow that would include: (1) establishing tobacco product design and development controls to prevent or minimize certain risks; (2) ensuring that finished and bulk tobacco products are manufactured in conformance with established specifications; (3) minimizing the likelihood of the manufacture and distribution of nonconforming tobacco products; (4) requiring investigation and identification of nonconforming products, including those that have been distributed in order to institute appropriate corrective actions, such as conducting a recall as needed; (5) requiring manufacturers to take appropriate measures to prevent contamination of tobacco products; and (6) establishing traceability to account for all components or parts, ingredients, additives, and materials, as well as each batch of finished or bulk tobacco product, to aid in investigations of nonconforming tobacco products. Therefore, this proposed regulation would establish requirements for the control of tobacco product manufacturing activities and the treatment of contaminated or otherwise nonconforming tobacco products, including the investigation, evaluation, and corrective and preventive actions (CAPA) necessary to protect the public health.

These provisions are generally similar to many existing industry practices and are drafted to provide tobacco product manufacturers with flexibility in the manner they comply with the proposed requirements while assuring the protection of public health. This proposal is intended to ensure that tobacco products conform to established specifications and to help prevent the manufacture and distribution of contaminated or otherwise nonconforming products, thereby assuring that the public health is protected and that tobacco products comply with the requirements in chapter IX of the FD&C Act.

B. Summary of the Major Provisions of the Proposed Rule

The proposed regulation is divided into 10 subparts. This proposed regulation is intended to provide a framework that requires all finished and bulk tobacco product manufacturers subject to the rule (including specification developers, contract manufacturers, and repackagers/relabelers) to establish and maintain procedures for various aspects of the manufacturing, preproduction design validation, packing, and storage processes, while allowing flexibility to establish procedures that are unique to the manufacturer's facilities and activities, and appropriate for a given tobacco product. The proposed requirements are written in general terms to allow manufacturers to establish procedures appropriate for their specific products and operations. The extent of the procedures necessary to meet the regulation requirements may vary with the size and complexity of the design and manufacturing operations. Tobacco product manufacturers who have a complex manufacturing process would likely need to establish more detailed procedures to comply with the rule, while tobacco product manufacturers who have a less complex manufacturing process may need less extensive procedures.

1. Subpart A—General Provisions

Subpart A contains two proposed sections: scope and definitions. The scope section describes the purpose of this proposed regulation and the products and activities to which it applies. This proposed regulation would apply to manufacturers (foreign and domestic) of finished and bulk tobacco products. The definitions section defines the terminology applicable to the proposed requirements laid out in this notice of proposed rulemaking (NPRM). The proposed rule would define ''tobacco product manufacturer'' to mean ''any person(s), including a repacker or relabeler, who: manufactures, fabricates, assembles, processes, or labels a tobacco product, or imports a finished or bulk tobacco product for sale or distribution in the United States. The manufacture of a tobacco product includes establishing the specifications of or the requirements for a tobacco product.''

2. Subpart B—Management System Requirements

Subpart B contains three proposed sections: organization and personnel; tobacco product complaints; and CAPA. The organization and personnel section would require finished and bulk tobacco product manufacturers to establish and maintain an organizational structure; have sufficient personnel; designate personnel with appropriate responsibility, including management with executive responsibility; train personnel; and maintain certain records of these activities. The tobacco product complaints section would require finished and bulk tobacco product manufacturers to establish and maintain complaint handling procedures for the receipt, evaluation, investigation, and documentation of all complaints. The CAPA section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for implementing CAPA and to maintain records of the activities required under this subpart.

3. Subpart C—Buildings, Facilities, and Equipment

Subpart C contains four proposed sections: personnel practices; buildings, facilities, and grounds; equipment; and environmental controls. The personnel practices section would require finished and bulk tobacco product manufacturers to establish and maintain procedures related to personnel practices to reduce the risk of contamination with filth biological materials, chemical hazards, or other deleterious substances, including rocks or metal shavings. The buildings, facilities, and grounds section would require such manufacturers to ensure that buildings and facilities are of suitable construction, design, and location to facilitate cleaning and sanitation, maintenance, and proper operations. In addition, manufacturers would be required to ensure that facility grounds are maintained in a condition to prevent contamination and to control the water used in the manufacturing process. The proposed requirements would also require such manufacturers to establish and maintain procedures for proper cleaning and sanitation and animal and pest control, and maintain records of these activities to demonstrate compliance with this proposed rule. The equipment section would provide requirements for design, construction, and maintenance of equipment as well as certain additional requirements (*e.g.,* calibration) for testing, monitoring, and measuring equipment used in the tobacco product manufacturing processes and for major

equipment and processing line identification. Lastly, the environmental controls section would require that environmental control systems be maintained and monitored to verify that environmental controls, including necessary equipment, are adequate and functioning properly. This subpart would also require manufacturers to maintain certain records to demonstrate compliance with this proposed rule.

4. Subpart D—Design and Development Controls

Subpart D contains two proposed sections: design and development activities and master manufacturing record (MMR). The design and development activities section would require finished and bulk tobacco product manufacturers to establish and maintain procedures to control the design and development of tobacco products, including the control of risks associated with the product, production process, packing, and storage, as well as procedures for design verification and validation. These requirements would include developing a process for identification, analysis, and evaluation of known and reasonably foreseeable risks associated with the tobacco product and its packaging as well as taking appropriate measures to reduce or eliminate risks using recognized tools for risk management. Manufacturers would also be required to maintain records of all activities required under this section.

The proposed MMR section would require manufacturers to establish and maintain an MMR for each finished and bulk tobacco product they manufacture for distribution. The proposed section would require each MMR to include tobacco product specifications, the manufacturing methods and production process procedures, and all packaging, labeling, and labels approved for use with the product. Additionally, the proposed MMR section includes requirements for the review and approval of the MMR, including any changes after initial approval.

5. Subpart E—Process Controls

Subpart E contains nine proposed sections: purchasing controls; acceptance activities; production processes and controls; laboratory controls; production record; sampling; nonconforming tobacco product; returned tobacco product; and reprocessing and rework. The purchasing controls section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for ensuring that purchased or otherwise received products and services related to the manufacture of a finished or bulk tobacco product are from qualified suppliers and conform to established specifications. The acceptance activities section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for incoming and for in-process and/or final acceptance activities, including acceptance criteria, to ensure that products meet established specifications. The production processes and controls section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for production processes, including process specifications and process controls, process validation, and manual methods and manufacturing material. The laboratory controls section would require finished and bulk tobacco product manufacturers to demonstrate laboratory competency to perform laboratory activities associated with the manufacture of finished and bulk tobacco products and to establish and maintain laboratory control procedures for any laboratory activities conducted under proposed part 1120. The production record section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for ensuring that a production record is prepared for each batch of finished or bulk product to demonstrate conformity with the requirements established under the MMR. The sampling section would require finished and bulk tobacco product manufacturers to establish and maintain an adequate sampling plan that uses representative samples based on a valid scientific rationale for any sampling performed under proposed part 1120. The nonconforming tobacco product section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for control and disposition of nonconforming tobacco product, including specific requirements for identification and segregation, investigation, and disposition and followup. The proposed returned tobacco product section would require procedures for the control and disposition of returned tobacco product, including specific requirements for identification, segregation, evaluation, and disposition. The reprocessing and rework section would require procedures for reprocessing and reworking tobacco products, including specific requirements for evaluation of the tobacco product to determine that it is appropriate for reprocessing or rework, authorization of the reprocessing or rework, and production processes, including process controls, to ensure that reprocessed and reworked tobacco product conforms to MMR specifications. Manufacturers also would be required to maintain records of all activities required under this subpart.

6. Subpart F—Packaging and Labeling Controls

Subpart F contains four proposed sections: packaging and labeling controls; repackaging and relabeling; manufacturing code; and warning plans. The packaging and labeling controls section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for ensuring that the correct packaging and labeling is used to prevent mixups and that all packaging and labeling is approved for use by the manufacturer and complies with all requirements of the MMR as well as other applicable requirements of the FD&C Act, the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA), and the Federal Cigarette Labeling and Advertising Act (FCLAA) and their implementing regulations. The section would also require the packaging and labeling control procedures to ensure that labels are indelibly printed on or permanently affixed to finished and bulk tobacco product packages; and that the packaging, labeling, storage, and shipping cases do not contaminate or otherwise render the tobacco product adulterated or misbranded. The repackaging and relabeling requirements would require finished tobacco product manufacturers to establish and maintain procedures for repackaging and relabeling operations. The manufacturing code section would require finished and bulk tobacco product manufacturers to apply a manufacturing code that contains the manufacturing date and batch number to the packaging or label of all finished and bulk tobacco products. The warning plans section would require manufacturers of finished tobacco products that are required to comply with a warning plan for tobacco product packaging, to establish and maintain procedures for implementing the requirements of such plan. Manufacturers would also be required to maintain records of all activities required under this subpart.

7. Subpart G—Handling, Storage and Distribution

Subpart G contains two proposed sections: handling and storage and distribution. The handling and storage

section would require finished and bulk tobacco product manufactures to establish and maintain procedures to ensure that tobacco products are handled and stored under appropriate conditions to prevent nonconforming products as well as mixups, deterioration, contamination, adulteration, and misbranding of tobacco products. The distribution section would require finished and bulk tobacco product manufacturers to establish and maintain procedures to ensure that tobacco products are distributed to the initial consignee under appropriate conditions and that only those finished and bulk tobacco products approved for release are distributed. The distribution section would also require finished and bulk tobacco product manufacturers to maintain distribution records and a list of direct accounts.

8. Subpart H—Recordkeeping and Document Controls

The recordkeeping and document control requirements section establishes certain requirements for documents and records required by this rule. This section would require that all documents and records be maintained at the manufacturing establishment or another location that is readily accessible to responsible individuals of the manufacturer and to FDA and that they be written in English or an English translation be made available upon request. Documents and records required under this section that are associated with a batch of finished or bulk tobacco product must be retained for a period of not less than 4 years from the date of distribution of the batch or until the product reaches its expiration date if one exists, whichever is later. Documents and records required under this section that are not associated with a batch of finished or bulk tobacco product must be retained for a period of not less than 4 years from the date they were last in effect. FDA is soliciting comment on whether the timeframe for manufacturers to retain the documents and records under this section is sufficient for FDA's inspections and compliance activities or if it should be extended for an additional 1 or 2 years after the tobacco product reaches its expiration date if one exists. They also must be made readily accessible to FDA during the retention period for inspection and photocopying or other means of reproduction. This section also would require finished and bulk tobacco product manufacturers to ensure that all records are attributable to a responsible individual, legible, contemporaneously recorded, original, and accurate and to establish and maintain procedures for the approval and distribution of documents and for making changes to documents.

9. Subpart I—Small Tobacco Product Manufacturers

Subpart I explains that small tobacco product manufacturers of finished and bulk tobacco products would not have to comply with the TPMP regulation until 4 years after the effective date of the final rule.

10. Subpart J—Exemptions and Variances

Subpart J consists of five sections, and it sets forth the proposed procedures and requirements for petitioning for an exemption or variance from a TPMP requirement. Pursuant to section 906(e)(2)(B) of the FD&C Act (21 U.S.C. 387f), this subpart also would establish that a petition for an exemption or variance may be referred to the Tobacco Products Scientific Advisory Committee (TPSAC) and describe how FDA would make a determination on a petition for an exemption or variance. Finally, pursuant to section 906(e)(2)(E) of the FD&C Act, this subpart would provide that the petitioner has an opportunity for a hearing after the issuance of an order denying or approving a petition for an exemption or variance.

C. Legal Authority

Section 906(e) of the FD&C Act (21 U.S.C. 387f) states that in applying manufacturing restrictions to tobacco, FDA shall prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice (cGMP) or hazard analysis and critical control point (HACCP) methodology as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with chapter IX of the FD&C Act (21 U.S.C. 387 through 387u). The proposed requirements flow from this authority and serve these goals of protecting public health and assuring compliance with chapter IX of the FD&C Act.

The proposed rule is also being issued based upon: FDA's authorities related to adulterated and misbranded tobacco products under sections 902 and 903 (21 U.S.C. 387c); FDA's authorities related to records and reports under section 909 (21 U.S.C. 387i); and FDA's rulemaking and inspection authorities under sections 701 (21 U.S.C. 371), 704 (21 U.S.C. 374), and 905(g) (21 U.S.C. 387e(g)) of the FD&C Act.

D. Costs and Benefits

The proposed rule, if finalized, would establish requirements for manufacturers of finished and bulk tobacco products on the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation, packing, and storage of tobacco products. The TPMP requirements described in the proposed rule are expected to ensure that tobacco product manufacturers control the design and specifications of finished and bulk tobacco products, providing a level of assurance of conformity in the production of tobacco products to established and required specifications that does not occur in the existing market for tobacco products, to prevent the adulteration and misbranding of finished and bulk tobacco products, and establish controls for traceability purposes.

Estimated quantified benefits of the proposed rule arise from the value of reduced adverse events due to nonconforming finished and bulk tobacco products and from the reduction of costs associated with reduced product recalls and market withdrawals. We estimate the mean present value of benefits annualized over ten years using a seven and three percent discount rate to be $27.2 million and $29.9 million.

There are other potential benefits associated with the proposed rule which we have not quantified. First, the proposed recordkeeping provisions would support FDA's regulatory compliance activities and help FDA implement and enforce other provisions of the FD&C Act which will likely generate government cost savings. Second, the proposed rule, if finalized, may further reduce losses to health and property for users and nonusers associated with nonconforming tobacco products, beyond those estimated in the quantified benefits. Third, the proposed rule's risk assessment, CAPA, tobacco product complaints, and related provisions will facilitate investigation and identification of causes and root causes of consumer complaints and other reports of adverse events. Other benefits include avoided spillover costs to capital markets.[1]

[1] Estimated quantified benefits of avoided recalls include reduced external costs in the supply chain of the recalled or withdrawn products (or they exclude reduced recall costs to manufacturers). Estimated external costs of conducting a recall or market withdrawal include lost sales to retailers

Continued

Initial and recurring costs from this proposed rule arise from conducting tasks associated with establishing and maintaining procedures for various aspects of the manufacturing, preproduction design validation, packing and storage processes. We estimate the mean present value of costs annualized over ten years using a seven and three percent discount rate to be $27.0 million and $28.2 million.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
AAMI	Advancement of Medical Instrumentation.
ALCOA	Attributable, Legible, Contemporaneously Recorded, Original, and Accurate.
ANSI	American National Standards Institute.
ASTM	American Society for Testing and Materials.
ASQ	American Society for Quality.
CAPA	Corrective and Preventive Actions.
CDC	Centers for Disease Control and Prevention.
cGMP	Current Good Manufacturing Practice.
CoA	Certificate of Analysis.
CORESTA	Cooperation Centre for Scientific Research Relative to Tobacco.
CSTHEA	Comprehensive Smokeless Tobacco Health Education Act.
Deeming Rule	Deeming Tobacco Products To Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements.
EA	Environmental Assessment.
E. coli	*Escherichia coli*.
EIS	Environmental Impact Statement.
ENDS	Electronic Nicotine Delivery Systems.
E.O.	Executive Order.
FCLAA	Federal Cigarette Labeling and Advertising Act.
FCTC	Framework Convention on Tobacco Control.
FDA or Agency	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FR	FEDERAL REGISTER.
HACCP	Hazard Analysis and Critical Control Point.
HHS	Health and Human Services.
HVAC	Heating, Ventilation, and Cooling.
IARC	International Agency for Research on Cancer.
IEC	International Electrotechnical Commission.
ISO	International Organization for Standardization.
MITC	Manufacturer Detected Methyl Isothiocyanate.
MMR	Master Manufacturing Record.
MRTPs	Modified Risk Tobacco Products.
MRTPA	Modified Risk Tobacco Product Application.
NNK	4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone.
NNN	N-nitrosonornicotine.
NPRM	Notice of Proposed Rulemaking.
NTRMs	Nontobacco Related Materials.
OMB	Office of Management and Budget.
OOS	Out-Of-Specification.
SE	Substantial Equivalence.
PMTA	Premarket Tobacco Product Application.
PRA	Paperwork Reduction Act of 1995.
PRIA	Proposed Regulatory Impact Analysis.
QMS	Quality Management System.
QSR	Quality System Regulation.
RYO	Roll-Your-Own.
Tobacco Control Act	Family Smoking Prevention and Tobacco Control Act.
TPMP	Tobacco Product Manufacturing Practice.
TPSAC	Tobacco Products Scientific Advisory Committee.
TSNAs	Tobacco-Specific Nitrosamines.
UPC	Universal Product Code.
USB	Universal Serial Bus.
U.S.C	United States Code.
WHO	World Health Organization.

III. Background

A. Legal Authority

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products (Pub. L. 111–31). Specifically, section 101(b) of the Tobacco Control Act amended the FD&C Act by adding chapter IX, which provides FDA with the authority to regulate tobacco products and imposes certain obligations on tobacco product

and wholesalers, expenses associated with notifying tobacco retailers (for wholesalers) and consumers, removal and storage of inventory costs collection and shipping costs, disposal costs, and legal costs, among others. Estimated quantified benefits do not include avoided spillover costs to capital markets.

manufacturers (including importers), distributors, and retailers.

Section 901(b) of the FD&C Act establishes FDA's immediate authority over cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, smokeless tobacco, and tobacco products containing nicotine that is not made or derived from tobacco,[2] and permits FDA, by regulation, to deem additional tobacco products subject to chapter IX of the FD&C Act. In the **Federal Register** of May 10, 2016 (81 FR 28973), FDA published a final rule entitled ''Deeming Tobacco Products To Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements'' (Deeming Rule) deeming all tobacco products meeting the statutory definition of ''tobacco product,'' except accessories of deemed tobacco products, to be subject to chapter IX of the FD&C Act. FDA intends for this proposed rule to apply to manufacturers of all finished and bulk tobacco products that are subject to chapter IX of the FD&C Act, except finished and bulk accessories of cigarettes, cigarette tobacco, RYO tobacco, smokeless tobacco, and tobacco products containing nicotine that is not made or derived from tobacco.

Section 906(e) of the FD&C Act provides that in applying manufacturing restrictions to tobacco, FDA shall prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to cGMP or HACCP methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with chapter IX of the FD&C Act. The requirements in proposed part 1120, including management system requirements; buildings, facilities, and equipment requirements; design and development controls; process controls; packaging and labeling controls; handling, storage, and distribution requirements; and recordkeeping and document controls, are derived from this authority. Section 902(7) of the FD&C Act provides that a tobacco product shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 906(e)(1) of the FD&C Act or an applicable condition prescribed by an order under section 906(e)(2) of the FD&C Act. As a result, a product will be adulterated if a manufacturer fails to comply with the requirements prescribed in this proposed regulation. Violations relating to section 906(e) of the FD&C Act are subject to regulatory action by FDA, including seizure and injunction.

In addition, section 909 of the FD&C Act authorizes FDA, by regulation, to require manufacturers and importers of tobacco products to establish and maintain records, make reports, and provide information to assure that such tobacco products are not adulterated or misbranded, and to otherwise protect public health. Section 909 thus provides additional legal authority for the proposed rule's recordkeeping, reporting, and related requirements. In addition, under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA has the authority to issue regulations for the efficient enforcement of the FD&C Act. The proposed rule will help assure that tobacco products are not adulterated or misbranded under other provisions of the FD&C Act and will assist in the efficient enforcement of those other provisions. For example, section 902 of the FD&C Act provides that a tobacco product is adulterated in several circumstances including: (1) if a tobacco product consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health; (2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health. (Section 902(1)–(3) of the FD&C Act.) The proposed rule will help ensure that tobacco products are not adulterated in these ways, and that appropriate records, reports, and information will be available to enforce section 902's adulteration provisions. To similar effect, section 903 provides that a tobacco product is misbranded if, for example, its labeling is false or misleading in any particular or if the product does not bear labeling that is required by an applicable tobacco product standard established under section 907 (section 903(a)(1) and (a)(9) of the FD&C Act). The proposed rule's labeling requirements will help prevent tobacco products from being misbranded in violation of section 903.

Further, section 801(a) of the FD&C Act gives FDA authority to refuse admission of tobacco products imported or offered for import into the United States in situations where it appears such products: (1) have been manufactured, processed, or packed under insanitary conditions; (2) are forbidden or restricted in sale in the country in which they were produced or from which they were exported; or (3) are adulterated or misbranded. As noted earlier, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act. The proposed rule will assist in the efficient enforcement of the FD&C Act's import requirements under section 801(a) by requiring manufacturers of finished and bulk tobacco products to implement certain controls over their product manufacturing, preproduction design validation, packing, and storage activities, including recordkeeping, to prevent the import of tobacco products that appear to be adulterated or misbranded.

Finally, the proposed rule will assist in the performance of FDA inspections under section 704 (21 U.S.C. 374) and 905(g) (21 U.S.C. 387e(g)) of the FD&C Act.

B. Rationale for the Proposed Regulation

While all tobacco products have inherent risks to the public health, FDA is proposing TPMP requirements to minimize or prevent product problems, as well as health issues not normally associated with use of a tobacco product. For example, these requirements would help minimize or prevent the manufacture and distribution of tobacco products contaminated with foreign substances (*e.g.,* nontobacco related materials (NTRMs) such as metal, glass, nails, pins, wood, dirt, sand, stones, rocks, fabric, cloth, and plastics) which have been found in finished tobacco products as will be discussed further below. These requirements also would help minimize or prevent the manufacture and distribution of nonconforming electronic nicotine delivery systems (ENDS) e-liquids that contain nicotine concentration levels that vary from the labeled amount and vary from one ENDS product to another within the same brand (Ref. 1, Ref. 178). As explained elsewhere in this document, this potential variability in nicotine concentration, in which an e-liquid product contains significantly higher

[2] *See* Consolidated Appropriations Act, 2022, Public Law 117–103, div. P, tit. I, subtit. A, sec. 111(b) (March 15, 2022).

levels of nicotine than what is stated on the label, could be misleading to consumers concerned about nicotine delivery levels, potentially intensifying or prolonging their addiction and potentially exposing users to increased toxins (Refs. 4 and 5). Tobacco products may introduce preventable harms not normally associated with use of tobacco products due to inadequate design or manufacturing controls; for example, defective solder joints from an ENDS cartomizer (atomizer plus replaceable fluid-filled cartridge) may cause respiratory distress due to metallic particles in the aerosol (Ref. 2). This proposed regulation would help to assure that the public health is protected from these, and other, types of hazards and that tobacco products comply with chapter IX of the FD&C Act.

FDA is proposing a TPMP regulation under section 906(e) of the FD&C Act that employs a Quality Management System (QMS) approach. QMS approaches are well established and have been required (*e.g.,* 21 CFR part 820) or utilized by FDA (*e.g.,* ''FDA Guidance for Industry—Quality Systems Approach to Pharmaceutical CGMP Regulations'') in other product categories. A QMS can protect the public health in several ways. First, a QMS can enable the manufacturer to demonstrate its ability to consistently produce products that meet applicable statutory and regulatory requirements. Second, a QMS can enable a manufacturer to establish and maintain a robust design and development process for its product and to adequately identify and control nonconforming products to prevent their distribution and related potential harm. Finally, if nonconforming products are discovered, a QMS can provide the manufacturer with a recognized framework to effectively investigate and identify the nonconforming products in order to institute appropriate corrective actions such as conducting a recall as needed. If a firm is manufacturing a tobacco product that is contaminated or inconsistent with the specifications identified in an application under which it has received marketing authorization, the tobacco product may be adulterated or misbranded pursuant to section 902 or section 903 of the FD&C Act and subject to regulatory action. Thus, the proposed regulation based on a QMS approach, if finalized, would help assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act.

1. Assuring That the Public Health Is Protected

The proposed regulation would help assure that the public health is protected by, among other things, minimizing the likelihood of the manufacture and distribution of nonconforming tobacco products. A ''nonconforming tobacco product'' is proposed to be defined as any tobacco product that: (1) does not meet a product specification as set by the MMR (see proposed § 1120.44(a)(1)); (2) has packaging, labeling, or labels other than those included in the MMR (see proposed § 1120.44(a)(3)); or (3) is a contaminated tobacco product (proposed § 1120.3). Nonconforming products occur for many different reasons, including inadequate sanitation practices, design issues, failures of or problems with purchasing controls, inadequate process controls, improper facilities or equipment, inadequate personnel training, inadequate manufacturing methods and procedures, the introduction or presence of hazards, or improper handling or storage of the tobacco product. A tobacco product that does not conform to established specifications, has incorrect packaging, labeling, or labels, or is contaminated could increase the product's risk compared to what would normally be associated with use of the product.

Tobacco products with contaminants that could have been prevented with the implementation of this proposed TPMP rule have been identified. For example, consumer complaints of foreign metal material, including sharp metal objects, in a manufacturer's smokeless tobacco (*e.g.,* chewing) products ultimately led the manufacturer to issue a voluntary recall of certain products on January 31, 2017 (Ref. 3). In other instances, smokeless tobacco products have contained rocks or metal shavings as well as other NTRMs (*e.g.,* glass, nails, pins, wood, dirt, sand, fabric, cloth, and plastics) in finished tobacco products. These NTRMs can cause cuts or lacerations to the lips and gums or result in broken teeth. This proposed regulation includes measures that will help avoid such contamination, in addition to provisions for how manufacturers would be required to handle complaints in similar situations, as well as the subsequent investigation, evaluation, and CAPA they would need to take to address such issues.

Consumers have reported additional substances not ordinarily contained in tobacco products such as biological materials (*e.g.,* mold, mildew, hair, fingernails) and chemical hazards (*e.g.,* ammonia, cleaning agents, and kerosene). Caustic cleaning chemicals may cause vomiting, nausea, allergic reactions, dizziness, numbness, or headaches.

Even when nonconforming tobacco products are not contaminated with foreign objects or substances, they may contain higher levels of a constituent than the consumer is expecting, which can have negative health effects not normally associated with the tobacco product. For example, researchers have reported on the variability of nicotine in certain ENDS e-liquids and that the labeling of these products did not accurately reflect the actual nicotine levels. For example, there have been reports of wide variability in e-cigarette manufacturing, including nicotine concentrations in e-liquid, that were inconsistent with the information contained on the product label (Ref. 178). In one study, researchers found that actual nicotine amounts differed from label amounts by more than 20 percent in 9 out of 20 original e-cigarette cartridges tested, and in 3 out of 15 refill cartridges tested (Ref. 1). In a second study, 9 of 21 samples had nicotine levels that deviated from the labeled value by more than 10%, with inconsistencies ranging from −21 percent to +22.1 percent (Ref. 4). Nicotine delivery varies not only across brands, but also within brands (Refs. 178–180). A finished ENDS that contains a nicotine concentration higher than the established specification can be more addictive. Similarly, a cigarette that does not conform to its pH specification can affect the amount of nicotine that is delivered to the user and its rate of absorption that can increase the tobacco product's toxicity and addictiveness (Ref. 6).

Nonconforming products may also occur because of design issues, which can cause the tobacco product to be more harmful. For example, an ENDS product, as designed, may have a design feature that contributes to an increased risk of fire and/or explosion. The ENDS product, during use or foreseeable misuse, can expose consumers to increased harm if the product catches fire or explodes resulting in serious burns that would not be expected from use of the product (*e.g.,* Ref. 7).

Given the dangers associated with contaminated and otherwise nonconforming tobacco products, FDA is proposing this regulation to help assure that the public health is protected by requiring that finished and bulk tobacco product manufacturers establish and maintain certain controls to prevent the manufacture and distribution of nonconforming products

that may have an adverse effect on public health.

2. Ensuring Compliance With Chapter IX of the FD&C Act

The proposed regulation would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act pursuant to section 906(e) of the FD&C Act. In particular, by requiring controls over the manufacturing process, the proposed regulation would help assure that tobacco products are manufactured in accordance with the specifications provided in their applications authorized by FDA. Specifications generally are included in four types of applications:

- Substantial equivalence (SE) report—To request marketing authorization for a new tobacco product, manufacturers may submit a report pursuant to section 905(j) of the FD&C Act (21 U.S.C. 387e) to demonstrate that the new tobacco product has the same characteristics as a predicate tobacco product, or has different characteristics than the predicate tobacco product but the information submitted demonstrates that it is not appropriate to regulate the product under section 910 because the product does not raise different questions of public health.
- Exemption from SE—To request marketing authorization for a new tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, manufacturers may request an exemption from demonstrating SE under certain circumstances (see 21 CFR 1107.1 and section 905(j) of the FD&C Act).
- Premarket tobacco product application (PMTA)—To request marketing authorization for a new tobacco product, manufacturers may submit a PMTA, which must include, among other things, a full statement of the components, ingredients, additives, and properties of the product as well as a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of the product. This pathway requires the applicant to demonstrate that marketing the new tobacco product is appropriate for the protection of public health pursuant to section 910 of the FD&C Act.
- Modified risk tobacco product application (MRTPA)—To request that a product be sold or distributed for use to reduce harm or the risk of tobacco-related diseases associated with commercially marketed tobacco products, manufacturers may submit an MRTPA, which must include, among other things, a description of the product and the formulation of the product. Applicants must demonstrate that, among other things, the product will or is expected to benefit the health of the population as a whole.

If a firm is manufacturing a tobacco product that is inconsistent with the specifications identified in the application under which it has received marketing authorization, the tobacco product may be adulterated or misbranded pursuant to section 902 or section 903 of the FD&C Act and subject to regulatory action. Such a product could have negative effects on public health. For example, a cigarette that does not meet its specifications for ventilation such that ventilation is reduced can pose public health risk through the resulting higher delivery of harmful and potentially harmful constituents (HPHCs) including nicotine (Refs. 8–9, 106, 173, and 183). FDA believes that the proposed TPMP rule (if finalized) would help ensure that tobacco products conform to the specifications in their authorized marketing applications and do not provide a more addictive or toxic product to consumers.

Pursuant to section 910(a)(1) of the FD&C Act, tobacco products that were commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007 (''pre-existing products''), are not considered ''new tobacco products'' and thus are not subject to the premarket requirements of the FD&C Act. These products are subject to other provisions of the FD&C Act, including proposed TPMP requirements. The proposed rule would help manufacturers ensure that pre-existing tobacco products are manufactured to their original specifications, and thus do not undergo any modification that would render them ''new'' and in violation of the requirements of chapter IX of the FD&C Act because they lack proper marketing authorization. It would also help FDA identify and determine if any changes to established specifications or manufacturing methods and procedures result in a modification that would render the tobacco product ''new.''

Manufacturers must also ensure that their tobacco products are in compliance with tobacco product standards under section 907 of the FD&C Act. Tobacco product standards may reduce the death and disease caused by tobacco use, encourage cessation, decrease initiation, or reduce the harms not normally associated with tobacco use, such as nicotine poisoning. The proposed requirements would help a finished or bulk tobacco product manufacturer to ensure that, and FDA to review whether, the tobacco products conform to applicable tobacco product standards.

In addition to helping assure that tobacco products are manufactured in accordance with the specifications provided in their marketing applications authorized by FDA and that products are manufactured in accordance with applicable product standards, the proposed TPMP rule would help tobacco product manufacturers assure compliance with other requirements in chapter IX of the FD&C Act. For example, tobacco product manufacturers must submit a listing of ingredients, additives, and harmful and potentially harmful constituents to FDA under section 904 and applicable regulations under section 915 of the FD&C Act. The proposed TPMP recordkeeping requirements, including the MMR and production record requirements, could help FDA verify that the ingredients of these products are consistent with the listing of ingredients reported to FDA under section 904(a)(1) of the FD&C Act.

Similarly, under section 905(i) of the FD&C Act, copies of all labeling, and section 910(b)(1)(F) of the FD&C Act, specimens of labeling, must be submitted by tobacco product manufacturers to FDA. This helps the Agency determine if a manufacturer has included unauthorized modified risk claims on product labels or labeling or if product labeling is false or misleading or otherwise renders the product misbranded under section 903 of the FD&C Act. The recordkeeping requirements in the proposed regulation related to packaging and labeling would help the Agency make similar assessments, as well as identify variations between the submitted labeling and actual packaging and labeling.

Finally, the proposed contamination and risk management controls would help prevent products from becoming contaminated. Finished or bulk tobacco products that contain substances such as physical, chemical, and/or biological hazards may be adulterated under sections 902(1) to (3) of the FD&C Act. The proposed requirements for facilities and controls covering the manufacture, packing, and storage of tobacco products would help minimize the occurrence of these kinds of hazards and would therefore help ensure that products are in compliance with the requirements of chapter IX of the FD&C Act.

C. Development of the Proposed Regulation

FDA's development of this proposed regulation reflects its experience in regulating tobacco products, including the inspections and facility visits of tobacco manufacturing facilities it has conducted, recommendations for good manufacturing practice requirements for ENDS submitted by tobacco product manufacturers, and public comments filed in response to these recommendations (Docket No. FDA–2013–N–0227). FDA is also drawing on its experience with cGMP and HACCP regulations for other regulated products, such as foods, medical devices, drugs, and dietary supplements.

FDA's experience with biennial inspections of tobacco products has informed this proposal. Pursuant to section 905(g) of the FD&C Act, FDA has conducted hundreds of inspections of establishments engaged in the manufacture of regulated tobacco products, including cigarettes, cigarette tobacco, RYO tobacco, and smokeless tobacco since October 1, 2011. FDA believes that this experience is also relevant to establishments that manufacture deemed products, which engage in many similar activities and processes. Beginning in 2017, the Agency also began inspecting manufacturing establishments of deemed tobacco products, including ENDS products.

In August 2012, FDA issued a notice in the **Federal Register** announcing an invitation to participate in its Tobacco Product Manufacturing Facility Visits program (77 FR 48992, August 15, 2012). The purpose of the program was to provide an opportunity for tobacco product manufacturing facilities, including facilities related to laboratory testing, to invite FDA staff to visit these facilities and observe their manufacturing operations. As part of this program, FDA staff visited tobacco product manufacturers, including small tobacco product manufacturers, of cigarettes, smokeless tobacco products, and cigarette papers, as well as facilities that conduct laboratory testing services for the tobacco industry. In response to a similar notice issued in 2016 (81 FR 39053, June 15, 2016), FDA staff also visited manufacturing facilities of domestic and foreign manufacturers, including small tobacco product manufacturers, of deemed tobacco products including cigars, ENDS, and e-liquids. FDA's experiences during these visits have helped to inform this proposal.

In addition, on January 10, 2012, 13 tobacco companies and a trade association of tobacco product manufacturers submitted to FDA their recommendations for regulations on cGMP. This group of industry stakeholders included manufacturers of a variety of tobacco products including cigarettes, smokeless tobacco, and snus. On May 2, 2012, representatives of the tobacco companies met with the Agency to present an overview of the recommendations and their approach to developing them. FDA established a public docket requesting public comment on these industry recommendations (78 FR 16824, March 19, 2013). These industry GMP recommendations included proposed requirements for an extensive range of manufacturing practices including: qualification of personnel; complaints and recordkeeping; procedures for nonconforming product; contamination prevention; buildings, facilities, and equipment; MMR; acceptance activities; supplier evaluation; manufacturing records; packaging and labeling; handling and storage; and general recordkeeping and document control procedures. We received comments on the industry recommendations from a variety of stakeholders including manufacturers of cigarettes, cigars, smokeless tobacco, and snus, as well as from public health advocates.

Further, on June 7, 2017, a group of 13 tobacco companies, a trade coalition representing small tobacco product manufacturers, and a standards organization representing vaping manufacturers and retailers submitted updated supplemental industry recommendations in order to provide additional cGMP recommendations for ENDS products. The supplemental industry GMP recommendations were generally similar to industry manufacturing practices that the Agency has observed through its biennial inspections. Among the cGMP requirements that industry recommended for ENDS products were specific ENDS design process and procedures, process qualification requirements to ensure that products consistently meet specifications, procedures to validate and approve test methods, and requirements for stability testing, reserve samples, and sampling plans.

FDA established a public docket requesting comment on these updated industry recommendations for good manufacturing practice requirements for ENDS (82 FR 55613, November 22, 2017). FDA received additional comments from manufacturers of a variety of tobacco products, public health advocates, and individuals sharing their experiences with ENDS. In developing this regulation, FDA reviewed and considered the recommendations from both industry proposals, as well as the comments submitted to the public docket.

FDA is proposing many requirements similar to those included in the industry GMP recommendations, particularly in the areas of personnel; contamination prevention; requirements for buildings, facilities, and equipment; development of an MMR; purchasing controls; process controls; production records; procedures for nonconforming tobacco product; complaints; packaging and labeling; distribution; and document control procedures.

However, FDA's proposal deviates from the industry GMP recommendations in several ways. First, the proposed TPMP regulation generally includes more robust provisions for procedures and records than provisions in the industry GMP recommendations. For example, the industry recommendations do not propose requirements for design and development activities generally, returned tobacco product, and warning plans, as discussed throughout this preamble. Such provisions are critical for the efficient enforcement of the FD&C Act.

Second, FDA's proposal includes additional provisions that are necessary to assure that the public health is protected and that manufacturers' tobacco products are in compliance with chapter IX of the FD&C Act. As noted, the industry GMP recommendations do not propose requirements for returned tobacco product and warning plans (see sections IV.E and IV.F.3 for a discussion of these FDA proposals and why FDA believes they will help assure the protection of the public health). In addition, to ensure that tobacco product manufacturers can demonstrate that their tobacco products consistently conform to established specifications, an important public health objective, the proposed rule includes additional requirements for environmental controls, process validation, laboratory controls, and sampling. Moreover, this document includes proposed requirements for design and development activities, as well as complaint, CAPA, and nonconforming product investigations. To address risks not normally associated with use of tobacco products, FDA is also proposing manufacturing code and distribution record requirements to facilitate the traceability of nonconforming products and enable tobacco product manufacturers and FDA to take appropriate corrective actions to protect the public health.

FDA also has chosen not to propose certain requirements in the industry cGMP recommendations which, in some cases, would have been more burdensome than FDA's proposed requirements. For example, FDA considered industry recommendations stating that TPMP requirements should be modified for ENDS given that they are different from other tobacco products. FDA's proposed rule, instead, utilizes an ''umbrella'' approach with flexible requirements, similar to other cGMP regulations, that would apply to the wide variety of tobacco products offered for sale or distribution. For example, the scope of covered tobacco products in the 2017 supplemental industry cGMP recommendations covers manufacturers and suppliers of ENDS components and parts and included an additional requirement for stability tests to determine appropriate storage conditions and expiration dates for finished ENDS products. However, FDA believes that such requirements are unnecessary and that the FDA proposal to cover bulk tobacco product manufacturers and the proposed requirements for design and development controls, process controls, and handling and storage requirements are sufficient to address the design, manufacture, and storage of ENDS products.

Further, the industry GMP recommendations include a requirement for a HACCP analysis for ENDS and e-liquids. While the Agency considered requiring HACCP plans in this proposal, as discussed in section IV.D.1, FDA determined that use of a risk management process would be more flexible for manufacturers while still assuring that the public health was protected.

FDA also did not include the industry's proposed GMP recommendation to require reserve samples of the e-liquid-containing component/product from each lot or batch of finished ENDS products, similar to the reserve samples that are required for medical products. While reserve samples could be useful for determining a root cause for any nonconforming products or addressing any customer complaints, we believe that the proposed documentation and recordkeeping requirements are sufficient to address any investigation required under the proposed rule. For example, for a released product found to be nonconforming because of its nicotine concentration, under the proposed rule, the manufacturer and/or FDA could review the MMR and the purchasing, acceptance activities, and production records to determine the nicotine concentration of the released product as well as who conducted the testing and signed off on the release of the product. FDA's request for comments includes comments both on industry GMP recommendations that FDA is proposing in these requirements, and industry GMP recommendations that FDA is not proposing.

In addition to the industry GMP recommendation, FDA considered its existing cGMP regulations for other regulated products and evaluated them for their suitability and applicability to tobacco products. Specifically, FDA considered the medical device quality system regulation (QSR) (part 820), and the food, dietary supplement, and drug cGMP regulations (21 CFR parts 110, 111, 210, and 211, respectively). In addition, FDA examined its regulations on HACCP systems, such as preventive controls for human foods, juice HACCP regulations, and fish and fishery products HACCP regulations (21 CFR parts 117, 120, and 123, respectively).

FDA also considered voluntary industry cGMP and quality system standards in developing this proposal. For example, FDA evaluated the American E-Liquid Manufacturing Standards Association's voluntary E-Liquid Manufacturing Standards (Ref. 10). The Agency also considered the International Organization for Standardization (ISO) ISO 9001:2015—Quality management systems—Requirements (Ref. 11); ISO 31000: 2018—Risk Management—Principles and Guidelines (Ref. 12).

FDA considered the quality systems and QMS requirements in FDA's medical device QSR and pharmaceutical cGMP for the 21st century (Ref. 13) in designing the proposed rule. The Agency believes certain aspects of those regulations are informative but not wholly applicable to tobacco products because of certain key differences between tobacco products and medical products regulated by FDA. For example, marketing applications for medical products are evaluated to determine whether they are ''safe and effective.'' Unlike medical products, tobacco products cannot be ''safe and effective'' even if used as intended and, therefore, the FD&C Act requires that marketing applications for tobacco products be evaluated under different standards (see, *e.g.,* the ''appropriate for the protection of the public health'' standard under section 910 of the FD&C Act). FDA has taken these differences into account in developing the proposed rule. For example, while the Agency has included requirements for CAPA, it has decided not to propose continuous process improvement requirements as part of this rule.

The Agency's proposed rule utilizes an ''umbrella'' approach to the regulation of all types of finished and bulk tobacco products, which is similar to the approach taken by the other cGMPs and voluntary standards considered in the development of this proposal. Because this regulation would apply to many different types of tobacco products, the proposal does not prescribe in detail how a manufacturer must produce a specific tobacco product. Rather, the proposed regulation provides the framework that all manufacturers would follow by requiring that manufacturers establish and maintain procedures and fill in the details that are appropriate to a given tobacco product.

V. Description of the Proposed Regulation

A. General Provisions

1. Scope

The Tobacco Control Act gave FDA immediate authority over cigarettes, cigarette tobacco, RYO tobacco, and smokeless tobacco. In addition, the Tobacco Control Act gave FDA the authority to promulgate regulations deeming other tobacco products subject to its authorities in chapter IX of the FD&C Act. In the **Federal Register** of May 10, 2016, FDA issued the Deeming Rule deeming all other products meeting the statutory definition of tobacco product to be subject to FDA's regulatory authority under chapter IX of the FD&C Act, except accessories of deemed products. 81 FR 28974. That rule became effective on August 8, 2016.

As discussed in proposed § 1120.1(a), FDA is proposing TPMP requirements that would apply to manufacturers of all finished and bulk tobacco products that are subject to chapter IX of the FD&C Act (*e.g.,* cigarettes, cigarette tobacco, RYO tobacco, smokeless tobacco, ENDS, e-liquids, pipe tobacco, cigars, hookah tobacco, nicotine gels, and dissolvable tobacco products) but not their related accessories.

FDA proposes to define a ''finished tobacco product'' as a tobacco product, including any component or part, sealed in final packaging (*e.g.,* a pack of cigarettes, a can of moist snuff). For the purposes of the ''finished tobacco product'' definition, a ''package'' is a pack, box, carton, or container of any kind or, if no other container, any wrapping, including cellophane, in which a finished tobacco product is offered for sale, sold, or otherwise distributed to consumers. As discussed in more detail below, the proposed

definition of finished tobacco product also includes components or parts of tobacco products sealed in final packaging (*e.g.,* rolling papers, filters, filter tubes, or e-liquids sold separately to consumers or as part of kits). FDA intends for this TPMP rule to cover manufacturers of finished tobacco products to help assure that the public health is protected and that those products are in compliance with chapter IX of the FD&C Act.

FDA proposes to define a ''bulk tobacco product'' as any tobacco product that is not sealed in final packaging but is otherwise suitable for consumer use as a tobacco product (*e.g.,* bulk cigarettes, bulk RYO tobacco, bulk pipe tobacco). As discussed in more detail below, the proposed definition of bulk tobacco product also includes components or parts of tobacco products that are not sealed in final packaging but are otherwise suitable for consumer use as tobacco products (*e.g.,* bulk filters, bulk e-liquids). Products that are suitable for consumer use as tobacco products are those products that do not require further processing by a tobacco product manufacturer, such as mixing, cutting, curing, blending, or adding components or parts, ingredients, additives and materials, before they can be used by a consumer. For example, an e-liquid not sealed in final packaging is suitable for consumer use as a tobacco product because it requires no additional processing by a tobacco product manufacturer before it can be used by a consumer in an ENDS device; it requires only final packaging and labeling to be a finished tobacco product. A product can be suitable for consumer use as a tobacco product even if it *could* undergo additional processing by a manufacturer, such as blending, as long as it does not *require* further processing by a manufacturer before use by a consumer. For example, coconut and pineapple e-liquids not sealed in final packaging would be considered bulk tobacco products because they are suitable for consumer use as tobacco products, even if they might later be blended together by a manufacturer to make piña colada e-liquid.

FDA is including bulk manufacturers within the scope of this proposed rule in order to cover critical regulatory gaps that would occur if the rule were to only cover manufacturers of finished tobacco products. Bulk manufacturers provide bulk tobacco products, such as bulk cigarettes, bulk RYO or pipe tobacco, and bulk e-liquids, to finished tobacco product manufacturers who merely package and/or label the products for consumer use. Bulk tobacco products are suitable for consumer use as tobacco products with no additional processing by a tobacco product manufacturer and, therefore, should be regulated in the same manner as finished tobacco products. If the scope of the rule were limited to finished tobacco product manufacturers, then entities that perform key manufacturing steps other than final packaging and labeling for consumer use, such as design and development, blending, mixing, cutting, processing, assembling, and compounding, might not be subject to any TPMP requirements. Inadequate controls in earlier stages of manufacturing could result in contaminated or otherwise nonconforming bulk tobacco products that would not be detected by a finished tobacco product manufacturer during packaging and labeling operations. In addition, a finished tobacco product manufacturer that packages or labels a bulk tobacco product may not be able to conduct adequate investigations of product complaints and implementing CAPA for issues related to product design or production processes.

As noted above, the proposed definitions of finished and bulk tobacco products would include finished and bulk components or parts of tobacco products. FDA proposes to define ''component or part'' for purposes of proposed part 1120 consistent with the definition of ''component or part'' in the Deeming Rule, codified at 21 CFR 1143.1. Accordingly, a component or part would mean any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics, or (2) to be used with or for the human consumption of a tobacco product; but would exclude anything that is an accessory of a tobacco product. The requirements of proposed part 1120 would apply to manufacturers of finished and bulk components or parts of tobacco products. This would include manufacturers of finished or bulk RYO tobacco, papers, and filters, ENDS e-liquids, atomizers, batteries (with or without variable voltage), and cartomizers (atomizer plus replaceable fluid-filled cartridge).

In determining whether software or an assembly of materials might be ''intended or reasonably expected'' to alter or affect a tobacco product's performance, composition, constituents, or characteristics, or to be used with or for the human consumption of a tobacco product (and, therefore, whether the software or assembly of materials is a ''component or part''), the manufacturer's subjective claims of intent are not controlling. Rather, FDA considers all relevant evidence, including direct and circumstantial objective evidence, which encompasses a variety of factors, such as circumstances surrounding the distribution of the product or the context in which it is sold, sales data, and how the product is used by consumers.

The requirements of proposed part 1120 would also apply to manufacturers of finished or bulk products for general consumer use (*i.e.,* products not specifically designed for use with tobacco products) that meet the definition of finished or bulk tobacco products (including finished or bulk components or parts). For example, the requirements of proposed part 1120 would apply to manufacturers of finished or bulk batteries who intend them to be used in an ENDS device, for example by labeling or co-packaging the batteries with an ENDS device. Similarly, the rule would apply to manufacturers of finished or bulk food grade flavors who intend the flavors to be used with e-liquids. Likewise, the rule would apply to the manufacturer of a screen sold at a hardware store for a variety of general uses if that manufacturer labels the screen for use with a tobacco product, such as an ENDS, or co-packages the screen with a tobacco product.

The proposed rule would not apply to manufacturers of accessories of finished or bulk tobacco products. FDA proposes to define an ''accessory'' as any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored tobacco product; or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product. This proposed definition is the same as the definition of ''accessory'' under 21 CFR 1100.3 and under 21 CFR 1143.1. Examples of accessories of finished and bulk tobacco products include ashtrays, spittoons, hookah tongs, cigar clips and stands, and pipe pouches, because they do not contain tobacco, are not derived from tobacco, and do not affect or alter the performance, composition, constituents, or characteristics of a

tobacco product. Examples of accessories also include humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product. An electric heater or charcoal used for prolonged heating of waterpipe tobacco is not an accessory because it is maintaining the combustion of the tobacco. Accessories of deemed products are not currently subject to chapter IX of the FD&C Act. At this time, FDA believes that the proposed requirements of this rule assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act without applying the requirements to manufacturers of accessories of cigarettes, cigarette tobacco, RYO tobacco, smokeless tobacco, and deemed tobacco products.

2. Umbrella Approach

This proposed rule utilizes an ''umbrella'' approach to the regulation of all types of finished and bulk tobacco products, which is similar to the approach taken by the other cGMPs and voluntary standards considered in the development of this proposal. Thus, the proposed regulation provides the framework that requires all finished and bulk tobacco product manufacturers subject to the rule (including specification developers, contract manufacturers, and repackagers/relabelers) to establish and maintain procedures that are unique to the manufacturer's facilities and activities, and appropriate for a given tobacco product. The proposed requirements are written in general terms to allow manufacturers to establish procedures appropriate for their specific products and operations. The extent of the procedures necessary to meet the regulation requirements may vary with the size and complexity of the design and manufacturing operations. Tobacco product manufacturers who have a complex manufacturing process would likely need to establish more detailed procedures to comply with the rule, while tobacco product manufacturers who have a less complex manufacturing process may need less extensive procedures.

3. Specification Developers

As discussed in proposed § 1120.1(a), manufacturers of finished and bulk tobacco products include specification developers, contract manufacturers, and repackagers and relabelers. If a specification developer designs and establishes tobacco product specifications of a finished or bulk tobacco product and provides the specifications to a contract manufacturer to physically manufacture the product, both the specification developer and the contract manufacturer would be engaged in the manufacture and/or preproduction design validation of finished or bulk tobacco products for purposes of this rule and would be required to comply with this proposed rule. This approach is similar to other cGMP and HACCP regulations that have been applied to other FDA-regulated products, such as part 820, QSR for medical devices, and part 211, cGMP for finished pharmaceuticals.

A specification developer is a person who controls the design and development of a tobacco product and/or initiates or creates the specifications for the product. Such activities are important steps in the manufacture and preproduction design validation of a tobacco product. A specification developer is, in concept, like an architect who creates a ''blueprint'' of a tobacco product. A specification developer may be the same party that physically manufactures the tobacco product or a separate entity that only provides specification development services to another manufacturer, who then physically manufactures the tobacco product. FDA is aware that some tobacco product manufacturers have established an organizational structure that places the specification development functions in an entity separate from the entity in charge of physically manufacturing the finished or bulk tobacco product; these entities develop and usually control changes to the specifications of the tobacco product. Such entities are specification developers under the proposed rule.

A tobacco product manufacturer may utilize a specification developer to initiate or create the specifications of a finished or bulk tobacco product when the manufacturer lacks knowledge or expertise in product design and development. Specifically, a manufacturer may want to produce a tobacco product with certain features but lack the knowledge needed to design such a product and translate the desired features into particular product specifications. For example, a cigarette manufacturer who wants to manufacture a cigarette with certain constituent yields and consumer sensory qualities may use a specification developer to create appropriate specifications for the product, such as the specific tobacco blend, paper type and grade, filter ventilation, additives, and other features. A tobacco product manufacturer who intends to manufacture a dissolvable lozenge, orb, or strip smokeless tobacco product may similarly involve a specification developer to create appropriate product specifications such as tobacco mixtures, pH, additives, colorants, size and shape, and packaging materials. A tobacco product manufacturer who wants to commercially market an e-cigarette with certain performance features such as particular power levels, aerosol particle size, pressure drop, airflow, and puff count may similarly use a specification developer who can design a product with such features and translate them into appropriate specifications, including cartridge, atomizer, heating element, battery, and circuit board/software specifications.

FDA proposes to regulate specification developers under this rule because product design and the development of product specifications are integral parts of the manufacturing and preproduction design validation process. Product design and specification development are important because these can affect the level of risk or harm (*e.g.,* toxicity, addictiveness) a tobacco product consumer may be exposed to when using tobacco products, and, in the absence of proper controls, can also result in harm not normally associated with the use of a tobacco product.

FDA has authority to include requirements about product design in its TPMP regulation. Specifically, section 906(e) of the FD&C Act provides, in part, that FDA shall prescribe regulations requiring that the methods used in and the facilities and controls used for tobacco-product manufacture and preproduction design validation (including a process to assess the performance of a tobacco product) conform to current good manufacturing practice, or HACCP methodology. Requiring specification developers to comply with TPMP provisions is consistent with that authority.

FDA believes that it is necessary to apply the proposed TPMP regulation to specification developers because of their key role in the manufacture and preproduction design validation of finished and bulk tobacco products and because, under certain circumstances, a specification developer may be the most appropriate party or even the only capable party, to adequately perform certain activities required under the proposed regulation. Design and development frequently involve knowledge of trade secrets and/or other confidential commercial information, and a specification developer may not

share such information with the entity that physically manufactures the finished or bulk tobacco product.

Such activities include, for example, conducting adequate investigations of product complaints and implementing CAPA for issues related to product design. For example, if complaints are received that users are experiencing respiratory distress from the aerosol of an ENDS product, only a specification developer may be able to conduct an adequate investigation to determine the cause of problems and implement the necessary actions to correct and prevent the problems. The finished or bulk ENDS manufacturer who physically manufactures the product may be able to rule out a manufacturing problem (*e.g.,* defectively manufactured solder joints), but it may not be able to determine the cause of the problem if the issue relates to design (*e.g.,* metallic particles that result from improper material selection for the cartomizer wires). In that case, only the specification developer may have the unique knowledge regarding the product's design and history of specification development necessary to determine the cause of the problem and how to address it.

Similarly, if complaints are received that the software of an ENDS product that controls the heat and temperature functions is being altered or hacked by users and causing malfunctions that result in overheating, fires, or explosions, the specification developer—not the manufacturer who physically manufactures the product—would have the expertise to conduct a thorough investigation and initiate a CAPA to redesign the software to prevent this user misuse.

Specification developers are also the only party capable of adequately performing certain activities included in the proposed product development control requirements, such as identifying known or reasonably foreseeable risks associated with the design of the tobacco product and/or package as well as design verification and validation activities. With product design and development knowledge, the specification developer would be in the best position to identify and take appropriate measures to treat risks associated with the design of the tobacco product and package that are not normally associated with the use of the tobacco product and package, or that it determines constitute an unacceptable level of risk. For example, a specification developer of a dissolvable tobacco product (*e.g.,* a tobacco lozenge) would have the knowledge to address possible misuse of the product by a child that could cause choking or inadvertent exposure and to take appropriate measures to redesign the size and shape of the tobacco product or redesign the packaging. As another example, a specification developer of a heat-not-burn tobacco product would have the knowledge to assess whether the product could reach temperatures that could cause burns and to take appropriate measures to reduce this risk.

Accordingly, FDA believes that requiring specification developers to comply with the proposed TPMP requirements is essential to ensure that the proposed TPMP regulation operates as intended.

4. Foreign Manufacturers

Further, FDA is proposing that foreign manufacturers of finished or bulk tobacco products that are imported or offered for import into the United States be covered under this TPMP rule. In accordance with section 906(e) of the FD&C Act, FDA believes that covering foreign manufacturers is necessary to assure the protection of the public health. The risks associated with the tobacco product, production process, packaging, and storage are the same for all tobacco products covered by this proposed rule, regardless of where they are manufactured, and all can be addressed by the same types of controls. For example, the proposed design and development controls (proposed subpart D) would address these risks, including risks associated with the design of ENDS products that are primarily designed and manufactured in China and for which there have been numerous reports of battery fires and explosions (*e.g.,* Ref. 7).

In addition, having the proposed rule apply to foreign manufacturers of finished or bulk tobacco products would be necessary to ensure that imported tobacco products comply with chapter IX of the FD&C Act. For example, the proposed controls (*e.g.,* design and development controls, MMR, acceptance activities, and production record requirements) would help to ensure that imported tobacco products meet all applicable tobacco product standards, and thus avoid being adulterated or misbranded. A tobacco product which is subject to a tobacco product standard is adulterated under section 902(5) of the FD&C Act unless the product is in all respects in conformity with the standard. Similarly, a tobacco product subject to a tobacco product standard is misbranded under section 903(a)(9) of the FD&C Act unless it bears such labeling as may be prescribed in the standard.

5. Vape Shops Engaged in the Manufacture of Tobacco Products

Vape shops are establishments that generally, among other things, sell a variety of products including ENDS, replacement pieces, hardware, custom mixed e-liquids, and other related accessories. Sales of such products, standing alone, would not constitute finished or bulk tobacco product manufacturing. However, some vape shops are also tobacco product manufacturers under the Deeming Rule, 81 FR at 29044, because they also (for example) mix or prepare e-liquids or create or modify aerosolizing apparatuses for direct sale to consumers for use in ENDS. Under the proposed regulation, vape shops engaged in these additional activities would be manufacturers of finished or bulk tobacco products. When such vape shops are engaged in the manufacture, preproduction design validation, packing, and storage of finished or bulk tobacco products within the meaning of the proposed rule, they would be subject to the requirements in this proposed TPMP rule. Requiring such manufacturers to comply with TPMP requirements, as proposed, is important for protecting the public health because products manufactured at the retail level pose many of the same public health risks as those manufactured upstream, and possibly additional risks related to the lack of standard manufacturing practices and controls. A vape shop that does not engage in the activities described above would not be a finished or bulk tobacco product manufacturer subject to the requirements of this proposed part 1120. In addition, as set out immediately below, proposed § 1120.1(b) would require a finished and bulk tobacco product manufacturer to comply only with requirements applicable to its finished and bulk tobacco product manufacturing operations. Therefore, smaller tobacco product manufacturers (such as vape shops that engage in some but not all of the activities described above) would be able to tailor their procedures to suit their smaller operations while still complying with the proposed TPMP requirements.

6. Compliance With Requirements Applicable to Operations

Proposed § 1120.1(b) clarifies that if a tobacco product manufacturer engages in some operations subject to the requirements of proposed part 1120, but not others, the manufacturer need only comply with those requirements applicable to the operations in which it is engaged. This is the same approach

used in the drug cGMP regulation at § 210.2(b) and the device QSR at § 820.1(a)(1).

For example, a manufacturer of finished e-liquids would not need to comply with the warning plan requirements in proposed § 1120.98 because e-liquids are only required to bear a single warning. Similarly, a finished cigarette manufacturer who does not engage in repackaging or relabeling operations would not need to comply with the repackaging and relabeling requirements in proposed § 1120.94. Likewise, a specification developer who only designs/creates the MMR for another manufacturer's tobacco product and does not engage in any physical manufacturing would not be subject to, for example, the proposed requirements in subparts C (Buildings, Facilities, and Equipment), E (Production Processes and Controls), and G (Handling, Storage, and Distribution). If manufacturers believe a requirement is not appropriate or necessary to ensure that the public health is protected and that the tobacco product will be in compliance with this chapter, they may petition for an exemption or variance from all or part of the regulation pursuant to proposed § 1120.142.

Proposed § 1120.1(c) clarifies the term ''where appropriate,'' which appears several times in proposed part 1120. As discussed in proposed § 1120.1(c), when a requirement is qualified with ''where appropriate,'' it is deemed to be appropriate unless the tobacco product manufacturer documents in writing (on paper or electronically) an adequate justification prior to abstaining from implementing the requirement. An adequate justification would address why abstaining from the requirement would not result in a nonconforming tobacco product or in the manufacturer not being able to carry out necessary corrective actions. In this circumstance, the manufacturer need not petition for or receive an exemption or variance under § 1120.140. Proposed § 1120.1(d) notes that requirements in proposed part 1120 are intended to protect the public health and assure that tobacco products are in compliance with the relevant provisions of the FD&C Act and explains that the failure to comply with any applicable provision in proposed part 1120 would render the tobacco product adulterated under section 902(7) of the FD&C Act.

7. Other Manufacturers and Request for Comment

At this time, FDA is not proposing to apply these proposed TPMP requirements to manufacturers of tobacco products other than finished and bulk tobacco products. In particular, the proposed regulation will not reach manufacturers of components or parts that are not offered for sale, sold, or otherwise distributed to consumers, *i.e.,* components or parts for further manufacture. For example, the rule would not apply to manufacturers of filter tow material and cigarette tipping paper that are intended or reasonably expected to be used to manufacture a cigarette, because those products are not sold to consumers. The proposed rule's current scope does not reach such components or parts directly, but rather requires incoming tobacco product components or parts, ingredients, additives, and materials to be subject to purchasing controls and acceptance activities implemented by finished and bulk tobacco product manufacturers to ensure that they meet established specifications. In addition, FDA is not currently proposing to apply these proposed requirements to manufacturers of accessories.

FDA is soliciting comment on the scope of the proposed rule, as well as whether the scope of this regulation should be expanded to reach more than finished and bulk tobacco products. If you believe that FDA should expand the scope of this proposed rule to reach additional tobacco products, please explain why you believe FDA should take that approach; which proposed requirements, if any, should apply to other manufacturers; whether the regulation should cover manufacturers of all regulated tobacco products, including all components or parts, or only manufacturers of certain products; as well as any public health data and information that would support what you believe would be the appropriate scope of this rule. Alternatively, if you believe that FDA should limit the scope of the proposed regulation, please explain why you believe the scope of the rule should be more limited than finished and bulk tobacco product manufacturers and provide any data or information that would support that such a limited scope would still assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act.

8. Definitions

Proposed § 1120.3 sets forth the meaning of terms used in proposed part 1120.

- *Accessory.* We propose to define ''accessory'' as any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored tobacco product; or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product. Examples of accessories are ashtrays, spittoons, hookah tongs, cigar clips and stands and pipe pouches, because they do not contain tobacco, are not derived from tobacco, and do not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. Examples of accessories also include humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product. An electric heater or charcoal used for prolonged heating of waterpipe tobacco is not an accessory because it is used to maintain the combustion of the tobacco.
- *Additive.* We propose to define ''additive'' as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical. An additive can be a type of ingredient in a tobacco product; an example is methyl salicylate in smokeless tobacco, which can serve as an absorption enhancer and affect the characteristics of the tobacco product by changing the rate of absorption into the body.
- *Batch.* We propose to define ''batch'' as a specific identified amount of tobacco product produced in a unit of time or quantity and that is intended to have the same specifications. FDA proposes to give tobacco product manufacturers flexibility to determine what unit of time or quantity is appropriate for their product, and how batches would be designated. For example, manufacturers likely would define a batch for cigarette production, which is almost continuous, differently

than a batch for smokeless tobacco, which likely would be defined based on the amount processed in a vat through the fermentation process.

• *Brand.* We propose to define ''brand'' as a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

• *Bulk tobacco product.* We proposed to define ''bulk tobacco product'' as a tobacco product not sealed in final packaging but otherwise suitable for consumer use as a tobacco product. Products that are suitable for consumer use as a tobacco product are those products that do not require further processing by a tobacco product manufacturer before they can be used by a consumer, such as mixing, cutting, curing, blending, and adding components or parts, ingredients, additives and materials. A tobacco product can be suitable for use even if it *could* undergo additional processing by a manufacturer as long as it does not *require* further processing by a manufacturer before use by a consumer. Examples of bulk tobacco products include bulk RYO tobacco, bulk pipe tobacco, bulk RYO filters, and bulk e-liquids. However, cigarette paper that is supplied on a bobbin roll would not be considered a bulk tobacco product because it would need to be cut into rolling paper sizes or combined/glued with filters to make cigarette tubes. The terms ''bulk tobacco product'' and ''finished tobacco product'' are distinguishable because bulk tobacco products are not sealed in final packaging, whereas finished tobacco products are sealed in final packaging.

• *Characteristic.* We propose to define ''characteristic'' as the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

• *Component or Part.* We propose to define ''component or part'' as any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

• *Contaminated tobacco product.* We propose to define ''contaminated tobacco product'' as a tobacco product that contains a substance not ordinarily contained in that tobacco product. ''Not ordinarily contained'' refers to a substance that is not intended or expected to be in that tobacco product. As stated in proposed § 1120.3, an example of a contaminated tobacco product is a smokeless tobacco product with metal fragments in the tobacco filler.

• *Design.* We propose to define ''design'' as the form and structure concerning and the manner in which components or parts, ingredients, additives, and materials are integrated to produce a tobacco product.

• *Direct accounts.* We propose to define ''direct accounts'' as all persons who are customers of the tobacco product manufacturer that receive finished or bulk tobacco products directly from the manufacturer or from any person under control of the manufacturer. Direct accounts may include wholesalers, distributors, and retailers. Direct accounts do not include individual purchasers of tobacco products for personal consumption.

• *Establish and maintain.* We propose to define ''establish and maintain'' as to define, document in writing (on paper or electronically), implement, follow, and update. Multiple requirements in the proposed regulation direct manufacturers to ''establish and maintain'' certain procedures. For example, proposed § 1120.12(e)(1) would require tobacco product manufacturers to establish and maintain procedures for identifying training needs and establishing training frequency for personnel based on the work the employee performs. Therefore, to comply with proposed § 1120.12(e)(1), a manufacturer would be required to create written procedures for identifying and meeting training needs, implement and follow the written procedures, and update the procedures as needed.

• *Equipment.* We propose to define ''equipment'' as any machinery, tool, instrument, utensil, or other similar or related article, used in the manufacture, preproduction design validation, packing, or storage of a tobacco product. Equipment used during testing and laboratory activities conducted as part of the manufacturing process would be covered under this proposed definition.

• *Finished tobacco product.* We propose to define ''finished tobacco product'' as a tobacco product, including any component or part, sealed in final packaging. Additional examples of finished tobacco products include a pack of cigarettes, a can of moist snuff, and rolling papers, filters, filter tubes, or e-liquids sold to consumers. One finished tobacco product may contain others. For example, a carton of cigarette packs (which are finished tobacco products) is also a finished tobacco product, because, like a cigarette pack, a carton is a tobacco product sealed in final packaging. As noted below, final packaging means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a finished tobacco product is offered for sale, sold, or otherwise distributed to consumers. (See definition of packaging).

• *Ingredient.* We propose to define ''ingredient'' as tobacco, substances, compounds, or additives contained within or added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through chemical action during tobacco product manufacturing.

For example, an ingredient may be a single chemical substance, leaf tobacco, or the product of a reaction, such as a chemical reaction, in manufacturing. Examples of substances and compounds (ingredients) reasonably expected to be formed through a chemical reaction during tobacco product manufacturing include the following:

—The reaction of sugars with amines to form families of compounds with new carbon-nitrogen bonds, including Maillard reaction products and Amadori compounds;
—the reaction of sodium hydroxide with citric acid to form sodium citrate;
—the production of ethyl alcohol, a residual solvent, from ethyl acetate during production of tipping paper adhesive;
—products of thermolytic reactions,
—such as the production of carboxylic acids from sugar esters;
—products of enzymatically or nonenzymatically catalyzed reactions, such as the hydrolytic production of flavor or aroma precursors from nonvolatile glucosides; and
—products of acid-base reactions, such as removal of a proton from protonated nicotine to generate the basic form of nicotine (''free'' nicotine). 86 FR 55300 at 55313 (Oct. 5, 2021).

• *Label.* We propose to define ''label'' as a display of written, printed, or graphic matter upon the immediate container of any article. For finished tobacco products, the term label means a display of written, printed, or graphic matter upon the immediate container of any finished tobacco product. Likewise, for a bulk tobacco product, the term label means a display of written, printed, or graphic matter upon the immediate container of any bulk tobacco product.

• *Labeling.* We propose to define ''labeling'' as all labels and other

written, printed, or graphic matter: (1) upon any article or any of its containers or wrappers or (2) accompanying such article.

• *Management with executive responsibility.* We propose to define ''management with executive responsibility'' as one or more designated personnel who have the authority and responsibility to ensure compliance with TPMP requirements, including allocating resources and making changes to the organizational structure, buildings, facilities, equipment or the manufacture, preproduction design validation, packing, and storage of a tobacco product. These employees are typically senior employees with the authority to establish or make changes to tobacco product manufacturing policies. Such person(s) also would be responsible for ensuring that TPMP requirements are communicated, understood, implemented, and followed at all levels of the organization.

• *Manual method, process, or procedure.* We propose to define ''manual method, process, or procedure'' as any nonautomated method, process, or procedure, including processes performed by hand with or without the use of equipment.

• *Manufacturing.* We propose to define ''manufacturing'' as the manufacturing, fabricating, assembling, processing, or labeling, including the repackaging or relabeling, of a tobacco product. The term ''manufacturing'' includes establishing the specifications of a finished or bulk tobacco product. Examples of manufacturing activities include expanding (a process used with the tobacco leaf, typically dry ice expanded tobacco), homogenizing, mixing, and formulating a tobacco product.

• *Manufacturing code.* We propose to define ''manufacturing code'' as any distinctive sequence or combination of letters, numbers, or symbols that begins with the manufacturing date followed by the batch number. The purpose of the manufacturing code is to allow manufacturers and FDA to identify the production batch of a particular finished or bulk product that has been released for distribution. This information is intended to help determine the product's history (*e.g.,* batch production records) and assist manufacturers and FDA in the event of a nonconforming product investigation and any corrective actions to be taken as a result of the investigation.

• *Manufacturing date.* We propose to define ''manufacturing date'' as the month, day, and year in 2-digit numerical values in the format (MMDDYY) that a finished or bulk tobacco product is packaged for distribution. The manufacturing date is included in the manufacturing code.

• *Manufacturing material.* We propose to define ''manufacturing material'' as material used in or used to facilitate the manufacturing process that is not equipment and is not intended to be part of the product. Such material would have to contact the tobacco product or tobacco product-contact surface. An example of manufacturing material would be a mold release agent used to facilitate the release of a tobacco product from a mold.

• *Master manufacturing record (MMR).* We propose to define ''master manufacturing record'' as a document or designated compilation of documents containing the established specifications for a tobacco product including acceptance criteria for those specifications, all relevant manufacturing methods and production process procedures for the tobacco product, and all approved packaging, labeling, and labels for the tobacco product. Tobacco product specifications, as used in this definition, may be established by the manufacturer or required by FDA. The MMR may be prepared either as a single document (or single file of documents) or as a product-specific index system that references and includes the location of all the required information.

• *Nonconforming tobacco product.* We propose to define ''nonconforming tobacco product'' as any tobacco product that does not meet a product specification in the MMR (see proposed § 1120.44(a)(1)); has packaging, labeling, or labels other than those included in the MMR (see proposed § 1120.44(a)(3)); or is a contaminated tobacco product.

• *Not normally associated.* We propose to define ''not normally associated'' as not an inherent risk of using the tobacco product. In this context, the inherent risk would be associated with using the specific category of tobacco product. For example, inherent risks of using cigarettes include cancers of the mouth, throat, larynx, esophagus, trachea, lung, stomach, liver, pancreas, kidney, bladder, cervix, and colon/rectum, as well as one form of leukemia (Ref. 14). Other examples of inherent risks of using cigarettes include stroke, heart disease, peripheral vascular disease, COPD, tuberculosis, asthma, pneumonia and other respiratory diseases (id.). Examples of inherent risks of cigars include oral, laryngeal, pharyngeal, and esophageal cancers, as well as lung cancer and heart disease (Ref. 15). Examples of inherent risks of smokeless tobacco include oral and pancreatic cancers (Ref. 16).

Examples of risks not normally associated with tobacco products include lacerations of the gums or lips due to metal fragments found in chewing tobacco; broken teeth caused by rocks found in chewing tobacco; bodily injury caused by an exploding battery of an ENDS product; vomiting, nausea, allergic reactions, dizziness, numbness, or headaches caused by toxic chemical compounds found in nonconforming products; a serious illness caused by a tobacco product contaminated by aflatoxin from a fungus; and acute breathing difficulties associated with an allergic reaction to a contaminated tobacco product (*e.g.,* Ref. 17).

• *Package* or *packaging.* We propose to define ''package'' or ''packaging'' as a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a finished tobacco product is offered for sale, sold, or otherwise distributed to consumers (this is also referred to as final package or final packaging), or in which a bulk tobacco product is offered for sale, sold, or otherwise distributed (including commercial distribution and interplant transfers). For example, under the proposed definition, a carton offered for sale to consumers, which holds individual cigarette packages, would be considered a ''package'' or ''packaging.'' However, a shipping crate that holds multiple cartons of cigarettes, or other multiple quantities of finished tobacco products, for distribution to retailers would not be considered ''packages'' or ''packaging,'' because such shipping crates for distribution to retailers are not containers or wrapping in which a finished tobacco product is offered for sale, sold, or otherwise distributed to consumers. We use the terms ''package'' and ''packaging'' interchangeably throughout this proposed rule.

• *Personnel.* We propose to define ''personnel'' as all persons, including managers, staff, consultants, contractors, and third-party entities, performing services for the manufacturer subject to proposed part 1120. The term ''personnel'' includes independent contractors performing services for the manufacturer.

• *Relabeling.* We propose to define ''relabeling'' as operations in which the labeling of a finished tobacco product is subsequently changed or replaced. This may be performed by the same person who originally labeled the product. For example, if a finished tobacco product fails an acceptance activity because it bears the wrong label, the manufacturer

may relabel the product with the correct label.

• *Repackaging.* We propose to define ''repackaging'' as operations in which the packaging of a finished tobacco product is subsequently changed or replaced. This may be performed by the same person who originally packaged the product. For example, if the package of a finished tobacco product is damaged during storage, the manufacturer may repackage the finished product in a new package.

• *Representative sample.* We propose to define ''representative sample'' as a sample that consists of a number of units that are drawn based on a valid scientific rationale (such as random sampling) and intended to ensure that the sample accurately reflects the material being sampled.

• *Reprocessing.* We propose to define ''reprocessing'' as using tobacco product that has been previously recovered from manufacturing in the subsequent manufacture of a finished or bulk tobacco product. FDA has observed that reprocessing is a routine manufacturing process. An example of reprocessing would be using tobacco recovered through a ripper short process for cigarettes (where tobacco is removed from rejected cigarettes using equipment such as feeders, shakers, and separators) to make other cigarettes. Similar reprocessing occurs for smokeless tobacco, where the tobacco is recovered from rejected finished or bulk tobacco products, for example, due to incorrect weight or defective packaging/labels, and then used to make other smokeless tobacco products.

• *Returned tobacco product.* We propose to define ''returned tobacco product'' as commercially distributed finished or bulk tobacco product returned to the tobacco product manufacturer by any person not under the control of the tobacco product manufacturer, including a wholesaler/distributor, retailer, consumer, or member of the public. Individuals may return tobacco products to the manufacturer for a number of reasons, including improper weight or taste.

• *Rework.* We propose to define ''rework'' as action taken on a nonconforming or returned tobacco product to ensure that the product meets the specifications and other requirements in the MMR of a subsequently manufactured tobacco product before it is released for further manufacturing or distribution. For example, a smokeless tobacco product that fails an acceptance activity for pH level can be reworked by further fermentation.

• *Small tobacco product manufacturer.* We propose to define ''small tobacco product manufacturer'' as a tobacco product manufacturer that employs fewer than 350 employees. For purposes of this definition, the number of employees of a manufacturer includes those employees and personnel of each entity that controls, is controlled by, or is under common control with such manufacturer.

• *Specification.* We propose to define ''specification'' as any requirement with which a product, process, service, or other activity must conform. A tobacco product specification is a requirement established by the manufacturer (including specification developer, contract manufacturer, or repackager/relabeler), including a requirement established to ensure that the tobacco product meets any applicable product standard under section 907 of the FD&C Act. Tobacco product specifications can include physical, chemical, and biological specifications. Examples of physical specifications include length, circumference, and pressure drop for cigarettes, and cut size and weight for smokeless tobacco products. An example of a chemical specification is a pH level for smokeless tobacco products, and an example of a biological specification is a specification related to the use of a biological fermentation agent used during the manufacturing process for smokeless tobacco products. Examples of a production process specification are the upper and lower temperature and humidity limits for specified durations, as part of the fermentation process for a smokeless tobacco product. An example of a service specification is a requirement with which a pest control service must conform.

This proposed rule would require that the tobacco product specifications and acceptance criteria for those specifications be included in the MMR for each finished and bulk tobacco product. For example, if an ENDS manufacturer establishes a voltage specification for an adjustable, variable voltage product with a range of 3–6V, the MMR would have to indicate the voltage acceptance criteria that reflect the tolerance that is established around the upper and lower specifications.

• *Tobacco product.* The term ''tobacco product'' means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that is a drug under section 201(g)(1) (21 U.S.C. 321(g)(1)), a device under section 201(h) (21 U.S.C. 321(h)), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)). The term ''tobacco product'' does not mean an article that is a food under section 201(f) (21 U.S.C. 321(f)), if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

• *Tobacco product-contact surface.* We propose to define ''tobacco product-contact surface'' to mean a surface that comes into contact with a tobacco product or a surface from which drainage (or other transfer) ordinarily occurs onto the tobacco product or onto surfaces that come into contact with the tobacco product during the normal course of operations. This definition would include surfaces of equipment that come into contact with the tobacco product.

• *Tobacco product manufacturer.* We propose to define the term ''tobacco product manufacturer'' as any person(s), including any repacker or relabeler, who: manufactures, fabricates, assembles, processes, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States. Tobacco product manufacturer includes any person(s) who establishes the specifications for a tobacco product.

FDA does not propose to define ''tobacco product manufacturer'' to include third-party laboratories. A finished or bulk tobacco product manufacturer who uses a third-party laboratory is responsible for ensuring that the laboratory is qualified to provide services under proposed § 1120.62 and is competent to perform laboratory activities associated with the manufacture of a finished or bulk tobacco product under proposed § 1120.68. A finished or bulk tobacco product manufacturer who uses a third-party laboratory is also responsible for ensuring that it receives from the third-party laboratory all the documents and records (including all metadata) needed to comply with the proposed TPMP requirements, including, for example, proposed §§ 1120.68(c) and 1120.122. It is the finished or bulk tobacco product manufacturer, not the laboratory, that is required to comply with the laboratory control requirements in proposed § 1120.68.

• *Unique identifier.* We propose to define ''unique identifier'' as information, such as a code or number, that is maintained for each accepted incoming product that would enable the

tobacco product manufacturer and FDA to identify the supplier and unique shipment of the incoming product.

- *Validation.* We propose to define ''validation'' as confirmation by examination and objective evidence that the particular requirements can be consistently fulfilled. An example of a validation activity would be the validation of the smokeless tobacco fermentation process, which would demonstrate that when key parameters (*e.g.,* temperature, pH, oven volatiles, and number of turns) are met, conforming product will be produced in that batch. The relevant parameters would be monitored to confirm that the batch was produced within the validated ranges for the fermentation process.
- *Verification.* We propose to define ''verification'' as confirmation by examination and objective evidence that specified requirements have been fulfilled. Examples of verification activities would include measuring a dimension such as the length or circumference of a cigarette or cigar to confirm it meets a specified requirement, conducting a laboratory analysis of a pH level to confirm it is within a specified range, and performing a visual comparison of a hand-rolled cigar against a standard or approved model to confirm the proper shape and dimensions of that finished cigar.

B. Management System Requirements

1. Organization and Personnel

Proposed § 1120.12 describes the proposed requirements for finished and bulk tobacco product manufacturers' organization and personnel. This section forms the foundation for manufacturers to adequately perform and comply with the proposed requirements under proposed part 1120. These proposed requirements are generally similar to the organization and personnel requirements in the industry recommendations, and similar practices that FDA has observed during establishment inspections.

Specifically, proposed § 1120.12(a) would require finished and bulk tobacco product manufacturers to establish and maintain an organizational structure that will ensure that their manufacturing operations meet the requirements of part 1120. The organizational structure should clearly delineate the parts of the organization and personnel responsible for complying with the proposed requirements. FDA has observed that it is standard industry practice to maintain an organizational structure, position descriptions, and employee training programs.

Proposed § 1120.12(b) would require finished and bulk tobacco product manufacturers to employ sufficient personnel to carry out the requirements of proposed part 1120. Personnel must have the background, education, training, and experience, or any combination thereof, needed to carry out the requirements of proposed part 1120. Each manufacturer should determine the appropriate background and necessary education for personnel to carry out these requirements. A manufacturer may determine that appropriate certifications and job-related trainings are necessary for a particular job function. For example, employees responsible for quality assurance could take classes or coursework relevant to their role auditing the production process and evaluating the final product for conformance to tobacco product specifications and other requirements established in the MMR. FDA recommends that such training be updated on a regular basis so that responsible employees are aware of current procedures and controls to ensure that they can consistently meet the requirements of proposed part 1120. Proposed § 1120.12(b) would also require manufacturers to maintain appropriate written records of the background, education, training, and experience of its personnel in the format described in proposed § 1120.12(f) and discussed in more detail below.

Proposed § 1120.12(c) would require each finished and bulk tobacco product manufacturer to designate, in writing (on paper or electronically), the appropriate responsibility and authority for all personnel who perform an activity subject to proposed part 1120. Therefore, while proposed § 1120.12(a) would require manufacturers to establish an organizational structure, this provision would require manufacturers to specifically designate the responsibilities and authority for those personnel who would be responsible for performing the activities required under proposed part 1120. This provision would help manufacturers to ensure that their tobacco products conform to their established specifications and reduce the likelihood that nonconforming products would be distributed to consumers.

Proposed § 1120.12(d) would require finished and bulk tobacco product manufacturers to designate, in writing (on paper or electronically), management with executive responsibility that has the duty, power, and responsibility to implement the proposed requirements under proposed part 1120. Management with executive responsibility refers to those individual(s) who are ultimately responsible for ensuring compliance with proposed part 1120. This responsibility would include the allocation of resources, including facilities, equipment, materials, controls, and personnel used for the manufacture, preproduction design validation, packing, and storage of a tobacco product. These employees are typically senior employees with the authority to establish or make changes to tobacco product manufacturing policies and ensure that they are effectively communicated throughout the organization. Management with executive responsibility would be required to establish and maintain required processes and procedures to ensure compliance with requirements under proposed part 1120. Such person(s) also would be required to ensure that TPMP requirements are communicated, understood, implemented, and followed at all levels of the organization. FDA believes that this proposed requirement is generally similar to existing industry practice.

Proposed § 1120.12(e) would require finished and bulk tobacco product manufacturers to establish and maintain training procedures. This provision would require that training procedures identify training needs and establish training frequency for personnel based on the work the employee performs. Under this provision, manufacturers should assess whether employees need periodic or refresher training. FDA is not proposing to prescribe the extent and frequency of training or type of training, but rather the Agency believes that manufacturers should have the flexibility to determine how to adequately train their personnel to perform their assigned responsibilities in accordance with proposed part 1120. For example, some tobacco manufacturing facilities are only open for portions of the year and staffed with seasonal personnel. In this case, a manufacturer may opt to train its personnel at the start of each new manufacturing season.

Proposed § 1120.12(e) would also require finished and bulk tobacco product manufacturers to train personnel on their assigned responsibility and on the TPMP requirements relevant to their responsibility. Under this provision, manufacturers would not be required to train personnel on all the requirements of the proposed regulation, but rather on the provisions of the regulation that are relevant to their assigned responsibility,

including their understanding of the relevant procedures and how to maintain applicable records. Training should also cover the consequences of improper performance so that personnel will be apprised of nonconformities that can result if they do not adequately perform their assigned responsibility and implement the tobacco product manufacturing requirements relevant to their responsibility.

Proposed § 1120.12(f) establishes the format for training records required by § 1120.12(b). These training records would be required to include the type and description of the training, the training date, the names of the parties performing and taking the training, and documentation supporting completion. Training records should demonstrate which personnel were trained, identify the training completed, and illustrate whether that personnel received the proper training for their job functions. Documentation supporting completion may include the results of an assessment or examination given to personnel upon completion of the training.

The Agency believes that the proposed organization and personnel requirements would assure that the public health is protected by requiring that the responsible individuals at all levels of the organization have the knowledge, experience, and training to ensure that the establishment manufactures and distributes tobacco products that conform to established specifications and are not contaminated during the manufacturing process. Deficiencies in personnel qualification and training could increase the likelihood that a company manufactures and distributes nonconforming tobacco products. For example, one company found that spotting and staining of nonconforming finished cigarettes was due to improper training, when personnel used plasticizer instead of casing in the manufacturing process (Ref. 18). In addition, if an employee responsible for analyzing samples in the lab is not properly trained on the techniques for sample preparation and extraction to measure for pH in smokeless tobacco, the results may be unreliable and could lead to products that do not conform to the established specifications for distribution. The pH can influence the availability of nicotine and increase the risk to consumers beyond those normally associated with the product (Ref. 19).

In addition, the Agency believes that the proposed personnel requirements would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. In particular, the proposed requirements would help ensure that personnel with proper background and expertise are participating in and monitoring the production process, thus ensuring that the tobacco product does not become adulterated or misbranded under section 902 or section 903 of the FD&C Act. The proposed requirements also would help ensure that new and modified risk tobacco products (MRTPs) are manufactured consistent with the specifications provided in their applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA) and that pre-existing products are manufactured consistent with their original characteristics. For example, for an SE product, qualified personnel are needed to ensure that tobacco products are manufactured to the specifications described in the SE report. Similarly, these proposed personnel requirements would help ensure that tobacco products that were commercially marketed in the United States as of February 15, 2007 (pre-existing products), continue to be manufactured consistently with their original characteristics.

Qualified and trained personnel are vital to a controlled production process. Requiring manufacturers to have qualified personnel with designated roles and who are appropriately trained would help ensure that personnel are competent in their assigned roles. This, in turn, would help ensure that manufacturing operations are performed correctly and would reduce the chances of adulteration during the manufacturing process. For example, qualified personnel with specific responsibilities to clean tobacco product-contact surfaces would help decrease the likelihood that products contain filthy, putrid, or decomposed substances, or are otherwise contaminated by added poisonous or deleterious substances that may render the product injurious to health. This would also help ensure that products are not prepared or held under insanitary conditions.

2. Tobacco Product Complaints

Proposed § 1120.14 sets forth the requirements for the receipt, evaluation, investigation, and documentation of all complaints. FDA considers a ''complaint,'' in this context, to be any communication (including written, electronic, and oral communication) that the tobacco product does not meet expectations, is unsatisfactory or unacceptable, or appears to be a nonconforming product. Tobacco product complaints may come from any source, including healthcare professionals, consumers, the public, and businesses (*e.g.,* retailers, other tobacco product manufacturers).

The proposed requirements are generally similar to complaint handling processes that FDA has observed during establishment inspections. For example, FDA is aware that tobacco product manufacturers generally maintain complaint records containing information about nonconforming tobacco products, such as incorrectly packaged tobacco products, filters that fall off the filter rod of a cigarette, broken or torn cigarettes, filter plug problems, and irregular and improper burning of cigarettes. FDA is also aware of complaint records containing information about contaminants and hazards in finished tobacco products such as NTRMs (*e.g.,* metal, glass, nails, pins, wood, dirt, sand, stones, rocks, fabric, cloth, plastics), biological materials (*e.g.,* mold, mildew, hair, fingernails), oil or greasy spots on cigarettes, chemicals (*e.g.,* ammonia, cleaning agents, kerosene), and the presence or infestation of tobacco beetles or insects. Further, FDA is aware that manufacturers maintain reports of complaints such as exploding e-cigarettes, excessive heating during use and charging of ENDS, as well as cuts and lacerations, broken teeth, vomiting, nausea, burns, allergic reactions, dizziness, numbness, headaches, and other personal or property damage reported to tobacco product manufacturers. These experiences and records have informed the proposed complaint requirements.

Given the clear importance of tobacco product complaints in alerting manufacturers and FDA to product problems, proposed § 1120.14(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the receipt, evaluation, investigation, and documentation of all tobacco product complaints. FDA believes it is necessary for manufacturers to establish and maintain procedures to address all activities related to complaints (*i.e.,* receipt and processing; evaluation, investigation, and documentation) in order to ensure that manufacturers properly handle complaints.

Proposed § 1120.14(a)(1) through (3) would require that the tobacco product complaint procedures ensure that each complaint is: (1) processed upon receipt in a uniform and timely manner; (2) evaluated and, if necessary, investigated, in accordance with § 1120.14(b) and (c); and (3) documented in accordance with § 1120.14(e). All complaints would need to be processed upon receipt by the

manufacturer. Even complaints that may not appear to be directly related to illness or injury (such as failure to meet a specification, defective packaging, mixup of products, product bearing wrong labeling/warning, or incorrect quantity of product) may be important in identifying a nonconforming product or other manufacturing issue. Such complaints may indicate that the product is adulterated or misbranded and that a corrective action, such as a recall, is needed. Moreover, even a complaint regarding a side effect that appears to be normally associated with tobacco use may indicate a nonconforming product or a product design issue and, therefore, would be required to be investigated. For example, a complaint about respiratory distress could be determined to be attributed to a nonconforming product due to defective solder joints from an ENDS cartomizer that results in metallic particles in the aerosol (Ref. 2). Similarly, a complaint about dizziness or nausea could be due to the addition of too many ammonia compounds and other substances to reconstituted tobacco in a cigarette, which can affect free nicotine levels.

FDA is aware that some manufacturers have a corporate complaint department that handles complaints for all establishments and others have different complaint handling units for different product types and different establishments, which could result in multiple processes for handling complaints. Therefore, under proposed § 1120.14, manufacturers should designate in their procedures which individual(s) are responsible for coordinating and performing all complaint handling functions to ensure consistent handling, categorization, and evaluation/investigation of complaints across the corporation and establishments.

Proposed § 1120.14(b) elaborates on the evaluation requirement found in proposed § 1120.14(a)(2). Proposed § 1120.14(b) would require that personnel evaluate each complaint to determine whether it could be related to: (1) a nonconforming tobacco product; (2) a product design issue; or (3) any adverse experience that is required to be reported under a regulation issued under section 909(a) of the FD&C Act or implementing regulations.[3]

Complaint information may need to be incorporated into the risk management process in proposed § 1120.42 to inform the manufacturer's risk assessment and risk treatment. For example, a manufacturer that previously determined in its risk assessment that a dissolvable tobacco product is unlikely to cause a safety hazard to users would be required to reassess its risks, pursuant to proposed § 1120.42(a)(1)(iii), if it receives complaints alleging choking adverse experiences that could change the previous risk assessment.

Proposed § 1120.14(c)(1) states that if the evaluation determines that the complaint could be related to the circumstances identified in proposed § 1120.14(b)(1) through (3), an investigation must be performed (unless it is subject to the exception as provided in proposed § 1120.14(d). For example, if a complaint evaluation indicates that an ENDS product explosion could be related to an issue with the product's design, the tobacco product manufacturer would be required to perform an investigation under § 1120.14(c). Records of previously received complaints may be relevant to this evaluation. The evaluation phase would not be required to include an analysis regarding the veracity of the complaint.

Accordingly, this proposed section would require that all complaints be processed and evaluated. However, only certain complaints would need to be investigated (*i.e.,* complaints that could be related to a nonconforming product, a product design issue, or reportable adverse experience). For example, a complaint regarding the price of the product or the size offerings distributed by the manufacturer (for example, customer complaints that the manufacturer should offer a larger package size) would need to be processed and evaluated but would not need to be investigated under the proposed rule. However, complaints regarding an exploding battery, metal or rocks found in the tobacco, or nicotine poisoning of the user (or nonuser) would need to be investigated.

As stated in proposed § 1120.14(c)(2), the complaint investigation would be required to identify the scope and cause of the issue and the risk of illness or injury it poses. If a manufacturer's investigation shows that the scope and cause of the issue cannot be determined without the involvement of another entity, such as a specification developer, contract manufacturer, or other entity or establishment that performs a manufacturing operation for the product, then the manufacturer should work together with the other entity to determine the scope and cause of the issue. This would include the timely reporting to other entities of all relevant information related to the complaint.

For example, if complaints are reported to a contract manufacturer and, after investigation, are determined to pertain to a possible product design issue, the contract manufacturer should report these complaints to the specification developer for further investigation. The specification developer has the specific knowledge of the design and development information of the finished tobacco product and would be required to conduct an investigation of the product complaints and implement CAPA, as needed pursuant to proposed § 1120.16, including potential redesign of the product. The contract manufacturer, in turn, should continue to work with the specification developer to ensure that the complaint is resolved in accordance with the proposed requirements in this section. Similarly, if a finished tobacco product manufacturer that only packages or labels bulk tobacco products receives complaints of nonconforming products that may be related to the design or manufacture of the incoming bulk tobacco product, it should report these complaints to the bulk manufacturer who must then also conduct an investigation into the scope and cause of the issue, the risk of illness or injury posed by the issue, and whether any followup action is necessary, and implement CAPA, as needed pursuant to proposed § 1120.16. The finished tobacco product manufacturer should follow up with the bulk manufacturer as needed to ensure that the product complaints have been resolved in accordance with these proposed requirements. This would include the finished tobacco product manufacturer documenting the evaluation, investigation, and any associated followup action regarding the complaint, including any information provided by the bulk manufacturer.

A complaint investigation also must determine whether any followup action is necessary, including whether a CAPA is necessary under proposed § 1120.16. Followup action could include, for example, updating a procedure, requiring refresher training, making a manufacturing process change, or other action to correct and prevent a nonconforming product or design problem; initiating a recall; reporting an adverse experience under a section 909(a) regulation; or beginning to monitor the issue to see if there is a trend that might require further action. This proposed requirement is necessary to ensure that finished and bulk tobacco product manufacturers adequately

[3] We note that, currently, there are no adverse events required to be reported under section 909(a) of the FD&C Act; however, this provision would trigger automatically should FDA issue a regulation based on section 909(a).

investigate complaints that could relate to nonconforming tobacco products, issues related to product design, and reportable adverse experiences to protect consumers, correct the issue, and prevent the same or similar problems from occurring in the future.

A complaint investigation may lead the tobacco product manufacturer to initiate a corrective action, such as a recall or a change to the manufacturing process. For example, in one case, FDA received a consumer complaint that an ENDS product created thick and searing smoke that caused an unexpected health problem, specifically, sore, raw, and swollen throat that persisted for several days (Ref. 20). If, during the investigation, the manufacturer determined that the user's health problem was due to excess voltage causing the atomizer coil to burn, these proposed requirements would ensure that manufacturers investigate the scope of such an issue, the risk of illness or injury it poses, and whether any followup action, such as a CAPA, is necessary. A tobacco product manufacturer may initiate a CAPA under proposed § 1120.16, to implement a design change to control the maximum voltage output to prevent coil overheating. While some tobacco product manufacturers may initiate such actions on their own, FDA believes that these requirements are needed to ensure that all manufacturers take these steps to assure the public health is protected.

Complaints could also identify a reasonably foreseeable risk not previously known to the manufacturer, including risks that may occur with normal use and reasonably foreseeable misuse of the tobacco product, which could relate to a design issue. FDA acknowledges that a manufacturer cannot possibly foresee every single potential misuse during the design of a tobacco product, but should the manufacturer become aware through a complaint of information about risks posed by the product due to misuse, the corrective and preventive action requirements under proposed § 1120.16 and the risk management requirements under proposed § 1120.42 would be triggered, which would include reassessing and treating the risk pursuant to proposed § 1120.42(a)(1)(iii). For example, an ENDS manufacturer may receive complaints of respiratory distress for an ENDS product and determine in its investigation that users are modifying the heating element to increase voltage in order to produce greater clouds of vapor, resulting in higher aerosol temperatures than designed that generate harmful constituents such as formaldehyde, acetaldehyde, and acrolein (Ref. 21). Knowing that information, the manufacturer would reassess and treat the risk and initiate appropriate corrective action, which may include implementing design changes to prevent a user from disassembling and modifying the heating element.

When conducting investigations, tobacco product manufacturers should also review available records related to the complaint (*e.g.,* acceptance records, nonconforming product records, or CAPA records). For example, a tobacco product manufacturer may receive complaints about an ENDS overheating. Even if the product is not returned, the manufacturer may review other complaint files and determine that complaints related to other ENDS models have been received. An investigation and review of acceptance records (see proposed § 1120.64) may reveal an increase in the number of heating element components being rejected from a particular supplier. As a result of the investigation, the tobacco product manufacturer may initiate a CAPA to increase monitoring of the supplier and require additional testing to ensure that received components meet established specifications.

Proposed § 1120.14(d) provides an exception to the requirement to conduct an investigation under § 1120.14(c). This paragraph would provide that a tobacco product manufacturer is not required to complete an investigation if it has already conducted an investigation of a similar complaint and the tobacco product manufacturer determines and documents that the previous investigation results apply and another investigation is not necessary. FDA interprets a similar complaint to be one related to the same type of nonconformity or issue and likely to have the same cause or source. Therefore, a tobacco product manufacturer would not need to conduct an investigation if its documentation includes a reference to a previous investigation and a statement explaining why the complaints were sufficiently similar such that the previous investigation results apply and another investigation is not necessary. This analysis would be based on the particular facts and circumstances at issue. For example, a tobacco product manufacturer may determine and document that it need not investigate a complaint of an ENDS overheating, because it had previously investigated a complaint and found that a particular component caused the overheating and the production record shows that the product at issue used the same component from the same supplier, before the problem was corrected.

Proposed § 1120.14(e) would require a manufacturer of finished or bulk tobacco products to maintain complaint records containing the information required by § 1120.14(e)(1) through (14). Complaints requiring investigation that may result in a risk of illness, injury, or death not normally associated with tobacco product use must be clearly identified or separated. Additional discussion of the meaning of ''not normally associated'' can be found in section II.A.2. This proposed requirement would enable tobacco product manufacturers to recognize these types of complaints and prioritize appropriate followup action.

Proposed § 1120.14(e)(1) through (14) states that the complaint record must include the following information, if available: the name of the product, including brand and sub-brand; a description of the product; manufacturing code; date the complaint was received; format of complaint (*i.e.,* oral or written); name, address, and phone number of complainant; nature and details of the complaint, including how the product was used; identification of individual(s) receiving complaint; record of evaluation by the manufacturer, including the name of the individual(s) performing the evaluation; if no investigation is undertaken, the name of the individual(s) responsible for that decision and the rationale for the decision; investigation date(s); record of investigational activities performed and personnel who performed the activities; results of investigation; and any follow up action taken, including any reply to the complainant or any corrective and preventive action taken. Some of this information would be obtained during the evaluation stage while other information would be obtained during the investigation stage, if an investigation is required. The complaint record would also include activities performed by other entities that assist in the investigation. For example, if a manufacturer reports a complaint to another entity, such as a specification developer, or contract manufacturer, because the manufacturer's investigation shows that the scope and cause of the issue cannot be determined without the involvement the other entity, then the manufacturer should include in the complaint record information regarding the investigation performed by the other entity, if available.

The information in proposed § 1120.14(e) is basic information that is

essential to any complaint investigation and necessary to ensure a thorough complaint investigation and facilitate an appropriate followup. The manufacturer should make a reasonable effort to obtain the information listed in proposed § 1120.14(e)(1) through (14). For example, should some of the basic information in proposed § 1120.14(e)(1) through (14) be missing with respect to a particular complaint, a single unsuccessful attempt to reach the complainant would not be considered by FDA to be a reasonable effort to obtain information related to the complaint. If the information described in proposed § 1120.14(e)(1) through (14) cannot be obtained, this provision would require the manufacturer to document the attempts to obtain this information and explain why the information was not included, as described in proposed § 1120.14(f).

FDA believes that these proposed requirements would assure that the public health is protected by requiring tobacco product manufacturers to systematically handle the receipt, evaluation, investigation, and documentation of all complaints to determine if there is a problem with the tobacco product, a related tobacco product, or the manufacturing process, and take appropriate action. If a tobacco product manufacturer does not have a written complaint procedure, the manufacturer may not properly evaluate and if necessary, investigate the received complaint and may fail to identify a nonconforming tobacco product, a product design issue, or a reportable adverse experience. For example, if a customer reports to a manufacturer that there are metal objects in a can of smokeless tobacco (*e.g.,* Ref. 3), and the complaint procedures do not describe how to perform an investigation, the manufacturer may not conduct an adequate investigation and take an appropriate followup action, including a corrective and preventive action that would prevent consumer illness or injury from such contaminants.

Complaints from users and nonusers are an invaluable source of information for tobacco product manufacturers. The evaluation and investigation of complaints can help a tobacco product manufacturer identify problems with a tobacco product's design, established specifications, or production process. For example, if a manufacturer is receiving complaints alleging explosions of ENDS, this proposed rule would require the manufacturer to investigate the scope and cause of the issue to determine if, for example, it is due to a design problem or manufacturing problem. The investigation may determine that the problem is due to use of a non-Original Equipment Manufacturer battery charger that does not meet the manufacturer's established specification. The U.S. Fire Administration has found that nearly 25 percent of e-cigarette fires occurred when the battery was being charged (Ref. 22). Many e-cigarettes are charged using an ordinary universal serial bus (USB) port charging connection that allows users to connect the e-cigarette to power adapters that are not provided by the original manufacturer of the device. Because the voltage and current provided by USB ports can vary significantly between manufacturers, use of a USB port or power adapter not supplied by the original manufacturer may subject the battery to a higher current than is safe, leading to thermal runaway that results in an explosion and/or fire. As a result of this complaint information, the manufacturer may initiate a CAPA pursuant to proposed § 1120.16 (and further discussed in section IV.B.3) to redesign the battery to have a proprietary connection that could only be connected to a charging unit designed to be compatible or redesign the battery management system to detect an incompatible power adapter and prevent the battery from charging. New information on increased likelihood of occurrence or severity of harm obtained from tobacco product complaints should be incorporated into the manufacturer's ongoing risk management activities (*i.e.,* review of new information that could change the original risk assessment and risk treatment) under proposed § 1120.42.

In addition, FDA believes that the proposed tobacco product complaint requirements would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. Consumer complaints about adverse experiences or product problems may indicate nonconforming tobacco products that are not being manufactured to established specifications. Therefore, these proposed complaint requirements would help tobacco product manufacturers to ensure that new tobacco products and MRTPs are manufactured consistent with the specifications provided in their applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA) and that pre-existing products are manufactured consistent with their original characteristics. For example, if numerous complaints are received about a product, the manufacturer may investigate and learn that the product does not have the same characteristics it had as of the pre-existing date.

Complaints can also indicate that distributed tobacco products are adulterated or misbranded under section 902 or 903 of the FD&C Act. For example, complaints could indicate that products have been ''prepared, packed, or held under insanitary conditions'' (section 902(2) of the FD&C Act). In addition, as noted previously, complaints can uncover cross-contamination in a production process that resulted in an adverse experience to the user, necessitating a change in the manufacturing process to prevent the further production of cross-contaminated products. The proposed requirements in this rule that would require manufacturers to process, evaluate, investigate, and document complaints would help them to address and prevent recurrence of such adulteration.

These proposed complaint requirements also may help ensure that the packaging, labeling, or labels of finished and bulk tobacco products comply with applicable statutory and regulatory requirements. For example, a complaint may note that tobacco products are missing labels with required warning statements causing the products to be misbranded under section 903 of the FD&C Act. The investigation may determine that adequate acceptance activities are not being performed during the packaging and labeling operations. This provision would enable the manufacturer to ensure that required warning statements are applied to prevent misbranded products from being commercially marketed.

3. Corrective and Preventive Actions

Proposed § 1120.16 sets forth the requirements for CAPA. CAPA, for purposes of proposed § 1120.16, is a systematic assessment of nonconforming tobacco products and design problems to determine the cause and implement appropriate changes to the product specifications, relevant manufacturing methods and production process procedures, and/or packaging, labeling, and labels to correct and prevent the cause of the nonconformity or design problem. CAPA also helps prevent the distribution of identified nonconforming product and helps identify design problems. These proposed requirements are generally similar to the industry recommendations and to practices of tobacco product manufacturing establishments that follow ISO 9001–2015 (Ref. 11). Tobacco product manufacturers have utilized CAPA in

the past to take appropriate actions to correct and prevent identified causes of nonconformities and design problems (*e.g.,* Refs. 23–27). FDA believes that all tobacco product manufacturers should implement CAPA procedures.

Proposed § 1120.16(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for implementing CAPAs. Specifically, proposed § 1120.16(a)(1) would require such manufacturers to review and analyze processes, process control records, complaints, production records, returned products, reprocessed products, reworked products, and other sources of data to identify existing and potential causes of nonconforming tobacco product and design problems. These sources would help manufacturers identify possible causes of nonconformities and design problems and may also help manufacturers identify previously undetected problems.

Under the proposed rule, FDA expects that manufacturers would periodically examine manufacturing processes to look for causes of nonconforming tobacco products or design problems, and take steps to prevent their occurrence. For example, under proposed § 1120.16(a)(1) (and the proposed production processes and controls provision discussed further below (see § 1120.66)), a finished or bulk e-liquid manufacturer would periodically review the mixing process for an e-liquid to determine if it has been trending towards the upper control limit for the nicotine concentration. Such an issue would require a corrective action to maintain the mixing operation within the control limits so as not to produce nonconforming product. Further, records associated with other tobacco products manufactured using the same equipment or production process, including records of tobacco complaints, acceptance activities, nonconforming product, and returned products could help determine if a repeated nonconformity is associated with a manufacturing method or procedure.

Appropriate statistical methodology must be employed where necessary to detect recurring problems. Statistical techniques (*e.g.,* Ref. 28) are useful to identify trends of nonconforming product or processes and records that indicate systemic problems that contribute to nonconformities. Appropriate statistical tools, such as trend analysis, can be used to review tobacco product complaints, process controls, nonconforming product, acceptance activities, and production records. It may be necessary to employ statistical techniques such as trend analysis to identify recurring problems across multiple batches and identify potential causes of nonconforming product or design problems, which is an important part of preventive action.

Proposed § 1120.16(a)(2) would require finished and bulk tobacco product manufacturers to investigate the cause of design problems or nonconformities relating to the tobacco product or the manufacturing process. For example, if a validated cigarette-making process has a normal 2 percent rejection rate and that rate rises to 10 percent, this provision (along with proposed § 1120.74(b)) would require the manufacturer to perform an investigation into the nonconformance of the process. In this example, we would expect the investigation to include an assessment of production batches manufactured before and after the suspect batch, including records of monitoring of the process control parameters required by proposed § 1120.66(a)(2) and continued process verification results required by proposed § 1120.66(b)(3) to determine if other batches have been affected and whether there are process deviations that require revalidation of the manufacturing process pursuant to proposed § 1120.66(a)(3).

If a manufacturer's investigation shows that the cause of the design problem or nonconformity cannot be determined without the involvement of another entity, such as a specification developer, contract manufacturer, or other entity that performs a manufacturing operation for the product, then the manufacturer should work together with the other entity to determine the cause of the design problem or nonconformity. This would include the timely reporting to other entities of all relevant information related to the design problem or nonconformity. For example, if a contract manufacturer investigates the cause of a nonconformity in accordance with proposed §§ 1120.16(a)(2) and 1120.74(b) and determines that it does not pertain to its contract manufacturing process, the contract manufacturer should report the information to the specification developer for investigation. The specification developer has knowledge of, and controls the design and development information of, the finished tobacco product and may be in the best position to investigate whether the nonconformity relates to a design problem, and to implement CAPA for issues related to product design. Similarly, if a finished tobacco product manufacturer who repackages or relabels tobacco products performs a CAPA investigation and determines that the cause of a nonconformity does not relate to its repackaging or relabeling process, it should report the nonconformity to the other manufacturer(s), who then can conduct an adequate investigation, determine the cause of the nonconformity, and implement appropriate CAPA, for example changes to process controls.

Proposed § 1120.16(a)(3) would require finished and bulk tobacco product manufacturers to identify and take actions needed to correct and prevent the recurrence of design problems and nonconformities and other related problems found in the investigation. Correction and prevention of inadequate procedures and practices should result in fewer tobacco product nonconformities. To comply with this provision, for example, a manufacturer could decide to revise and update inadequate procedures, identify and correct improper personnel training, or require refresher training on a procedure to address employees' failure to follow such procedure. When identifying such actions, manufacturers should take into account the risk of illness or injury posed by the design problem or nonconformance. The degree of corrective and preventive action taken to eliminate or minimize design problems or nonconformities should be appropriate to the magnitude of the problem and commensurate with the associated risks. For example, to address a more serious problem such as a design problem resulting in a fire or explosion, the manufacturer may need to take a more significant corrective and preventive action, such as a product redesign. When performing the CAPA in such a scenario, the manufacturer may need to incorporate its risk management process (see proposed § 1120.42(a)(1)) to assess and treat the risk.

Proposed § 1120.16(a)(4) would require finished and bulk tobacco product manufacturers to verify or validate CAPAs to ensure that the actions are effective and do not adversely affect the product. Verification, as defined in proposed § 1120.3, would refer to confirmation by examination and objective evidence that specified requirements have been fulfilled. Examples of verification activities would include measuring a dimension such as the length or circumference of a cigarette or cigar to confirm it meets a specified requirement, conducting a laboratory analysis of a pH level to confirm it is within a specified range, and performing a visual comparison of a hand-rolled cigar against a standard or

approved model to confirm the proper shape and dimensions of that finished cigar. Validation, as defined in proposed § 1120.3, would refer to confirmation by examination and objective evidence that the particular requirements can be consistently fulfilled. An example of a validation activity would be the validation of the smokeless tobacco fermentation process, which would be used to demonstrate that when key parameters (*e.g.,* temperature, pH, oven volatiles, and number of turns) are met, conforming product will be produced in that batch. The relevant parameters would be monitored to confirm that the batch was produced within the validated ranges for the fermentation process.

Verification and validation could also include the collection and analysis of data, such as from acceptance activities and nonconforming products, to confirm that a CAPA has effectively addressed the problem. Moreover, if a tobacco product manufacturer determines that a process change is required because the existing process cannot be maintained, proposed § 1120.16(a)(4) would require the manufacturer to verify or validate that this CAPA does not adversely affect the tobacco product by, for example, modifying an established specification. Verification and validation activities provide an opportunity to demonstrate through examination and objective evidence that the proposed corrective and preventive action is effective and does not introduce new or increased risks associated with the product, production process, packing, and storage. For example, if a manufacturer receives complaints about the presence of mold in finished tobacco product, it may decide to initiate a CAPA to address this issue by changing the packaging to control the moisture content of the tobacco product. The manufacturer must verify or validate the newly redesigned packaging, for example, by confirming that the new packaging material's moisture barrier meets specified requirements or conducting shelf life testing, respectively.

Proposed § 1120.16(a)(5) would require finished and bulk tobacco product manufacturers to implement and document changes to tobacco product specifications, manufacturing methods and production process procedures, and packaging, labeling, and labels needed to correct and prevent identified causes of the design problem or the nonconformity. A tobacco product manufacturer could comply with this provision in many different ways. For example, a tobacco product manufacturer that receives consumer complaints regarding respiratory distress, may redesign an ENDS cartomizer to minimize metal and silicate particles in the aerosol (Ref. 2). Similarly, a cigarette manufacturer may determine that calibration procedures need to be revised to correct the improper application of casings applied to cut filler and prevent the recurrence of nonconforming product (Ref. 29). Another example is a manufacturer that may change solvents used on packaging (*e.g.,* benzene, toluene, methyl ethyl ketone, methyl cellosolve, cellosolve) that are found to contaminate cigarettes (Ref. 30).

Proposed § 1120.16(a)(6) would require that information related to the design problem or nonconformity and the CAPA taken be disseminated to management with executive responsibility, those responsible for acceptance activities of a tobacco product, and personnel responsible for identifying training needs in accordance with proposed § 1120.12(e). This requirement would help ensure that designated individuals who are responsible for implementing TPMP requirements are notified about design problems, nonconformities, and CAPAs and can adjust procedures accordingly.

Proposed § 1120.16(b) would require that finished and bulk tobacco product manufacturers maintain records of all activities conducted under this section and that these records include the date and time, the individual performing the activity, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. For purposes of this proposed part 1120, FDA interprets ''reconstruct,'' in this context, to mean the ability to re-create the results by analyzing all data, including source and metadata data, and records, including calculations. Although FDA is not proposing to prescribe a particular format to document CAPA activities, this provision would require tobacco product manufacturers to document all of the actions taken to address the requirements under this section (*e.g.,* Refs. 24–26).

The proposed § 1120.16 requirements would help assure that the public health is protected by requiring tobacco product manufacturers to perform a systematic assessment of nonconforming products and design problems to determine and address the cause. For example, nonconforming product can result from inadequate or nonexistent tobacco product or process specifications; failures of or problems with purchasing controls; inadequate process controls; improper facilities or equipment; inadequate training; and inadequate manufacturing methods and procedures.

The proposed requirements would help ensure that nonconformities and design problems are thoroughly investigated and effective CAPA are taken to eliminate or minimize them and potential harms to the consumer. For example, under this proposed section, an ENDS manufacturer that receives complaints about respiratory distress and metallic aftertaste from use of an ENDS product may initiate a CAPA investigation. The manufacturer may determine that the cartomizer aerosol contains traces of tin, copper, nickel, and silver metals attributed to poor solder joints from the cartomizer supplier (Ref. 2), and take a CAPA to change suppliers, use different cartomizer materials, and implement solder joint reliability testing as an acceptance activity (see § 1120.64). While individual tobacco product manufacturers may have used CAPA in the past, these proposed requirements would ensure that all finished and bulk manufacturers take these actions to prevent harms that could occur as a result of design problems and nonconforming products.

CAPA can also help minimize or prevent contamination of finished or bulk tobacco product. For example, due to increased consumer complaints of plastic or Styrofoam material in finished tobacco products, a manufacturer may initiate a CAPA to implement an optical sorter to prevent the introduction of non-ferrous NTRMs into finished and bulk tobacco products.

The proposed CAPA requirements would also help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act by establishing procedures for the manufacturer to follow in taking appropriate action on nonconforming and contaminated tobacco products both prior to, and after the manufacturer starts, marketing the products. For example, a CAPA to prevent the introduction of non-ferrous NTRMs into finished or bulk tobacco products, as discussed above, would help ensure that the product is not adulterated under section 902(a)(1) of the FD&C Act. Moreover, these provisions would help ensure that appropriate measures are taken to address new or MRTPs that do not conform to the specifications provided by the manufacturer to FDA in the relevant tobacco product applications (*i.e.,* SE Report, SE exemption request, PMTA, MRTPA) and that pre-existing tobacco products are manufactured consistent with their original characteristics.

C. Buildings, Facilities, and Equipment

1. Personnel Practices

Proposed § 1120.32 would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the cleanliness, personal practices, and apparel of personnel. Under this proposed requirement, the procedures must include requirements to ensure that contact between the personnel and the tobacco product manufacturer or the environment would not result in contamination of the tobacco product. These proposed requirements are generally similar to personnel practices that FDA has observed during establishment inspections. Personnel can contaminate tobacco products by unintentionally transferring bacteria, viruses, or disease through the handling of tobacco products, and contamination (*e.g.,* physical or microbial) may occur at any time during the manufacturing process. Therefore, this proposed rule would require each tobacco product manufacturer to set up appropriate, consistent, and effective measures to prevent personnel from contaminating tobacco products. Examples of such measures for ''cleanliness, personal practices, and apparel'' can include outer garment requirements, personal cleanliness, restrictions on jewelry and other loose items, adequate hand washing before handling a tobacco product, use of gloves, head coverings, or other protective equipment, and daily checks on these practices.

This proposed requirement would help ensure that the public health is protected by helping to prevent tobacco products from becoming contaminated, which can adversely affect public health over and above the risk normally associated with the use of the product. The proposed requirements also would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. These measures would prevent a likely source of contamination and nonconformity and help ensure that products are not manufactured under insanitary conditions. Therefore, the requirements would help ensure that products are not adulterated under section 902 of the FD&C Act.

2. Buildings, Facilities, and Grounds

Proposed § 1120.34(a) would require finished and bulk tobacco product manufacturers to ensure that any buildings and facilities used in or for the manufacture, packaging, or storage of a tobacco product are of suitable construction, design, and location to facilitate cleaning and sanitation, maintenance, and proper operations. These proposed requirements are generally similar to the controls for buildings, facilities, and grounds in the industry recommendations, and to practices that FDA has observed during establishment inspections.

The construction, design, and location of the physical plant provide the infrastructure that enables a tobacco product manufacturer to conduct its manufacturing operations. Therefore, this proposed rule would require that each building and facility be maintained in an appropriate condition to prevent tobacco product contamination. The term ''suitable,'' as used in this provision, would mean that the construction, design, and location of facilities would enable proper cleaning and sanitizing, maintenance, and operation. Examples of buildings and facilities that are inadequately constructed, designed or located would include facilities that are constructed of particle board that have exposed wood chips or flakes that could become a physical hazard, facilities that are constructed of porous material and cannot be adequately cleaned and sanitized, and buildings and facilities whose equipment is so tightly placed that it prevents adequate cleaning and maintenance of the building or facility. For the buildings and facilities to facilitate ''proper operations'', they should be constructed, designed, and located in a manner to facilitate the logical flow of manufacturing activities from receipt and storage of incoming materials, processing, packaging, and warehousing. FDA is not proposing to require specific activities to satisfy this requirement; rather the proposed rule is intended to provide flexibility for manufacturers to determine what is appropriate based on the specific manufacturing activities performed at the establishment.

Proposed § 1120.34(a)(1) would require that buildings and facilities have adequate lighting. FDA would consider this requirement satisfied if lighting conditions enable the tobacco product manufacturer to perform necessary manufacturing operations, including cleaning, sanitation, and maintenance. Among other things, this requirement is necessary to identify insanitary conditions that may not be visible with inadequate lighting. For example, tobacco product manufacturers may utilize visual inspection to remove NTRMs from the production area and inadequate lighting may make it difficult for personnel to identify and remove these materials. Manufacturers should also take measures to make sure that lighting is not a source of contamination. For example, lighting should not attract pests that can contaminate or otherwise render the tobacco products adulterated or misbranded under section 902 or 903 of the FD&C Act. Manufacturers should cover lighting fixtures or use shatter-proof bulbs to prevent tobacco products from becoming contaminated with glass shards if the light bulbs shatter.

Proposed § 1120.34(a)(2) would require that buildings and facilities have adequate heating, ventilation, and cooling (HVAC). HVAC equipment and systems are used to maintain the environmental conditions of buildings and facilities. For example, a manufacturer may establish temperature, relative humidity, and air flow conditions necessary for storage, handling, or processing (such as mixing, cutting, or blending) of tobacco product. Use of fans and other air-blowing equipment can maintain air ventilation to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate product or otherwise render product adulterated. This requirement would help ensure that the HVAC equipment is designed and maintained to prevent contamination of tobacco products. For example, manufacturers should prevent conditions such as damaged or exposed HVAC duct insulation hanging over processing equipment or leakage of hydraulic fluid from an HVAC system on tobacco products that may contaminate tobacco products (*e.g.,* Ref. 31). While some tobacco product manufacturers may already take such actions to control environmental conditions, these proposed requirements would ensure that all manufacturers take these actions to prevent contamination that could occur due to an inadequate HVAC system.

Proposed § 1120.34(a)(3) would require finished and bulk tobacco product manufacturers to utilize adequate plumbing (including control of drainage, backflow, sewage, and waste) to avoid being a source of contamination or creating insanitary conditions. For example, water pipes should be designed so condensation does not fall on the tobacco product or tobacco product-contact surfaces, which can cause contamination. In addition, floors cleaned with water (or water-soluble products) should be designed with floor drains to facilitate adequate drainage. Water by-products, sewage, and waste can be a source of contamination if they touch a tobacco product-contact surface or become a part of the tobacco product. Improper control of drainage, sewage, and waste also can result in pooling and create insanitary conditions or attract

pests that may contaminate tobacco products with filth. Filthy conditions from improper control of drainage, sewage, and waste can be transferred throughout the facility on shoes and equipment.

Proposed § 1120.34(a)(4) would require that buildings and facilities have adequate waste collection, storage, and disposal. Adequate waste collection, storage, and disposal includes not creating malodors that contaminate tobacco products or result in an attraction, harborage, or breeding places for animals and pests. Trash bins should have lids and be periodically emptied to help reduce the potential for insanitary conditions from microbial contamination and pests.

Proposed § 1120.34(a)(5) would require finished and bulk tobacco product manufacturers to provide adequate readily accessible handwashing and toilet facilities. The facilities must provide for water at suitable temperatures and appropriate cleaning and sanitation materials. FDA considers adequate hand-washing and toilet facilities to have hand-cleaning and sanitizing preparation areas, towel service or suitable drying stations, water control valves, appropriate signs, shelving or hooks on which to rest garments while using the toilet, and trash bins that are properly constructed and maintained. Handwashing and sanitizing, when used with water at suitable temperatures and with appropriate cleaning and sanitation materials, are an important means of preventing tobacco product contamination by personnel.

Proposed § 1120.34(b) would require finished and bulk tobacco product manufacturers to maintain the facility grounds in a condition to prevent contamination. The grounds consist of the actual physical property where the buildings and facilities are located. Inadequately maintained grounds can, for example, present a pest harborage area that can be a source of contamination.

Proposed § 1120.34(c) would require finished and bulk tobacco product manufacturers to ensure that water used in the manufacturing process, including water that is or may become part of the tobacco product (*e.g.,* water used as an ingredient or water used on a tobacco product-contact surface) is potable, will not contaminate the tobacco product, is maintained under positive pressure (*e.g.,* to prevent back siphonage that can draw water from a contaminated source into the water supply system due to leaks or gaps in the mains, cross-connections, or valves), and is supplied from sources that comply with all applicable Federal, State, and local requirements. Water is commonly used in the manufacture of tobacco products, and water that is untreated may be contaminated with *Escherichia coli* (*E. coli*) and coliform bacteria. All piping systems, hydrants, taps, faucets, hoses, buckets, and other equipment used for the delivery of water that is used as an ingredient or for use on tobacco product-contact surfaces, should be designed, constructed, maintained, and operated in such a manner as to prevent contamination of the water.

Under this proposal, the manufacturer's water supply should come from a source for which adequate controls exist for testing, treatment, and removal of contaminants (*e.g.,* microbes and heavy metals).

Therefore, proposed § 1120.34(c) would require that the water be supplied from sources that comply with all applicable Federal, State, and local requirements. For example, state governments have water departments that administer the public water system and have specific requirements to ensure that the water is safe for consumption and use.

Proposed § 1120.34(d) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the cleaning and sanitation of buildings, facilities, and grounds, including procedures for the use of any cleaning compounds, sanitizing agents, pesticide chemicals, rodenticides, insecticides, fungicides, fumigating agents, and other toxic materials. An establishment's poor cleaning and sanitation practices can increase the likelihood of tobacco product contamination. A tobacco product manufacturer should take into account the construction, design, and location of the buildings and facilities as well as the manufacturing operations, when establishing cleaning and sanitation procedures.

Specifically, proposed § 1120.34(d)(1) would require that manufacturers' cleaning and sanitation procedures detail the cleaning schedules, equipment, and materials to be used in the cleaning and sanitization, as appropriate, of the buildings, facilities, and grounds.

Proposed § 1120.34(d)(2) would require that these procedures include measures to ensure that materials used for cleaning and sanitation are identified, held, used, and stored in a manner to protect against contamination of tobacco products and tobacco product-contact surfaces. For example, FDA has observed on inspections that cleaning and sanitation materials are sometimes stored in unmarked containers in the manufacturing area (*e.g.,* Ref. 32) and, consequently, may be inadvertently used or mixed with tobacco product ingredients, additives, or materials. This proposed provision would help prevent this potential source of contamination. To help ensure that the use of cleaning and sanitation materials are used in a manner that protects against contamination, manufacturers should ensure that such materials are appropriate for their intended purpose and nontoxic where possible.

Proposed § 1120.34(d)(3) also would require that the use of cleaning and sanitation materials comply with all applicable Federal, State, and local requirements related to their application, use, or storage. For example, hazardous cleaning and sanitation chemicals must be handled, used, and stored in a manner consistent with the information contained in their safety data sheets in accordance with the hazard communication standard at 29 CFR 1910.1200(g).

Proposed § 1120.34(e) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for monitoring, controlling, and minimizing the presence of animals and pests in the buildings, facilities, and grounds to protect against contamination of tobacco products. This proposed requirement would be limited to manufacturing activities and not extend to agricultural activities including growing, cultivation, or curing of raw tobacco (21 U.S.C. 387). FDA acknowledges that tobacco is an agricultural crop and, therefore, there is the likelihood that there will be a certain level of animals and pests (such as tobacco beetles) in the tobacco. However, it is important that manufacturers take appropriate action to control these animals and pests, which can cause contamination (*e.g.,* Refs. 33–35). FDA is proposing that these procedures include requirements for establishing threshold criteria for animals and pests. This provision is intended to provide manufacturers with flexibility to quantitatively establish acceptable levels of animals or pests, such as insects, that may be present and the levels that would necessitate action to control and minimize infestation in order to avoid contamination. Manufacturers may employ pest control or fumigation to minimize the presence of animals or pests (*e.g.,* Ref. 36). This approach is recognized in the Cooperation Centre for Scientific Research Relative to Tobacco's (CORESTA's) Good Agricultural Practices Guidelines (Ref. 37).

This paragraph also would require that the procedures include a requirement that any pesticide, including rodenticides, insecticides, or fungicides used in the buildings, facilities, and grounds be registered in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) and used in accordance with its label, as applicable and used in a manner that protects against contamination. Pesticides, such as rodenticides, insecticides, or fungicides are useful to manufacturers to monitor, control, and minimize animals and pests effectively. The tobacco product manufacturer should follow all applicable pesticide labels, identify proper compounds to be used, use the correct concentration, and apply it as directed to avoid contamination (*e.g.,* Refs. 38–40). Use of inappropriate pest control chemicals or use in an inappropriate manner can contaminate tobacco products (*e.g.,* Refs. 39–41).

Proposed § 1120.34(f) would require finished and bulk tobacco product manufacturers to maintain records of cleaning and sanitation and animal and pest control activities required under this section. These records would be required to include the date and time, the individual performing the activity, the type of activity performed, any information demonstrating the requirement was met, and any data or calculations necessary to reconstruct the results. We believe these records are necessary for tobacco product manufacturers to ensure that the required activities have been conducted and for FDA to verify that the activities have been adequately performed.

The proposed requirements for buildings, facilities, and grounds would help assure that the public health is protected by helping to prevent tobacco product contamination by, among other things, toxic cleaning compounds, inadequate maintenance, or cross-contamination from inadequate cleaning (*e.g.,* Refs. 42–44). Insanitary conditions can create the potential for growth of microorganisms that may render tobacco products injurious to health beyond what is normally associated with tobacco products (*e.g.,* Refs. 45 and 46).

These proposed requirements also would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act by helping to ensure that tobacco products are not ''prepared, packed, or held under insanitary conditions'' that may contaminate tobacco products and render them adulterated under section 902 of the FD&C Act. As discussed above, inadequate or inappropriate maintenance, cleaning and sanitizing procedures, or animal and pest control may result in conditions that can adulterate tobacco products.

3. Equipment

Proposed § 1120.36(a) would require finished and bulk tobacco product manufacturers to ensure all equipment is appropriately designed and constructed, and is suitable for its intended purpose. These proposed requirements are generally similar to the equipment controls in the industry recommendations and to controls that FDA has observed during establishment inspections. The term ''equipment'' means any machinery, tool, instrument, utensil, or other similar or related article, used in the manufacture, preproduction design validation, packing, or storage of a tobacco product. Equipment that is appropriately designed, constructed, and suitable for its intended purpose is designed and constructed in a manner that facilitates its function, use, maintenance, and cleaning. For example, under this proposal, a tobacco cutter would be required to be designed and constructed to enable use, cleaning, and maintenance (*e.g.,* inspection and replacement of its cutting blade). It would also be required to be suitable for its intended purpose to cut tobacco to particular specifications (*e.g.,* different cut sizes).

Proposed § 1120.36(b) would require finished and bulk tobacco product manufacturers to establish and maintain procedures, including the methods and schedules, for the routine cleaning and maintenance of equipment, to ensure proper performance of equipment and prevent contamination. This provision is intended to give each tobacco product manufacturer the flexibility to determine the appropriate methods and frequency of cleaning and maintenance of equipment based on their manufacturing practices. For example, a manufacturer may require that cutting equipment be cleaned after each batch of tobacco is produced, using approved sanitizing agents that will not contaminate the tobacco product. The manufacturer also could schedule maintenance involving disassembling, inspection, and replacement of the cutting blade to be performed every 6 months. Proposed § 1120.36(b) would also require that the procedures provide for any change-over of tobacco product and account for changes, limitations, or adjustment to the equipment. For example, if a manufacturer uses the same equipment to manufacture flavored and nonflavored tobacco products,[4] the cleaning and maintenance procedures must address the change-over activities to prevent mixups or cross-contamination (*e.g.,* Refs. 47 and 48).

Proposed § 1120.36(c) would require finished and bulk tobacco product manufacturers to identify (electronically, by signage, or other method of identification), if applicable, all processing lines and major equipment to be used during manufacturing to prevent mixups and contamination. The intent of this identification requirement is to prevent mixups (*e.g.,* flavored vs. nonflavored, regular vs. mentholated) and distribution of nonconforming product. FDA is also proposing that related information (*i.e.,* which major equipment and processing line was used in the manufacture of a batch of finished or bulk tobacco product) be maintained in the production record, pursuant to proposed § 1120.70(b)(3) to establish traceability and assist with, for example, nonconforming tobacco product investigations.

FDA recognizes that it is impractical to identify every piece of equipment used during manufacturing. Thus, the Agency proposes to require identification of major equipment only. Major equipment includes blending silos, conditioning cylinders, makers, filling machines, assembly equipment (for cartridge production), and packers. For example, if a manufacturer has multiple blending silos to hold different blends, conditioning cylinders at different stages that add different moisture levels, dedicated makers for different cigarette lengths/circumferences, filling machines for dry vs. moist snuff, and packers for soft vs. hard packs, this provision would require all such equipment to be appropriately identified. Examples of equipment that would not need to be identified under this proposed provision include a portable hand-held mixer, optical detectors (to remove foreign matter), metal detectors, string doffers (to remove string), and moisture meters/detectors. In addition, manufacturers would be required to identify all processing lines. For example, if there are dedicated maker and packer lines for regular and mentholated products, these processing lines would be required to bear appropriate identification to prevent mixups and contamination. If a

[4] FDA recently issued proposed tobacco product standards that would prohibit menthol as a characterizing flavor in cigarettes, 87 FR 26454 (May 4, 2022), and characterizing flavors (other than tobacco) in all cigars and their components and parts, 87 FR 26396 (May 4, 2022).

manufacturer does not have multiple or dedicated processing lines or major equipment that could lead to product mixup, it should document this as a justification for not implementing these proposed identification requirements.

Manufacturers may also choose to include in the identification of the processing line or major equipment the identification of the product being processed. FDA has observed that some manufacturers place designated, color coded, indicator to identify the flavor of the product (for example, pink for cherry flavor) being manufactured with that equipment. This requirement is intended to work in conjunction with the requirements for identification and acceptance status established in proposed § 1120.64. Identifying the product as well as major manufacturing equipment, will help minimize or eliminate mixups during the manufacturing process.

Proposed § 1120.36(d) sets out additional requirements for testing, monitoring, and measuring equipment. Testing, monitoring, and measuring equipment is used in all stages of manufacturing. Examples of testing, monitoring, and measuring equipment include pH meters, moisture meters, and weight or measurement scales that are used to verify established tobacco product specifications.

Proposed § 1120.36(d)(1) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for all testing, monitoring, and measuring equipment to ensure such equipment is capable of producing accurate and reliable results. For example, if a manufacturer uses a pH meter, this proposal would require procedures for the use of such a meter to address how its reference and pH electrodes are to be maintained in order to produce accurate results; otherwise, it could result in unstable and off-scale readings (Ref. 49). In addition, if an ingredient specification is measured by weight in grams, the scale would need to be sensitive enough to accurately and reliably provide these measurements to ensure the correct amount of the ingredient is added to the tobacco product.

Proposed § 1120.36(d)(2) would require that all testing, monitoring, and measuring equipment be identified and disabled, removed, replaced, or repaired when it is no longer suitable for its intended purpose or when it is no longer capable of producing accurate and reliable results. Defective equipment is not suitable for use in the manufacturing process and can result in nonconforming or contaminated tobacco product.

Proposed § 1120.36(d)(3) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the routine calibration of testing, monitoring and measuring equipment. Calibration provides assurance that equipment is properly performing and providing accurate and reliable measurements. Under this proposal, the procedures must describe an appropriate reference standard and include specific directions and acceptance criteria for the limits of accuracy and precision. Testing, monitoring, and measuring equipment must be calibrated before first use; thereafter, at a frequency determined by the equipment manufacturer or at intervals necessary to ensure accurate and reliable results; and after repair or maintenance. The appropriate frequency of calibration would likely depend on the particular equipment, the equipment manufacturer's recommendation, the activity the equipment is used for, and the individual calibration process. Calibration should be performed at suitable intervals in accordance with an established procedure containing specific directions, schedules, and limits for accuracy and precision based on the type of instrument being used and other factors such as operating environment and wear and tear.

Proposed § 1120.36(e) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. Records would be required to include the date and time, the individual performing the activity, the type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

The proposed equipment requirements would assure that the public health is protected, by helping to prevent the use of malfunctioning equipment that can produce nonconforming product. For example, if a tobacco cutter is not designed, constructed, or maintained properly, it can result in tobacco strips that do not conform to established specifications for cut size. The size of the cuttings of tobacco is a physical design specification that can influence the release of nicotine in a tobacco product (Ref. 6). Maintenance of equipment is also necessary to prevent contamination of tobacco product. For example, a finished tobacco product manufacturer previously recalled tobacco products due to heavy oil spots from a cutter head oil leak (Ref. 50). While some manufacturers may already have controls similar to the proposed requirements in place, FDA believes it is important that all manufacturers comply with these requirements to help protect against the manufacturing and distributing of contaminated or otherwise nonconforming product. The proposed identification requirement would help assure that the public health is protected by preventing mixups and contamination of tobacco products that could have an adverse impact on public health.

The proposed equipment requirements also would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. For example, the equipment requirements would help ensure that tobacco products meet applicable statutory requirements under sections 905, 907, 910, and 911 of the FD&C Act. Equipment that functions properly and produces accurate and reliable results is necessary to ensure that new tobacco products and MRTPs are manufactured consistent with the specifications described in their applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA); that the specifications for pre-existing tobacco products continue to be consistent with their original characteristics; and that tobacco products subject to tobacco product standards are manufactured in accordance with those standards.

For example, consider a cigarette product marketed pursuant to an SE Report. If laboratory equipment used in the cigarette manufacturing provides a check on the nicotine content in the manufactured products, improperly functioning equipment may allow higher nicotine content in the manufactured products. Such products would not conform to the specifications described in the SE Report. Because FDA authorizes the marketing of tobacco products based on the specifications described in the relevant marketing application, nonconforming products, such as the cigarette in this example, would be on the market without FDA authorization in violation of chapter IX of the FD&C Act.

In addition, a bulk manufacturer that does not properly maintain or calibrate its testing, monitoring, and measuring equipment can produce nonconforming bulk tobacco products. For example, cutting equipment that has not been properly maintained can result in bulk cigarette tobacco, RYO, or pipe tobacco products with an incorrect cut size. Similarly, filling equipment that has not been properly calibrated can produce bulk e-liquids with nicotine concentration that exceeds the labeled concentration.

4. Environmental Controls

Proposed § 1120.38(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures to adequately control environmental conditions where appropriate. In addition, under the proposed requirement, environmental control systems would have to be maintained and monitored to verify that environmental controls, including necessary equipment, are adequate and functioning properly. Environmental control systems include associated equipment (*e.g.,* HVAC equipment, humidifier, air filters) that manages the facility's environmental conditions (*e.g.,* temperature, humidity, ventilation, filtration). These proposed requirements, which are intended to ensure that the tobacco product meets its specifications and is not adversely affected by environmental conditions, complement those in proposed § 1120.34, which are intended, in part, to ensure that buildings and facilities have adequate controls to prevent contamination. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001–2015 (Ref. 11).

The appropriate environmental control procedures needed to comply with this proposed requirement can vary by product, manufacturing process, and other factors. For example, if a tobacco product manufacturer uses a sterilization process for a moist snuff product to achieve a product stability specification, it should establish environmental controls for temperature, moisture, and time (Ref. 51). If a tobacco product manufacturer determines that specific conditions are necessary to minimize mold growth, it would need to establish appropriate environmental controls, such as controlling the relative humidity (Ref. 52). In addition, if an ENDS manufacturer determines that airborne particulates can contaminate e-liquids, appropriate environmental controls, such as use of air filters or precautions against potential sources of airborne contaminants, should be taken (*e.g.,* Ref. 10).

Proposed § 1120.38(a) also would require that environmental control systems be maintained and monitored to verify that environmental controls, including necessary equipment, are adequate and functioning properly. Monitoring of these systems can be performed by recording data, using alarms to determine if the environmental controls deviate from the operating range or fail, or other means to ensure that environmental controls are operating as intended.

Proposed § 1120.38(b) would require finished and bulk tobacco product manufacturers to maintain records regarding environmental controls, including maintenance and monitoring. Records would be required to include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. We believe these records are necessary to ensure that the required activities have been conducted and for FDA to verify that the activities have been adequately performed.

The proposed environmental controls requirements would help assure that the public health is protected by maintaining proper environmental conditions to protect products from contamination and to ensure they meet specifications. For example, improper humidity and temperature during storage of tobacco can result in spoilage and the growth of mold (Ref. 53). Studies have shown that mold can grow on reconstituted tobacco at certain humidity and temperature conditions (Ref. 54). FDA is aware that some tobacco product manufacturers have a microbiological monitoring plan and perform environmental monitoring of water and air in accordance with that plan and assess the effectiveness of their sanitation procedures (Ref. 55). As an example of how environmental controls can also be important to ensure that products meet specifications, if a smokeless tobacco product uses a heat treatment process (Ref. 56) or a cigar uses a fermentation process (Ref. 57) to achieve a pH specification, the tobacco product would not conform to its established specification if the manufacturer does not establish and maintain environmental controls for the temperature, moisture, and time. As explained in more detail in the discussion of proposed § 1120.74 (see section II.E below), a specification such as pH can affect the speed and amount of nicotine that is delivered to a user (Refs. 6 and 19). Moisture and pH also can be associated with concentrations of nicotine in smokeless tobacco (Refs. 58 and 59). While some manufacturers may already have similar controls in place, this proposed rule would help ensure that all manufacturers establish such controls to help protect against the manufacturing and distributing of contaminated or otherwise nonconforming product.

In addition, the proposed environmental controls would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. As discussed, specific controlled environmental conditions may be necessary to manufacture a tobacco product that conforms to established specifications, including specifications described in any relevant tobacco product applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA), and to ensure that the specifications for pre-existing tobacco products continue to be consistent with their original characteristics.

D. Design and Development Controls

1. Design and Development Activities

Proposed § 1120.42 addresses risks associated with design and development activities by requiring finished and bulk tobacco product manufacturers to establish and maintain procedures to control the design and development of each finished and bulk tobacco product and its package, including the control of risks associated with the product, production process, packing, and storage. Procedures to control the design and development of finished and bulk tobacco products would need to address risk management as well as design verification and validation. The proposed requirements incorporate principles similar to those found in, for example, ISO 9001; the QSR for medical devices; current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food; and HACCP regulations.

Proposed § 1120.42(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures to control the design and development of each product and its package, including the control of risks associated with the product, production process, packing, and storage. While FDA is aware that some tobacco product manufacturers already engage in a wide variety of activities to control the design and development of tobacco products, including chemistry, toxicology, and nonclinical testing; clinical assessment and investigations; and consumer and market research (*e.g.,* Ref. 55), the Agency believes that these requirements are needed to ensure that all manufacturers address risks associated with design and development activities. A manufacturer's procedures may vary based on the type of tobacco product and may be specific to one or multiple products. Therefore, FDA is proposing a flexible framework to allow manufacturers to implement procedures that best suit their specific design and development approach.

Design activities can be performed by different parts of a tobacco product manufacturer's organization, (*e.g.,* manufacturing, marketing, purchasing, and regulatory affairs). Procedures to control the design and development of a tobacco product should establish the roles that any groups have in process and describe the information that they should receive and transmit, including any approvals that may be necessary.

Under proposed § 1120.42(a), design and development controls must control for risks associated with each finished and bulk tobacco product and its package, production process, packing, and storage. Specifically, proposed § 1120.42(a)(1) would require that the design and development procedures include a risk management process. For purposes of this rule, a risk management process is a preventive means to identify and control for potential risks throughout the product lifecycle (*i.e.,* during design, manufacturing, distribution, and use of products). Risk management is an established practice used by manufacturers in many industries, including in the manufacture of FDA-regulated products such as foods, drugs, biologics, and medical devices. General risk management standards such as ISO 31000:2018—Risk Management—Principles and Guidelines (Ref. 12) can be used by manufacturers to provide guidance in establishing and maintaining a risk management system. In some industries, industry-specific risk management standards have been developed (*e.g.,* Refs. 60 and 61), whereas other industries use a more broadly developed framework (*e.g.,* Ref. 62). While FDA is not proposing to require compliance with a particular risk management framework or standard, FDA recommends that finished and bulk tobacco product manufacturers use an established risk management framework such as a standard or guideline.

The proposed provision would give manufacturers flexibility in devising their risk management process and the type of risk assessment technique(s) employed; however, at a minimum, proposed § 1120.42(a)(1) would require that the risk management process include the following steps: risk assessment (including risk identification, risk analysis, and risk evaluation), risk treatment, and reassessment. A tobacco product manufacturer can perform their risk management process for categories, types, or families of products that share similar specifications and design characteristics. During inspections, the Agency has observed that some tobacco product manufacturers currently use a risk management framework (including, *e.g.,* HACCP plans) that is consistent with these proposed requirements (Ref. 63).

Under proposed § 1120.42(a)(1)(i), each finished and bulk manufacturer must perform a risk assessment that includes risk identification, risk analysis, and risk evaluation. Manufacturers can utilize various risk assessment techniques to help ensure compliance with this section, such as preliminary hazard analysis, Delphi, scenario analysis, fault tree analysis, cause-and-effect analysis, failure mode and effect analysis, hazard and operability studies, and hazard analysis and critical control points (Ref. 62). Risk assessment for risks associated with the tobacco product would need to be performed for each tobacco product manufactured, packed, or stored, taking into account the individual attributes of each product, its package, and manufacturing process. For example, a manufacturer performing a risk assessment for e-liquids would need to consider potential risks associated with access of e-liquid by children or leakage of e-liquid from cartridges during and after use, which can cause acute nicotine toxicity to users and nonusers.

The first step of risk assessment that would be required under proposed § 1120.42(a)(1)(i) is risk identification. At this step, manufacturers would be required to identify all known or reasonably foreseeable risks associated with the tobacco product and its package, as well as its production process, packing, and storage (see Refs. 12 and 62). In identifying all known or reasonably foreseeable risks associated with the tobacco product, a manufacturer would be required to identify known or reasonably foreseeable risks that may occur naturally or be introduced, intentionally or unintentionally, in the growing, harvesting, curing, leaf processing, and warehousing of tobacco leaf, and during primary production, manufacturing, packing, or storage of finished or bulk tobacco products. These risks may include biological, chemical, or physical hazards in a tobacco product, such as harmful bacteria, pesticides, and NTRMs. Risk identification would also need to take into account risks associated with product design. An example of a risk associated with product design is a dissolvable tobacco product whose size and shape resembles candy, resulting in potential misuse by and harm to children.

''Known'' risks refer to those risks that a tobacco product manufacturer knows about through, for example, its manufacturing and distribution experience, records, and reports (such as complaints, returned products, nonconforming product, and CAPA). ''Reasonably foreseeable'' risks are those risks that a reasonably prudent tobacco product manufacturer would become aware of through scientific literature, publications, or public information, such as an industry standard or FDA guidance document. To identify risks, the manufacturer should evaluate relevant information, such as complaint file investigations, published literature, articles, and reports. For example, in identifying reasonably foreseeable risks associated with an ENDS product with a lithium battery, a manufacturer should take into consideration, among other things, available information regarding design features of lithium ion batteries that could cause overheating, fires, and explosions (*e.g.,* Refs. 64–69).

Proposed § 1120.42(a)(1)(i) would also require that risk identification include risks that may occur with normal use (*i.e.,* labeled and customary uses) and with reasonably foreseeable misuse (*i.e.,* any use not intended by the manufacturer, including user error) of a tobacco product. Risks that may occur with normal use and with reasonably foreseeable misuse are discussed in greater detail below.

The concept of ''reasonably foreseeable misuse'' is well-established and utilized in risk management. For example, the American National Standards Institute (ANSI)/Advancement of Medical Instrumentation (AAMI)/International Electrotechnical Commission (IEC) 62304:2006 regarding medical device software, states that manufacturers must identify potential causes of hazardous situations, including reasonably foreseeable misuse (Ref. 70). Since misuse of a product can be a source of harm, FDA believes it is appropriate to consider reasonably foreseeable misuse when completing risk management activities for tobacco products. An example of a risk related to reasonably foreseeable misuse would include a child accessing an e-liquid container that does not have a secure container closure system and ingesting the product, which could lead to serious injury or death due to nicotine toxicity.

Proposed § 1120.42(a)(1)(i) would require each finished and bulk tobacco product manufacturer to identify all known or reasonably foreseeable risks associated with the tobacco product and its package, as well as its production process, packing, and storage. Risks associated with a tobacco product under proposed § 1120.42(a)(1)(i) would include risks associated with finished or bulk tobacco product specifications,

including product risks attributable to components or parts, ingredients, additives and materials; product design; and issues addressed in a tobacco product standard under section 907 of the FD&C Act. For example, use of an improper charger on a rechargeable e-cigarette may result in a battery fire or explosion due to differences in specifications. Similarly, use of e-liquid flavors containing diacetyl may cause acute-onset bronchiolitis obliterans, a severe and irreversible obstructive lung disease (Ref. 71).

Risk identification would also need to be performed for known or reasonably foreseeable risks associated with the tobacco product package. Risks associated with a tobacco product package would include substances that may render the contents injurious to health and cause the tobacco product to become adulterated under section 902(3) of the FD&C Act or a package design which can cause or expose users and nonusers to harm. For example, an e-liquid manufacturer would need to consider potential risks of leakage of e-liquid from cartridges, which can cause product malfunction (Ref. 72) or skin irritation (Ref. 73), as well as risks to nonusers such as children who can access the e-liquid and experience acute nicotine toxicity (Refs. 74–76).

Risk identification would also need to be performed for all known or reasonably foreseeable risks associated with the production process, packing, and storage. Risks associated with the production process, packing, and storage would include substances and conditions that can contaminate and/or render the tobacco product injurious to health and thereby cause the tobacco product to become adulterated under section 902(1) and (2) of the FD&C Act, including but not limited to, biological, chemical, and physical hazards described below. Risk identification should take into account the type of tobacco product being manufactured, the manufacturing processes, and the facility where the product is manufactured, packed, or stored. Risks identified in one facility may not be significant in another facility, even if it manufactures the same or a similar product, due to differences in equipment, process controls, and/or maintenance programs. Additionally, risks associated with a facility's tobacco products may differ based on the type of tobacco product manufactured, packed, or stored.

Risk identification should take into account biological, chemical, and physical hazards. For example, biological hazards such as bacteria, mold, yeast, microbes, and other biological organisms can grow on tobacco and tobacco products as a result of environmental conditions in their warehousing, packing, and storage. These hazards vary widely in their prevalence, mode of action, infectious dose, growth and survival specifications, and resistance to heating, chemical agents, and other processes or treatments. The Agency has observed on inspection that a cigarette manufacturer identified potential mold on incoming ''tobacco with yellow spots'' during visual inspection that was determined by microbiological analysis to be *Aspergillus flavus* (the major producer of aflatoxin, which is associated with an increased risk of liver cancer) (Ref. 77). In addition, microbes that can be found on tobacco and tobacco products include bacteria, bacterial spores, fungi (yeast and mold), fungal spores, cell wall components (certain glucans and flagellum), and diverse microbial toxins that include exotoxins and endotoxins (Ref. 78). Examples of bacterial-derived toxins include endotoxins (lipopolysaccharide, LPS; inflammatory factor) and mold-derived mycotoxins (Ref. 78).

Similarly, risk identification should include chemical hazards. Chemical hazards, including pesticide residues, can be naturally occurring or intentionally, unintentionally, or incidentally added to tobacco, tobacco products, or tobacco-product contacting surfaces. For example, pesticide chemical residues have been found on commercially available cigarettes. In 2003, the European Commission's Joint Research Centre investigated the content of organochlorine pesticides in a selection of commercially available cigarette brands and found that they contained pesticide chemical residues (Ref. 79). Organochlorine pesticides act on the nervous system to prevent the normal flow of nerve impulses to muscles that control both voluntary movement, such as walking, and involuntary movement, such as breathing and heartbeat (Ref. 80). These classes of pesticides are also associated with a range of adverse health effects that could result in immediate and life-threatening effects, such as respiratory failure, or conditions that do not appear immediately, such as cancer (Ref. 80).

When identifying chemical hazards, tobacco product manufacturers should assess the chemicals that are used in the manufacturing establishment for cleaning, sanitation, and pest control purposes that may be associated with the manufacturing, packing, and storage of tobacco products, including rodenticides, insecticides, fungicides, and fumigating agents. For example, FDA is aware of situations where packaging solvents, cleaning solutions, hydraulic oil leakage, and machine grease may have caused contamination (Refs. 50 and 81).

Risk identification should also take into account any physical hazards that may be associated with the tobacco product. These hazards include animals, animal parts and excrement, insects and insect excrement, such as tobacco beetles and insect parts; rocks, stones, and sand; plastic string, plastic sheet, foam, and rubber; metal, glass, hessian/burlap, wood products, cloth, and cotton strings; and other forms of NTRMs that may be introduced on the farm, during harvesting, and during the manufacturing process. The facility and equipment also can be a source of physical hazards (*e.g.,* metal fragments such as nuts and bolts from equipment used in manufacturing and processing, glass pieces from overhead light bulbs, or debris from overhead equipment). FDA is aware that glass shards have been found in smokeless tobacco products (Ref. 81). If glass is present in chewing tobacco, it may lacerate the gums or lips of the user of the tobacco product. FDA believes it is critical to identify NTRMs that may be introduced throughout the supply chain (Ref. 37).

FDA is proposing that the risk management process require identification of all known and reasonably foreseeable risks associated with the tobacco product, including risks that cause illness, injury, or death normally associated with the use of tobacco products. Identifying risks normally associated with the use of the tobacco product is necessary to perform an adequate risk analysis and evaluation. Some symptoms or health effects of risks not normally associated with the use of the tobacco product can be similar to the symptoms or health effects of risks normally associated with the use of the tobacco product, and therefore this requirement would help ensure that risks that may appear to be normally associated with the use of tobacco products, but are not, are included in the risk analysis and evaluation. In addition, identifying symptoms or health effects of risks normally associated with the use of the tobacco product and their likelihood and consequence of occurrence will help inform the investigation of user reports and complaints about such symptoms or health effects, because they may also point to risks not normally associated with the use of the tobacco product. For example, an increase of reported frequency or severity of respiratory distress from use of an ENDS product may help a

manufacturer detect a previously unidentified risk of metallic particles in the cartomizer aerosol due to defective solder joints from the cartomizer (Ref. 2). Similarly, increased complaints of pneumonia, exacerbation of asthma, bronchitis, chronic obstructive pulmonary disease, eosinophilic pneumonitis, and laryngitis may be associated with chemical contamination of a tobacco product (Ref. 82).

After risk identification, the next step of risk assessment is risk analysis. Risk analysis is an analysis of the nature and level of the risk for each identified known or reasonably foreseeable risk that takes into account the likelihood of occurrence of the risk and the consequences of occurrence of the risk (*i.e.,* severity of the potential harm). When considering the likelihood of occurrence of the risk, the manufacturer should consider the frequency that such risk may occur in the type of product, the production process, and the particular manufacturing establishment. When considering the consequences of the occurrence of the risk, the manufacturer should consider the health effects of the risk, including the severity, immediacy, or near-term onset of any potential injury or illness, and long-term effects from chronic or cumulative exposure, on both users and nonusers.

For example, FDA is aware that some manufacturers have identified styrene (Styrofoam) as a risk that requires risk control. Styrene is a chemical hazard that can be introduced in tobacco products as an NTRM such as via food containers that contaminate tobacco products during manufacturing or via a packaging coating that can be transferred to the tobacco product (Ref. 83). Styrene can enter into the body of consumers by inhalation or ingestion. Styrene consumption can affect the nervous system, resulting in changes in color vision, tiredness, feeling drunk, slowed reaction times, concentration problems, and balance problems (Ref. 84). The International Agency for Research on Cancer (IARC) has determined that styrene is a possible carcinogen (Ref. 85). Under the proposed rule, a manufacturer performing a risk analysis for styrene would consider the likelihood of styrene being introduced into the tobacco product and reaching consumers. It would also consider the health effects of styrene exposure on users and nonusers. For example, storage conditions such as temperature and duration can affect microbial growth and nitrite formation, which can influence tobacco-specific N-nitrosamines (TSNA) content in processed and packaged smokeless tobacco products. (*See* Ref. 16, Ref. 181–182). Under the proposed rule, a manufacturer should perform a risk analysis of the tobacco product using the expected storage period and conditions and determine the likelihood of changes to TSNA content that may result in an increased risk to public health as the product sits in storage.

Following risk analysis, the last step of risk assessment is risk evaluation. The proposed risk evaluation requirement would require an evaluation of each identified risk. Risk evaluation is a determination of the significance of the risk and the type of risk treatment needed (*e.g.,* avoiding the risk, mitigating the risk, or choosing to retain the risk), including the priority of the risk treatment. A comprehensive risk evaluation demonstrates that the manufacturer has considered all relevant information about the tobacco products being manufactured, packed, or stored and determined the significance of the identified risks and what type of risk treatment is needed.

In this context, determining the significance of the risk means evaluating whether the risk and its magnitude are acceptable, tolerable, or unacceptable. In determining the significance of the risk, manufacturers should develop criteria against which the risk and its magnitude can be evaluated. For example, a manufacturer may determine that, based on its risk criteria, a risk of nonusers ingesting e-liquids resulting in toxic nicotine exposure is not tolerable and must be controlled. The manufacturer may similarly determine that, based on its risk criteria, a nicotine concentration that is a certain percentage higher than the established specification is not tolerable and must be controlled through additional manufacturing controls such as acceptance testing. Determining the significance of a risk would inform the manufacturer's decision regarding what type of risk treatment is appropriate and the priority of that risk treatment. FDA is aware that during the evaluation stage of a risk assessment, manufacturers across industries sort risks into categories based on established risk criteria to determine whether risk control/mitigation is required, should be considered, or is not necessary (Ref. 12).

Proposed § 1120.42(a)(1)(ii) would require that each finished and bulk manufacturer treat all identified risks, including risks addressed in applicable tobacco product standards. Risk treatment can include implementing controls to avoid or remove the risk, or making an informed decision to retain the identified risk (Ref. 12). The proposed risk treatment requirements would require the manufacturer to significantly minimize or prevent risks identified in proposed § 1120.42(a)(1)(i) that are reasonably likely to occur and that may cause serious illness, injury, or death not normally associated with the use of the tobacco product, or that the manufacturer determines constitute an unacceptable level of risk. Additionally, risks addressed in any applicable tobacco product standards would be required to be treated in a manner that ensures the tobacco product will conform to the specifications and requirements established in the tobacco product standard. FDA requests comment on whether these are the appropriate risks for which risk prevention or mitigation should be required.

FDA's application of risk management concepts acknowledges that the use and consumption of tobacco products entails some degree of risk inherent to tobacco use. Therefore, the risk mitigation and prevention requirements in the proposed rule focus on reducing or eliminating those risks associated with the tobacco product, its design and packaging, and its associated production process, packing, and storage that are reasonably likely to occur and may cause an illness, injury, or death not normally associated with the use of tobacco products. These requirements are also intended to address issues that the manufacturer determines constitute an unacceptable level of risk. This proposed provision would, therefore, require tobacco product manufacturers to, at a minimum, undertake risk treatment to significantly minimize or prevent such risks. Additionally, any risks identified in an applicable tobacco product standard would need to be treated in a manner that ensures the tobacco product will conform to the tobacco product standard.

For example, a manufacturer may determine that NTRMs such as glass, metal, rocks, and stones are introduced on the farm, during harvesting, or during the manufacturing process, and that, as a result, hard or sharp NTRMs are reasonably likely to occur in a tobacco product. The manufacturer may also determine that, when these hard or sharp NTRMs are present in a tobacco product, they may cause traumatic injury, including laceration and perforation of tissues of the mouth, tongue, throat, stomach, and intestine as well as damage to the teeth and gums. Based on this information, the manufacturer would be required to significantly minimize or prevent the risk under § 1120.42(a)(1)(ii) of the proposed rule.

Risk treatment measures will vary based on the type of product and the risks identified as well as the manufacturing facility. Risk treatment can include manufacturing controls, redesigning the tobacco product, clarifying user instructions, or ordering a component or part from a different supplier. Risk treatment also may include personnel requirements (*e.g.,* health, cleanliness, personal practices, and apparel of personnel), cleaning and sanitation controls, animal and pest controls, maintenance of equipment, environmental controls, purchasing controls (*e.g.,* Good Agricultural Practices, supplier guarantee, testing raw tobacco for pesticide chemical residues (Ref. 86)), acceptance activities (*e.g.,* visual inspection, tests, and other verification activities), and process controls (*e.g.,* metal detectors, x-rays, optical sorters). For example, FDA has noted on inspections that certain manufacturers have implemented manufacturing policies that include a requirement to use pens that do not have caps, are color-coded, and contain ferrous material to prevent physical hazards from being introduced in the tobacco product during the production process and enable the hazard to be readily identified by metal detectors and magnets if necessary (Ref. 87).

Where risk treatment measures required by proposed § 1120.42(a)(1)(ii) are implemented to significantly minimize or prevent a risk associated with the production process, packing, and storage that is reasonably likely to occur and may cause serious illness, injury, or death not normally associated with the use of the tobacco product and package, or that the manufacturer determines constitutes an unacceptable level of risk, the manufacturer should incorporate these measures in the relevant procedure(s) under proposed part 1120. For example, the manufacturer may need to incorporate the risk treatment measures into its procedures for personnel practices under proposed § 1120.32, buildings, facilities, and grounds under proposed § 1120.34, environmental controls under proposed § 1120.38, purchasing controls under § 1120.62, acceptance activities under proposed § 1120.64, and production processes and controls under proposed § 1120.66. Manufacturers also would be required to validate or verify their production process in accordance with proposed § 1120.66.

A manufacturer may determine that a risk is unacceptable if it occurs infrequently but the consequences are severe. Likewise, a risk may be unacceptable if the risk occurs frequently, even if it is not associated with serious illness or injury. For example, if a cigarette manufacturer uses a new filter supplier that uses methyl isothiocyanate (which can cause throat irritation) in its filter processing, it may determine that this is an unacceptable level of risk if it occurs frequently, even though the severity of the risk is moderate or low.

Although testing alone is rarely considered an effective risk treatment, testing can be useful to verify that control measures are effectively minimizing or preventing risks. For example, microbial testing of raw materials may verify that suppliers have controlled for biological hazards. Environment testing also may verify whether sanitation or environmental controls have addressed the potential for environmental pathogens to contaminate tobacco products. For example, during acceptance moisture testing, a manufacturer may determine a finished product has excessive moisture content during the packing process that has resulted in spoilage of cigarettes due to growth of *Aspergillus restrictus* and *Aspergillus glaucus* mold, a biological hazard (Ref. 88).

Where a manufacturer has identified a risk associated with consumer misuse of a product, the manufacturer may need to redesign the product in order to comply with this proposed provision. If there is a potential for misuse that causes harm and such misuse could be prevented, the manufacturer should address it. For example, a tobacco product manufacturer may determine that a package redesign could reduce choking hazards associated with dissolvable tobacco products or toxic exposure to e-liquids (*e.g.,* Refs. 89 and 90). Similarly, an ENDS manufacturer could redesign a battery charger connection if the manufacturer identifies the risk that users are misusing the USB charging connection port and using a nonstandard USB power source that does not match the manufacturer's specifications. Depending on the manufacturer's assessment of the risk, a redesign may not always be necessary. However, if new information suggests that risk treatment short of redesign has not been effective, the proposed rule would require the manufacturer to reassess their risk treatment activities pursuant to proposed § 1120.42(a)(1)(iii) and consider additional mitigation.

Proposed § 1120.42(a)(1)(iii) would require each finished and bulk tobacco product manufacturer to reassess the risks whenever the manufacturer becomes aware of new information that could change the risk assessment and risk treatment, including information about previously unidentified risks or the adequacy of risk treatment measures.

The risk management process FDA is proposing is an ongoing process whereby manufacturers update their risk assessment as new information is learned. The purpose of the reassessment requirement is to determine if existing risk assessment and risk treatment need to be updated in light of new information that bears on the effectiveness of the risk management process. New information can inform the scientific understanding of a previously assessed risk or identify a new risk. A finished or bulk tobacco product manufacturer may become aware of new information in a variety of ways, including user and nonuser reports of adverse experiences, records and reports (such as complaints, returned products, nonconforming product, and CAPA), and through scientific literature, publications, or public information, such as an industry standard or FDA document.

Proposed § 1120.42(a)(1)(iii) would specifically require finished and bulk tobacco product manufacturers to reassess risks whenever the manufacturer becomes aware of new information that indicates a previously unidentified risk. For example, an ENDS manufacturer may become aware that the ENDS product's power settings can result in carbonyl generation which can increase cancer potency (Refs. 91 and 92). Under these circumstances, the ENDS manufacturer would have to undertake the risk assessment and risk treatment steps for the newly identified risk.

Additionally, this provision would also require the manufacturer to reassess the risks when it becomes aware of new information that indicates that a previously identified risk they did not believe was reasonably likely to occur is, in fact, reasonably likely to occur. For example, a tobacco product manufacturer may have previously identified metal fragments in chewing tobacco as a risk that was not reasonably likely to occur. If the manufacturer begins to receive consumer complaints about metal fragments being found in its chewing tobacco, this new information would necessitate a reassessment of the risk to determine whether the initial risk analysis and evaluation must be updated and new risk treatment measures must be implemented.

In addition, this provision would also require manufacturers to reassess risks when they become aware of new information that indicates the existing risk treatment measures are ineffective.

For example, if consumer complaints report that finished tobacco products continue to have NTRM after risk treatment measures have been implemented, the tobacco product manufacturer would need to reassess the risk and modify the treatment measures as necessary.

FDA recognizes that batteries and other components may be a source of risk. Therefore, FDA is proposing that finished and bulk tobacco product manufacturers, which are responsible for component selection and design (*e.g.,* an ENDS manufacturer responsible for the selection of the battery and the manner in which it operates in the ENDS product), would need to do a risk assessment of the risks associated with the finished or bulk tobacco product, including risks attributable to such components. For example, an ENDS manufacturer should perform a risk assessment of the battery design (such as an internal or a commercially available off-the-shelf external battery), safety rating, and suppliers to consider potential risks associated with use of the battery with their ENDS product that may occur during normal use (*e.g.,* charging) and during reasonably foreseeable misuse (*e.g.,* customer replacement with a non-OEM battery).

FDA is aware that not all tobacco product manufacturers design the tobacco products they manufacture. Under this proposed rule, contract manufacturers who are not responsible for product design would not be required to assess the design risks associated with the products' specifications. For example, if a contract manufacturer does not engage in design activities but only manufactures a tobacco product for another party based on specifications provided by that party, the contract manufacturer would not be responsible for assessing the design risks associated with the product's specifications.

For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, proposed § 1120.42(a)(2) would require finished and bulk tobacco product manufacturers to perform design verification to confirm that the tobacco product and its packaging meet specifications and design validation to assess the performance of the tobacco product. These activities would be informed by the risk management process in proposed § 1120.42(a)(1). Process verification and process validation would be separate requirements and are found in proposed § 1120.66. Design verification confirms that the product and packaging meet their specifications. Design verification activities can include testing and studies, and reviewing design documents before their release as specifications in the MMR. For example, an ENDS manufacturer may establish that the specification for a battery is a power of 4 volts, temperature range of 200 °C to 300 °C, it must be charged in less than 90 minutes, and that it can be recharged 1,000 times. Under the proposed rule, the manufacturer would be required to perform battery testing to verify that the battery performance meets those specifications.

Design validation is a process to assess the product performance to confirm that it consistently performs or functions as intended. For example, a manufacturer could perform testing of child resistant packaging to validate the effectiveness of the package design in preventing children from accessing the tobacco product while allowing adult users to open the package.

For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, proposed § 1120.42(a)(3) would require that the product and packaging design be approved by a designated, authorized individual. The review and approval would be required to ensure that the product and packaging specifications are supported by the product design verification and validation activities and that appropriate risk treatment measures have been implemented.

For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, proposed § 1120.42(a)(4) would require finished and bulk tobacco product manufacturers to transfer the approved product and packaging specifications to the MMR. Proposed § 1120.42(a)(5) would require finished and bulk tobacco product manufacturers, where appropriate, to utilize the processes under proposed § 1120.42(a)(2) through (4) for design changes before the changes are implemented.

Proposed § 1120.42(b) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. These records would be required to include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. Manufacturers would have flexibility to determine the format in which these records are maintained. For example, these records may be maintained in a single record or single file of records, or as part of a product- or product-type-specific index system that references and includes the location of all the required information. The results of the design and development activities would produce the information documented in the MMR, including specifications, manufacturing methods and procedures, and packaging and labeling (see proposed § 1120.44(a)).

The proposed requirements for design verification and validation, design approval, and design transfer under § 1120.42(a)(2) through (4) would not apply to existing tobacco products already commercially marketed before the effective date of this rule, including, for example, pre-existing tobacco products commercially marketed in the United States as of February 15, 2007. Finished and bulk tobacco product manufacturers would not be required to perform retroactive design verification to confirm that such tobacco products and their packages meet specifications, or retroactive design validation to assess their performance. Similarly, finished and bulk tobacco product manufacturers would not be required to perform retroactive design approval and design transfer for such products under proposed § 1120.42(b)(3) and (4). However, the proposed § 1120.42(a)(2)–(4) requirements would apply to finished and bulk tobacco products first commercially marketed after the effective date of the rule, and to any finished and bulk tobacco products that are modified after the effective date of the rule, including changes made in order to comply with a tobacco product standard. When changes are made to finished or bulk tobacco products commercially marketed before the effective date of any final TPMP rule, the proposed requirements of § 1120.42(a)(2) must be followed to confirm that the tobacco product and its package, as modified, meet specifications and that the tobacco product will perform as intended.

The proposed design and development activities requirements would help assure that the public health is protected by helping to prevent illness, injury, or death not normally associated with the use of the tobacco product, including to users and nonusers. The proposed provisions would require finished and bulk tobacco product manufacturers to perform an assessment of the known and reasonably foreseeable risks associated with the tobacco product, its package, and its production process, packing, and storage that may occur with normal use of the tobacco product or with any reasonably foreseeable misuse of the product, including user error. For

example, ENDS can overheat, resulting in fires and explosions (*e.g.,* Refs. 64, 93 and 94). Under these proposed requirements, an ENDS manufacturer would be required to assess the risk the battery poses in the design of its finished tobacco product, as lithium batteries can contribute to ''thermal runaway'' and cause a battery fire or explosion (Ref. 67). If the ENDS manufacturer determines that this risk is reasonably likely to occur and that it may cause serious illness, injury, or death not normally associated with the use of the tobacco product, it would then be required to take appropriate treatment measures to significantly minimize or prevent the risk, such as use of overcharging protection circuits, thermal power cutoffs, and internal overpressure relief mechanisms that can help prevent and mitigate thermal runaway. The proposed provision would then require manufacturers to verify and validate the design of the product taking into account these risk treatment measures.

FDA believes that engaging in a risk management process is the most effective and efficient way to proactively ensure that risks associated with finished and bulk tobacco products, their package, and their production process, packing, and storage, are adequately assessed and treated. FDA believes such an approach is more effective than identifying and controlling risks through finished product testing or sanitation controls alone (Ref. 95). Additionally, other TPMP requirements such as product complaints, acceptance activities, nonconforming product, and returned product may not be sufficient to address all risks.

The requirement to maintain records of required design and development activities could help FDA understand how a tobacco product manufacturer has established the specifications in the MMR for the finished or bulk tobacco product and their impact on public health. In addition, in the event of a recall, FDA could use these records to learn information that may be related to the recall and ascertain the appropriate way to address the issue. For example, FDA is aware of instances where contamination of cigarettes with a suspected chemical hazard resulted in a recall. One cigarette manufacturer announced a voluntary recall of approximately 8 billion cigarettes because the company detected unusual tastes and peculiar odors in 36 product lines (Ref. 82). Consumers who smoked the affected cigarettes reportedly suffered from pneumonia, exacerbation of asthma, bronchitis, chronic obstructive pulmonary disease, eosinophilic pneumonitis, and laryngitis (Ref. 82). The manufacturer detected methyl isothiocyanate (MITC) in the cigarette filters (Ref. 82). Adverse health effects from MITC exposure (*e.g.,* mucosal irritation of the respiratory and gastrointestinal tracts, conjunctival irritation, and neurologic symptoms) have been documented, although it was not established in this recall event that the reported illnesses were associated with users smoking contaminated cigarettes (Ref. 82). In such a scenario, if MITC was not previously an identified risk but was subsequently determined to pose a risk because it was used in the production of cigarette filters by the filter supplier, this provision would have required the manufacturer to reassess the risk and to take appropriate risk treatment steps. The risk assessment and risk treatment steps could include notifying the filter supplier to cease the use of this substance to minimize or prevent this risk if the manufacturer determined the level of risk to be unacceptable. Alternatively, the manufacturer could use the updated risk assessment to choose an alternate filter supplier who does not use MITC in the manufacture of filters.

The proposed design and development activities requirements also would help assure that the finished or bulk tobacco product is in compliance with the requirements of chapter IX of the FD&C Act. For example, finished or bulk tobacco products that pose risks such as physical, chemical, and/or biological hazards may be adulterated under section 902 of the FD&C Act. While some finished and bulk tobacco product manufacturers may already have similar controls in place, FDA believes that manufacturers should be required to engage in a risk management process and perform design validation and verification to help protect against the manufacture and distribution of nonconforming and/or contaminated product.

3. Master Manufacturing Record

Proposed § 1120.44(a) would require finished and bulk tobacco product manufacturers to establish and maintain an MMR for each finished and bulk tobacco product they manufacture for distribution. These proposed requirements are similar to those in other FDA-regulated industry manufacturing regulations (*e.g.,* § 820.181). An MMR is a document or a designated compilation of documents containing the established specifications for a tobacco product, including acceptance criteria for those specifications, all relevant manufacturing methods and production process procedures for the tobacco product, and all approved packaging, labeling, and labels for the tobacco product.

Under proposed § 1120.44(a)(1), the MMR must include the tobacco product specifications and acceptance criteria for those specifications. A tobacco product specification is any requirement established by the manufacturer (including specifications necessary to ensure that the tobacco product meets any applicable product standard) with which a product must conform. Tobacco product specifications can include physical, chemical, and biological specifications. Examples of physical specifications include length, circumference, and pressure drop for cigarettes and cut size and weight for smokeless tobacco products. An example of a chemical specification is a pH level for smokeless tobacco products, and an example of a biological specification is a specification related to the use of a biological fermentation agent used during the manufacturing process for smokeless tobacco products.

Tobacco product specifications in the MMR could include specifications for the finished or bulk tobacco products as well as specifications for incoming components and in-process tobacco products. For example, a tobacco product manufacturer may establish specifications for the cut size of incoming tobacco cut filler or the length, diameter, and tow of incoming filters. Tobacco product manufacturers may also establish specifications for in-process tobacco products, for example, a specification for the pH of fermented tobacco before it is packaged as a finished smokeless tobacco product or a specification for the length, circumference, and pressure drop of cigarette filter rods before they are packaged as finished cigarettes. In addition, tobacco product manufacturers may establish specifications for finished tobacco products, for example, specifications for the length, circumference, and pressure drop for cigarettes, or cut size and weight for smokeless tobacco products.

Proposed § 1120.44(a)(1) also would require that the MMR include acceptance criteria for the tobacco product specifications. The acceptance criteria should indicate if there is a particular value, range, minimum or maximum value, and/or standard deviation associated with a specification for an incoming component, in-process product, or finished or bulk tobacco product. For example, if a smokeless

tobacco product manufacturer establishes a pH and a weight specification for a finished smokeless tobacco product, proposed § 1120.44(a)(1) would require that the MMR for the product indicate the specific pH and weight acceptance criteria, for example, 7.2 ±0.5 pH and 3g ±0.2 gram (g), respectively. Similarly, if an ENDS manufacturer establishes a voltage specification for an adjustable, variable voltage product, the MMR would have to indicate the voltage acceptance criteria, for example, a range of 3–6 V. While this proposed rule would require acceptance criteria, the tobacco product manufacturer would determine the specific acceptance criteria that are appropriate for each established specification.

Under the proposed requirement, it would generally be up to manufacturers to determine what specifications to include in the MMR for each particular product they manufacture. However, proposed § 1120.44(a)(1)(i) through (iv) would require that, at a minimum, tobacco product specifications in the MMR include certain specifications related to product content, design, any applicable product standards established by FDA under section 907 of the FD&C Act, and pesticide chemical residues for raw tobacco.

Proposed § 1120.44(a)(1)(i) would require the product specifications in the MMR to include the identity and amount of any components or parts, ingredients, additives, and materials in the finished or bulk tobacco product. This information could be presented, for example, in a bill of materials that describes the identity and amount of the ingredients, additives, and materials in a finished tobacco product. The identity of all components or parts, ingredients, additives, and materials in the finished or bulk tobacco product should include a uniquely identifying name and/or number information. The proposed approach for uniquely identifying information is intended to be consistent with FDA's current thinking on listing of ingredients under section 904 of the FD&C Act as articulated in FDA's guidance entitled ''Listing of Ingredients in Tobacco Products.'' For example, for ingredients that are single chemical substances, uniquely identifying information should be a unique scientific name or code, such as the FDA Unique Ingredient Identifier code, Chemical Abstracts Service number, or International Union of Pure and Applied Chemistry name. Leaf tobacco (*i.e.,* whole leaf or parts) that has been prepared solely by mechanical processing that involves no chemical, additive, or substance other than potable water should be uniquely identified by, if known: the type (*e.g.,* burley, bright, oriental); the variety; the cure method (*e.g.,* flue, fire, sun, steam, air) and heat source (*e.g.,* propane, wood); and a description of any recombinant DNA technology used to engineer the tobacco. Complex purchased ingredients, as described in FDA's revised guidance, ''Listing of Ingredients in Tobacco Products,'' should be identified by: the complete name of the manufacturer of the complex purchased ingredient and the uniquely identifying item name and/or number (*e.g.,* catalog number or Universal Product Code (UPC)) used by that manufacturer. Complex ingredients made by the tobacco product manufacturer or made to the tobacco product manufacturer's specifications should be included in the MMR in a manner that uniquely identifies each individual ingredient.

We recognize that some tobacco product manufacturers obtain certain components or parts for their products from other manufacturers or suppliers and may not be in a position to know every individual ingredient in those components or parts. This is especially true if the component or part is, for example, a proprietary blend. In these instances, the tobacco product manufacturer could comply with proposed § 1120.44(a)(1)(i) by including the complete name of the manufacturer of the component or part and a uniquely identifying item name and/or number (*e.g.,* catalog number or UPC) used by that manufacturer. The tobacco product manufacturer, however, would have to comply with additional requirements intended to ensure awareness of any changes to purchased components or parts that may affect the tobacco product (see proposed § 1120.62(c), *Purchasing controls*).

Proposed § 1120.44(a)(1)(ii) would require the MMR to include the finished or bulk tobacco product design, meaning the form and structure concerning and the manner in which components or parts, ingredients, additives, and materials are integrated to produce a tobacco product. For example, a cigarette's design could include design features such as ventilation, paper porosity, tobacco cut width, and filter efficiency and the manner in which the tobacco cut filler, filter, cigarette paper, tipping paper, and plug wrap are assembled to produce a finished cigarette.

Under proposed § 1120.44(a)(1)(ii), a manufacturer must also include an identification of the product's heating source, if any (*e.g.,* burning coal, electric, chemical reaction, carbon tip), a discussion of the intended user operation (how the tobacco product will be used or operated by a user), and any relevant product drawings or schematics. For example, a discussion of the intended user operation of an ENDS product could include the appropriate and intended methods to charge the ENDS battery or how to handle, refill, and store the e-liquids for the ENDS product.

Proposed § 1120.44(a)(1)(iii) would require the MMR to include any specification necessary to ensure that the tobacco product meets any applicable product standard established under section 907 of the FD&C Act. For example, under section 907 of the FD&C Act, FDA could establish a product standard requiring the reduction of an additive or constituent in a tobacco product. In this case, the tobacco product manufacturer would be required to include any specification necessary to ensure that the product meets the established standard for that additive or constituent. Finally, proposed § 1120.44(a)(1)(iv) would require the MMR to include specifications for pesticide chemical residues for raw tobacco.

Proposed § 1120.44(a)(2) would require the MMR to include all relevant manufacturing methods and production process procedures. This requirement is intended to capture all the manufacturing steps involved in making the tobacco product, from receipt of incoming materials to distribution of the finished or bulk product. Under this requirement, the tobacco product manufacturer would be required to include any process controls, production process specifications with relevant acceptance criteria, and monitoring and acceptance activities (inspections, testing, evaluation, and other verification activities). For example, a smokeless tobacco product manufacturer may control its fermentation process by using a specific amount of a biological agent, controlling temperature and humidity, and setting turn cycle specifications. Under the proposed requirements, the manufacturer must include these production process specifications and activities in the MMR for the finished or bulk tobacco product. The manufacturer would also be required to include any established acceptance criteria associated with these activities and process specifications, for example, acceptable temperature and humidity ranges for the fermentation process.

The manufacturing methods and production process procedures in the MMR would also be required to include any monitoring and acceptance

activities. These are the activities the manufacturer performs to ensure that the production process meets the established process specifications. Acceptance and monitoring activities may include inspections, tests, evaluation, and other verification activities. Under proposed § 1120.44(a)(2), the manufacturer would be required to document all these activities in the MMR.

Specific aspects of the requirement in proposed § 1120.44(a)(2) and related requirements are further discussed in the proposed sections that follow, including proposed §§ 1120.64 (Acceptance activities), 1120.66 (Production processes and controls), and 1120.68 (Laboratory controls).

Proposed § 1120.44(a)(3) would require the MMR to include all packaging, labeling, and labels approved by the manufacturer for use with the finished or bulk tobacco product. To satisfy this requirement, a tobacco product manufacturer could maintain actual copies of the packaging, labeling, and labels approved for use with the finished and bulk tobacco products. Alternatively, a manufacturer could maintain artwork files that describe the design, layout, and content of the packaging, labeling, and labels approved for use with the products. For example, a finished tobacco product manufacturer may have packaging and labeling materials with different warning statements or different product package inserts or onserts. Under the proposed requirement, the MMR for the finished tobacco product would have to include or reference the location of these materials so that they can be readily accessible to FDA during inspections.

The MMR could be prepared either as a single document (or single file of documents) or as a product-specific index system that references and includes the location of all the required information. For example, if a specific manufacturing procedure is relevant to multiple tobacco products, the manufacturer would not need to reproduce that procedure in the MMR file for each product; instead the MMR file for each product could simply list and cross-reference the procedure (*e.g.,* identify it by a name and/or number) and indicate where the procedure can be found. Similarly, MMR files for multiple products could be included in one single document, as long as it is clear from the document what information pertains to each specific finished or bulk tobacco product.

Proposed § 1120.44(b) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the review and approval of the MMR, including any changes made to the MMR after initial approval. Under these procedures, a designated, qualified individual would be required to review and approve all MMR information before it is implemented in the manufacture of finished or bulk tobacco products for distribution. The designated, qualified individual's approval of the MMR would be required to be documented by date of approval and name and signature of the individual(s) approving the document.

When reviewing and approving the MMR for a tobacco product, the designated, qualified individual would be required to confirm that any design activities conducted to support the tobacco product specifications have been completed in accordance with the product design and development procedures established by the manufacturer under § 1120.42 and that the resulting production specifications are correctly transferred into the established MMR. These proposed requirements are intended to ensure that the tobacco product manufacturer has adequate control over the MMR, including changes to the MMR, and therefore over the product, prior to its release for distribution.

Proposed § 1120.44(c) would require that the MMR describe which methods and procedures established under § 1120.44(a)(2) and related sections, including §§ 1120.62 (Purchasing controls), 1120.64 (Acceptance activities), 1120.66 (Production processes and controls), and 1120.68 (Laboratory controls), are used to ensure that the tobacco product is manufactured in conformance with each tobacco product specification established under § 1120.44(a)(1). Thus, under proposed § 1120.44(a)(1), the MMR would include all established product specifications; under proposed § 1120.44(a)(2), the MMR would include all relevant manufacturing methods and production process procedures; and under proposed § 1120.44(c), the MMR would link the methods and procedures with the specifications by indicating which method or procedure would be used to ensure that each particular specification is met.

For example, under proposed § 1120.44(a)(1) a finished cigarette manufacturer may establish specifications for the porosity, ink type and color, and burn properties of a cigarette paper. If the manufacturer receives the paper from a qualified cigarette paper supplier (consistent with the purchasing controls in proposed § 1120.62) and ensures that the paper meets its specifications by relying on a Certificate of Analysis (CoA) from the supplier that addresses these specifications, under proposed § 1120.44(c), the manufacturer would be required to indicate in the MMR that a supplier's CoA is used to ensure that the cigarette paper meets specifications for porosity, ink type and color, and burn properties. Similarly, a smokeless tobacco product manufacturer may use a laboratory test as its acceptance activity (consistent with the acceptance activity requirements in proposed § 1120.64) to ensure that a smokeless product meets its pH specification, or a cigarette manufacturer may use a validated cutting process (consistent with the production processes and controls in proposed § 1120.66 and laboratory controls in proposed § 1120.68) to demonstrate that the tobacco cut filler meets its cut size specification. Under proposed § 1120.44(c), the manufacturers would be required to indicate the link between these activities and controls and the tobacco product specifications in the MMR.

The Agency believes that the proposed requirements would help assure that the public health is protected and that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. The proposed requirements would accomplish this by requiring manufacturers to establish specifications for each finished or bulk tobacco product and follow manufacturing methods and procedures that ensure that those specifications are met and, therefore, that products are manufactured in a controlled and consistent manner. The proposed MMR requirements provide a foundation for several of the requirements in part 1120. Building on the specifications established in the MMR, the purchasing controls, acceptance activities, process controls, and production record requirements would help ensure that each batch of tobacco product is manufactured in conformance with its established specifications. A manufacturer that fails to maintain control over its production process could manufacture and distribute nonconforming tobacco products, which could adversely affect public health. Because the MMR forms the foundation for the process controls that ensure that the production process operates as intended, the proposed MMR requirements would help ensure that nonconforming tobacco products are not manufactured and released for distribution.

Under the proposed MMR requirements, manufacturers would be required to establish specifications

related to the content and design of their finished and bulk tobacco products. Content and design are two critical parameters of finished and bulk tobacco products that can have a direct effect on public health. The physical design specifications of a tobacco product interact with its chemical composition to influence its function and effect on consumers. Thus, the content and design of finished and bulk tobacco products can impact the health consequences and addictiveness of the product. For example, the design of a cigarette filter's ventilation impacts the level of tar, nicotine, and carbon monoxide produced in the cigarette's smoke (Ref. 96). If a cigarette deviates from this ventilation design, the amount of tar, nicotine, and carbon monoxide delivered to the user may vary, affecting the tobacco product's toxicity and addictiveness. Because the content and design of a tobacco product can directly (*e.g.,* by increasing harmful emissions) or indirectly (*e.g.,* by increasing the addictiveness and the amount of use) contribute to the harm of a product, tobacco products that are manufactured inconsistently with established specifications may cause increased harm to the public health beyond what is normally associated with the product (Ref. 6). Requiring manufacturers to establish product specifications and manufacture products that meet those specifications helps minimize harm to public health associated with nonconforming products.

In addition, the Agency believes that the proposed MMR requirements would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. For example, the proposed requirements would enable the Agency to monitor and confirm that tobacco products are not manufactured in a manner that causes them to become adulterated or misbranded in violation of section 902(1) through (3) or 903 of the FD&C Act.

By requiring manufacturers to establish product specifications and manufacturing methods and procedures, the proposed requirements would reduce the chances of adulteration during the production process. For example, maintaining a state of control would help decrease the likelihood that products contain filthy, putrid, or decomposed substances, or are otherwise contaminated by added poisonous or deleterious substances that may render the product injurious to health. A controlled production process would also help ensure that products are not prepared, packed, or held under insanitary conditions.

The proposed MMR requirements, in particular proposed § 1120.44(a)(3), would also help ensure that the packaging, labeling, or labels of finished tobacco products comply with applicable statutory and regulatory requirements. For example, the packaging and labeling information maintained in the MMR would help FDA ascertain whether manufacturers are adulterating or misbranding products by approving and using packaging or labeling that is false or misleading, lacks required health warnings, or contains unauthorized modified risk claims.

The proposed MMR requirements, together with the proposed process controls, also would enable tobacco product manufacturers to ensure, and FDA to verify, that tobacco products are manufactured in compliance with the applicable premarket requirements under sections 905 and 910 of the FD&C Act. Specifically, the proposed requirements would enable FDA to verify that the established specifications for new or MRTPs are consistent with the tobacco product specifications provided by the manufacturer to FDA in the relevant tobacco product applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA) and that the specifications for pre-existing tobacco products are consistent with their original characteristics. The proposed MMR requirements would also help manufacturers to ensure, and FDA to verify, that manufacturers are not making changes to tobacco products that may render the products new and adulterated under section 902(6) of the FD&C Act or misbranded under section 903(a)(6) of the FD&C Act.

The MMR requirements would also help ensure that tobacco products are manufactured in compliance with any tobacco product standards established under section 907 of the FD&C Act. Under section 907, the Agency can adopt a tobacco product standard if it finds that the standard is appropriate for the protection of the public health. Proposed § 1120.44(a)(1)(iii) would require the manufacturer to establish in the MMR any specifications necessary to ensure that the tobacco product meets any applicable product standard. For example, under section 907, FDA could require a reduction or elimination of an additive or constituent. In such an instance, proposed § 1120.44(a)(1)(iii) would require manufacturers to establish specifications in the MMR to ensure that the additive or constituent is reduced or eliminated in accordance with the standard.

E. Process Controls

1. Purchasing Controls

Proposed § 1120.62 would require manufacturers to ensure that purchased or otherwise received products and services from suppliers conform to established specifications and that suppliers are qualified. Specifically, proposed § 1120.62(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures to ensure that each purchased or otherwise received product or service related to the manufacture of a finished or bulk tobacco product is from a qualified supplier and conforms to established specifications. In this context, ''products or services related to the manufacture of a finished or bulk tobacco product'' means products or services that are used in the manufacture of the product or that could impact the performance, composition, constituents or characteristics of the product.

A purchased or otherwise received product related to the manufacture of a finished or bulk tobacco product would include a component or part, ingredient, additive, or other material purchased or received for use in the manufacture of a finished or bulk tobacco product. It also would include manufacturing materials as well as other materials purchased or received for use in the manufacture, packing, and storage of tobacco products, on tobacco product contact surfaces, or for the manufacturing operation, including cleaning and sanitation, of buildings, facilities, and grounds.

A supplier of such product may be internal (from an establishment within the manufacturer's organization; *e.g.,* a sister facility) or external (from an entity outside of the manufacturer; *e.g.,* an external third-party entity that supplies tobacco blends or flavorings). For example, a cigarette manufacturer may establish filter specifications for circumference, length, and pressure drop in the MMR in accordance with proposed § 1120.44(a)(1) and purchase filters from an external supplier. The proposed purchasing controls provision would require that the cigarette manufacturer establish and maintain procedures to ensure that the filter supplier is qualified and that the filters purchased and received from the external filter supplier conform to the established specifications. Such purchasing control procedures would be required whether payment for the products or services occurs or not. Thus, for example, a cigarette manufacturer would be required to comply with these requirements even when it receives

filters from an internal supplier, such as a ''sister facility'' or another corporate or financial affiliate.

A ''purchased or otherwise received service related to the manufacture of a finished or bulk tobacco product'' would include any activity associated with a manufacturing method or production process procedure established in § 1120.44(a)(2) as well as any activity regulated under proposed part 1120. Such services would include manufacturing or other activities (*e.g.,* specification development, laboratory testing, packaging and labeling) that are contracted to others. For example, a tobacco product manufacturer may contract with a third-party laboratory to perform laboratory tests, or contract with others to perform certain activities required under proposed part 1120, such as complaint handling, facility cleaning, or pest control. Purchasing controls for such outsourcing services would be an additional requirement to help ensure that any service purchased or otherwise received from a supplier complies with the relevant requirements in proposed part 1120 (*e.g.,* §§ 1120.44(a)(2), 1120.68, 1120.14, 1120.34) and meets specified requirements. In such cases, the finished or bulk tobacco product manufacturer would still be responsible for complying with all applicable requirements under proposed part 1120, even though it has chosen to outsource certain activities.

Proposed § 1120.62(b) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for qualifying their suppliers. It is important that suppliers be qualified to demonstrate their ability to provide products and services to tobacco product manufacturers that meet established specifications. Proposed § 1120.62(b)(1) would require the qualification procedures to include evaluating and selecting potential suppliers based on their ability to meet requirements set by the manufacturer in writing (on paper or electronically). Supplier evaluation and selection may be based, in part, on a supplier's past performance (*i.e.,* a supplier's historical ability to meet a manufacturer's specifications or requirements consistently). Qualification could also include onsite visits, audits of the supplier's practices or records, or periodic testing or sampling of the supplier's products or services to determine if they conform to established specifications and if the supplier complies with applicable requirements under proposed part 1120. It would be the finished and bulk tobacco product manufacturer's responsibility to establish the appropriate supplier evaluation and selection process to ensure that purchased or otherwise received products and services related to the manufacture of a finished or bulk tobacco product meet established requirements.

Proposed § 1120.62(b)(2) would require the qualification procedures to include provisions that define the type and extent of control to be exercised over selected suppliers and their product or service, based on evaluation results. Manufacturers should determine the degree of control necessary based on the specific product or service purchased or otherwise received. When determining the type and extent of control to be exercised over qualified suppliers, manufacturers should use an appropriate mix of evaluations, which can include audits and acceptance activities, to ensure that products and services conform to established specifications. Factors such as the tobacco product manufacturer's knowledge or control of the supplier's manufacturing practices, the supplier's history of providing acceptable products or services, history or trends of delivering products or services that do not meet specifications, and the impact of the product or service on the finished or bulk tobacco product meeting its established specifications, can inform the type and extent of control needed for a particular supplied product or service. For example, if a tobacco product manufacturer determines that a component supplier has a history of providing acceptable product that meets established specifications, it may determine that a CoA is an adequate control. However, if the tobacco product manufacturer observes a trend that a supplier has been providing nonconforming products that have been rejected and returned, it may determine that increased audits or incoming product acceptance activities such as testing may be needed to comply with these proposed requirements. FDA has observed on inspections that manufacturers may implement more rigorous control over those suppliers that are determined to have a ''critical'' impact on product specifications and controls (Ref. 97).

Proposed § 1120.62(b)(3) would require the qualification procedures to include developing a list of qualified suppliers and their product(s) or service(s) and updating this information periodically. This list of qualified suppliers is intended to help provide assurance to the manufacturer and FDA that each supplier has been evaluated and selected based on its ability to meet established requirements.

Proposed § 1120.62(b)(4) would require that, as part of the qualification procedures, finished and bulk tobacco product manufacturers monitor qualified suppliers to ensure they meet specified requirements and perform reevaluation as needed. This requirement could be met by periodic testing or sampling, or through periodic reevaluation of the types of information considered for initial evaluation and selection of a supplier (*e.g.,* records of nonconforming product, onsite audits, independent test results) under proposed § 1120.62(b)(1). Thus, the same kinds of information or records could be used for both initial qualification and ongoing monitoring of suppliers. For example, a manufacturer may use records of a supplier's performance (*e.g.,* records showing that a product meets established specifications) to initially qualify suppliers as well as to monitor their continued ability to meet specified requirements and determine whether any adjustments to the type and extent of control over qualified suppliers are necessary (see proposed § 1120.62(b)(2)). A manufacturer may determine that a supplier with a history of deficient auditing results or that repeatedly fails to meet established requirements should no longer be a qualified supplier.

FDA notes that this proposed rule would allow for different approaches to monitoring suppliers. While some suppliers might warrant onsite visits depending on the products at issue, some products could be monitored through acceptance activities. For example, if a supplier supplies a manufacturer with labels bearing the required warnings for its finished tobacco product and the historical rejection rate of the labels at receipt is 1 percent, but that rate has recently risen to 25 percent, the manufacturer may consider that supplier no longer qualified. Given that manufacturers are required to establish and maintain records of acceptance activities under proposed § 1120.64(e), reviewing trend lines across these activities would be an acceptable way to comply with this provision.

Proposed § 1120.62(c) would require finished and bulk tobacco product manufacturers to maintain records of all activities conducted under proposed § 1120.62. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

The records described in this proposed provision would include all types of purchasing records. Purchasing records are those records associated with any supplier contract, the established specifications for the product or service being provided, and any activities undertaken to qualify, requalify, and monitor suppliers. Purchasing records contain information on the specifications or requirements for a specific product or service. They could include a purchasing contract between a manufacturer and supplier, documents and records that set forth the quality requirements (*i.e.,* procedures and controls) that the supplier must comply with, documents and records that reflect the activities that the manufacturer uses to control and monitor the supplier (*e.g.,* audits), and documents and records provided by the supplier that indicate the established specifications for the product or service (*e.g.,* certificate of analysis (CoA), drawings, specifications sheets, catalogue numbers, engineering change order). Some types of purchasing records also may demonstrate compliance with other provisions of this proposed rule. For example, a CoA that documents the specified requirements for filters purchased from a supplier may constitute a purchasing record for purposes of this section, but it could also be used as an acceptance activity record to verify that a received batch of filters meets established specifications. Similarly, a finished tobacco product manufacturer using a contract pest control service to comply with the proposed animal and pest control requirement in § 1120.34(e) would be required to maintain the invoice documenting purchase of this service to satisfy the recordkeeping requirements under proposed § 1120.62(c) as well as the recordkeeping requirements under proposed § 1120.34(f).

Proposed § 1120.62(c) would also require that records maintained under this section include a written agreement (*e.g.,* purchase order, contractual agreement) that the supplier will notify the manufacturer of any change in the product or service so that the manufacturer can determine whether the change may affect the specifications of the finished or bulk tobacco product established in accordance with § 1120.44(a)(1). This provision is necessary to ensure that a supplier does not make any changes to the product or service without the knowledge of the finished or bulk tobacco product manufacturer that would result in a change to a finished or bulk tobacco product's specifications, rendering it a nonconforming product.

If a tobacco product manufacturer conducts audits to address the supplier qualification requirements at proposed § 1120.62(b), FDA, as a matter of policy, generally would not request to review or copy such audit records during routine inspections. Instead, FDA would consider a written certification by the manufacturer's management with executive responsibility stating that the audits have been performed and documented, the dates on which they were performed, and that any action taken in response to the audit results has been completed, as sufficient to meet the recordkeeping requirement under proposed § 1120.62(c). Nevertheless, this provision would not limit the Agency's ability to request for review or copy any procedures created to meet the requirement at proposed § 1120.62(b).

A tobacco product manufacturer could contract out certain activities required under proposed part 1120. To ensure purchased or otherwise received products or services conform to specified requirements, each tobacco product manufacturer would need to establish and maintain procedures to ensure that purchasing is carried out subject to adequate controls, including the evaluation and selection of suppliers, and the clear and unambiguous specification of requirements for such suppliers. In addition, the manufacturer would be required to have acceptance activities in accordance with proposed § 1120.64. These controls would help ensure that only suppliers that meet the specified requirements are used.

The finished or bulk tobacco product manufacturer would have the ultimate responsibility for ensuring that all applicable requirements under proposed part 1120 are met. For example, if a finished or bulk tobacco product manufacturer outsources laboratory testing services performed as part of an acceptance activity to a contractor, the manufacturer would be required to use purchasing controls to help ensure that the contract laboratory's procedures, processes, and records comply with the proposed laboratory controls requirements. The finished or bulk tobacco product manufacturer would be responsible if the contract laboratory does not adequately implement laboratory control processes. Additionally, the finished or bulk tobacco product manufacturer would be responsible for ensuring it receives all the documents and records needed to comply with proposed § 1120.122, including all relevant metadata. A supplier (including a contractor or consultant) would be directly responsible for complying with part 1120 to the extent that it is a finished or bulk tobacco product manufacturer under this proposed rule. For example, if a finished tobacco product manufacturer sends ENDS products to a contract packager to package and label the products for consumer use, the finished tobacco product manufacturer would be required to use purchasing controls to help ensure that the contract packager's packaging and labeling activities meet specified requirements; additionally, the contract packager would be covered under the proposed rule as a finished tobacco product manufacturer and would be directly responsible for the packaging and labeling requirements under the proposed rule (see the discussion of proposed subpart F in section IV.F).

The proposed regulation is intended to allow flexibility in the way finished and bulk tobacco product manufacturers ensure the acceptability of products and services. Under the proposed purchasing control requirements, manufacturers would be required to establish and maintain procedures that clearly define the type and extent of control they intend to apply to suppliers and their products and services. A finished or bulk tobacco product manufacturer may choose to provide greater in-house controls such as additional acceptance activities (see discussion of proposed § 1120.64 in section IV.F.2) to ensure that products and services meet specified requirements, or the manufacturer may require that the supplier adopt measures necessary to ensure acceptability, as appropriate, for example, batch testing. FDA believes that a mix of purchasing controls and in-house manufacturing controls will generally be necessary to ensure acceptability of received products and services. A manufacturer could review and approve the supplier's procedures or perform supplier audits to assess the supplier's continued capability to provide acceptable product. The manufacturer could also review historical data, monitor and look for trends in data such as acceptance and nonconforming product records, and perform inspection and testing of received products.

FDA has observed that tobacco product manufacturers use a variety of different purchasing controls to ensure that received products and services conform to established specifications. For example, a manufacturer may use different purchasing controls based on the degree of impact that the supplied product or service may have on the

finished or bulk tobacco product. A manufacturer may determine that a supplier of liquid nicotine would need to provide a certificate of analysis of the nicotine concentration for each batch, undergo a yearly audit, and send every fifth batch for an independent laboratory analysis to confirm a nonconformance rate of less than 1 percent. In contrast, the manufacturer may determine that a supplier of outer packaging for shipping (that does not come into contact with the tobacco product) only needs to be initially qualified and to maintain production records for review by the manufacturer as requested. In addition, these proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001.

The proposed purchasing controls requirements would help assure that the public health is protected by ensuring that suppliers are capable of providing products and services that conform to established specifications and other specified requirements set by the manufacturer. A change in a received product may impact one or more of the established specifications of the finished or bulk tobacco product, rendering it nonconforming. For example, a menthol supplier may change its menthol formulation by using a different chemical compound, such as L-menthol instead of D-menthol stereoisomer. This change in formulation may affect the specification for this ingredient and cause the finished tobacco product not to meet the specifications for menthol established in the MMR. This change is formulation may also impact public health as the change from D-menthol to L-menthol may promote smoking initiation and nicotine addiction (Ref. 98).

A change in service also may impact an established specification. For example, if a contract laboratory changes the sampling plan for product acceptance, the test results may no longer be representative of the product, which may result in a nonconforming product. Use of components or parts, ingredients, additives, and materials that do not meet specifications may result in the manufacture of a nonconforming tobacco product. In addition, use of an unqualified laboratory to perform testing and sampling may result in a failure to conduct adequate product acceptance activities and in the manufacture of a nonconforming tobacco product.

The proposed purchasing controls requirements would also help assure that tobacco products are in compliance with chapter IX of the FD&C Act. For example, purchasing controls would help ensure that products meet relevant requirements under sections 905 and 910 of the FD&C Act and that such products are not adulterated under section 902(6) or misbranded under section 903(a)(6) of the FD&C Act. The proposed requirements would enable the tobacco product manufacturer to be aware of any change to supplied products so that it may determine whether the change may affect the established specifications of the finished or bulk tobacco product in the MMR. A change in an established tobacco product specification can result in a modification and the creation of a new tobacco product under section 910(a)(1)(B) of the FD&C Act for which premarket review is required. For example, a change in the denier per filament specification of the acetate tow material of a cigarette filter would change the filter's pressure drop, rendering it a new tobacco product (Ref. 99). Therefore, this section would help manufacturers to ensure, and FDA to verify, that manufacturers are not making changes to their tobacco products that may render the products adulterated under section 902(6) or misbranded under section 903(a)(6) of the FD&C Act. In addition, if a tobacco product standard establishes requirements respecting a component of a tobacco product, the proposed purchasing controls requirement would help a finished tobacco product manufacturer that obtains such component from a supplier to ensure that the purchased or received component conforms to the standard. Likewise, if a tobacco product standard establishes requirements for testing of a tobacco product and the testing is performed by a contract laboratory, the proposed requirement would help ensure that the purchased or received service results in a product that conforms to the tobacco product standard.

The proposed purchasing controls requirements would also help ensure that tobacco products are not adulterated under section 902 of the FD&C Act by ensuring that purchased or received products are not contaminated or held under insanitary conditions. For example, a bulk manufacturer may require through purchasing controls that leaf producers follow a Good Agricultural Practice program, including the use of approved pesticides. This would help ensure that purchased leaf tobacco is not treated with unapproved pesticides that may contain ''any added poisonous or added deleterious substance that may render the product injurious to health'' and, therefore, adulterated under section 902(1) of the FD&C Act.

2. Acceptance Activities

Proposed § 1120.64(a) would require tobacco product manufacturers to establish and maintain procedures for acceptance activities, including acceptance criteria. Acceptance activities can be used throughout the production process—incoming, during the receipt of incoming materials; in-process, during the manufacturing process; and final, prior to the release of the finished or bulk product for distribution. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001.

Acceptance activities could include inspections, tests, evaluations, and other verification activities. Inspections could include visual inspection of incoming, finished, or bulk tobacco products (Refs. 100 and 101). Testing could include laboratory testing, such as testing the resistance to draw of a cigarette (Ref. 102). Other verification activities could include, for example, review of a supplier's CoA to ensure that an ingredient meets its specification for purity (*e.g.,* Ref. 103), or use of worksheets or programs to determine that the correct amount or weight of materials, ingredients, and additives has been used. In addition, tobacco product acceptance activities could include use of a validated production process with appropriate continued process verification under proposed § 1120.66(b).

Although a manufacturer could rely on the review of purchasing records during incoming acceptance such as a CoA, there may be circumstances where testing or inspection may be necessary for accepting incoming product. For example, if a manufacturer determines that a supplier's product is close to the outer parameters of acceptability, the manufacturer could establish a testing requirement to audit the supplier under § 1120.62(b)(2) to confirm the information that is supplied in the CoA. Manufacturers would have the flexibility to choose which acceptance activity method(s) is most suitable to their needs, products, and manufacturing process.

Proposed § 1120.64(a) also would require that procedures for all acceptance activities include acceptance criteria. Acceptance criteria could be expressed as values, ranges, or tolerances or may include criteria such as appearance, color, or specific gravity (*e.g.,* Ref. 104). For example, under these proposed requirements, an e-liquid manufacturer who uses liquid

nicotine to make e-liquids could perform laboratory testing as an acceptance activity to verify that a specification for the concentration of incoming liquid nicotine is met. If the manufacturer's MMR establishes the specification at 90 percent nicotine and the specification's acceptance criteria is designated with a tolerance of ±0.40 percent, the laboratory testing results would need to show that the concentration of nicotine is between 89.6 percent and 90.4 percent to meet the established specification. Under the proposed requirements, if the incoming liquid nicotine has a nicotine concentration of less than 89.6 percent or greater than 90.4 percent, the manufacturer would need to treat the incoming liquid nicotine as a nonconforming product in accordance with proposed § 1120.74.

In addition, acceptance activities that involve sampling would be required to use representative sampling under proposed § 1120.72. Representative samples are frequently used to determine whether a batch of tobacco product meets specifications. While FDA is aware that some tobacco product manufacturers use sampling plans for acceptance activities, the Agency believes that this requirement is needed to ensure that all manufacturers who perform sampling in their acceptance activities use representative samples to demonstrate that a batch meets established specifications. CORESTA has also developed recommended methods for sampling plans for the preparation of samples of different types of tobacco products, such as cigarettes, smokeless tobacco, fine-cut tobacco, and cigars (Refs. 105, 107, 108).

Proposed § 1120.64(b)(1) would require that the acceptance activity procedures address acceptance activities for all incoming products to ensure that any specifications established under § 1120.44 or through purchasing controls under § 1120.62 are met and that such products are not contaminated or deteriorated. The term ''incoming products'' would include not only incoming tobacco products, but also any incoming equipment that is used in the manufacturing of tobacco products, such as cigarette makers, as well as any other materials that may be used, such as cleaning agents that may be used to clean the tobacco contacting equipment and may leave residues that might contaminate the tobacco. Some tobacco product manufacturers already use acceptance activities to verify that incoming products meet established specifications. For example, organic solvents such as toluene often are used for the printing of cigarette packages. A tobacco product manufacturer could evaluate a CoA for incoming cigarette packages that indicates an upper limit for the acceptance criteria of each organic solvent. The tobacco product manufacturer could review the analysis results in the CoA showing the actual measurement of the organic solvent to determine whether these incoming materials are acceptable for use in manufacturing (*e.g.,* Ref. 109). A tobacco product manufacturer could also conduct its own laboratory testing of incoming material to determine that it meets established specifications (*e.g.,* Ref. 110).

Proposed § 1120.64(b)(1) also states that each accepted incoming tobacco product would need to be designated by a unique identifier, which must be maintained throughout manufacturing and documented in accordance with § 1120.70(b)(5). Incoming acceptance would apply to all incoming products, but the unique identifier requirement would be limited to those products that meet the definition of a tobacco product. Once the tobacco product manufacturer accepts an incoming tobacco product for use in the manufacturing process, a unique identifier would be assigned. A unique identifier is information, such as a code or number that is maintained for each accepted incoming tobacco product, that would enable the tobacco product manufacturer and FDA to identify the supplier and unique shipment (*e.g.,* purchase order) of the incoming tobacco product. The proposed unique identifier requirement would establish traceability for all components or parts, ingredients, additives, and materials in a finished or bulk tobacco product and would aid in investigations related to tobacco product complaints, CAPAs, and nonconforming products. For example, during an investigation of a nonconforming product, the unique identifiers of all components or parts, ingredients, additives, and materials in a finished or bulk tobacco product would enable the manufacturer to determine the scope and cause of the nonconformance. If a nonconformity is attributed to a nonconforming component or part, ingredient, additive, or material, the manufacturer could take appropriate corrective action with respect to any other affected finished or bulk tobacco product that uses the affected tobacco product. For an incoming finished or bulk tobacco product, the unique identifier would be required to include, or be traceable to, the manufacturing code on the packaging or label of the incoming finished or bulk tobacco product. This could be a separate unique identifier or it could incorporate the manufacturing code of the incoming finished or bulk tobacco product. This requirement would be important for tobacco product manufacturers who perform only packaging and labeling, including repackaging and relabeling, as the unique identifier would establish traceability to the specific batch of the incoming finished or bulk tobacco product.

FDA is not proposing to prescribe the format or mechanism (*e.g.,* affixing a batch or control number to the immediate container or product label) of the unique identifier requirement. Rather, manufacturers would have the flexibility to determine the method that they would use to track and identify the received and accepted incoming tobacco products that are used in the manufacture of finished and bulk tobacco products. On inspections, FDA has observed manufacturers using various means of implementing unique identifiers, including programmable and scannable bar codes and tags affixed to the immediate container.

FDA is proposing that the unique identifier for each accepted incoming component or part, ingredient, additive, and material used in the manufacture of finished and bulk tobacco products would need to be documented in the production record in accordance with proposed § 1120.70(b)(5). Although not required by this proposed rule, as components and parts undergo further manufacturing and become a new component or part, ingredient, additive, or material, a manufacturer may choose to assign a new unique identifier to the combined product, subassembly, or batch of tobacco product. The new unique identifier would establish more accurate traceability to account for all components or parts, ingredients, additives, and materials in a finished or bulk tobacco product and would aid in investigations related to tobacco product complaints, CAPAs, and nonconforming products. However, any original unique identifier would need to be maintained in the production record, even if a subsequent unique identifier is assigned to the product after further manufacturing. For example, if an e-liquid manufacturer assigns a unique identifier for banana and vanilla flavor ingredients under § 1120.64(b)(1) and further processes these ingredients to make a batch of banana crème flavor, it may assign a new identifier for the new flavor. If this approach is used, traceability to the unique identifiers of the new, as well as the original, individual components and parts, ingredients, additives, and materials would need to be maintained in

accordance with proposed § 1120.70(b)(5).

This provision also would require that the results of incoming acceptance activities be reviewed and approved to ensure that the incoming tobacco product specifications established under proposed § 1120.44 or through purchasing controls under proposed § 1120.62 are met and that the product is not contaminated or deteriorated. Therefore, prior to using incoming product in the manufacturing process, a designated qualified individual would be required to review the results of the incoming tobacco product acceptance activities, determine that the specifications established in the MMR and through purchasing controls are met and that the product is not contaminated or deteriorated, and approve the release of the product for manufacturing. The acceptance status of the released tobacco product would be maintained under proposed § 1120.64(d). FDA has observed on inspections that the number of personnel or the complexity of the manufacturing process may determine whether the review and approval of incoming acceptance activities is performed by the individual who conducted the acceptance activity or a designated quality assurance employee who reviews and approves acceptance activity results conducted by others. The proposed rule would afford the manufacturer flexibility to determine how it would perform this activity, as long as it occurs prior to the release of incoming product for manufacturing.

Proposed § 1120.64(b)(2) would require that acceptance activities procedures address the testing and acceptance of raw tobacco to ensure that raw tobacco from suppliers (internal and external to the organization) complies with established specifications for pesticide chemical residue(s). The specifications for pesticide chemical residue(s) would need to be established by the manufacturer and comply with any applicable tolerance(s) established under Federal law.[5] FDA considers raw tobacco to include tobacco leaf and tobacco cut rag that is received from importers, wholesalers, and distributors.

Manufacturers would be required to comply with this requirement for all tobacco products containing raw tobacco. A tobacco product manufacturer could comply with this proposed requirement by performing its own testing or accepting a CoA from the supplier of the raw tobacco showing that relevant specifications for pesticide chemical residue(s) are met (*e.g.,* Refs. 111 and 112). On inspections, FDA has observed that several tobacco product manufacturers have established specifications for pesticide chemical residues for raw tobacco, taking into account recommendations in CORESTA's Guide No. 1—The Concept and Implementation of CPA (crop protection agent) Guidance Residue Levels (Ref. 86), and voluntary U.S. Department of Agriculture pesticide residue standards at 7 CFR 29.427.

Proposed § 1120.64(b)(3) would require that all incoming tobacco products, *i.e.,* components or parts, ingredients, additives, and materials, be evaluated during incoming acceptance activities to ensure that they are not contaminated or deteriorated. FDA is aware that tobacco product manufacturers have considered and used different methods to evaluate products for physical and some biological contamination including metal detectors, x-rays, and optical sorters (*e.g.,* Refs. 113 and 114). Tobacco product manufacturers could establish procedures to visually inspect incoming product for contamination or sources of potential contamination (*e.g.,* Refs. 115 and 116). Any of these methods could be suitable for compliance with this proposed section, depending on the product being inspected. Deterioration of components or parts, ingredients, additives, and materials could result in nonconforming product or otherwise render the product adulterated or misbranded. Examples of possible deterioration include discoloration, spotting, and staining of components (such as packaging, labels, filters) or flavors or additives that have passed their expiration date.

Proposed § 1120.64(c) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for in process and/or final acceptance activities to ensure that each finished or bulk tobacco product meets the specifications established under proposed § 1120.44. Tobacco product manufacturers could comply with proposed § 1120.64(c) in process or after manufacturing a finished or bulk tobacco product. A manufacturer could comply with this provision by performing batch testing on finished or bulk product. Any acceptance activities that involve sampling would be required to comply with proposed § 1120.72. On inspections, FDA has observed that tobacco product manufacturers may perform acceptance activities at discrete points in the production process or use a stage-gate approach to accept tobacco product and release it to the next stage of processing (*e.g.,* Ref. 117). For example, acceptance activities could be performed on tobacco blends after primary processing, on smokeless tobacco blends after fermentation, and on cigarettes or smokeless tobacco product after making. Acceptance activities could also be performed after the tobacco product is packaged; for example, testing the finished tobacco product to ensure that it meets established specifications (*e.g.,* Ref. 118) and inspecting the product packaging to determine it meets all packaging and labeling requirements.

This provision also would require that the results of in-process and final acceptance activities be reviewed and approved to ensure that the finished and bulk tobacco product specifications established under § 1120.44 are met. Therefore, a designated qualified individual would need to review the results of the tobacco product acceptance activities to determine that the specifications established in the MMR are met, and approve the release of the finished or bulk tobacco product for distribution. As discussed previously regarding proposed § 1120.64, the proposed rule would afford the manufacturer flexibility to determine how it would perform this activity, as long as it occurs prior to distribution.

Proposed § 1120.64(d) would require tobacco product manufacturers to identify, by suitable means, the acceptance status of a tobacco product throughout the different stages of the manufacturing process, indicating whether the tobacco product is a conforming or nonconforming tobacco product. The identification of the acceptance status would need to be maintained from receipt of incoming products throughout manufacturing and until the finished or bulk tobacco product passes required acceptance activities and is released for distribution. FDA considers ''suitable means'' to mean that the acceptance status of a tobacco product can be readily determined. For example, tobacco product manufacturers could use various methods to identify the acceptance status of tobacco products, including scannable barcodes, labels, markings and other methods (*e.g.,* Refs. 119 and 120). This requirement is intended to ensure that manufacturers can effectively identify the acceptance status of tobacco products and prevent mixups.

[5] Under 907(a)(1)(B) of the FD&C Act, a tobacco product manufacturer cannot use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco. As of publication of this proposed rule, such a tolerance level has not been established by Federal statute or regulation.

This provision seeks to ensure that the acceptance status of all tobacco products, including incoming tobacco products, in-process tobacco products, and finished and bulk tobacco products is properly identified throughout manufacturing to ensure that only tobacco products that pass required acceptance activities are incorporated into the finished or bulk tobacco product and ultimately released for distribution. This requirement is intended to prevent nonconforming tobacco product from being used in the manufacture of a finished or bulk tobacco product. For example, if a smokeless tobacco blend does not conform to a fermentation specification during a tobacco product acceptance activity, its nonconforming acceptance status would need to be identified so that it would not be used in the manufacture of a finished smokeless tobacco product.

Proposed § 1120.64(e) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. This provision would require records to include the date and time, individual performing the activity, type of activity performed, acceptance criteria, any information that demonstrates the requirement was met, equipment used if applicable, and any data or calculations necessary to reconstruct the results. This provision is necessary to help ensure that acceptance activities are performed according to established procedures and that the tobacco product meets the specifications established in proposed § 1120.44. The date and time when the acceptance activities were conducted and the name of the individual who performed the activities could help manufacturers and FDA identify the scope of any nonconformity.

The proposed acceptance activities requirements would help assure that the public health is protected. Tobacco product specifications could impact the toxicity and addictiveness of the product, and acceptance activities would help ensure that tobacco products do not exceed established specifications that affect these parameters. For example, if a tobacco product manufacturer establishes a nicotine concentration level for an ENDS product, acceptance activities would help ensure that the tobacco product meets that specification. This would be important because a finished ENDS that contains a nicotine concentration higher than the established specification could be more addictive (Refs. 4 and 5).

In addition, the physical design specifications of a tobacco product interact with its chemical composition to influence its function and effect on consumers, which can impact the toxicity and addictiveness of the product (Ref. 6). For example, the design of a cigarette filter's ventilation impacts the level of nicotine in the cigarette's smoke (Ref. 96). If a cigarette's filter deviates from its established ventilation design specification, the amount of nicotine delivered to the user may be affected, which can increase addictiveness. A tobacco product's operating and design specifications and features can affect the toxicity and addictiveness of the product. For example, a variable voltage ENDS product can enable a user to control the power input. The electrical power input—which is proportional to the square of the voltage and inversely proportional to the heater resistance—influences the temperature at which the aerosol is produced, which may influence nicotine and other toxicant emissions (Ref. 121). Acceptance activities would verify that the tobacco product conforms to its established design specification and, therefore, help to minimize additional harm associated with nonconforming products.

The proposed acceptance activities requirements also would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. Acceptance activities would help tobacco product manufacturers to verify, and enable FDA to confirm, that finished and bulk tobacco products conform to established specifications. These provisions would help ensure that new tobacco products and MRTPs are manufactured consistent with the specifications provided in their applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA) and that pre-existing products are manufactured consistent with their original characteristics. The acceptance activities requirements also would help ensure that the packaging, labeling, and labels of finished tobacco products comply with applicable statutory and regulatory requirements. For example, by ensuring that correct packaging, labeling, and labels are used with each product, the acceptance activities and associated records would help ensure that labeling does not contain false or misleading statements, that packages and labels bear required health warnings or statements, and that the labeling or labels do not contain unauthorized modified risk claims. Additionally, the acceptance activities requirements and associated records would help ensure that a product is compliant with any product standards established by FDA under section 907 of the FD&C Act. For example, under section 907, FDA could require a reduction or elimination of an additive or constituent. The acceptance activity records would help enable FDA to verify that the amount of the additive or constituent in the manufacturers' products meets the product standard.

The proposed requirements also would help ensure that tobacco products do not contain a contaminant or hazard that may cause the product to be adulterated under section 902(1)–(3) of the FD&C Act. For example, visual inspection of incoming tobacco leaf for mold or NTRM (including glass or metal fragments) or use of metal detectors, x-rays, optical sorters, and other methods would help minimize the likelihood that tobacco products contain such substances.

3. Production Processes and Controls

Proposed § 1120.66(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for their production processes, including process controls, to ensure that tobacco products conform to requirements established in the MMR in accordance with proposed § 1120.44. Production processes include the methods, activities, or steps that a tobacco product manufacturer uses to manufacture a tobacco product. Production processes may include primary processing such as blending, casing, and cutting tobacco; fermenting tobacco; mixing flavors and liquid nicotine; and assembling components or parts.

Under proposed § 1120.66(a)(1), production process procedures would be required to address production process specifications with relevant acceptance criteria. For example, a manufacturer could establish production specifications for moisture with relevant acceptance criteria at different points in the production process to ensure that the tobacco product moisture specification is met at the point of each acceptance activity. Similarly, a manufacturer could establish time, temperature, and humidity production process specifications with relevant acceptance criteria to ensure that the tobacco product pH specification is met.

Proposed § 1120.66(a)(2) would also require that the production process procedures include relevant process controls such as monitoring and acceptance activities (inspection, testing, evaluation, and other verification activities). For example, if a

manufacturer established production process specifications with acceptance criteria, such as time, temperature, and humidity, the manufacturer would be required to implement relevant process controls such as monitoring or testing tobacco product to verify that such production process specifications are met. Under proposed § 1120.66(a)(2), such process controls would be included in the production process procedures. The proposed requirements are intended to provide tobacco product manufacturers with the flexibility to establish the production process procedures that are appropriate for their particular manufacturing operations and type of tobacco products to ensure that manufactured tobacco products conform to the requirements established in the MMR in accordance with proposed § 1120.44.

Proposed § 1120.66(a)(1) and (2) are intended to help ensure that the production process is controlled so that tobacco products meet their product specifications at the appropriate acceptance activity stage. For example, the fermentation of smokeless tobacco must occur under specific environmental conditions to assure that at the end of fermentation desired specifications, such as pH and oven volatiles are met. The production process procedures required by this proposed provision would, therefore, specify that fermentation occur in an environmentally-controlled room. The manufacturer would need to establish time, temperature, and humidity ranges for the room to ensure that the room is maintained within the environmental ranges required to meet product specifications. In this example, the production process specifications would be the upper and lower temperature and humidity limits for specified durations. The manufacturer would also use relevant process controls such as monitoring activities to confirm that the process occurred within the required time, temperature, and humidity ranges and to alert staff if these conditions are not met, for example, if the room temperature is drifting towards a temperature that does not meet the established production process specification.

Proposed § 1120.66(a)(3) would require that the production process procedures include a requirement for investigating any deviations from the production process specifications and established acceptance criteria, or from relevant process controls, to determine if the deviation results in a nonconforming product. Process deviations can be identified from process and product sources, such as process monitoring, acceptance activities, production records, and records of nonconforming products. For example, if the fermentation of a tobacco blend deviates from established production processes and controls for fermentation, such as maintaining temperature and humidity through specified turn cycles necessary to meet a pH specification, the tobacco product manufacturer would be required to perform an investigation to determine if the deviation results in a nonconforming product. Proposed § 1120.66(a)(3) would also require that the manufacturer document the disposition of any product affected by the deviation. A product manufactured under conditions that deviate from the process specifications could be released for further processing or distribution if the investigation determines that the product conforms to product specifications, for example, if data from process validation activities demonstrates that product produced within those process specifications still conforms to product specifications. Product found to be nonconforming would need to be handled in accordance with proposed § 1120.74.

If a manufacturer finds that its originally established process specifications are difficult to maintain (*i.e.,* result in many process deviations), the manufacturer may decide to use a wider range of process specifications for future production where it is supported by the original process validation activities, rather than investigating each time a product is produced outside the narrower range. In such a case, the proposed rule would require that the updated process specifications be documented in the MMR in accordance with the procedures established under § 1120.44. If the manufacturer decides to adopt new ranges beyond the originally validated process specifications, the manufacturer would need to evaluate the change under proposed § 1120.66(a)(4) and revalidate the process, where appropriate.

Proposed § 1120.66(a)(4) would require that the production process procedures include a requirement for evaluating all changes to production processes, including process controls, to determine their impact on the tobacco product specifications in the MMR. If any production process changes result in a change to the tobacco product specifications, the proposed rule would require that the manufacturer ensure that procedures applicable to the changes in tobacco product specifications are followed in accordance with §§ 1120.42 and 1120.44 and update the tobacco product specifications in the MMR as needed. This requirement is intended to ensure that the manufacturer identifies changes to a production process that may affect a tobacco product specification and, therefore, lead to a nonconforming product. For example, if a manufacturer uses a 3-turn fermentation process to manufacture a smokeless tobacco product with an established pH specification, and the tobacco product manufacturer changes the fermentation process to a 2-turn process, under this proposed provision, the manufacturer would need to evaluate the production process change to determine if it results in a change to the pH (or any other specifications) of the smokeless tobacco product. If it does, then the manufacturer could decide against making the process change or could change the tobacco product specifications in accordance with proposed §§ 1120.42 and 1120.44.

Proposed § 1120.66(a)(4) would also require that any changes to validated processes be revalidated before implementation, where appropriate. For example, if a tobacco product manufacturer makes a change to the validated forming and drying process for reconstituted leaf tobacco by adjusting the thickness and pressure of the size press, these changes would need to be evaluated and revalidated, where appropriate, before being implemented.

In addition to the requirements in proposed § 1120.66(a), proposed § 1120.66(b) would require that the production process procedures include requirements for process validation, if applicable. Specifically, if the results of a process cannot be fully verified (including any automated processes), this provision would require finished and bulk tobacco product manufacturers to validate the process to demonstrate that the process will produce a tobacco product that conforms to the tobacco product specifications established under § 1120.44(a)(1). The results of a process cannot be fully verified, for example, where the manufacturer cannot demonstrate that the tobacco product meets established specifications through acceptance activities using representative samples (*e.g.,* automated cigarettes manufactured with millions or tens of millions of cigarettes in a batch, because the size of the batch is too large) or where acceptance activities cannot fully determine whether the product meets established specifications (*e.g.,* laser welding of an ENDS atomizer to a tolerance of ±0.0002 inches)). Although this provision would not require processes to be validated where the results can be fully verified, the

Agency encourages manufacturers to validate all processes.

Process validation includes activities to establish scientific evidence that a process is capable of consistently producing product that conforms to established specifications. FDA is aware that some tobacco product manufacturers use validation master plans to validate the processes and equipment for the manufacturing and packaging of tobacco products; these plans cover the criteria for review and approval of the processes, specific methods and procedures to qualify the process, methods for continued process verification through monitoring and measurement of the processes, and revalidation.

This proposal would require process validation to use appropriate objective measures and valid scientific tools and analyses to maintain the process in a state of control. Examples of valid scientific tools and analyses used in process validation would include a capability study to measure the ability of the process to consistently meet specifications, challenge tests to demonstrate where nonconformities are due to variation and off-target processes under worst-case conditions, and acceptance sampling plans to determine the number of samples to be tested to provide a gross check for defect rate increase with respect to a predetermined acceptable quality level (*e.g.,* Ref. 122). Acceptance sampling can be based on standards (*e.g.,* ISO 28590:2017, ISO 3951:2013, ANSI Z1.4, ANSI Z1.9) (Refs. 123–126).

Proposed § 1120.66(b)(1) would require finished and bulk tobacco product manufacturers, as part of process validation, to design a production process for manufacturing a tobacco product. The process design would need to address the capability and functionality of the production process. The process design also would establish a strategy for process control to develop operational limits and monitoring of the production process that should take into account the building, facility, and equipment and possible sources of variability posed by personnel and environmental conditions. This provision is intended to help ensure that products conform to established specifications.

For example, a cigarette maker can operate at speeds up to 20,000 cigarettes per minute and manufacture cigarettes to specifications of weight, length, and diameter. In this case, proposed § 1120.66(b)(1) would require a manufacturer to address the capability and functionality of its production process at various operational speeds and establish a strategy for process control. The tobacco product manufacturer may determine that the cigarette maker operates at an optimal speed of 16,000 cigarettes per minute and the process control could consist of samples being taken every 30 minutes to monitor the production process. However, if the maker operates at its maximum 20,000 cigarettes per minute speed, a process control could consist of samples being taken more frequently (*e.g.,* every 15 minutes) to assure that the tobacco product remains conforming at the increased production speed.

Alternatively, in a case where the product attribute is not readily measurable due to limitations of sampling or detectability, operational limits and in-process monitoring parameters could be established for process control. For example, a manufacturer may establish process specifications for manufacturing cigarette filter rods. The manufacturer would have to validate the process used by the automated filter rod maker to ensure that filters meet product specifications. For this process, the manufacturer could establish a target specification for parameters such as the pressure drop. The lower specification and upper specification limits or tolerances would also need to be developed around the target specification. The manufacturer would then be required to determine lower and upper process control limits for parameters such as the speed of cellulose acetate fiber that is fed into the rod maker. These process control limits would be at values between the target and lower and upper specification limits. Based on the results obtained by a predetermined sampling plan, the values would be used to adjust the machine to ensure that filters are manufactured in accordance with the product specifications.

For any required process validation activities, proposed § 1120.66(b)(2)(i) would require finished and bulk tobacco product manufacturers to perform process qualification to determine if the process is capable of reproducible manufacturing. Manufacturers would need to demonstrate that the design of the facility is appropriate and qualify the equipment to confirm that it is suitable for its intended purposes and will perform properly. This could involve qualifying that the equipment is appropriate for its specific use, verifying that equipment is built and installed in conformance with its design specifications, and verifying that equipment operates properly in all anticipated operating ranges. Proposed § 1120.66(b)(2)(ii) would require manufacturers to perform process performance qualification to confirm the process design and to demonstrate that the manufacturing process performs as expected in accordance with established criteria, which would need to be documented in a written protocol. This could involve utilizing the qualified equipment with trained personnel and production process procedures, including process controls, to confirm the process design and demonstrate that the commercial manufacturing process performs as expected.

Proposed § 1120.66(b)(3) would require finished and bulk tobacco product manufacturers to monitor the production process using data collected from records required under proposed part 1120 and valid scientific tools to detect variability and ensure that the process remains in a state of control. This proposed requirement is intended to help prevent process deviations. A manufacturer could accomplish this by monitoring for undesired process variability and determining the appropriate actions to correct, anticipate, and prevent problems. Relevant process and product data must be collected from records covered under proposed part 1120, and would include data regarding acceptance activities (proposed § 1120.64) and reviews of nonconforming product (proposed § 1120.74).

Valid scientific tools can include statistical process control techniques, control charts, recognized standards such as American Society for Testing and Materials (ASTM) E2281–03 ''Standard Practice for Process and Measurement Capability Indices'' and ASTM E2709–09 ''Standard Practice for Demonstrating Capability to Comply with a Lot Acceptance Procedure'' (*e.g.,* Refs. 127–130). The collection and analysis of data and use of valid scientific tools can detect trends caused by process deviations.

If continued process verification under proposed § 1120.66(b)(3) reveals that the process is no longer operating in a state of control and requires a change to the existing validated production process, such as to its method, procedure, or process control, revalidation under proposed § 1120.66(a)(4) would be required.

Proposed § 1120.66(c) would require that the production process procedures include certain additional requirements, if applicable. Under proposed § 1120.66(c)(1), if a production process includes a manual method or process, the production process procedures would be required to describe the manual method or process in sufficient detail to ensure that the tobacco product

meets established specifications and include, if applicable, the criteria for workmanship using a standard or approved model sample. An actual or diagrammatic representation of a model sample could show the design and construction of a tobacco product. For example, a hand-rolled cigar could be represented by a model sample that defines the type and size of tobacco leaf to be used for the wrapper, the type and amount of filler tobacco to be used, the brand label to be applied, and the size/shape/length/diameter of the finished, rolled cigar. Similarly, a documented standard could establish specific length, gauge width, and shapes of certain types of standardized cigars (*e.g.,* Corona, Churchill, and Panetela) (Ref. 131).

Proposed § 1120.66(c)(2) would require that the production process procedures address the use and removal of manufacturing material if such material could reasonably be expected to contaminate a tobacco product or otherwise result in a nonconforming tobacco product. For example, if a tobacco product manufacturer uses a mold release agent for an injection molding process for smokeless tobacco containers, and that agent contains volatile solvents that can contaminate the tobacco product and be toxic to users, the production process procedures would need to address how to clean and remove the manufacturing material (*e.g.,* Refs. 132–134).

Proposed § 1120.66(d) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. Under this proposed provision, records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. These records could include drawings of the process validation process, a general outline of steps for process validation, or meeting agendas and notes regarding the validation process (*e.g.,* Refs. 135–137).

The proposed production processes and controls requirements would help assure that the public health is protected because they can prevent, monitor, and detect variability in the manufacturing process. Variability in the manufacturing process may result in the manufacture of tobacco product that does not conform to established specifications. For example, many tobacco product manufacturers establish moisture specifications for finished and bulk tobacco products. The regulation of moisture throughout the production process is important because of the influence of moisture on tobacco and other components and parts, their processing properties, and on the finished tobacco product itself (Ref. 138). Moisture also can affect the properties of tobacco and other components and parts (*e.g.,* paper, filters), such as the level of micro-organisms and mass, hardness, circumference, pressure drop, and filter ventilation (id.). In addition, the moisture content of a finished cigarette is one of the physical variables that can affect the level of total particulate matter and the chemical composition of particulate phase smoke, such as during the initial puffs (Ref. 139). Similarly, many tobacco product manufacturers establish a pH specification for smokeless tobacco products using production processes such as curing, fermentation, or pasteurization. An increase in pH can result in an increase in the speed of nicotine absorption, which is associated with the development of tolerance and physical dependence to nicotine (Ref. 19). Inadequate production processes and controls may also contribute to substantial variability in actual nicotine concentration as compared to labeled nicotine concentration in e-liquids intended to be used with ENDS (Ref. 1). This variability could be particularly problematic for users seeking to limit or cease tobacco product use. Therefore, these proposed provisions are needed to prevent the manufacture and distribution of nonconforming products that may have an adverse effect on public health.

In addition, the proposed requirements for production processes and controls would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. If tobacco products are not consistently manufactured to conform to established specifications, new tobacco products and MRTPs may not conform to the specifications that are described in their applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA) and pre-existing tobacco products may not be manufactured consistent with their original characteristics. Relatedly, the proposed requirements would help manufacturers to ensure, and FDA to verify, that manufacturers are not making changes to tobacco products that may render them new and adulterated under section 902(6) of the FD&C Act or misbranded under section 903(a)(6) of the FD&C Act. Further, a finished or bulk tobacco product whose contents, such as nicotine concentration, are not consistent with its labels or labeling also may be deemed misbranded and subject to regulatory action.

4. Laboratory Controls

Proposed § 1120.68 establishes requirements for laboratory controls. Under proposed § 1120.68(a), finished and bulk tobacco product manufacturers would be required to demonstrate laboratory competence when using a laboratory (either in-house or contract laboratory) to conduct activities under proposed part 1120. Under proposed § 1120.68(b), finished and bulk tobacco product manufacturers would also be required to establish and maintain laboratory control procedures for any laboratory activities that are conducted under proposed part 1120. Laboratory activities conducted under proposed part 1120 may include, for example, those used for design and development activities, acceptance activities, and process controls, and for the calibration of testing, monitoring, and measuring equipment. The requirements under proposed § 1120.68(a) are intended to ensure that the facilities and personnel of in-house laboratories, as well as those of contract laboratories, are competent to perform the laboratory testing conducted under proposed part 1120. The requirements under proposed § 1120.68(b) establish the specific requirements that the laboratory control procedures would be required to address in order to ensure that the laboratory testing is adequately performed.

Proposed § 1120.68(a) would require finished and bulk tobacco product manufacturers, when using a laboratory (either in-house or contract) to conduct activities under proposed part 1120, to demonstrate the laboratory's competence to perform laboratory activities associated with the manufacture of finished and bulk tobacco products. This proposed requirement is intended to ensure that tobacco product manufacturers confirm that laboratories are technically competent and able to produce precise and accurate data to comply with proposed part 1120. While manufacturers would have the flexibility to determine how they would demonstrate a laboratory's competency, they would be required to have appropriate documentation. Tobacco product manufacturers could utilize various means to show their laboratory's competency to carry out its activities such as a standard accreditation, such as ISO 17025:2005 (Ref. 140), or otherwise documenting a laboratory QMS (*i.e.,* standard operating procedures for test methods, equipment maintenance and calibration logs, quality control

sampling protocols, and personnel training).

Proposed § 1120.68(b) would require finished and bulk tobacco product manufacturers to establish and maintain laboratory control procedures for any laboratory activities that are conducted under proposed part 1120. The laboratory control procedure requirements in proposed § 1120.68(b)(1) through (3) are inter-related and intended to ensure that manufacturers utilize appropriate laboratory facilities and equipment, and that laboratory activities associated with the manufacture of tobacco products are performed with controls sufficient to ensure accurate and reliable results. For example, a manufacturer may use a laboratory to test pH levels of smokeless tobacco products to ensure that the pH levels meet the product specifications (Ref. 141). The laboratory control requirements in this section would help ensure that the data from such laboratory testing are accurate and precise, for example, by helping ensure that the laboratory uses properly calibrated pH meters, nonexpired pH check solutions, and a valid test method (Ref. 141).

If a tobacco product manufacturer contracts its laboratory activities to an outside entity, the manufacturer would remain responsible for complying with the proposed laboratory control requirements. However, we note that these proposed requirements would not apply to laboratory activities outside the scope of manufacturing activities. For example, the proposed requirements would not apply to testing for harmful and potentially harmful constituents performed solely to comply with section 904(a)(3) of the FD&C Act.

Proposed § 1120.68(b) would require the laboratory control procedures to include several specific laboratory control requirements. First, proposed § 1120.68(b)(1) would require the laboratory controls to include the use of scientifically valid laboratory methods that are accurate, precise, and appropriate for their intended purpose. A laboratory method can be scientifically valid if it is based on scientific data or results published in, for example, scientific journals, references, or text books.

Second, proposed § 1120.68(b)(2) would require laboratory controls to include the use of representative samples based on valid scientific rationale, in accordance with proposed § 1120.72. As further described in proposed § 1120.72, samples for laboratory control activities required under § 1120.68(b)(2) would need to follow an established sampling plan to ensure that samples being tested or evaluated are representative of the material being sampled (*i.e.,* the batch or part of the batch).

Third, proposed § 1120.68(b)(3) would require laboratory controls to include demonstration of analytical control, which means a laboratory must be able to show that its laboratory method and instrumentation reliably generate accurate and valid results. Demonstration of analytical control can be shown using a variety of quality control activities including but not limited to the use of certified reference materials, positive and negative controls, replicate testing, and/or internal standards. Quality control activities should be appropriate for the type and frequency of testing, suitable to monitor the analytical performance of the method and instrumentation used by the laboratory, and enable the laboratory to determine if the test yielded the expected result or response. One way to demonstrate compliance with this requirement would be to generate and maintain a quality control chart, which tracks and assesses results of quality control sample analysis with known amounts, to demonstrate analytical control of the equipment and test method. Demonstration of analytical control allows a tobacco product manufacturer to have confidence in the test sample measurements and investigate any anomalies early in the production process (*e.g.,* Refs. 142 and 143).

Under this proposed provision, for example, if a tobacco product manufacturer uses a laboratory to test or measure the moisture content of a cigarette as part of its acceptance activities to ensure that the product meets established specifications, a scientifically valid laboratory method would have to be used, such as the Weighing-Drying-Method with Oven and Balance, described in the Tobacco Moisture, Water and Oven Volatiles CORESTA Technical Report (Ref. 138). In addition, a sampling plan would have to be used to collect representative samples based on a valid scientific rationale, such as ISO 8243:2013 (*e.g.,* Ref. 144).

Proposed § 1120.68(c) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under proposed § 1120.68. Under this paragraph, records would be required to include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculation necessary to reconstruct the results. As stated elsewhere in this preamble, for purposes of proposed part 1120, FDA interprets ''reconstruct'' to mean the ability to re-create the results by analyzing all data, including source and metadata data, and records, including calculations. Whether the laboratory control activities are conducted by the tobacco product manufacturer or contracted out to another facility, the manufacturer would be responsible for ensuring laboratory records, including results, are maintained in compliance with proposed §§ 1120.68(c) and 1120.122. These records could be included directly in the relevant production record or cross-referenced in another record that is readily accessible for inspection.

This proposed provision would help assure that the public health is protected. Laboratory controls, such as those used for acceptance activities, are important analytical tools for evaluating and testing a tobacco product to determine if it conforms to specifications established in the MMR, which could help to minimize the harm to public health associated with nonconforming products. For example, a smokeless tobacco product that does not conform to established pH specifications could adversely affect public health because it may have a more rapid rate of nicotine delivery and absorption, which can lead to increased dependence (Refs. 6 and 19).

This proposed provision also would require tobacco product manufacturers to control the laboratory activities that are part of the production process, which would further help to protect against the manufacture of a nonconforming product. For example, a tobacco product manufacturer may determine that monitoring the water content by measuring oven volatiles in the production process is necessary to control the level of microorganisms. Laboratory controls would ensure that the laboratory method used to monitor and control the moisture content in the production process is maintained within production process specifications, minimizing the chance for development of potentially harmful microorganisms.

In addition, the Agency believes that the proposed laboratory controls requirements would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. These proposed requirements would enable the Agency to monitor and confirm that tobacco products are not manufactured in a manner that causes them to become adulterated under section 902(1) through (3) of the FD&C Act, that

tobacco products conform to specifications established in their MMRs, that new tobacco products and MRTPs are manufactured consistent with the specifications provided in their applications (*i.e.,* SE Report, request for exemption from SE, PMTA, MRTPA), and that pre-existing products are manufactured consistent with their original characteristics.

5. Production Record

Proposed § 1120.70(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures to ensure that a production record is prepared for each batch of finished or bulk tobacco products to demonstrate conformity with the requirements established in the MMR in accordance with § 1120.44. These proposed requirements are generally consistent with the practices of manufacturing establishments that follow ISO 9001. The production record could consist of a single record or compilation of records that represent the complete production history of the finished or bulk tobacco product by batch, including identification of all of its components or parts, ingredients, additives, and materials (*e.g.,* Ref. 145).

Proposed § 1120.70(a) also would require that designated personnel review and approve the production record for release of each batch of finished and bulk tobacco products into distribution. This requirement is intended to ensure that each batch is acceptable for release into distribution (*e.g.,* that the products conform to MMR specifications; there were no unaddressed nonconformities as a result of deviations from process specifications or process controls; and the manufacturer has completed all acceptance activities and the results demonstrate that the acceptance criteria were met). The review and approval could take place at the end of manufacturing or at the end of stages of the production process such as, for example, primary, making, and packing stages in cigarette production.

Proposed § 1120.70(b)(1) through (7) would require that the production record include, or refer to the location of, certain information. Proposed § 1120.70(b)(1) would require the production record to include the manufacturing code of the finished or bulk tobacco product, which is defined in proposed § 1120.3 to include the manufacture date and batch number (see also proposed § 1120.96). This information is needed to identify affected tobacco product, for example, during a tobacco product complaint and/or nonconforming product investigation. A tobacco product manufacturer could also choose to include manufacturing time in the production record to further narrow the scope of any nonconforming product investigation. In this context, ''manufacturing time'' generally refers to the time that the finished or bulk tobacco product was packaged (*e.g.,* designated by year/month/date/hour/minute).

Proposed § 1120.70(b)(2) would require the production record to include the quantity of finished or bulk tobacco product manufactured in the batch. This information would be helpful for conducting tobacco product complaint and nonconforming product investigations because it would help determine how many tobacco products may be affected and, therefore, the scope of the investigation.

Proposed § 1120.70(b)(3) would require the production record to identify the major equipment and processing lines used in manufacturing the batch of finished or bulk tobacco product. If a tobacco product manufacturer has more than one piece of major equipment and/or processing line, this provision would require the manufacturer to document the specific major equipment and/or processing line that was used in the manufacture of the batch. This information would help to determine whether a nonconforming product is attributable to an issue with a particular piece of equipment or processing line and help determine the scope of product that might be affected.

Proposed § 1120.70(b)(4) would require that the production record also include records of any activities performed under proposed part 1120 necessary to demonstrate that the batch of finished or bulk tobacco product was manufactured to conform with the MMR requirements established under proposed § 1120.44. The records to be maintained in a production record under paragraph (b)(4) include purchasing records, acceptance activity records, continued process verification records, laboratory testing records, reprocessing and rework records, and packaging and labeling records. To the extent that these records may overlap with other records required under proposed part 1120, the manufacturer need not maintain duplicate copies in the production record but may instead simply cross-reference the location of the relevant records. We note, relatedly, that the records would not have to be physically located in the same place but the location of all relevant records must be included in the production record, and the records must comply with the requirements in proposed § 1120.122 (*e.g.,* the records must be readily accessible to responsible officials of the tobacco product manufacturer and to FDA).

Proposed § 1120.70(b)(5) would require the production record to include all unique identifiers of all accepted incoming tobacco products, including components or parts, ingredients, additives, and materials, used in the manufacture of the batch of finished or bulk tobacco product. This information could help a tobacco product manufacturer or FDA to determine if there is a problem with a particular component or part, ingredient, additive, or material and to establish traceability to identify other affected tobacco products.

Proposed § 1120.70(b)(6) would require that, if any finished or bulk tobacco product was used in the manufacture of the batch, the manufacturing code for that finished or bulk tobacco product must be included in the production record. For example, if a finished tobacco product manufacturer uses bulk tobacco product from a supplier, under § 1120.70(b)(6), the production record for the batch of finished tobacco product must include the manufacturing code for the bulk tobacco product (as received from the supplier and provided on the label of the bulk product). Similarly, if returned and reworked finished product is used in the subsequent manufacture of another finished product, under § 1120.70(b)(6), the production record for the subsequent finished product must include the manufacturing code of the incorporated returned and reworked product. We note that the requirement in proposed § 1120.70(b)(6) is distinct from and in addition to the requirement in proposed § 1120.70(b)(1) that the production record for each batch of finished or bulk tobacco product include the manufacturing code assigned by the manufacturer for that finished or bulk tobacco product. This information is needed to establish traceability and help identify affected tobacco products during a tobacco product complaint and/or nonconforming product investigation.

Proposed § 1120.70(b)(7) would require actual or copies of the packaging, labeling, and labels (as defined in proposed § 1120.3) used with the finished and bulk tobacco product, including inserts and onserts that accompany the product.

Finally, proposed § 1120.70(b)(8) would require the name(s) and signature(s) of the designated individual(s) reviewing and approving the production record for release of the batch of finished or bulk tobacco

product into distribution. The designated individual can perform the function of a gatekeeper by conducting a final review and approval of the production record for the batch for release into distribution. Alternatively, review and approval of the relevant portions of the production record can be conducted in stages. If review and approval is performed in stages throughout the production process, the manufacturer could also perform a final review and approval of the production record to verify that approvals of all production process stages had been made and documented.

The proposed production record requirements would help assure that the public health is protected. The proposed requirements would ensure that tobacco product manufacturers review and approve the production record prior to the release of each batch of finished and bulk tobacco product. The manufacturer would ensure that all records required to be included in the production record (*e.g.,* records from acceptance activities) have been included, or their location referenced, and that the production record demonstrates that the batch of finished or bulk tobacco product conforms to the MMR. These requirements would help prevent the distribution of nonconforming product.

In addition, the proposed production record contents are essential to the conduct of adequate tobacco product complaint and nonconforming product investigations to identify the scope and cause of an issue and ensure traceability to determine affected tobacco products. For example, if there are complaints that report a particular problem, review of the relevant production records (*e.g.,* manufacturing code, identification of major equipment and processing lines) can help determine the scope of the problem (*e.g.,* whether it is limited to a specific piece of equipment or processing line or certain production batches, or whether it includes all products from the establishment), the cause, and the quantity of affected tobacco product manufactured. If a manufacturer has to initiate a corrective action such as a recall, the manufacturing code included in the production record could also be used to identify the corresponding distribution records to help determine where the affected products were distributed.

The proposed production record requirements would also help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. For example, information regarding the identity and amount of all components or parts, ingredients, additives, and materials used in the manufacture of a finished or bulk tobacco product could be used to confirm ingredient listings submitted to FDA under section 904(a)(1) of the FD&C Act. Documenting in the production record the packaging, labeling, and labels used with finished tobacco products also would help enable FDA to determine if the tobacco products display required warning statements and are in compliance with the MRTP provisions in section 911 of the FD&C Act (21 U.S.C. 387k) and relevant requirements of section 903(a)(2) of the FD&C Act.

6. Sampling

For any sampling performed under proposed part 1120, proposed § 1120.72 would require finished and bulk tobacco product manufacturers to establish and maintain an adequate sampling plan using representative samples. These proposed requirements are similar to those in other FDA-regulated industry manufacturing regulations. To comply with this requirement, each manufacturer would be required to create a written sampling plan using representative samples, implement and follow the sampling plan, and update the sampling plan as needed. The proposed sampling requirements in proposed § 1120.72 would apply to all sampling performed under proposed part 1120, including sampling used for acceptance activities, process control monitoring, and continued process verification. Acceptance sampling is performed to determine the disposition of products tested (*e.g.,* accept, reject) whereas statistical process control and the sampling associated with monitoring a process are used to distinguish between variation that is inherent in the process and variation induced by some external factor that would result in nonconforming product.

A sampling plan is a written, detailed document that describes: (1) the purpose of the sampling, (2) the scientific technique or method used to establish the number of samples, including an explanation of how the sample size is representative of the material being sampled, and (3) the method of sampling. A sampling plan is essential to ensure that sampling is reliable, consistent, replicable, and suitable for its intended purpose. Under the proposed rule, manufacturers could tailor their sampling plans to specific activities and purposes. For example, a sampling plan for an acceptance activity could be different than one for monitoring whether a production process remains in a state of control or for continued process verification to detect sources of variability.

The basic principles of an adequate sampling plan include the following: the samples are representative of the batch or quantity being sampled, the number of samples is based on a valid scientific rationale, and the number of samples is sufficient for the intended purpose. ''Valid scientific rationale'' refers to scientific techniques or methods used to establish the number of representative samples and should take into account tolerance for variability, confidence levels, and the degree of precision required (Refs. 105, 107, 108). FDA believes that requiring the number of samples to be based on a ''valid scientific rationale'' would provide manufacturers with the flexibility to determine the appropriate number of representative samples for any sampling plan. While FDA is proposing this flexibility, this provision would require that manufacturers have support for the scientific technique or methods used to establish the number of representative samples used and to show that the sampling size is representative of the material being sampled.

Proposed § 1120.72(a) through (c) specifies the required elements of a sampling plan. First, proposed § 1120.72(a) would require the sampling plan to describe the intended purpose of the sampling (*e.g.,* product acceptance, monitor a production process, or detect sources of variability). Second, proposed § 1120.72(b) would require the plan to describe the scientific technique or method used to establish the sample size, including an explanation of how the sample size is representative of the material being sampled. Examples of scientific techniques or methods for sampling can include the ''ISO 2859 series of standards for sampling procedures for inspection by attributes,'' as well as ANSI/American Society for Quality (ASQ) Z1.4 (Refs. 146 and 125). Information regarding the scientific techniques and methods used would be required to include an explanation of the sample size (*i.e.,* the quantity or amount of product to be sampled) and how the sample size is representative of the material being sampled. The sample size would need to be sufficient for the intended purpose of the sampling plan and analysis to be performed. Third, proposed § 1120.72(c) would require the plan to describe the method of sampling. This refers to when and how samples are collected. For example, CORESTA Recommended Method No 24—Cigarettes—Sampling, A.3 states that samples should be drawn from one or more cartons of cigarettes at random from each sampling point to form the necessary gross and there should be at

least 10 sampling points distributed between factories where the cigarettes are made (Ref. 105).

The proposed representative sample requirements would help assure that the public health is protected by ensuring that any sampling performed under proposed part 1120 is scientifically sound and appropriate for its intended purpose and does not erroneously support the release of a batch containing tobacco products that do not conform to established specifications. If a sampling plan is not adequate, the results of an acceptance activity may not accurately demonstrate whether the batch meets established specifications, the established production process may not be properly controlled, and a validated process may not be adequately monitored to detect sources of variability, all of which could result in the manufacture and distribution of nonconforming product.

The proposed sampling requirements would also help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. Appropriate sampling methods would help manufacturers ensure that the new tobacco products and MRTPs they manufacture meet the specifications described in their applications (*i.e.,* SE report, request for exemption from SE, PMTA, MRTPA) and that the specifications for pre-existing tobacco products continue to be consistent with their original characteristics.

7. Nonconforming Tobacco Product

Proposed § 1120.74 would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the control and disposition of nonconforming tobacco product. A nonconforming tobacco product is defined as any tobacco product that does not meet a product specification as set by the MMR (see proposed § 1120.44(a)(1)); has packaging, labeling, or labels other than those included in the MMR (see proposed § 1120.44(a)(3)); or is a contaminated tobacco product. These procedures are necessary to help prevent the distribution of nonconforming tobacco products, which could pose risks not normally associated with tobacco products, by ensuring that all potential nonconforming products are identified, segregated, and investigated, and that appropriate disposition and followup is taken for products determined to be nonconforming. These provisions are also intended to help manufacturers determine the extent of any nonconformity and, in cases in which nonconforming product has already been released for distribution, determine where it was distributed. These proposed requirements are generally consistent with the practices of manufacturing establishments that follow ISO 9001 and the industry recommendations.

These proposed requirements would be applicable throughout the manufacturing process. For example, if an ENDS manufacturer determines through its in-process product acceptance activities that the liquid nicotine contains contaminants such as metal or silicate particles (known to cause respiratory disease and distress), the liquid nicotine would be a nonconforming product and would have to be handled according to the procedures outlined in proposed § 1120.74 (Ref. 2). Similarly, if an ENDS manufacturer determines through its process controls that the liquid nicotine concentration does not meet the concentration specification established in its MMR, the liquid nicotine would be a nonconforming product and the manufacturer would have to identify, segregate, investigate, and determine its disposition (*e.g.,* rework as appropriate or discard) in accordance with proposed § 1120.74(c) (Ref. 5). As another example, if a smokeless tobacco product manufacturer determines through its tobacco product acceptance activities that its chewing tobacco is contaminated with aflatoxins (Ref. 17), the manufacturer would be required to follow its nonconforming product procedures in accordance with this provision.

Proposed § 1120.74(a) would require finished and bulk tobacco product manufacturers to identify and segregate potential nonconforming product in a manner that prevents mixups and use of potential nonconforming product prior to investigation and disposition. This requirement would be triggered upon discovery of a potential nonconforming product. For example, if a manufacturer establishes acceptance activities to visually inspect incoming tobacco for the presence of mold, and a product appears to be discolored or blighted, the manufacturer would determine that the tobacco may be nonconforming and therefore subject to this provision. If an ENDS manufacturer performs laboratory testing on the nicotine concentration of an e-liquid as part of acceptance activities and the testing results do not conform to the established specification and acceptance criteria, the manufacturer would determine that the e-liquid is a potential nonconforming product that must be identified and segregated. If a tobacco product was manufactured under conditions outside of an established production process specification where failure to meet the process specification is reasonably likely to cause the tobacco product to fail to meet a product specification, the product should be treated as a potential nonconforming product.

Identification of potential nonconforming product can be accomplished in many ways (*e.g.,* applying a label with the relevant information directly to the product container; or, if an electronic system is utilized, associating the nonconforming product information with the relevant barcode). Identification is a critical first step to preventing further processing, production, or distribution of potential nonconforming tobacco product.

Proposed § 1120.74(a) would also require finished and bulk tobacco product manufacturers to segregate potential nonconforming product in a manner that prevents mixups and use of potential nonconforming product prior to investigation and disposition. This provision would require potential nonconforming product to remain segregated pending an investigation until it is determined to be conforming. If a potential nonconforming product is determined to be nonconforming, it would need to remain segregated throughout investigation and disposition, including any rework. For purposes of proposed part 1120, ''segregation'' means setting the identified potential nonconforming product apart from other product (*i.e.,* placing it away from conforming in-process material). This segregation could be accomplished by placing it in a quarantined or specifically marked-off area. Manufacturers should use prudence and segregate potential nonconforming tobacco product in a manner that is appropriate, given the nature of the potential nonconformity. For example, if a product is potentially nonconforming because it may be contaminated with pests, pathogens, or other substances that are likely to spread, it should be segregated and stored in a manner that prevents contamination of other tobacco products.

Proposed § 1120.74(b) would require finished and bulk tobacco product manufacturers to investigate all potential nonconforming tobacco products. The purpose of the investigation is to determine whether the product is in fact nonconforming and, if it is found to be nonconforming, to determine the scope and cause of the nonconformity, and the risk of illness or injury it poses. Under proposed § 1120.74(b)(1), in order to determine if

the product is nonconforming, FDA is proposing to require that the investigation include an examination of relevant production processes and controls, laboratory testing, complaints, and any other relevant records and sources of information.

For example, in accordance with proposed §§ 1120.66(a)(3) and 1120.74(b), if there was a deviation from a production process, a tobacco product manufacturer would be required to conduct an investigation to determine if the production process deviation resulted in a nonconforming product. For example, if the fermentation of a tobacco blend deviates from established production processes and controls for fermentation, such as maintaining temperature and humidity through specified turn cycles necessary to meet a pH specification, the tobacco product manufacturer would be required to perform an investigation to determine if the deviation resulted in a nonconforming product.

Similarly, if a manufacturer uses a laboratory to perform product acceptance activities, and there is an out-of-specification (OOS) laboratory test result, the manufacturer would need to investigate the OOS test result under proposed § 1120.74(b) to determine whether the product is nonconforming or the OOS result is due to another cause such as laboratory error. Under proposed § 1120.74(b)(1), the investigation would be required to include an examination of relevant production processes and controls and any other relevant records and sources of information such as the laboratory method and review of initial testing and calibration of the laboratory equipment. Such an investigation could determine that the OOS test results came from an aberration of the measurement process (*e.g.,* laboratory error, defective testing equipment, or deviation from an established laboratory test method) and that the potential nonconforming product is not nonconforming. Alternatively, an investigation could conclude that the OOS test result was valid and that the product was nonconforming as a result of the manufacturing process.

If a tobacco product is determined to be nonconforming, under proposed § 1120.74(b)(2), the investigation also would be required to determine the scope and cause of the nonconformance and the risk of illness or injury posed by the nonconformance. Examination of relevant production processes and controls and any other relevant records and sources of information could help a manufacturer determine if any other batches are affected or if nonconforming product has been distributed. For example, if the investigation of a nonconforming product determines that the cause is due to fragments from a cutting blade, the manufacturer may need to investigate other batches on which the cutting blade was used since it was last inspected and take appropriate follow up action. For any product determined to be nonconforming, documentation of the investigation activities under proposed § 1120.74(d) should include the product name (brand and sub-brand), additional product identification, and quantity of nonconforming tobacco product. The additional product identification should include all unique identifiers associated with the tobacco product and, if applicable, the manufacturing code of the finished or bulk tobacco product.

The proposed rule would also require that, for products determined to be nonconforming, the investigation include an examination of the risk of illness or injury posed by the nonconformance, because this risk would be relevant to the manufacturer's disposition decision under proposed § 1120.74(c). Furthermore, this information can feed into the manufacturer's risk management process under proposed § 1120.42.

Under proposed § 1120.74(b), an investigation would be required to be performed for all potential nonconforming products. However, if a previous investigation has been completed and it is determined to be applicable to the current investigation, the results and followup of the previous investigation could be cross-referenced and applied to the current investigation. In other words, if the cause of a nonconforming product is determined to be the same as that of a previous nonconforming product, the manufacturer could cross-reference the results of the previous investigation and would not need to repeat aspects of the investigation that would be redundant.

Proposed § 1120.74(c) would require finished and bulk tobacco product manufacturers to determine the disposition of all nonconforming tobacco products and to conduct any necessary follow up action. Under proposed § 1120.74(c), nonconforming product could not be released for distribution without rework or an adequate justification. Thus, nonconforming product could be reworked as appropriate under proposed § 1120.78, distributed with an adequate justification (as explained below), or discarded. If a manufacturer determines that nonconforming product can be reworked, the disposition decision should address how the rework will correct the nonconformity without adversely affecting the product. For example, if an ENDS manufacturer decides to rework a nonconforming circuit board by resoldering a joint, the manufacturer should document how such rework does not adversely affect the circuit board by melting or delaminating board components.

A manufacturer may determine that a nonconforming tobacco product can be released for distribution without rework; however, proposed § 1120.74(c) would require the manufacturer to provide an adequate written justification before releasing such product. An adequate written justification would be required to address why releasing the product would not result in an increased risk of illness or injury or in the tobacco product being adulterated or misbranded. For example, if a manufacturer determines that a product is nonconforming because of a minor discrepancy in the color of its packaging (*e.g.,* Pantone 2415 C vs. an established specification of Pantone 2415 CP) and that the product can be released for distribution without rework, the manufacturer could provide an adequate written justification (*i.e.,* explain that the minor color discrepancy will not increase the risk of illness or injury or render the product adulterated or misbranded) and release the nonconforming product. However, nonconforming product that would increase the risk of illness or injury, or that would result in the tobacco product being adulterated or misbranded would not be acceptable for release without rework. For example, if a nonconformity results in a modification of a product that would require a new marketing application under section 905 or 910 of the FD&C Act and make the product misbranded under section 903(a)(6) of the FD&C Act or adulterated under section 902(6)(A) of the FD&C Act, the nonconforming product could not be released for distribution without rework. Similarly, a tobacco product that becomes contaminated by glass fragments from an unprotected light fixture would present an increased risk of injury to the user that would warrant discarding the product as it may not be possible for it to be reworked.

Proposed § 1120.74(c) would also require finished and bulk tobacco product manufacturers to conduct any necessary followup actions. Follow up actions could include initiating a CAPA under proposed § 1120.16 and taking appropriate corrective action on other affected batches. If nonconforming product has already been distributed, the manufacturer could initiate a recall.

Necessary followup should be informed by the results of the investigation under proposed § 1120.74(b); for example, the risk of illness or injury posed by the nonconformance may affect the type of CAPA to be taken.

Proposed § 1120.74(d) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. This provision would require that such records include the date and time of the activity, the individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. As stated elsewhere in this preamble, for purposes of this proposed part 1120, FDA interprets ''reconstruct'' to mean the ability to re-create the results by analyzing all data, including source and metadata data, and records, including calculations. For any product determined to be nonconforming, the records should document the product name (brand and sub-brand), any additional product identification information (*e.g.,* manufacturing code(s), batch number, or unique ID as applicable), and the quantity of nonconforming tobacco product. This information is important for verifying that all potential nonconforming product is properly handled, that nonconforming product investigations are appropriately thorough and complete, and that disposition decisions are made to prevent the release of nonconforming product for distribution and are properly justified.

In addition to helping to prevent the distribution of nonconforming product, the proposed nonconforming product requirements would help assure that the public health is protected by requiring tobacco product manufacturers to perform a systematic assessment of nonconforming product and take appropriate followup. Nonconforming product can result from a design problem, failure to meet tobacco product specifications, failures of or problems with purchasing controls, inadequate process controls, improper facilities or equipment, inadequate training, inadequate manufacturing methods and procedures, or improper handling of the tobacco product. The proposed provisions would require manufacturers to investigate the cause of nonconforming product and take appropriate followup, such as CAPAs, to eliminate or minimize future nonconformities. For example, if a cigarette manufacturer determined that a cigarette did not meet its filter pressure drop specification (a nonconformity that can expose consumers to increased risk of exposure to constituents compared to what would normally be expected from cigarette use (Ref. 147), these provisions would require that the manufacturer undertake a systematic assessment to determine the cause of the nonconformity and the need for CAPAs to be taken, which would help prevent the manufacture and sale of similar nonconforming product. If the results of acceptance activities demonstrate that the product does not meet the specification, the manufacturer would be required to take the steps to address nonconformities in accordance with proposed § 1120.74. Specifically, the manufacturer would need to identify and segregate the nonconforming product to prevent mixups and distribution of nonconforming product, investigate the nonconformity, and determine the disposition of the product.

As another example, where a tobacco product manufacturer determines that its product does not conform to established pH specifications, it would be required to comply with this proposed provision. The amount and speed of nicotine delivered by a tobacco product is related to the proportion of nicotine in a tobacco product and/or its emissions that is in the unprotonated or ''free-base'' form (also known as the un-ionized free-base form); therefore, a product that delivers more unprotonated nicotine at a faster rate is more addictive and toxic than other tobacco products. Because the pH scale is logarithmic, the proportion of unprotonated nicotine increases or decreases sharply with relatively small changes in pH. For example, at a pH of 7, about 7 percent of the nicotine is free; at a pH of 9 or more, 80 percent of the nicotine is in the free form. Tobacco and smoke pH appear to be controlled primarily by the use of ammonia compounds and other substances used in tobacco processing and final cigarette production, which serve to optimize the free nicotine levels (Ref. 6). Accordingly, a tobacco product's specifications (including the amount of ingredients, additives, and materials such as ammonia compounds) can affect the product's pH. A manufacturer's investigation and disposition of such nonconforming product would help to ensure that such products are not placed into distribution and that such nonconformities do not occur in the future, thereby helping ensure that consumers are not exposed to greater risks than those normally associated with the use of the product.

The proposed nonconforming product requirements would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act by providing thorough steps and actions to be taken on nonconforming tobacco products. These measures would help ensure that tobacco products that are nonconforming are either not placed into distribution or are reworked so that they conform to established specifications, including those provided by the manufacturer to FDA in any relevant tobacco product applications (*i.e.,* SE Report, request for exemption from SE, PMTA, MRTPA). In addition, they would help manufacturers to ensure, and FDA to verify, that manufacturers are not making changes to finished tobacco products that may render them new tobacco products adulterated under section 902(6) of the FD&C Act or misbranded under section 903(a)(6) of the FD&C Act.

8. Returned Tobacco Product

Proposed § 1120.76(a) would require each finished and bulk tobacco product manufacturer to establish and maintain procedures for the control and disposition of returned tobacco product. Returned tobacco products are commercially distributed finished or bulk tobacco products returned to the tobacco product manufacturer by any person not under the control of the tobacco product manufacturer, including a wholesaler/distributor, retailer, consumer, or a member of the public. These proposed requirements are generally similar to practices of manufacturing establishments that follow ISO 9001.

Proposed § 1120.76(a)(1) would require finished and bulk tobacco product manufacturers to identify returned tobacco product with the product name, manufacturing code, quantity returned, date the manufacturer received the returned product, and reason for return. Returned tobacco products should be identified using appropriate means such as a tag or label to prevent mixups and inadvertent use or distribution.

Proposed § 1120.76(a)(2) would require finished and bulk tobacco product manufacturers to segregate the identified returned tobacco product in a manner that prevents mixups and use of returned tobacco product prior to evaluation and disposition. Returned tobacco products could be segregated by being placed in a quarantined area or in an identified location that prevents mixups.

Proposed § 1120.76(a)(3) would require finished and bulk tobacco product manufacturers to evaluate identified returned tobacco product and determine its disposition (*i.e.,* discard,

rework, release for distribution). Evaluation is necessary to determine whether the returned product should be discarded, whether it is appropriate for rework under proposed § 1120.78, or whether the product can be released for distribution. If during an evaluation, a manufacturer determines that returned tobacco product is potentially nonconforming, the manufacturer would be required to follow its nonconforming product procedures in accordance with proposed § 1120.74. Under proposed § 1120.76(a)(3), tobacco product manufacturers would have flexibility to determine how to evaluate returned tobacco product. A tobacco product manufacturer could use inspection, testing, or other verification methods to evaluate the returned tobacco product and make an appropriate disposition determination. Returned tobacco product would be required to be discarded unless the manufacturer determines that it can be reworked, or released for distribution based on an adequate written justification. An adequate written justification would show that the returned product is not nonconforming or explain why releasing nonconforming returned product would not result in an increased risk of illness or injury or in the tobacco product being adulterated or misbranded (see also proposed § 1120.74(c)).

In some circumstances, a manufacturer could determine that returned nonconforming product can be reworked to meet established specifications. For example, if a tobacco product is returned because the package contained an incorrect quantity, the manufacturer could repackage the product with the correct quantity. The release of nonconforming returned product for distribution should not occur except in limited circumstances where the manufacturer can provide an adequate written justification that addresses why releasing the product would not result in an increased risk of illness or injury or in the tobacco product being adulterated or misbranded (see proposed § 1120.74(c)). For example, a manufacturer could release a returned product for distribution without rework if the product was mistakenly sent to a distributor or retailer and returned in unopened and intact packaging with no visible signs of damage or contamination.

FDA notes that when returned products are determined to be potentially nonconforming under proposed § 1120.74, or are associated with complaints under proposed § 1120.14 or with a CAPA under proposed § 1120.16, the requirements in those sections, including all investigation requirements, would apply and take precedence. If returned products are needed (*e.g.,* for product testing) in order to conduct an adequate investigation under those sections, a manufacturer should complete the investigation before discarding the returned product under proposed § 1120.76. For example, if a manufacturer determines that a returned product might contain a contaminant, it should keep the product and complete an investigation on the nature and scope of the contamination before the returned product is discarded.

If a tobacco product manufacturer's disposition decision is to rework the returned tobacco product, the rework would need to be performed in accordance with proposed § 1120.78.

Proposed § 1120.76(b) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. Under this proposed provision, records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. As stated elsewhere in the preamble, FDA interprets ''reconstruct'' to mean the ability to re-create the results by analyzing all data, including source and metadata data, and records, including calculations. In addition, records of evaluation and disposition would be required to include the product name, manufacturing code, quantity returned, date the manufacturer received the returned product, reason for the return, disposition decision and any justification, and the name of the individual making the decision.

The industry GMP recommendations do not include returned product provisions. The Agency believes the proposed returned tobacco product requirements would help assure that the public health is protected by requiring that manufacturers of finished and bulk tobacco products evaluate returned tobacco products and adequately justify their disposition decisions. For example, FDA has learned that some tobacco products have been contaminated with insecticides, gasoline or diesel fuel, or other toxic substances during shipment (*e.g.,* Refs. 148 and 149). In addition, FDA is aware that tobacco products such as ENDS may be altered or customized by a vape shop, resulting in nonconformity, including contamination. If these products are returned to the manufacturer, this provision would help ensure that they are handled appropriately and that any subsequent distribution of the products is adequately justified.

The proposed returned tobacco product requirements would assure that the public health is protected and that products are in compliance with chapter IX of the FD&C Act by helping to prevent contamination and adulteration of tobacco products. Contaminated and adulterated tobacco products can adversely affect public health over and above the risk normally associated with the use of the product.

9. Reprocessing and Rework

Proposed § 1120.78 would require finished and bulk tobacco product manufacturers to establish and maintain procedures for reprocessing and reworking tobacco product. These proposed requirements are similar to practices that are already being implemented by the tobacco industry, as FDA has observed during inspections, and to the practices of manufacturing establishments that follow ISO 9001. FDA has found that tobacco product manufacturers use reprocessing procedures in their manufacturing process (Refs. 150–154).

Proposed § 1120.3 defines ''reprocessing'' as using tobacco product that has been previously recovered from manufacturing in the subsequent manufacture of a finished or bulk tobacco product. An example of reprocessing would be using tobacco recovered during the production process, such as cigarette tobacco recovered from the ripper short process (*e.g.,* Ref. 155) or tobacco recovered from smokeless tobacco cans that are rejected for being the incorrect weight, in the subsequent manufacture of cigarettes or smokeless tobacco cans that use the same tobacco blend. Proposed § 1120.3 defines ''rework'' as action taken on a nonconforming or returned tobacco product to ensure the product meets the specifications and other requirements in the MMR of a subsequently manufactured product before it is released for further manufacturing or distribution. An example of rework would be the repackaging or relabeling of a finished tobacco product due to nonconforming packaging or labeling.

Specifically, proposed § 1120.78(a)(1) would require the reprocessing and rework procedures to include evaluation of the tobacco product to determine whether the product is appropriate for reprocessing or rework and authorization of any reprocessing or rework by a designated individual. Under proposed § 1120.78(a)(1), tobacco

product would be appropriate for reprocessing if it is uncontaminated and has the same specifications as those in the MMR of the subsequently manufactured tobacco product. For example, tobacco recovered through a ripper short process would be appropriate for reprocessing if it is uncontaminated and has the same tobacco blend/type, size, and length, as specified in the MMR of the subsequently manufactured tobacco product. Tobacco recovered from one brand of a finished or bulk tobacco product could be reprocessed for use in the subsequent manufacture of another brand/sub-brand of a finished or bulk tobacco product if it has the same tobacco blend/types, cut size, and length and otherwise meets the MMR specifications for the other brand/sub-brand. However, mentholated tobacco, for example, would not be appropriate for reprocessing in the subsequent manufacture of a nonmentholated finished or bulk tobacco product.

A tobacco product would be appropriate for rework if further manufacturing can correct the nonconformity and the product could meet the specifications and other requirements in the MMR of a subsequently manufactured tobacco product. For example, if a tobacco product is nonconforming because of a contaminant, it would be appropriate for rework if further manufacturing could eliminate the contaminant and the tobacco product could meet the specifications and other requirements in the MMR for the subsequently manufactured product.

The evaluation required under proposed § 1120.78(a)(1) could be done by conducting testing or other inspection or verification activities, or by providing an adequate written justification for why the tobacco product is appropriate for reprocessing or rework. FDA has observed on inspections that reprocessing often occurs in the following in-line situations: incomplete cigarettes produced by a maker machine (*e.g.,* loose ends, ripper shorts, paper damage, or empty tip (no filter attached)); and smokeless tobacco cans that are rejected for missing or having an incorrect label or being the incorrect weight. In these types of situations, manufacturers typically determine that the tobacco is appropriate for reprocessing without further investigation or testing because it is uncontaminated and can be directly recovered from manufacturing for use in the subsequent manufacture of finished or bulk tobacco products. For example, if the manufacturer decides to reprocess tobacco from unformed cigarettes that are rejected by the maker equipment, under proposed § 1120.78(a)(1), the manufacturer would be required to evaluate the tobacco to ensure that it is appropriate for reprocessing. The evaluation could determine that the recovered tobacco is appropriate for reprocessing because these unformed cigarettes were collected directly from the maker and, therefore, further testing is not necessary to show that the tobacco is not contaminated and conforms to the specifications established in the MMR for the subsequently manufactured product. The manufacturer should provide an adequate written justification for its determination that is appropriate to reprocess the recovered tobacco, either in its reprocessing procedure or on an ad hoc basis. If the manufacturer chooses to reprocess tobacco products out-of-line (*i.e.,* tobacco not recovered directly from the production line), it should determine whether the evaluation should include testing the product to ascertain eligibility for reprocessing (*e.g.,* testing to ensure that the product is not contaminated).

A manufacturer would also have to perform an evaluation under proposed § 1120.78(a)(1) to determine whether tobacco product is appropriate for rework. For example, if finished packages of cigars are rejected for being the incorrect weight, a manufacturer would have to evaluate the nonconforming product to determine if it is appropriate for rework. The evaluation could determine that the nonconformity is due to the package having four cigars instead of the required five cigars, and that the product can undergo repackaging to address the nonconformity and meet the specifications and other requirements in the MMR for the subsequently manufactured product. In some cases, an evaluation may show that a product is not appropriate for rework. For example, an evaluation of returned tobacco product may determine that it is not appropriate for rework because further manufacturing cannot remove a contaminant, such as an insecticide (*e.g.,* Ref. 148).

Proposed § 1120.78(a)(2) would require the reprocessing and rework procedures to detail the production processes, including process controls, in accordance with proposed § 1120.66(a), and acceptance activities, in accordance with § 1120.64(c), used to ensure the reprocessed or reworked tobacco conforms to the requirements established in the MMR for the subsequently manufactured product. Usually, the production processes and controls used for reprocessing and rework would be the same as those used for the subsequently manufactured product under proposed § 1120.66(a) and reflected in its MMR under proposed § 1120.44(a)(2). However, there may be instances in which a manufacturer uses different production processes or process controls when reprocessing or reworking tobacco product. If reprocessing or rework involves different production processes and controls, proposed § 1120.78(a)(2) would require that reprocessing and rework procedures include these different production processes and controls. For example, if a manufacturer recovers tobacco product from a packing and labeling machine, determines that the product is nonconforming because it has incorrect labels, and decides to rework it using a manual relabeling process, the manufacturer would be required to include in its reworking procedures the production processes and controls for the manual relabeling process used to ensure that the subsequent reworked finished tobacco product conforms to the MMR specifications.

Proposed § 1120.78(b) would establish the requirement to maintain records of all activities required under this section. Under this proposed provision, records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. As stated elsewhere in this preamble, FDA interprets ''reconstruct'' to mean the ability to recreate the results by analyzing all data, including source and metadata data, and records, including calculations.

Additionally, proposed § 1120.78(b) would require that the production record of any finished or bulk tobacco product that includes reprocessed or reworked product include the amount, any unique identifier(s) assigned under proposed § 1120.64(b), any batch number, and any manufacturing code associated with the reprocessed or reworked product. These requirements are necessary to enable the tobacco product manufacturer to trace tobacco products consisting of (in whole or in part) reprocessed or reworked material and take appropriate corrective action, such as a recall or changes to procedures, if these products are determined to be nonconforming following reprocessing or rework. Reprocessing or rework records would be required to be maintained in the tobacco product's production record to show that the product conforms to the MMR.

The proposed reprocessing and rework requirements would assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act by helping to ensure that reprocessed or reworked tobacco products are not contaminated or adulterated or misbranded and meet the requirements in the MMR for the subsequently manufactured product. They would also help maintain traceability in case there is nonconformity as a result of ineffective reprocessing or reworking processes or procedures and corrective action is needed.

F. Packaging and Labeling Controls

1. Packaging and Labeling, and Repackaging and Relabeling, Controls

Proposed § 1120.92 would require finished and bulk tobacco product manufacturers to establish and maintain procedures to control packaging and labeling activities to prevent mixups and to ensure that all packaging and labeling are approved for use by the manufacturer and comply with all requirements of the MMR (see proposed § 1120.44) as well as all other applicable requirements of the FD&C Act, CSTHEA, FCLAA and their implementing regulations. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001 and to the proposed packaging and labeling controls in the industry recommendations.

Other applicable requirements of the FD&C Act, CSTHEA, FCLAA, and their implementing regulations include, among others: requirements related to false or misleading labeling of tobacco products under section 903(a)(1); requirements for including certain information on the label of tobacco products in package form under section 903(a)(2) of the FD&C Act; and package warning statement requirements for cigarettes under section 4 of FCLAA, for smokeless tobacco under section 3(a) of CSTHEA, for cigarette tobacco, RYO tobacco, and covered tobacco products other than cigars under § 1143.3(a) (21 CFR 1143.3(a)), and for cigars under § 1143.5(a). This includes warning rotation plan requirements for packages pursuant to section 4(c)(1) of FCLAA, section 3(b)(3)(C) of CSTHEA and § 1143.5(c). For example, under § 1143.5, packaging for cigars is required to contain certain warning statements in accordance with an FDA-approved warning plan. Accordingly, under this proposed provision, finished cigar manufacturers would have to establish and maintain procedures to control packaging and labeling activities to ensure that the correct required warning statement is applied to the cigar package, that the formatting requirements are met, and that the warnings on the package label follow the approved warning plan (§ 1143.5). See also proposed § 1120.98 for related requirements about warning plans.

As set forth in proposed § 1120.44(a)(3), the MMR would be required to include all packaging, labeling, and labels approved by the manufacturer for use with the finished or bulk tobacco product. The packaging and labeling control procedure requirement proposed in this section would ensure that only the approved packaging, labeling, and labels are used on finished and bulk tobacco products.

A tobacco product manufacturer could control packaging and labeling operations to prevent mixups using a variety of techniques. For example, a manufacturer could release approved and accepted packaging and labeling for each production batch (*i.e.,* a manufacturer could release the packaging and labeling in the same manner as it would release received components from a supplier that pass acceptance activities). Product acceptance could utilize verification activities, such as visual inspection and optical scanners, to inspect finished and bulk tobacco products to ensure the use of correct packaging and labeling, including correct package warning statements on finished products. Outdated or obsolete packaging and labeling should be destroyed.

Proposed § 1120.92(a)(1) would require that the packaging and labeling control procedures address label integrity. Specifically, this provision would require that labels be indelibly printed on or permanently affixed to finished and bulk tobacco product packages so they remain legible, prominent, and conspicuous during the customary conditions of processing, packing, storage, handling, distribution, and use. For a finished tobacco product, permanently affixed means the label must remain on the product package through the expected duration of use of the tobacco product by the consumer. For a bulk tobacco product, permanently affixed means the label must remain on the product package until the receipt by the subsequent manufacturer (*e.g.,* finished tobacco product manufacturer, packager or labeler). These label integrity requirements are intended to ensure that labels remain affixed to the tobacco product, and that the information contained on the label remains visible and readable and is not adversely affected by conditions such as ink bleeding, adhesion loss, or fading.

Proposed § 1120.92(a)(2) establishes design and construction requirements for packaging and labeling and for storage and shipping cases and containers. Specifically, proposed § 1120.92(a)(2)(i) would require that a manufacturer has procedures that ensure that a product's packaging and labeling do not contaminate or otherwise render the tobacco product adulterated or misbranded. To comply with this requirement, as part of its packaging and labeling procedures, a tobacco product manufacturer could evaluate the packaging materials to assess toxicological issues and verify that the material would not contaminate the tobacco product (Ref. 156). For example, packaging or label solvents such as benzene, toluene, methyl ethyl ketone, methyl cellosolve, and cellosolve are among the chemicals that can transfer from packaging materials to tobacco products and cause contamination (*e.g.,* Refs. 157–159). This proposed provision is intended to ensure that, among other things, a product's packaging and labeling do not render the product adulterated due to the use of these types of chemicals.

Proposed § 1120.92(a)(2)(ii) would require that the manufacturer has procedures that ensure storage and shipping cases or containers of finished or bulk tobacco products are designed and constructed to protect against contamination and adulteration of finished and bulk tobacco products during the customary conditions of storage, handling, and distribution. For example, if tobacco products are customarily stored, handled, or shipped in conditions where the tobacco product can be exposed to oils, hazardous materials, or insanitary conditions, the storage and shipping cases or containers would have to be able to protect the products from becoming contaminated or adulterated. Also, if customary environmental conditions of storage, handling, and distribution (such as temperature, moisture, and humidity) can contaminate or adulterate the tobacco products (*e.g.,* mold contamination), the storage and shipping cases or containers would have to protect the products from these conditions adequately.

Proposed § 1120.92(b) would require finished and bulk tobacco product manufacturers to maintain records of all activities required under this section. According to this provision, records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was

met, and any data or calculations necessary to reconstruct the results.

These proposed requirements would help assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act. Proper packaging and labeling of finished and bulk tobacco products are necessary to avoid mixups and to ensure that the packaging and labeling do not contaminate or otherwise render the tobacco product adulterated or misbranded. If a manufacturer applies the wrong label to a tobacco product, the label may be false or misleading, rendering the product misbranded under section 903(a)(1) of the FD&C Act. Such a product could impact public health. For example, in the case of a mixup, if a manufacturer applies the wrong nicotine concentration label to an e-liquid such that the product contains significantly higher levels of nicotine than what is stated on the label, this can increase the risk of addictiveness.

Proper packaging and labeling of tobacco products play an important role in FDA's comprehensive public health approach to tobacco control. The Tobacco Control Act contains a number of provisions related to the packaging and labeling of tobacco products. For example, certain tobacco product labeling must be submitted to FDA when tobacco manufacturers register under section 905(i)(1) of the FD&C Act. Specimens of tobacco product labeling must also be submitted with PMTAs under section 910(b)(1)(F) of the FD&C Act. Similarly, sample product labels and labeling must be included in MRTP applications under section 911(d)(4) of the FD&C Act. Additionally, section 903(a)(1) of the FD&C Act includes provisions related to false or misleading labeling of tobacco products, such as, for example, labeling that fails to bear required health warning statements (see section 201(n) of the FD&C Act). In addition, FDA's Deeming Rule requires warning statements on the packages of all covered tobacco products, cigarette tobacco, and RYO tobacco, with limited exceptions (see part 1143). The packaging and labeling of tobacco products contain required warning statements that promote greater understanding of the risks associated with the use of tobacco products (Ref. 160). For a discussion regarding why health warnings are appropriate for the protection of the public health and the effectiveness of warning statements, please see the analysis in the proposed Deeming Rule (79 FR 23142 at 23163–65). Requiring that tobacco product manufacturers establish and maintain procedures to control packaging and labeling activities would help to ensure that the manufacturers successfully carry out the labeling requirements in the Tobacco Control Act.

Proposed § 1120.94(a) would require finished tobacco product manufacturers to establish and maintain procedures to control repackaging and relabeling activities. These procedures would be required to address all requirements described in proposed § 1120.92. The terms ''repackaging'' and ''relabeling'' describe activities in which the package or label of a finished tobacco product is subsequently changed or replaced. Repackaging and relabeling may be performed by the same person who originally packaged and labeled the product or by someone other than the original packager/labeler. For example, if a manufacturer receives returned tobacco products and determines that the products could be distributed with new packages or labels, the manufacturer would have to comply with this provision, among others. In addition, this proposed provision would apply to an importer that changes or replaces the packages or labels of imported finished tobacco products. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001, and to the proposed repackaging and relabeling provision in the industry recommendations.

Proposed § 1120.94(b) would require finished tobacco product manufacturers to maintain records of all activities required under this section. According to this provision, records must include the date and time, the individual performing the activity, the type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

Like the proposed packaging and labeling control requirements (discussed in the preceding section), these proposed requirements would help assure that the public health is protected and that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. If a manufacturer applies the wrong label to the tobacco product, the product may be misbranded under section 903. In addition, if a finished tobacco product manufacturer recalls a product because the product was distributed with the wrong label, and determines that rework of that product is possible through repackaging or relabeling, the proposed requirements would help ensure that the reworked tobacco product conforms to the established specifications and other applicable requirements.

Proper packaging and labeling of tobacco products play an important role in FDA's comprehensive public health approach to tobacco control. The Tobacco Control Act contains a number of provisions related to the packaging and labeling of tobacco products (*e.g.,* sections 905(i)(1), 910(b)(1)(F), and 911(d)(4) of the FD&C Act), including provisions related to false or misleading labeling (section 903(a)(1) of the FD&C Act), such as labeling that fails to bear required health warning statements (see section 201(n) of the FD&C Act). For a discussion regarding why health warnings are appropriate for the protection of the public health and the effectiveness of warning statements, please see the analysis in the proposed Deeming Rule (79 FR 23142 at 23162). Requiring that tobacco product manufacturers establish and maintain procedures for repackaging and relabeling activities would help to ensure that the manufacturers successfully carry out the labeling requirements in the Tobacco Control Act.

2. Manufacturing Code

Proposed § 1120.96(a) would require that each finished and bulk tobacco product manufacturer apply a manufacturing code to the packaging or label of all finished and bulk tobacco products. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001 and practices that FDA has observed during establishment inspections, as well as to the proposed requirements of the industry recommendations.

For a finished tobacco product, the manufacturing code would need to be applied in a manner that assures it would remain on the packaging or label through the expected duration of a consumer's use of the tobacco product. For a bulk tobacco product, the manufacturing code would need to be applied in a manner that assures it would remain on the packaging or label until receipt by the subsequent tobacco product manufacturer.

For example, under this proposed provision, a finished cigarette manufacturer, who sells individual packs of cigarettes as well as cartons of cigarettes, would be required to apply a manufacturing code to each carton and to each pack of cigarettes. Similarly, a smokeless manufacturer who sells individual cans of smokeless tobacco as well as multiple cans packaged together in a plastic sleeve would need to apply a manufacturing code to the sleeve and to each individual can. Some cigarette manufacturers already apply similar

codes on cartons of cigarettes, and some smokeless tobacco product manufacturers apply similar codes on the plastic sleeve that holds individual and multiple cans of smokeless tobacco. Since the carton and the sleeve are typically discarded by the consumer during use, this section also would require that the manufacturing code be applied on the individual cigarette pack and smokeless can. FDA has observed on inspections that many manufacturers apply a code to the packaging, labeling, or shipping containers of finished tobacco products, which may be discarded prior to a consumer's use or immediately upon opening by the consumer, but FDA believes this practice is not sufficient. Under the proposed provisions, if a user stores the tobacco product and then later experiences an injury or illness due to a hazard or contaminant, or has another health-related problem, the user would be able to notify the manufacturer of the affected product using the product's manufacturing code, even if the packaging sleeve has been discarded.

Proposed § 1120.96(b) would require that the manufacturing code for each finished and bulk tobacco product be permanently affixed, legible, conspicuous, and prominent. The code should be easily visible, and it should not be obscured or be able to be mutilated or removed in whole or in part. For example, a manufacturing code that is partially smudged and cannot be read in its entirety would not meet the proposed requirement. This proposed requirement would allow for ready identification of the manufacturing code during distribution and sale. It also would help FDA to identify and trace nonconforming or violative tobacco products and perform relevant inspections to determine the scope of the problem and recommend or require appropriate corrective action such as a recall or stock recovery.

Proposed § 1120.96(c) would require that the manufacturing code contain the following information listed in the following order: (1) the manufacturing date in two-digit numerical values in the month-day-year format (MMDDYY), and (2) the finished or bulk tobacco product batch number. FDA proposes to require the manufacturing code to include the batch number because the batch number is the common identifier for the product in the production and distribution records. Because the batch number would be documented in the production record (see proposed § 1120.70) and the production record would include all the relevant manufacturing information for the batch (*e.g.,* unique identifiers of incoming components, acceptance activities results, identification of major equipment and processing lines used in the manufacturing of the batch), the manufacturing code on the product package or label would establish a link to the manufacturing history of the product and, as discussed in proposed § 1120.104, to certain records of distribution.

The proposed manufacturing code requirement would help assure that the public health is protected by providing for tobacco product traceability. The manufacturing code would enable tobacco product manufacturers to determine the manufacturing and distribution history of finished and bulk tobacco products. If a product user becomes ill or injured due to a hazard or contaminant, or otherwise has a tobacco-related health problem, the user would be able to notify the manufacturer of the affected product using the product's manufacturing code. The manufacturer could use this information to review the production record as part of a complaint, nonconforming product, or CAPA investigation to determine the scope and cause of the issue. In addition, the manufacturing code would help the manufacturer determine the distribution history of the affected tobacco product if it needs to take a corrective action, such as a recall or stock recovery.

In addition, the proposed requirement would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. If adulterated or misbranded products have been manufactured and distributed, the Agency can identify affected batches and take appropriate actions. For example, the manufacturing code would help FDA effectuate an order under section 908(a) of the FD&C Act to provide notification about tobacco products that present an unreasonable risk of substantial harm to the public health in order to eliminate such risk. This information would also help to effectuate an order under section 908(c) to recall tobacco products, where FDA finds that there is a reasonable probability that the tobacco product contains a manufacturing or other problem not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death. In addition, if FDA tests tobacco products at retail locations and determines that the products are adulterated or misbranded, it would be able to use the manufacturing code to conduct relevant inspections or investigations (*e.g.,* review production and distribution records) to determine the scope and cause of the issue and take appropriate action.

3. Warning Plans

Proposed § 1120.98(a) would require each finished tobacco product manufacturer that is required to comply with a warning plan for tobacco product packaging (under the FD&C Act, FCLAA, CSTHEA, or their implementing regulations) to establish and maintain procedures to implement the requirements of such warning plan. For example, under § 1143.5(c), certain cigar packages must bear warning statements that are randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar, and randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by, FDA. Proposed § 1120.98(a) would require cigar manufacturers that are required to comply with an FDA-approved plan under § 1143.5(c) to establish and maintain procedures to ensure that such a plan is implemented and followed. Similarly, finished cigarette and smokeless tobacco product manufacturers would have to establish and maintain procedures to ensure that warning plans for cigarette and smokeless tobacco product packaging required under FCLAA and CSTHEA are implemented and followed.

Under section 903(a)(1) of the FD&C Act, a tobacco product is deemed to be misbranded if its labeling is false or misleading in any particular. This could include, for example, a case in which a manufacturer includes the same single warning on all product packages, when there is a requirement to rotate a number of different warnings (see section 201(n) of the FD&C Act). This provision would help the Agency to ensure that tobacco product packaging displays all applicable required health warning statements. FDA has observed that some manufacturers do engage in activities that address warning plans but we have also found, during inspections, that some manufacturers do not have proper procedures in place at the manufacturing facility to ensure the warning statements are randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of product, and randomly distributed in all areas of the United States in which the product is marketed (*e.g.,* Refs. 55 and 161) (see 15 U.S.C. 4402).

Manufacturers could adopt a number of practices to comply with applicable warning plans. For example,

manufacturers could order labels on which the warnings are printed in sequence on the label rolls such that, for a given production run, each of the warnings is applied equally. Alternatively, manufacturers could use multiple label rolls that contain one of the required warning labels and have a supervisor tasked with calculating and documenting when to switch the roll to ensure that the required warning labels are equally applied in a batch. Further, manufacturers could establish procedures that define the specific number of each of the required warning statements needed for printing or affixing to the label of each brand of product during the manufacturing process and outline procedures for shipment of the products to ensure random distribution. Such practices could be included in the procedures required in this proposed provision.

Under proposed § 1120.98(a), the warning plan procedures would be required to include the inspection of the packaging before distribution to ensure that finished tobacco product labels bear the required warning statements in accordance with the warning plan. For example, FDA is aware that some manufacturers use visual inspection or electronic optical scanners to perform inspection of packaging and labeling to confirm that the correct warning statements have been applied.

Proposed § 1120.98(b) would require finished tobacco product manufacturers that are required to comply with a warning plan for tobacco product packaging (under the FD&C Act, FCLAA, CSTHEA, or their implementing regulations) to maintain records that demonstrate that they are in compliance with the warning plan. For example, if the manufacturer must comply with a cigar warning plan under § 1143.5, this provision would require the manufacturer to maintain records that demonstrate that the required warning statements are randomly displayed in each 12-month period, in as equal number of times as possible on each brand of cigar packaging. Such records also would need to demonstrate that the required warning statements on packaging are randomly distributed in all areas of the United States in which the cigar is marketed. Records required under this proposed provision could include a copy of the relevant FDA approved warning plan, copies of the product labels maintained in the production records (see proposed § 1120.70(b)(6)), distribution records maintained under proposed § 1120.104(b), and any additional records demonstrating compliance with any requirements for random distribution and random and equal display.

The Agency has observed that many tobacco product manufacturers have adopted a number of different practices that would meet the requirements in proposed § 1120.98(b). For example, FDA is aware that some smokeless tobacco manufacturers keep records from audits or an accounting of each of the four required warning statements that are ordered for and applied to smokeless tobacco product packaging to confirm that over a 12-month period, each of the four required warning statements are randomly displayed, in as equal a number of times as is possible for each brand of product. FDA is aware that other manufacturers have used a quality audit, to verify the production of required warning statements on packaging within a 12-month period (Ref. 162). Other manufacturers document in their production, inventory, or shipment records the specific warning statements that have been used or applied to packaging, and demonstrate through distribution records that the required warning statements have been randomly distributed.

The industry GMP recommendations do not call for warning plans. The Agency believes that the proposed requirements would help assure that the public health is protected. This provision would help ensure that manufacturers who produce finished tobacco products that are subject to a warning plan establish and maintain packaging procedures to ensure compliance with applicable laws and regulations to warn users of known health risks. The World Health Organization (WHO)'s Framework Convention on Tobacco Control (FCTC), an evidence-based treaty, provides a regulatory strategy for health warnings on packaging and labeling (Ref. 163), for addressing the serious negative impacts of tobacco products, calls for rotating health warnings to ensure that they do not become stale (Ref. 164). Salient warnings would be more visible to consumers, informing them of the consequences associated with use of tobacco products. Accordingly, this provision would help assure that the public health goals of the warning label requirements are met.

These proposed requirements also would help assure that tobacco products are in compliance with chapter IX of the FD&C Act. Under section 903(a)(1) of the FD&C Act, a tobacco product is deemed to be misbranded if its labeling is false or misleading in any particular. This could include, for example, a case in which a manufacturer includes the same single warning on all product packages, when there is a requirement to rotate a number of different warnings (see section 201(n) of the FD&C Act). By ensuring that tobacco product manufacturers establish and maintain packaging procedures that address required warning plans, the proposed provision would help ensure that tobacco products are not misbranded.

G. Handling, Storage, and Distribution

1. Handling and Storage

Proposed § 1120.102 would require finished and bulk tobacco product manufacturers to establish and maintain procedures to ensure that tobacco products are handled and stored under appropriate conditions to prevent nonconforming products as well as mixups, deterioration, contamination, adulteration, and misbranding of tobacco products. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001, the proposed handling and storage provision in the industry recommendations, and controls that are already being implemented by the tobacco industry, as observed by FDA during inspections.

Handling and storage procedures under proposed § 1120.102 could include, for example, establishing storage conditions to control temperature and humidity to prevent mold growth, and adopting certain product segregation practices to prevent mixups. If a manufacturer restricts access to designated storage areas through the use of keys, bar code readers, or other means, the procedures should detail, among other things, who is permitted access and what steps should be followed prior to handling. Such procedures are intended to prevent mixups or the use of unsuitable materials in manufacturing.

These proposed requirements would apply to all stages of handling and storage in which a manufacturer is involved, including handling and storage as part of the production process. The handling and storage procedures should complement other procedures required under this proposed rule, such as, for example, the procedures required in proposed Subpart C—Buildings, Facilities, and Equipment.

The proposed handling and storage requirements are intended, in part, to prevent deterioration of the tobacco product after it has undergone product acceptance activities and has been approved for release into distribution. For example, the tobacco-specific

nitrosamines (TSNAs) 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) and N-nitrosonornicotine (NNN) are formed from tobacco alkaloids and nitrosating agents, such as nitrite (Ref. 165). These TSNAs are potent carcinogenic agents found in smokeless tobacco products (82 FR 8004, January 23, 2017). The concentration of NNK and NNN may increase in smokeless tobacco when stored at room temperature due to microbial action (Refs. 56 and 166). Additionally, high storage temperature of cured tobacco has been shown to contribute to TSNA formation (Ref. 167). However, controls exist that can limit the formation of TSNA, including refrigeration of the tobacco products during storage (Ref. 165). If such handling and storage conditions are necessary to ensure that a finished or bulk tobacco product remains within its NNN or NNK specification, this provision would require a manufacturer to establish and maintain procedures for such handling and storage controls.

The proposed handling and storage requirements are also intended to prevent contamination. For example, in storage, the environment's moisture content and relative humidity can support mold growth and aflatoxin production by aflatoxigenic molds (Refs. 168 and 169). Manufacturers can decrease the likelihood of mold contamination in tobacco products by controlling the temperature and humidity during storage. Additionally, FDA is aware that tobacco products in many countries contain numerous contaminant by-products attributed to storage practices (Ref. 165). These storage practices can introduce NTRMs, including manufacturing materials, pesticides, cleaning compounds, microorganisms, and animal or insect excrement or parts into the tobacco product (Refs. 6 and 170). A tobacco product can also become contaminated if it is stored close to highly aromatic liquids or materials, such as kerosene, oils, grease, and paraffin (Ref. 171). The proposed requirements in this section are intended to ensure that tobacco product manufacturers adopt handling and storage practices that prevent such contamination.

The proposed handling and storage requirements are also intended to protect against problems that could occur from product or ingredient mixups. For example, if the manufacturer does not implement these handling and storage requirements and ingredients are mishandled during the manufacturing process without detection, a label might not accurately reflect the content of ingredients of the product.

The Agency believes that the proposed handling and storage requirements would help assure that the public health is protected and that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. Establishing and maintaining procedures for handling and storage is an important step in preventing nonconforming products and mixups, contamination, deterioration, adulteration, and misbranding.

2. Distribution

Proposed § 1120.104 would require finished and bulk tobacco product manufacturers to establish and maintain procedures related to the distribution of finished and bulk tobacco products. These proposed requirements would apply only to tobacco product distribution within the manufacturer's control (*i.e.,* to the initial consignee and direct account). These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001, the distribution provision in the industry recommendations, and practices that are already being implemented by the tobacco industry, as observed by FDA during inspections.

Specifically, proposed § 1120.104(a)(1) would require finished and bulk tobacco product manufacturers to establish and maintain distribution procedures to ensure that finished and bulk tobacco products are distributed to the initial consignee under appropriate conditions to prevent nonconforming product as well as mixups, deterioration, contamination, adulteration, and misbranding of tobacco products. FDA intends for this provision to provide manufacturers flexibility in determining what conditions are appropriate for protecting their tobacco products against mixups, deterioration, contamination, adulteration, or misbranding. For example, a tobacco product manufacturer could seek to ensure that distribution conditions are appropriate by inspecting the integrity of shipping containers to make sure that there are no problematic conditions such as holes or gaps, checking the cleanliness and environmental conditions of transport containers, and making sure that there are no conditions that can attract insects and rodents. Additionally, a tobacco product manufacturer could establish distribution requirements to prohibit the distribution of finished and bulk tobacco products in transport containers that ship agricultural products, such as livestock and manure remnants in the form of organic fertilizer, to prevent tobacco products from becoming contaminated with bacteria such as *E. coli* and fecal coliform (Ref. 172). A manufacturer could also establish shipping procedures that require inspection of the shipping conditions to prevent the shipment of tobacco product in circumstances where they may become contaminated by toxic or hazardous substances. For example, shipping procedures could address circumstances similar to a reported situation where a shipment of cigarettes was contaminated with ant and roach spray (Ref. 148).

Proposed § 1120.104(a)(2) would require finished and bulk tobacco product manufacturers to establish and maintain distribution procedures to ensure that only those finished and bulk tobacco products approved for release are distributed. (See proposed § 1120.70 for the proposed requirement for review and approval of the production record for release of each batch of finished and bulk tobacco product for distribution.) This requirement is intended to prevent the release of nonconforming product or products that have not undergone applicable product acceptance activities. Tobacco product manufacturers would have the flexibility to determine the appropriate procedures and practices to control the distribution of their tobacco products. For example, FDA has observed on inspections that tobacco product manufacturers have used printed or electronically scannable labels, tags, and signs to ensure that only tobacco products that have been approved for release may be distributed.

Proposed § 1120.104(b) would require finished and bulk tobacco product manufacturers to maintain distribution records. According to this paragraph, the distribution records would be required to include the name and address of the initial consignee, the identification and quantity of finished or bulk tobacco products shipped, date of shipment, and the manufacturing code(s) of the tobacco products. The meaning of ''consignee'' in this context would be the person to whom the tobacco product is delivered, which is consistent with the use of consignee in other Agency distribution recordkeeping requirements (*e.g.,* § 820.160). The initial consignee is the first person to whom the manufacturer (or any person(s) acting on behalf of the manufacturer) delivers the tobacco products. The initial consignee can be a warehouse, wholesaler, distributor, or retailer, who is a customer of the manufacturer. However, the requirement would not include

individual purchasers of tobacco products for personal consumption. This basic information is needed to identify where tobacco products have been initially distributed in order, for example, to facilitate a corrective action such as a recall or stock recovery.

Proposed § 1120.104(c) would require finished and bulk tobacco product manufacturers to maintain a list of direct accounts. For purposes of this rule, ''direct accounts'' means all persons who are customers of the tobacco product manufacturer that receive finished or bulk tobacco products directly from the tobacco product manufacturer or from any person under control of the manufacturer. Direct accounts may include wholesalers, distributors, and retailers. Direct accounts do not include individual purchasers of tobacco products for personal consumption.

The list of direct accounts would be required to contain the name, address, and contact information of each entity. This list is different from the distribution record, which only lists the individual initial consignee associated with a particular shipment. The list of direct account information is necessary, for example, to facilitate investigations of nonconforming product. In addition, this information would assist in tracing finished or bulk tobacco products to all persons to whom the tobacco product manufacturer has distributed or sold products. This requirement would be consistent with 21 CFR part 7 provisions regarding voluntary recalls initiated by manufacturers.

The proposed distribution requirements would help assure that the public health is protected by requiring finished and bulk tobacco products to be distributed under appropriate conditions to prevent nonconforming tobacco products as well as mixups, deterioration, contamination, adulteration and misbranding of tobacco products. A finished or bulk tobacco product may deteriorate or be adversely affected by distribution conditions (*e.g.,* environmental transport conditions).

The proposed requirements also would help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act by helping to establish traceability of finished and bulk tobacco products. Tracing finished and bulk tobacco products would enable tobacco product manufacturers and FDA to identify where tobacco products that do not meet the requirements of the FD&C Act have been distributed and sold. This information would facilitate notification of consignees and persons in the distribution chain in order to efficiently conduct a product recall under section 908 of the FD&C Act, if necessary. The scope of a product recall would likely be much broader than necessary if records of product distribution were not available to pinpoint distribution, thus potentially decreasing a recall's effectiveness and increasing cost to the tobacco product manufacturer.

The proposed requirements also, in conjunction with the proposed unique identifier, production record, and manufacturing code requirements, would help enable FDA to assure the integrity of the supply chain from suppliers to finished or bulk tobacco product manufacturers as well as from finished or bulk tobacco product manufacturers to the initial consignees.

H. Recordkeeping and Document Controls

Proposed § 1120.122 would establish recordkeeping and document control requirements.

For purposes of this proposed part 1120, documents generally refer to written (paper or electronic) procedures, forms, work instructions, etc., such as the procedures that a finished or bulk tobacco product manufacturer establishes and maintains to address a TPMP requirement. For example, a tobacco product complaint procedure and complaint form template that is established under proposed § 1120.14 are considered to be documents. For purposes of this proposed part 1120, records generally refer to the written (paper or electronic) output from activities undertaken to implement the documents. For example, records include written results of complaint and nonconforming product investigations, and laboratory testing activities. We note that this use of the term ''record'' is specific to proposed part 1120 and does not affect how that term is applied in other contexts.

All documents and records required under the proposed rule would be required to meet certain requirements under proposed § 1120.122(a). We are proposing additional requirements for records under proposed § 1120.122(b) and for documents under proposed § 1120.122(c). FDA notes that if a tobacco product manufacturer establishes and maintains documents and records required under proposed part 1120 in an electronic format, then they are subject to the requirements of 21 CFR part 11.

Specifically, proposed § 1120.122(a) would establish general requirements that apply to all documents and records required under proposed part 1120. Proposed § 1120.122(a)(1) would require that documents and records required under proposed part 1120 be written in English, or an accurate English translation must be made available upon request. Documents and records (including any associated source data) could be maintained in the native language of a foreign tobacco product manufacturer as long as a translation is made available upon request. FDA expects that a manufacturer would fulfill requests for documents or records translations promptly to ensure that there are no delays of inspections or investigations. The accuracy of the English translation could be demonstrated by, for example, providing a certification of the translation, using a certified translator, or providing information on the competency of the translator.

Proposed § 1120.122(a)(2) would require that all documents and records required by proposed part 1120, that are associated with a batch of finished or bulk tobacco product, must be retained for a period of not less than 4 years from the date of distribution of the batch or until the product reaches its expiration date if one exists, whichever is later. Examples of such records include purchasing, acceptance, production, laboratory testing, warning plans, and distribution records. FDA has selected 4 years as a means to help assure that the records would be available for at least one biennial FDA inspection under sections 704 (21 U.S.C. 374) and 905(g) of the FD&C Act.

Documents and records that would be required by proposed part 1120, that are not associated with a batch of finished or bulk, would be required to be retained for a period of not less than 4 years from the date they were last in effect. Examples of these documents and records include training, calibration, and pest control procedures and records required under proposed §§ 1120.12 (Organization and personnel), 1120.36 (Equipment) and 1120.34 (Buildings, facilities, and grounds), respectively.

Proposed § 1120.122(a)(3) would require that all documents and records required under proposed part 1120 be maintained at the manufacturing establishment or another location that is readily accessible to responsible officials of the tobacco product manufacturer and to FDA. FDA interprets ''readily accessible'' to FDA as the documents and records being made available to FDA upon request within the course of an inspection. Documents and records, regardless of location, would be considered readily accessible to FDA if the tobacco product manufacturer can respond to an FDA investigator's request promptly and

without delaying the inspection or investigation.

The requirement to maintain documents and records at the manufacturing establishment or other locations that are readily accessible to responsible officials of the tobacco product manufacturer is intended to enable the manufacturer to exercise control over the documents and records, which will help ensure accountability. FDA would consider ''responsible officials'' to include management with executive responsibility. The proposed requirement also would help ensure that the responsible officials at the manufacturing establishment have ready access to those documents and records that are essential for performing required activities and making critical decisions.

This provision would require that the documents and records required to be maintained, including those not stored at the establishment, be made readily accessible during the 4-year retention period to FDA for inspection and photocopying or other means of reproduction. Documents and records required under this part may be retained either as originals or as true copies such as photocopies, microfilm, microfiche or other reproductions which preserve the content and meaning of the data, including associated metadata and audit trails. Where reduction techniques are used, suitable reader, computer, and copying equipment should be readily accessible to FDA during an inspection. Documents and records that can be immediately retrieved from another location as originals or true copies, including by computer or other electronic means, would meet the requirements of this paragraph.

Proposed § 1120.122(b) would establish additional requirements that apply to all records required under proposed part 1120. Specifically, proposed § 1120.122(b) would require that all records, regardless of storage medium, must be attributable, legible, contemporaneously recorded, original, and accurate (ALCOA). The ALCOA requirements of proposed § 1120.122(b) are basic principles that describe minimum standards for how records should be collected and maintained in order to protect the integrity of the data they preserve. For purposes of this requirement, records include all records required to be maintained under proposed part 1120, such as, for example, written results from inspections, tests, other verification activities. These ALCOA requirements would apply to all records regardless of format or storage media, including paper-based and electronic records. For example, laboratory test records would be required to include all relevant raw data, graphs, and charts. This provision is intended to ensure the data integrity of information generated to demonstrate compliance with the proposed TPMP rule.

The ALCOA requirements are defined under proposed § 1120.122(b)(2) and further explained as follows:

- *Attributable* means that the data in a record is traceable to its source. This means it should be attributable to the originator of the data, whether that source is an individual, an automated piece of equipment, or individual operating equipment. For example, if an ENDS manufacturer conducts an acceptance test of e-liquid, using gas chromatography–mass spectrometry, to determine its nicotine concentration, the record would have to identify the gas chromatography-mass spectrometry equipment used and the personnel who performed the test and state the result. This applies to any changes, corrections, deletions, or revisions to a record.
- *Legible* means the record is permanently recorded in a readable format. A legible record prevents loss and preserves traceability of changes without obscuring the original entry or subsequent additions or deletions. For example, if test information is recorded on a laboratory notebook or form, it would have to be recorded in ink. If any changes are made, the original entry would have to be struck out to preserve the first capture of the data and initialed and dated for traceability. Electronic data that are first stored in temporary memory before creating a permanent record would not comply with the proposed requirement, because the process would fail to save the first capture of the data and would not preserve the traceability of changes. Practices like this, that allow data manipulation prior to transfer to the permanent record, compromise the data integrity of the record and would not comply with this requirement.
- *Contemporaneously recorded* means that data is recorded at the time the procedure, assessment, observation, or other activity is performed.
- *Original* means the record reflects the first capture of the data and all information related to all subsequent changes required to fully reconstruct the TPMP activities. An original record preserves the record content and the meaning of the data, including associated metadata. Original records may be static or dynamic. A static record, such as a paper record, is fixed and allows little or no interaction between the user and record content. Records in a dynamic state allow the user to interact with the information. For example, electronic records in database formats that allow the user to track, trend, and query data are examples of records in a dynamic state. This provision would require that information that is first captured in a dynamic state remain available in that state.
- *Accurate* means that the data in a record is correct, truthful, complete, valid, and reliable. All records required under this part, including the associated data and metadata, must be accurate. Depending on the manufacturing process and record systems used, data may be captured manually by human observation or automated electronic equipment (*e.g.,* an electronic manufacturing system, records, or laboratory system). If errors occur, they should be specifically noted. *Accurate* also would require that there are no changes or edits to the recorded data without documented amendments. Electronic data that are first stored in temporary memory before creating a permanent record would not comply with the proposed requirement because such practice allows for data manipulation prior to recording, thus compromising the data integrity.

In order to comply with proposed § 1120.122(b) and other requirements of this proposed rule, finished and bulk tobacco manufacturers would need to preserve the metadata associated with TPMP records. Metadata are the contextual information required to understand the data. For example, without metadata the number ''20'' is meaningless. With additional context such as the unit of measure (*e.g.,* 20 mg nicotine/cigarette), the value 20 is given meaning. Metadata are structured information that describes, explains, or otherwise makes it easier to retrieve, use, or manage data. Metadata include the unit of measure, date/time stamp for when the data were acquired, identification of the person who conducted the test or analysis that generated the data, and identification of the equipment used to capture the data. Specific pieces of metadata may be required by other subparts of this proposed rule.

Finished and bulk tobacco product manufacturers also may find that audit trails assist them in demonstrating that information or data in a record complies with the proposed recordkeeping requirements. An audit trail is a form of metadata that contains information associated with actions related to the creation, modification, or deletion of a TPMP record. An audit trail is a chronology of the ''who, what, when, and why'' of a record. For a paper

record, the audit trail of a change would be recorded via a single line cross-out that allows the original entry to remain legible and includes the initials of the person making the change, the date of the change, and the reason for the change. The audit trail for a paper record should be contained within the four corners of the record. For electronic records, an audit trail is a secure, computer-generated, time-stamped electronic file that that allows for reconstruction of the course of events relating to the creation, modification, or deletion of a record.

Finished and bulk tobacco product manufacturers may comply with the proposed requirement of § 1120.122(b) that records be ''original'' by maintaining original records or true copies of those records through the records retention period. A true copy, like the original record, would preserve the record content and meaning of the data, including associated metadata and any audit trails. A true copy may only be retained in lieu of the original if it preserves the static or dynamic state of the original and if the copy has been compared to the original and verified to contain the entire content and meaning of the original record, including all metadata and any audit trails. Consistent with the cGMP requirements for other FDA-regulated products, true copies may be photocopies, pictures, scanned copies, microfilm, microfiche, electronic records, or other equivalent reproductions depending on form and content of the original record.

The extent of what would need to be included in a true copy is dependent on the original record. For example, when an individual writes a contemporaneous observation in a notebook or on a worksheet or scrap of paper, this is the first capture of data; this piece of paper would need to be retained unless a true copy is created. If a true copy is made, it must capture any written notes, strikeouts, erasure marks, and all other alterations to the original record.

Proposed § 1120.122(c) would require tobacco product manufacturers to establish and maintain procedures to control all documents established to meet requirements under proposed part 1120. For the purposes of proposed part 1120, documents generally refer to written procedures (such as standard operating procedures), work instructions, and blank forms, such as the procedures that a finished and or bulk tobacco product manufacturer establishes and maintains to address a TPMP requirement. However, completed forms and testing results generated when implementing activities under proposed part 1120 are considered records and therefore would not be subject to § 1120.122(c). For example, a pH acceptance testing procedure and blank form to record the pH test result are documents that would be subject to the general requirements under § 1120.122(a) and to the document controls under proposed § 1120.122(c). When pH testing is performed according to the testing procedure and the results are recorded on the form, this creates a record subject to the requirements under proposed § 1120.122(a) and (b). Similarly, a complaint procedure and a complaint record template established to comply with proposed § 1120.14 are documents and would need to comply with the proposed requirements in § 1120.122(a) and (c); the record maintained for a specific complaint event would be required to comply with the proposed requirements in § 1120.122(a) and (b), but it would not be required to comply with the proposed requirements in § 1120.122(c).

Proposed § 1120.122(c)(1) would require the document control procedures to include requirements for document approval and distribution. To comply with this proposed provision, manufacturers would need to assign personnel to review and approve all documents established to meet the requirements of proposed part 1120. Such review and approval would have to be completed before the document is implemented. For example, under proposed § 1120.14, manufacturers would be required to establish and maintain procedures for the receipt, evaluation, investigation, and documentation of all complaints. Personnel must review and approve the complaint procedure prior to the issuance and use of the procedure. The approval would be required to include the date, name, and signature of the individual(s) approving the document. Documents that are established to meet requirements proposed part 1120 would be required to be available at all locations for which they are designated, used, or otherwise necessary, and all such documents that are superseded and obsolete would have to be promptly removed from all points of use or otherwise prevented from unintended use. On inspections, FDA has observed the use of obsolete documents on the production line. Personnel who use an obsolete document may not adequately perform a required activity, which can result in the manufacture of nonconforming products.

Proposed § 1120.122(c)(2) would require that the document control procedures include requirements related to document changes. Specifically, changes to documents would have to be reviewed and approved prior to implementation by an individual(s) in the same function or part of the organization (*e.g.,* Quality Assurance Department) that performed the original review and approval. The purpose of this proposed requirement is to ensure that individual(s) in the same job function as those who originally reviewed and approved the document review any changes because these individuals typically have the best insight on the impact of the changes.

Proposed § 1120.122(c)(2) also would require that approved changes be communicated to the appropriate personnel in a timely manner. For example, a manufacturer could comply with this requirement by making the changed documents readily accessible at all locations for which they are designated, used, or otherwise necessary, and by retraining affected personnel on the changed documents. FDA has observed on inspections instances where manufacturers made changes to procedures, but the changes were not communicated in a timely manner to the personnel utilizing the documents. Without these proposed requirements in place, personnel may not be aware that changes have been made to a procedure, which can result in the manufacture of nonconforming products.

In addition, proposed § 1120.122(c)(2) would require that superseded and obsolete documents be archived. For purposes of proposed part 1120, archiving means that the superseded or obsolete document would be retained for historical reference. These documents would have to be retained in accordance with the time period in proposed § 1120.122(a)(2) (*e.g.,* for 4 years after last use, when not associated with a batch of finished or bulk tobacco product). These documents may be useful to manufacturers when performing an investigation of products manufactured and distributed using a previous version of a document. For example, an obsolete MMR would provide helpful information on specifications when investigating a nonconforming product that was manufactured under that version of the MMR.

Further, proposed § 1120.12(c)(2) would require tobacco product manufacturers to maintain records of changes to documents. According to this paragraph, document change records must include the following information: a description of the change; identification of the affected documents; the name and signature of the approving individual(s); the approval date; and the

date the change becomes effective. Maintaining change records on computers would be acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures. Electronic signatures could be used to satisfy this requirement. All electronic records are subject to part 11.

The proposed requirements would help assure that the public health is protected. Documents and records are essential to the ability to conduct adequate investigations in case of problems (*e.g.,* to determine the scope and cause of a nonconforming product issue) and take an appropriate corrective action, such as a recall.

The Agency also believes that the proposed document control requirements would help assure that the public health is protected. Document controls would establish a formal, documented system that defines how and by whom documents will be reviewed and approved. They also would include the procedures used for updating documents, for the distribution and maintenance of all required documents, and for the removal of obsolete and superseded documents. Controlled documents are necessary to establish consistent practices in manufacturing operations and provide a basis for employee training and supervision. If documents are not appropriately approved and current versions distributed for use, or if obsolete documents are used to manufacture tobacco products, manufacturing operations might proceed in an ad hoc manner that could result in the manufacture of nonconforming products. For example, if a manufacturer changes an acceptance activity procedure document to include a visual inspection of a new type of foreign material to address consumers' complaints, this change would have to be reviewed, approved, and communicated to the appropriate personnel in a timely manner. If personnel who are responsible for conducting this visual inspection are not informed of this change, they may fail to perform this activity and release products that contain this foreign material.

The proposed requirements would also help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act by ensuring that FDA can verify that the activities required under proposed part 1120 have been implemented and that the documents and records are trustworthy and reliable. Data integrity is an essential foundation of the proposed rule and is critical to FDA's ability to protect the public health. The proposed ALCOA requirements are necessary in order to protect the integrity of TPMP records. Widely accepted, the ALCOA requirements are the basic principles of data integrity (Refs. 174–177). The effectiveness of FDA inspections depends on the veracity of the information provided by regulated entities to the Agency. The vast majority of the time, FDA is absent from the establishment. The Agency depends on records and documents to reconstruct events which it was not present to witness. FDA's experiences in other regulated product areas have shown that data-integrity-related manufacturing violations, including data fraud and falsification of records, have led to numerous regulatory actions. Other regulatory agencies and public health organizations, like the World Health Organization, the European Medicines Agency, the Medicines & Healthcare Products Regulatory Agency of the United Kingdom, and the Therapeutic Goods Administration of Australia share FDA's view that data integrity principles are a core component of good manufacturing practice (id.). Because data integrity principles are essential to the quality systems and QMS, they are among the portions of those approaches adopted by the Agency in this proposed rule. Data integrity lapses in the regulated manufacturing environments are critical deficiencies because they undermine the ability of FDA to verify if a product is manufactured in accordance with its marketing authorization. Consequently, the proposed ALCOA requirement helps assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act by giving the Agency confidence in the integrity of the records which are at the center of the regulatory scheme envisioned by the Tobacco Control Act.

In addition, the Agency believes that the proposed document control requirements would help ensure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act, because, for example, documents established to meet the requirements of proposed part 1120 are necessary to implement the manufacturing methods and procedures specified in the MMR and ensure that a tobacco product conforms to its specifications. Thus, these documents would enable FDA to help ensure that new tobacco products and MRTPs are manufactured consistent with the specifications provided in their applications (*i.e.,* SE Report, request for SE exemption, PMTA, MRTPA) and that pre-existing products are manufactured consistent with their original characteristics.

I. Small Tobacco Product Manufacturers

Proposed § 1120.130 provides for an extended compliance deadline that would grant small tobacco product manufacturers of finished and bulk tobacco products additional time to implement the requirements in part 1120, consistent with section 906(e)(1)(B)(v) of the FD&C Act. Instead of being required to comply with part 1120 on the effective date of the final rule, small tobacco manufacturers would be required to comply with the requirements in part 1120 4 years after the effective date of the final rule. FDA believes that this extended compliance deadline for small tobacco product manufacturers would provide them with sufficient time to implement the proposed requirements.

J. Exemptions and Variances

1. Exemptions and Variances

Proposed § 1120.140 explains that, under section 906(e)(2) of the FD&C Act, any person subject to any of the TPMP requirements could petition FDA for a permanent or temporary exemption or variance from any of these requirements. The petitioner remains subject to the relevant requirements unless FDA grants the petition for an exemption or variance under proposed § 1120.146. Thus, any person who petitions FDA for an exemption or variance would have to follow the TPMP requirements in proposed part 1120 unless and until FDA grants the petition.

Section 906(e)(2)(A) of the FD&C Act provides FDA the authority to prescribe the form and manner for submission of petitions. Under proposed § 1120.140, an individual petitioning for an exemption or variance would have to submit the petition, including all information supporting the petition, in an electronic format that FDA can process, review, and archive. FDA intends to provide information on its website on how to provide the electronic submission to FDA (*e.g.,* information on electronic media and methods of transmission). Electronic submission of information is consistent with the Government Paperwork Elimination Act (Pub. L. 105–277, Title VII). Because of the broad availability of the internet, FDA does not anticipate any need to submit a petition for an exemption or variance, and supporting materials, in a nonelectronic format. However, if the petitioner is unable to submit a petition in an electronic

format, the petitioner may submit a written request to FDA asking that FDA allow the submission in an alternative format, explaining in detail why the petitioner cannot submit the petition in an electronic format and why an alternate format is necessary. Proposed § 1120.140 would also require that all petitions, including supporting information, and all requests to submit a petition in an alternative format, be legible and in the English language. These proposed requirements would ensure that FDA could review the petitions expeditiously and appropriately.

2. Petition for an Exemption or Variance

Proposed § 1120.142 would require that a petition for an exemption or variance be submitted with supporting documentation and contain: (1) the petitioner's name, address, and contact information; (2) identification of the tobacco product(s); (3) the requirement(s) in part 1120 for which an exemption or variance is requested; a detailed explanation of why the exemption or variance is requested, including why the tobacco product manufacturer is not able to comply with the requirement(s) of proposed part 1120; and (4) the duration of the proposed exemption or variance. In addition, for a petition for a variance, this section would require a detailed explanation setting forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the requirement(s) in part 1120, as well as the basis for the petitioner's determination that the proposed methods will be sufficient to assure that the public health will be protected and that the tobacco product(s) will be in compliance with chapter IX of the FD&C Act. For a petition for an exemption, this provision would require a detailed explanation setting forth the basis for the petitioner's determination that compliance with the requirement(s) is not required to assure that the public health will be protected and the tobacco product will be in compliance with chapter IX of the FD&C Act. Additional information that would be required with a petition for an exemption or a petition for a variance includes: any other information justifying the exemption or variance; a statement certifying that, to the best of the petitioner's knowledge and belief, the information provided in the petition includes all information and views on which the petition relies, including representative data, and any information known to the petitioner that is unfavorable to the petition; and an environmental assessment (EA) under part 25 (21 CFR part 25) prepared in accordance with § 25.40.

FDA expects that the submission of this information, along with supporting documentation will enable FDA to determine whether to grant a petition for a variance or exemption. FDA is considering including additional requirements for the specific contents of petitions for variances and exemptions and is seeking comment on the kinds of information and/or evidence that would be helpful in determining whether a petition should be granted.

3. Referral to the Tobacco Products Scientific Advisory Committee (TPSAC)

Proposed § 1120.144 explains that FDA may refer any petition submitted under this subpart to the TPSAC. If FDA refers a petition for an exemption or variance to the TPSAC, the TPSAC would be required to report its recommendations to FDA with respect to the petition referred to it within 60 days after the date of the petition's referral.

4. Petition Determination

Proposed § 1120.146(a) explains how FDA would make a determination on a petition for an exemption. Under proposed § 1120.146(a)(1), the Agency may, upon review of the information submitted and any recommendation from the TPSAC, approve a petition for an exemption from a TPMP requirement if it determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with chapter IX of the FD&C Act. As discussed above, in deciding whether to grant or deny a petition FDA will consider all the information provided by the petitioner including the basis of the petitioner's determination that compliance with the requirement is not needed to assure that the public health is protected. Proposed § 1120.146(a)(2) provides that, if FDA determines that the information submitted by the petitioner is insufficient to enable FDA to make a determination whether an exemption is appropriate, the Agency could request additional information from the petitioner. Proposed § 1120.146(a)(2) also provides that if the petitioner fails to respond by the time specified in the request, FDA could consider the exemption request withdrawn. FDA specifically requests comments from stakeholders as to what information should be included in a petition for exemption and how long it would take for a typical firm to gather and prepare the information that would be included in the petition for exemption.

Proposed § 1120.146(b) explains how FDA would make a determination on a petition for a variance. Under proposed § 1120.146(b)(1), the Agency may, upon review of the information submitted and any recommendation from the TPSAC, approve a petition for a variance if it determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirements in part 1120 are sufficient to assure that the tobacco product will be in compliance with chapter IX of the FD&C Act. As discussed above, in deciding whether to grant or deny a petition FDA will consider all the information provided by the petitioner, including the basis of the petitioner's determination that the proposed alternative methods, facilities, and controls are sufficient to assure that the public health is protected. Proposed § 1120.146(b)(2) provides that, if FDA determines that the information submitted by the petitioner is insufficient to enable FDA to make a determination whether a variance is appropriate, the Agency may request additional information from the petitioner. Proposed § 1120.146(b)(2) also provides that if the petitioner fails to respond by the time specified in the request, FDA may consider the variance request withdrawn.

Proposed § 1120.146(c) explains the timeframe in which FDA would make a decision on a petition. Proposed § 1120.146(c) provides that FDA would either grant or deny a petition within 60 days after the date the complete petition was submitted to FDA under § 1120.142 or within 60 days after the day after FDA referred the petition to TPSAC under § 1120.144, whichever date is later. The 60-day review period under proposed § 1120.146(c)(1) would begin when FDA receives a complete petition. Thus, if FDA receives an incomplete petition and requests additional information under § 1120.146(a)(2) or § 1120.146(b)(2), the 60-day review period would not begin until FDA receives the additional information that completes the petition. FDA intends to request additional information, if necessary, within 60 days after the date the incomplete petition was submitted to FDA.

Proposed § 1120.146(d) provides that an order from FDA granting a variance would prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product as may be necessary to assure that the tobacco product will be

in compliance with chapter IX of the FD&C Act.

5. Hearing

Proposed § 1120.148 explains that after FDA issues an order under § 1120.146, the petitioner would have the opportunity for an informal hearing under part 16 (21 CFR part 16).

V. Proposed Effective and Compliance Dates

FDA proposes that any final rule become effective 2 years after the date the final rule publishes in the **Federal Register**. Section 906(e)(1)(B)(iv) of the FD&C Act specifies that, in establishing the effective date of any TPMP regulations, FDA must take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and must provide for a reasonable period of time for such manufacturers to conform to any TPMP regulations. FDA has considered these factors in determining the proposed effective dates for this rule.

The Agency's proposed rule utilizes a standards-based approach to the regulation of all types of finished and bulk tobacco products, which is similar to the approach taken by the other cGMPs and voluntary standards considered in the development of this proposal. Thus, the proposed regulation provides the framework that all manufacturers would utilize and apply in a manner that is appropriate to a given tobacco product. FDA is proposing this effective date to ensure that manufacturers of all types of covered tobacco products will have adequate time to comply regardless of the complexity of their manufacturing process.

In addition, FDA inspections have demonstrated that a number of manufacturers already have implemented many measures similar to the proposed TPMP requirements. FDA also believes that manufacturers other than small tobacco product manufacturers have the financial resources to comply with the proposed requirements within 2 years, as demonstrated by the proposed regulatory impact analysis (PRIA) and the fact that a number of manufacturers already have implemented similar provisions. Those manufacturers meeting the definition of small tobacco product manufacturers will have an additional 4 years to come into compliance (see proposed § 1120.130). FDA inspections and facility visits have noted that entities that manufacture the originally regulated products (*i.e.,* cigarettes, smokeless, cigarette tobacco, and RYO) as well as entities that manufacture deemed products generally already have some manufacturing controls in place that are similar to the proposed rule (*e.g.,* a QMS or some portions of a QMS). FDA believes that the proposed effective date is feasible and that different effective dates for different types of manufacturers are not needed.

Accordingly, FDA believes that 2 years is a reasonable period of time for manufacturers (other than small tobacco product manufacturers) to comply with any final TPMP regulations. During those 2 years, FDA expects that manufacturers would take steps to plan and implement business operations that will comply with the final rule. FDA specifically requests comment regarding this proposed 2-year effective date.

Section 906(e)(1)(B)(v) of the FD&C Act specifies that FDA may not require any small tobacco product manufacturer to comply with any TPMP regulations for at least 4 years following the effective date of the regulation. As discussed in subpart J of the proposed regulation, FDA proposes that small tobacco product manufacturers of finished and bulk tobacco products not be required to comply with the TPMP regulations until 4 years after the effective date of the final rule. This proposed compliance date would give small tobacco product manufacturers a total of 6 years to comply with the TPMP regulations, and FDA believes that this extended compliance date for small tobacco product manufacturers would provide them with sufficient time to implement the requirements in any final rule. This proposed effective date is consistent with the recommendation of some tobacco companies (Docket No. FDA–2013–N–0227). FDA requests comment on this proposed effective and compliance dates from all interested parties.

VI. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order (E.O.) 12866, E.O. 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O. 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small entities are likely to incur a large portion of the costs to comply with the proposed rule, we find that the proposed rule would have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The proposed rule, if finalized, would establish requirements for manufacturers of finished and bulk tobacco products on the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation, packing, and storage of tobacco products. The TPMP requirements described in the proposed rule are expected to ensure that tobacco product manufacturers control the design and specifications of finished and bulk tobacco products, providing a level of assurance of conformity in the production of tobacco products to established and required specifications that does not occur in the existing market for tobacco products, to prevent the adulteration and misbranding of finished and bulk tobacco products, and establish controls for traceability purposes.

We quantify two potential benefits of the proposed rule. First, the manufacturing controls required by the proposed regulation are likely to reduce the likelihood that nonconforming products are manufactured and commercially distributed which, in turn, would reduce social costs associated with product recalls and market withdrawals. The social costs of a recall, due to inadequate or

insufficient controls, may extend beyond the costs to the manufacturer conducting the recall and may include shareholders as well as consumers, retailers, and wholesalers. If a recall or market withdrawal were necessary, the records required by the proposed regulation would help locate nonconforming products that were commercially distributed, which would also be expected to reduce the cost of conducting recalls and market withdrawals, both voluntary and involuntary. Since 2009, tobacco product manufacturers have initiated eight voluntary recalls, resulting in at least three million cans of smokeless tobacco and 62 million cigarettes recalled or withdrawn from the market. Furthermore, we estimate that, if the proposed rule is finalized, the costs of product recalls and market withdrawals may fall by between $4 million and $213 million per year.

Another quantified potential benefit of the proposed rule is that adverse events due to nonconforming finished and bulk tobacco products would decrease as a result of improvements in the control of tobacco product manufacturing operations. We use data on exposure calls to Poison Control Centers (PCs) throughout the United States to quantify the impact of the proposed rule on the number of exposure calls reporting clinical effects such as vomiting, nausea, abdominal pain, etc. associated with the consumption of tobacco products that, according to the PCs Certified Specialists in Poison Information, had been tampered with or contaminated. We estimate from 2001 to 2030, a total of 11,135 projected exposures, or an annual average of 371 exposures per year, associated with the consumption of such products.[6] Based just on these data regarding calls to PCs, if the proposed rule is finalized, we estimate that the total (undiscounted) monetized health losses associated with contaminated tobacco products may be reduced by between $908 and $2,723 per year.

There are other potential benefits associated with the proposed rule which we have not quantified. First, the proposed recordkeeping provisions will also support FDA's regulatory compliance activities and help FDA implement and enforce other provisions of the FD&C Act which will likely generate government cost savings. Second, the proposed rule, if finalized, may further reduce losses to health and property for users and nonusers associated with nonconforming tobacco products, beyond those estimated in the quantified benefits. Third, the proposed rule's risk assessment, CAPA, tobacco products complaints and related provisions will facilitate investigation and identification of causes and root causes of consumer complaints and other reports of adverse events. Other benefits include avoided spillover costs to capital markets.[7]

The potential costs of the rule include tasks associated with establishing and maintaining procedures for various aspects of the manufacturing, preproduction design validation, packing and storage processes. Examples of these tasks include conducting new or more stringent manufacturing activities, writing and updating standard operating procedures (SOPs), training employees to engage in new or more stringent manufacturing activities, and keeping new or additional records. We estimate that (undiscounted) one-time costs range from $39 million to $73 million and (undiscounted) recurring costs range from $15 million per year to $56 million per year. FDA is also proposing that any final rule become effective two years after the date of the final rule's publication. FDA is further proposing in § 1120.130 of this rule that manufacturers meeting the definition of small tobacco product manufacturer would be required to comply with the requirements of this rule four years after the effective date of the final rule (*i.e.,* six years after the date of the final rule's publication). Because small manufacturers would have more time than non-small manufacturers to comply with the requirements of this proposed rule, we estimate all costs to reflect the staggered compliance dates. We estimate learning costs for both non-small and small manufacturers to begin one year after publication (year 1). Non-small manufacturers and small manufacturers would incur costs one and five years, respectively, after the publication date of a final rule as they work to come into compliance with the rule two and six years from the date of final publication.[8] We therefore estimate the present value of total domestic costs annualized over ten years using a discount rate of seven percent is estimated to range from $13 million per year to $54 million per year, and from $14 million per year to $43 million per year using a discount rate of three percent. Our estimated benefits will begin to accrue on the same years as the compliance dates (years 2 and 6). The present value of total benefits annualized over ten years using a discount rate of seven percent is estimated to range from $1.9 million per year to $97.0 million per year, and from $2.1 million per year to $106.5 million per year using a discount rate of three percent. Table 1 summarizes our estimate of the annualized costs and benefits of the proposed rule.

[6] The 11,135 projected exposures are estimated from observed 2001–2017 exposures (adjusted for under-reporting) and adjusted to account for apparent trend of increasing exposure calls from 2018 through 2030. We used this forecast to estimate a baseline trend of what would occur without implementing this proposed rule. Figures are also adjusted for underreporting as explained in the Benefits of the Proposed Rule, section D.2 of the Preliminary Regulatory Impact Analysis (Ref. 184).

[7] Estimated quantified benefits of avoided recalls include reduced external costs in the supply chain of the recalled or withdrawn products (or they exclude reduced recall costs to manufacturers). Estimated external costs of conducting a recall or market withdrawal include lost sales to retailers and wholesalers, expenses associated with notifying tobacco retailers (for wholesalers) and consumers, removal and storage of inventory costs collection and shipping costs, disposal costs, and legal costs, among others. Estimated quantified benefits do not include avoided spillover costs to capital markets.

[8] The year of publication is year zero and the effective date is year two. In order for non-small manufacturers to comply with the requirements of this rule by the effective date (year two), we assume they will begin to incur compliance costs on year one. For small manufacturers to comply four years after the effective date or year six, we assume they will begin to incur compliance costs on year five. Benefits from non-small and small manufacturers begin to accrue on year two and year six respectively. All values have been adjusted to reflect 2020 dollars. Estimated costs in Table 1 represent estimated costs incurred by domestic manufacturers and domestic importers. Estimated benefits in Table 1 are from reduced exposure and reduced recall related costs associated with both domestic and imported tobacco products sold in the U.S.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE
[$ millions/year]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year.	$27.2 29.9	$1.9 2.1	$97.0 106.5	2020 2020	7 3	10 10	Quantified benefits include a summation of potential reductions in (1) cost of recalls and market withdrawals and (2) adverse health effects associated with contaminated or otherwise nonconforming tobacco products.
Annualized Quantified					7 3	10 10	
Qualitative	Non-quantified benefits include (1) Government costs savings due to aiding FDA compliance efforts; (2) potentially reducing losses to health and property for users and nonusers associated with nonconforming tobacco products; and (3) facilitating the investigation and identification of causes and root causes of consumer complaints and other reports of adverse events.					10	
Costs:							
Annualized Monetized $millions/year.	27.0 28.2	13.3 13.7	41.1 43.0	2020 2020	7 3	10 10	Annualized total costs of compliance with the proposed rule. Range of estimates captures uncertainty.
Annualized Quantified					7 3	10 10	
Qualitative						10	
Transfers:							
Federal Annualized Monetized $millions/year.					7 3	10 10	
From/To	From:			To:		10	
Other Annualized Monetized $millions/year.					7 3	10 10	
From/To	From:			To:			

Effects:
State, Local or Tribal Government:
Small Business:
One-time costs per small entity are between 0.06% and 0.11% of their average annual revenue. Due to many missing values from Census data, average small-entity impacts are likely subject to large variability, due to the significant amount of heterogeneity in small-entity impacts across entities of different sizes (See Ref. 184).
Wages:
Growth:

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (as Ref. 184) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the OMB under the PRA (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Requirements for Tobacco Product Manufacturing Practice.

Description: The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products. Section 101(b) of the Tobacco Control Act amends the FD&C Act by adding new chapter IX, which provides FDA with authorities to regulate tobacco products and imposes certain obligations on tobacco product manufacturers, retailers, and importers. Among the amendments are provisions that relate to tobacco product manufacturing practice requirements. The proposed provisions include, among other things, the authority to issue regulations relating to good manufacturing practice requirements; hereinafter TPMP, in order to assure that the public health is protected and

tobacco products are in compliance with the requirements of the FD&C Act.

Description of Respondents: This proposed rule applies to manufacturers (foreign and domestic) of finished and bulk tobacco products. Finished tobacco products include tobacco products, including all components and parts, sealed in final packaging (*e.g.,* rolling papers, filters, filter tubes, or e-liquids sold to consumers. Bulk tobacco products are tobacco products that are not sealed in final packaging but otherwise suitable for consumer use as tobacco products (*e.g.,* bulk cigarettes, bulk filters, bulk e-liquids).

Subpart B prescribes the proposed requirements pertaining to finished and bulk tobacco product manufacturers' management systems that cover a manufacturer's organization and personnel (§ 1120.12), tobacco product complaints (§ 1120.14), and CAPA (§ 1120.16).

Proposed § 1120.12 would require manufacturers to establish and maintain an organizational structure; have sufficient personnel to carry out the requirements under part 1120; designate, in writing, appropriate responsibility for all personnel who perform an activity subject to part 1120 and designate, in writing, management with executive responsibility who have the duty, power, and responsibility to implement the requirements under part 1120; establish and maintain training procedures; and maintain records of personnel qualifications and training records. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.14 would require manufacturers to establish and maintain procedures to receive, evaluate, investigate, and document complaints. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.16 would require manufacturers to establish and maintain procedures for implementing CAPA. These procedures are to require review of various sources of data for identifying and investigating existing and potential causes of nonconformities and design problems, acting to correct and prevent nonconformities and design problems, verifying or validating the CAPAs, implementing and documenting the changes needed, and communicating that information to specified personnel. Manufacturers must maintain records of all activities conducted under this section. Manufacturers would be required to keep records of all activities required under this provision.

Subpart C prescribes the proposed requirements that are specific to personnel practices (§ 1120.32), building, facilities, and grounds (§ 1120.34), equipment (§ 1120.36), and environmental controls (§ 1120.38).

Proposed § 1120.32 would require manufacturers to establish and maintain procedures for the cleanliness, personal practices, and apparel, which must include requirements to ensure that contact between personnel and the tobacco product or environment would not result in contamination of the tobacco product.

Proposed § 1120.34 would require manufacturers to ensure each building, facility, and grounds is maintained in appropriate condition to prevent contamination and ensure that buildings and facilities are of suitable construction, design, and location to facilitate sanitation, maintenance, and proper operation. The provision also would require controls for water quality, and record keeping, as well as require manufacturers to establish and maintain procedures for cleaning and sanitation and animal and pest control. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.36 would require manufacturers to ensure that equipment used in manufacturing operations is appropriately designed, constructed, and suitable for its intended purpose, and must establish and maintain procedures for the routine cleaning and maintenance of equipment, as well as for the routine calibration of testing, monitoring, and measuring equipment to ensure proper performance. The provision also would require identification of major equipment and all processing lines. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.38 would require manufacturers to establish and maintain procedures to adequately control environmental conditions, where appropriate, and maintain and monitor environmental control systems to verify that the environmental controls are adequate and functioning properly. Manufacturers would be required to keep records of all activities required under this provision.

Subpart D of the proposed rule prescribes the requirements for design and development activities (§ 1120.42) and MMRs (§ 1120.44).

Proposed § 1120.42 would require manufacturers to establish and maintain procedures to control the design and development of each finished and bulk tobacco product and its package, including the control of risks associated with the product, production process, packing, and storage. To control for risks, manufacturers would be required to conduct a risk assessment: (1) risk identification of all known or reasonably foreseeable risks associated with the tobacco product and its package, production process, packing, and storage, including risks normally associated with the use of the tobacco product; (2) risk analysis of the nature and level of risk for each identified known or reasonably foreseeable risk; and (3) risk evaluation of each identified risk to determine the significance of the risk and the type of risk treatment needed. In addition, manufacturers would be required to perform risk treatment to significantly minimize or prevent risks identified that are reasonably likely to occur and that may cause serious illness, injury, or death not normally associated with the use of the tobacco product, or that the manufacturer determines constitutes an unacceptable level of risk as well as to address risks for any applicable tobacco product standards to ensure that the tobacco product will conform to the specifications and requirements established in the tobacco product standard. Finally, manufacturers would be required to conduct a risk reassessment whenever the manufacturer becomes aware of new information that could change the risks assessment and risk treatment, including information about previously unidentified risks or the adequacy of risk treatment measures. Manufacturers would maintain records of all activities required under this section.

Proposed § 1120.44 would require that manufacturers establish and maintain an MMR for each tobacco product manufactured. Manufacturers would also establish and maintain procedures for the review and approval of the MMR.

Subpart E of the proposed rule prescribes the proposed requirements for purchasing controls (§ 1120.62), acceptance activities (§ 1120.64), production and process controls (§ 1120.66), laboratory controls (§ 1120.68), production records (§ 1120.70), sampling (§ 1120.72), nonconforming tobacco products (§ 1120.74), returned tobacco products (§ 1120.76), and reprocessing and rework (§ 1120.78).

Proposed § 1120.62 would require manufacturers to establish and maintain purchasing procedures, purchasing records, and procedures for qualifying its suppliers. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.64 would require manufacturers to establish and maintain procedures for acceptance activities

including inspections, evaluations, tests, and other verification methods manufacturers use in the manufacturing process. The written procedures would also be required to contain procedures and records for ensuring that each accepted incoming tobacco product is designated by a unique identifier, which must be maintained throughout the manufacturing process and documented in the production record.

Proposed § 1120.66 would require manufacturers to establish and maintain production procedures that describe the process specifications and process controls used in the manufacturing of tobacco products. Process controls include monitoring and acceptance activities such as inspection, testing, evaluation, or other verification activities. The procedures should also address removal of manufacturing material if it could reasonably be expected to have an adverse effect on the product, if applicable; changes to a production process; and process validation procedures to demonstrate that the process will be maintained in a state of control to ensure that tobacco products conform to their established specifications and other requirements when it cannot be fully verified that tobacco product specifications conform to the MMR. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.68 would require manufacturers to establish and maintain procedures for any laboratory controls employed to satisfy requirements in the proposed rule. The procedures include scientifically valid laboratory methods that are accurate, precise, and appropriate for their intended purpose, sampling plans that comply with § 1120.72 of the proposed rule, and demonstration of analytical control. Manufacturers would also be required to demonstrate the laboratory's competence to perform laboratory activities associated with the manufacture of finished or bulk tobacco products. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.70 would require manufacturers to establish and maintain procedures for the preparation of a production record for each manufactured tobacco product batch.

Proposed § 1120.72 would require manufacturers to have an adequate sampling plan using representative samples.

Proposed § 1120.74 would require manufacturers to establish and maintain procedures for the control and disposition of nonconforming tobacco products. These procedures include: (1) identification and segregation of potential nonconforming products; (2) investigation of all potential nonconforming products, including determination of the scope and cause of the nonconformance and the risk of illness or injury posed by the nonconformance; and (3) disposition and followup. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.76 would require manufacturers to establish and maintain procedures for the control and disposition of returned products. These procedures must address identification, segregation, evaluation, and disposition of returned products. Returned products must be segregated in a manner that prevents mix-ups and use of returned products prior to evaluation and disposition. Returned product must be evaluated to determine its disposition. Manufacturers would be required to keep records of all activities required under this provision.

Proposed § 1120.78 would require manufacturers to establish and maintain procedures for reprocessing and reworking tobacco products. These procedures would require evaluation of the tobacco product to determine whether the product is appropriate for reprocessing or rework and authorization of any reprocessing or rework by a designated individual; and must include the production processes, including process controls, and acceptance activities, used to ensure the reprocessed or reworked tobacco product conforms to the requirements established in the MMR for the subsequently manufactured tobacco product. Manufacturers would be required to maintain records of all activities required under this provision.

Subpart F of the proposed rule prescribes the proposed requirements for packaging and labeling activities (§ 1120.92), repackaging and relabeling activities (§ 1120.94), manufacturing codes on the packaging or label of tobacco products (§ 1120.96), and warning plans for packaging (§ 1120.98).

Proposed § 1120.92 would require manufacturers to establish and maintain procedures to control packaging and labeling activities. Manufacturers would be required to maintain records of all activities required under this provision.

Proposed § 1120.94 would require manufacturers to establish and maintain procedures to control repackaging and relabeling activities for those establishments engaging in such activities. Manufacturers would be required to maintain records of all activities required under this provision.

Proposed § 1120.96 would require manufacturers to apply a manufacturing code to the packaging or label of all finished and bulk tobacco products. Manufacturers would be required to maintain records of all activities required under this provision.

Proposed § 1120.98 would require finished tobacco product manufacturers, who are required to comply with a warning plan for tobacco product packaging, to establish and maintain procedures to implement the requirements of such warning plan. Manufacturers would be required to keep records of all activities required under this provision.

Subpart G of the proposed rule prescribes the proposed requirements for activities associated with handling and storage (§ 1120.102) and distribution (§ 1120.104).

Proposed § 1120.102 would require tobacco product manufacturers to establish and maintain procedures for the handling and storage of tobacco products.

Proposed § 1120.104 would require tobacco product manufacturers to establish and maintain procedures for the distribution of finished and bulk tobacco products and to keep distribution records and records of direct accounts.

Proposed subpart H of the proposed rule prescribes the proposed general recordkeeping and document control requirements (§ 1120.122).

Proposed § 1120.122(a) would establish general requirements that apply to all documents and records required under proposed part 1120. Proposed § 1120.122(a)(1) would require that documents and records required under proposed part 1120 be written in English, or an accurate English translation must be made available upon request. All documents and records required by proposed part 1120, that are associated with a batch of finished or bulk tobacco product, must be retained for a period of not less than 4 years from the date of distribution of the batch or until the product reaches its expiration date if one exists, whichever is later. Documents and records not associated with a batch must be retained for not less than 4 years from the date they were last in effect. Furthermore, all documents and records required under proposed part 1120 be maintained at the manufacturing establishment or another location that is readily accessible to responsible officials of the tobacco product manufacturer and to FDA. FDA interprets ''readily accessible'' to FDA as the documents and records being made available to FDA upon request within the course of an inspection.

Proposed § 1120.122(b) would require that records required under the proposed rule are attributable, legible, contemporaneously recorded, original, and accurate. Proposed § 1120.122(c) would require tobacco product manufacturers to establish and maintain procedures to control all documents established to meet the requirements under proposed part 1120.

As required by section 906(e)(2) of the FD&C Act, subpart J of the proposed rule sets forth the procedures and requirements for petitioning for an exemption or variance from a TPMP requirement.

Proposed § 1120.140 explains that, under section 906(e)(2) of the FD&C Act, any person subject to any requirement of the TPMP regulations may petition FDA for a permanent or temporary exemption or variance from such requirement. The requirements under this part remain in effect unless FDA grants the petition for an exemption or variance under § 1120.146. Thus, any person who petitions FDA for an exemption or variance must follow the TPMP regulations while the petition is being considered and until FDA grants the petition. Under proposed § 1120.140, an individual petitioning for an exemption or variance must submit all information supporting the petition in an electronic form that FDA can process, review, and archive. Because of the broad availability of the internet, FDA does not anticipate any need to submit a petition for an exemption or variance and supporting materials in a non-electronic format. However, if the petitioner is unable to submit a petition in an electronic format, the petitioner may submit a written request to FDA requesting that FDA allow the submission in an alternative format and explain in detail why the petitioner cannot submit the petition in an electronic format.

Proposed § 1120.142 would require that a petition for an exemption or variance contain: (1) the petitioner's name, address, and contact information; (2) identification of the tobacco product; (3) the requirement in this part for which an exemption or variance is requested; (4) a detailed explanation of why the exemption or variance is requested; the duration of the proposed exemption or variance; (5) a detailed explanation setting forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the requirement in this part as well as the basis for the petitioner's determination that the proposed methods will be sufficient to assure that the public health is protected and the tobacco product(s) will be in compliance with chapter IX of the FD&C Act (for a petition for a variance); (6) a detailed explanation setting forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the public health is protected and that the tobacco product will be in compliance with chapter IX of the FD&C Act (for a petition for exemption); (7) any other information justifying the exemption or variance; a statement certifying that, to the best of the petitioner's knowledge and belief, the petition includes all information and views on which the petition relies including representative data and information known to the petitioner which are unfavorable to the petition; and (8) an EA under part 25 of this chapter prepared in accordance with the requirements of § 25.40 of this chapter.

FDA recognizes that many of the proposed provisions of the proposed rule are consistent with quality control and manufacturing practices that have already been voluntarily adopted by manufacturers. As a part of usual and customary business practices, FDA expects some baseline level of manufacturer compliance with the provisions of the proposed rule.

FDA's burden estimates are based on the PRIA, FDA inspection reports, estimates of the number of deemed tobacco product manufacturers published in the Deeming Rule (part 1143), and 2017 data on permits issued to tobacco manufacturers by the Alcohol and Tobacco Tax and Trade Bureau. The requirements in the proposed rule would apply to both domestic and foreign manufacturers of finished and bulk tobacco products.

As discussed in the PRIA, we estimate the number of affected entities, by major tobacco product group and size of operation group. We estimate that there is a total of 1,935 domestic entities and 3,273 foreign entities manufacturers potentially affected by the proposed rule. For purposes of the PRA estimates, FDA used a weighted average of the median hours and entities affected to calculate the respondents and burden hours. These estimates are a combination of small and large manufacturers and foreign and domestic manufactures. The estimated numbers of manufacturers in the tables below represent an estimated average portion of all domestic and foreign tobacco product manufacturers by the percentage of manufacturers that are currently not practicing one or more of the proposed requirements set forth in the proposed rule.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1120.40, 1120.142, and 1120.146 Petition for Exemption or Variance and Environmental Assessment (EA)	1	1	1	59	59

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2 describes the annual reporting burden as a result of the proposed requirements in § 1120.142 for submitting petitions for exemption or variance (including EA). FDA believes this will be infrequent, so we have assigned 1 token response acknowledging the requirement.

TABLE 3—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

21 CFR part and activity	Number of recordkeepers	Number of records per recordkeeper	One-time records	Average burden per recordkeeping	Total hours	Total capital costs
One-Time Recordkeeping Burden Subpart B						
1120.12 Organization and personnel procedures and training	1,598	3	4,794	4.12	19,751	
1120.14 Tobacco product complaints	1,946	8	15,568	1.82	28,334	
1120.16 Corrective and preventive actions	1,814	8	14,512	1.82	26,412	
Total Subpart B					74,497	
One-Time Recordkeeping Burden Subpart C						
1120.32 Personnel	1,416	67	94,872	0.59	55,974	
1120.34 Buildings, facilities, and grounds	1,642	20	32,840	2.62	86,041	
1120.36 Equipment	1,186	86	101,996	1.62	165,234	
1120.38 Environment controls	2,965	8	23,720	2.42	57,402	
Total Subpart C					364,651	
One-Time Recordkeeping Burden Subpart D						
1120.42 Product development controls	2,853	12	34,236	2.90	99,284	
1120.44 Master manufacturing record	1,381	14	19,334	1.91	36,928	
Total Subpart D					136,212	
One-Time Recordkeeping Burden Subpart E						
1120.62 Purchasing controls	2,539	17	43,163	3.39	146,323	
1120.64 Acceptance activities	2,029	26	52,754	1.85	97,595	
1120.66 Process controls	1,677	35	58,695	1.84	107,999	$1,014,697
1120.68 Laboratory controls	1,293	9	11,637	1.79	20,830	10,996,249
1120.70 Production record	2,163	9	19,467	0.96	18,688	
1120.72 Representative samples	3,631	8	29,048	1.86	54,029	
1120.74 Nonconforming product	1,458	9	13,122	1.80	23,620	
1120.76 Returned product	1,594	9	14,346	1.80	25,823	
1120.78 Reprocessing and rework	1,833	8	14,664	1.86	27,275	
Total Subpart E					522,182	12,010,946
One-Time Recordkeeping Burden Subpart F						
1120.92 Packaging and labeling controls	1,683	8	13,464	3.34	44,970	
1120.94 Repackaging and Relabeling	1,523	8	12,184	3.18	38,745	
1120.98 Warning plans	1,448	8	11,584	3.18	36,837	
Total Subpart F					120,552	
One-Time Recordkeeping Burden Subpart G						
1120.102 Handling and storage	1,855	12	22,260	1.82	40,513	
1120.104 Distribution	2,028	12	24,336	1.82	44,292	
Total Subpart G					84,805	
One-Time Recordkeeping Burden Subpart H						
1120.124 Document controls	3,155	1	3,155	6.99	22,053	
Total Subpart H					22,053	
Total One-Time Burden					1,324,952	12,010,946

[1] There are no operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL (RECURRING) RECORDKEEPING BURDEN [1]

21 CFR part and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Annual Recordkeeping Burden Subpart B					
1120.12 Organization and personnel Procedures and training	1,598	3	4,794	2	9,588
1120.14 Tobacco product complaints	1,946	8	15,568	4	62,272
1120.16 Corrective and preventive actions	1,814	8	14,512	4	58,048
Total Subpart B					129,908

TABLE 4—ESTIMATED ANNUAL (RECURRING) RECORDKEEPING BURDEN [1]—Continued

21 CFR part and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Annual Recordkeeping Burden Subpart C					
1120.32 Personnel	1,416	67	94,872	0.03	2,846
1120.34 Buildings, facilities, and grounds	1,642	20	32,840	0.55	18,062
1120.36 Equipment	1,186	86	101,996	0.14	14,279
1120.38 Environment controls	2,965	8	23,720	0.28	6,642
Total Subpart C					41,829
Annual Recordkeeping Burden Subpart D					
1120.42 Product development controls	2,853	12	34,236	1	34,236
1120.44 Master manufacturing record	1,381	14	19,334	0.36	6,960
Total Subpart D					41,196
Annual Recordkeeping Burden Subpart E					
1120.62 Purchasing controls	2,539	17	43,163	0.27	11,654
1120.64 Acceptance activities	2,029	26	52,754	1	52,754
1120.66 Process controls	1,677	35	58,695	1	58,695
1120.68 Laboratory controls	1,293	9	11,637	5	58,185
1120.70 Production record	2,163	9	19,467	3	58,401
1120.72 Representative samples	3,631	8	29,048	0.27	7,843
1120.74 Nonconforming product	1,458	9	13,122	4.77	62,592
1120.76 Returned product	1,594	9	14,346	4.37	62,692
1120.78 Reprocessing and rework	1,833	8	14,664	0.28	4,106
Total Subpart E					376,922
Annual Recordkeeping Burden Subpart F					
1120.92 Packaging and labeling controls	1,683	8	13,464	0.28	3,770
1120.94 Repackaging and Relabeling	1,523	8	12,184	0.27	3,290
1120.98 Warning plans	1,448	8	11,584	0.28	3,244
Total Subpart F					10,304
Annual Recordkeeping Burden Subpart G					
1120.102 Handling and storage	1,855	12	22,260	0.15	3,339
1120.104 Distribution	2,028	12	24,336	0.15	3,650
Total Subpart G					6,989
Annual Recordkeeping Burden Subpart H					
1120.124 Document controls	3,155	1	3,155	2.66	8,392
Total Subpart H					8,392
Total Annual Burden					615,540

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3 represents the one-time recordkeeping requirements in the rule. FDA believes that there will be a total of 5,208 recordkeepers (the sum of 1,935 domestic and 3,273 foreign entities) who would keep records. Most of the provisions in the proposed rule require tobacco manufacturers to establish and maintain procedures. In table 3, the columns entitled ''number of recordkeepers'' and ''one-time total responses'' is totaled in the text, but not the chart. For economic purposes, the numbers in these columns are not additive because the numbers representing each section are not mutually exclusive. However, for PRA purposes these numbers are additive. We total these columns in the narrative for PRA purposes of describing and matching the data that will be submitted to OMB for approval.

Subpart B describes the proposed requirements applicable to finished and bulk tobacco product manufacturers' management systems that cover a manufacturer's organization and personnel (§ 1120.12), tobacco product complaints (§ 1120.14), and CAPA (§ 1120.16). FDA estimates that under proposed subpart B 5,358 recordkeepers will establish a total of 34,874 one-time records for a total of 74,497 one-time hours.

Subpart C of the proposed rule prescribes the proposed requirements that are specific to personnel practices (§ 1120.32), building, facilities, and grounds (§ 1120.34), equipment (§ 1120.36), and environmental controls (§ 1120.38). FDA estimates that under proposed subpart C 7,209 recordkeepers

will establish a total of 253,428 one-time records for a total of 364,651 one-time hours.

Subpart D of the proposed rule prescribes the proposed requirements for design and development activities (§ 1120.42) and MMRs (§ 1120.44). FDA estimates that under proposed subpart D 4,234 recordkeepers will establish a total of 53,570 one-time records for a total of 136,212 one-time hours.

Subpart E of the proposed rule prescribes the proposed requirements for purchasing controls (§ 1120.62), acceptance activities (§ 1120.64), production and process controls (§ 1120.66), laboratory controls (§ 1120.68), production records (§ 1120.70), sampling (§ 1120.72), nonconforming tobacco products (§ 1120.74), returned tobacco products (§ 1120.76), and reprocessing and rework (§ 1120.78). FDA estimates that under proposed subpart E 18,217 recordkeepers will establish a total of 256,896 one-time records for a total of 522,182 one-time hours.

To conduct activities related to §§ 1120.64, 1120.66, and 1120.68, some tobacco product manufacturers may purchase capital equipment such as metal detectors, pH meters, thermometers, ultrasonic flow meters, scanners, and densimeters. We estimate one-time capital costs of $1,014,697 combined under § 1120.64 acceptance activities and § 1120.66 Production and process controls, and $10,996,249 under § 1120.68 Laboratory controls for a total of $12,010,946.

Subpart F of the proposed rule prescribes the proposed requirements for packaging and labeling controls (§ 1120.92), repackaging and relabeling (§ 1120.94), and warning plans (§ 1120.98). FDA estimates that under proposed subpart F 4,654 respondents will establish a total of 37,232 one-time records for a total of 120,552 one-time hours.

Subpart G of the proposed rule prescribes the proposed requirements for activities associated with handling and storage (§ 1120.102) and distribution (§ 1120.104). FDA estimates that under proposed subpart G 3,883 respondents will establish a total of 46,596 one-time records for a total of 84,805 one-time hours.

Proposed subpart H of the proposed rule prescribes the proposed general recordkeeping and document control requirements (§ 1120.122). FDA estimates that under proposed subpart H 3,155 respondents will establish a total of 3,155 one-time records for a total of 22,053 one-time hours.

FDA estimates a total of 1,324,952 one-time hours and $12,010,946 one-time capital costs.

Table 4 estimates the annual recurring burden under the proposed rule. FDA believes that there will be a total of 5,208 recordkeepers (the sum of 1,935 domestic and 3,273 foreign entities) who would keep records. In table 4, the columns number of annual recordkeepers, and total annual responses is totaled in the text, but not in the chart. For economic purposes the numbers in these columns are not additive because the numbers representing each section are not mutually exclusive. However, for PRA purposes these numbers are additive. We total these columns in the narrative for PRA purposes of describing and matching the data that will be submitted to OMB for approval.

FDA estimates that under proposed subpart B (Management System Requirements) 5,358 recordkeepers will maintain a total of 34,874 records annually for a total of 129,908 annual hours.

FDA estimates that under proposed subpart C (Buildings, Facilities, and Equipment) 7,209 recordkeepers will maintain a total of 253,428 records annually for a total of 41,829 annual hours.

FDA estimates that under proposed subpart D (Design and Development Controls) 4,234 recordkeepers will maintain a total of 53,570 records annually for a total of 41,196 annual hours.

FDA estimates that under proposed subpart E (Process Controls) 18,217 recordkeepers will maintain a total of 256,896 records annually for a total of 376,922 annual hours.

FDA estimates that under proposed subpart F (Packaging and Labeling Controls) 4,654 recordkeepers will maintain a total of 37,232 records annually for a total of 10,304 annual hours.

FDA estimates that under proposed subpart G (Handling, Storage and Distribution) 3,883 recordkeepers will maintain a total of 46,596 records annually for a total of 6,989 annual hours.

FDA estimates that under proposed subpart H (Recordkeeping and Document Controls) 3,155 recordkeepers will maintain a total of 3,155 records annually for a total of 8,392 annual hours.

FDA estimates a total of 615,540 annual hours for this proposed rule.

TABLE 5—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR part and activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1120.96 Manufacturing code	1	1	1	1	1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Proposed § 1120.96 would require that manufacturers apply a manufacturing code to the packaging and label of tobacco products. FDA lacks data on the percentage of manufacturers who apply such codes to the packaging and label of tobacco products but based on a cursory review of manufactured products it appears that many, if not all, manufacturers already apply a manufacturing code to their products. For purposes of the PRA, we have assigned one token burden hour for this activity.

Per the requirements of this proposed rule, FDA estimates the total burden will be 1,940,552 hours (59 + 1 + 1,324,952 + 615,540) and $12,010,946 one-time capital costs.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Requirements for Tobacco Product Manufacturing Practice.''

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves

the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

VIII. Analysis of Environmental Impact

The proposed regulation is issued pursuant to section 906(e) of the FD&C Act, which directs FDA to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation, packing, and storage of a tobacco product conform to cGMP, or HACCP methodology to assure that the public health is protected and that the tobacco product is in compliance with chapter IX of the FD&C Act. Under § 25.30(j), classes of actions that are categorically excluded include the issuance of cGMP and HACCP regulations. As a result, the proposed rule falls within a class of actions that are categorically excluded under § 25.30(j) and, therefore, ordinarily do not require the preparation of an EA or environmental impact statement (EIS).

An EA or EIS is required for categorically excluded actions only if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment (§ 25.21). The proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. The proposed action is not anticipated to pose the potential for serious harm to the environment or to adversely affect a species or the critical habitat of a species described in § 25.21(b). Thus, FDA has determined that no extraordinary circumstances exist that would require preparation of an EA or an EIS.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. Section 4(a) of the E.O. requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.''

Section 916(a)(2) of the FD&C Act (21 U.S.C. 387p) is an express preemption provision. Section 916(a)(2) provides that ''no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to . . . good manufacturing standards.''

This rule is being issued under section 906(e) of the FD&C Act, which directs FDA to prescribe regulations relating to good manufacturing practice. Thus, if this proposed rule is made final, the final rule would create requirements that fall within the scope of section 916(a)(2) of the FD&C Act.

X. Consultation and Coordination With Indian Tribal Governments

FDA has analyzed this proposed rule in accordance with the principles set forth in E.O. 13175. We have tentatively concluded that the rule does not contain policies that would have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. The Agency solicits comments from tribal officials on any potential impact on Indian tribes from this proposed action.

XI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright or other restrictions. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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List of Subjects in 21 CFR Part 1120

Smoking, Tobacco, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act [LEGAL CITATION] and under authority delegated to the Commissioner of Food and Drugs, amend chapter I of title 21 of the Code of Federal Regulations by adding part 1120 to subchapter K to read as follows:

PART 1120—REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICE

Sec.

Authority: 21 U.S.C. 371, 21 U.S.C. 374, 21 U.S.C. 381, 21 U.S.C. 387b, 21 U.S.C. 387c, 21 U.S.C. 387e(g), 21 U.S.C. 387f(e), and 21 U.S.C. 387i.

Subpart A—General Provisions

§ 1120.1 Scope.

(a) This part sets forth the current tobacco product manufacturing practice (TPMP) requirements under the Federal Food, Drug, and Cosmetic Act. The requirements of this part apply to manufacturers of all finished and bulk tobacco products that are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act, except finished and bulk accessories of cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and tobacco products containing nicotine that is not made or derived from tobacco. Manufacturers of finished and bulk tobacco products include specification developers, contract manufacturers, and repackagers/relabelers. The requirements in this part govern the methods used in, and the facilities and controls used for, the preproduction design validation, manufacture, packing, and storage of finished and bulk tobacco products by finished and bulk tobacco product manufacturers.

(b) If a tobacco product manufacturer engages in some operations subject to the requirements of this part, and not others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged.

(c) The term ''where appropriate'' is used several times in this part. When a requirement is qualified with ''where appropriate,'' it is deemed to be appropriate unless the tobacco product manufacturer documents in writing an adequate justification prior to abstaining from implementing the requirement. An adequate justification would address why abstaining from the requirement would not result in a nonconforming tobacco product, or in the manufacturer not being able to carry out necessary corrective actions.

(d) The requirements in this part are intended to protect the public health and assure that tobacco products are in compliance with the relevant provisions of the Federal Food, Drug, and Cosmetic Act. The failure to comply with any applicable provision in this part renders a product adulterated under section 902(7) of the Federal Food, Drug, and Cosmetic Act.

§ 1120.3 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored tobacco product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

Batch means a specific identified amount of a tobacco product produced in a unit of time or quantity and that is intended to have the same specifications.

Brand means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes.

Bulk tobacco product means a tobacco product not sealed in final packaging but otherwise suitable for consumer use as a tobacco product.

Characteristic means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Contaminated tobacco product means a tobacco product that contains a substance not ordinarily contained in that tobacco product. An example of a contaminated tobacco product is a smokeless tobacco product with metal fragments in the tobacco filler.

Design means the form and structure concerning and the manner in which components or parts, ingredients, additives, and materials are integrated to produce a tobacco product.

Direct accounts means all persons who are customers of the tobacco product manufacturer that receive finished or bulk tobacco products directly from the manufacturer or from any person under control of the manufacturer. Direct accounts may include wholesalers, distributors, and retailers. Direct accounts do not include individual purchasers of tobacco products for personal consumption.

Establish and maintain means to define, document in writing, implement, follow, and update.

Equipment means any machinery, tool, instrument, utensil, or other similar or related article, used in the manufacture, preproduction design validation, packing, or storage of a tobacco product.

Finished tobacco product means a tobacco product, including any component or part, sealed in final packaging. Examples of finished tobacco products include a pack of cigarettes, a

can of moist snuff, and rolling papers, filters, filter tubes, or e-liquids sold to consumers.

Ingredient means tobacco, substances, compounds, or additives contained within or added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through chemical action during tobacco product manufacturing.

Label means a display of written, printed, or graphic matter upon the immediate container of any article.

Labeling means all labels and other written, printed, or graphic matter:

(1) Upon any article or any of its containers or wrappers; or

(2) Accompanying such article.

Management with executive responsibility means one or more designated personnel who have the authority and responsibility to ensure compliance with TPMP requirements, including allocating resources or making changes to the organizational structure, buildings, facilities, equipment, or the manufacture, preproduction design validation, packing, and storage of a tobacco product.

Manual method, process, or procedure means any nonautomated method, process, or procedure, including processes performed by hand with or without the use of equipment.

Manufacturing means the manufacturing, fabricating, assembling, processing, or labeling, including the repackaging or relabeling, of a tobacco product. Manufacturing includes establishing the specifications of a finished or bulk tobacco product.

Manufacturing code means any distinctive sequence or combination of letters, numbers, or symbols that begins with the manufacturing date followed by the batch number.

Manufacturing date means the month, day, and year in 2-digit numerical values in the format (MMDDYY) that a finished or bulk tobacco product is packaged for distribution.

Manufacturing material means material used in or used to facilitate the manufacturing process that is not equipment and is not intended to be part of the product.

Master manufacturing record (MMR) means a document or designated compilation of documents containing the established specifications for a tobacco product, including acceptance criteria for those specifications, all relevant manufacturing methods and production process procedures for the tobacco product, and all approved packaging, labeling, and labels for the tobacco product.

Nonconforming tobacco product means any tobacco product that does not meet a product specification in the MMR (see § 1120.44(a)(1)); has packaging, labeling, or labels other than those included in the MMR (see § 1120.44(a)(3)); or is a contaminated tobacco product.

Not normally associated means not an inherent risk of using the tobacco product. For example, bodily injury caused by an exploding electronic nicotine delivery system (ENDS) battery would be considered not normally associated with the use of ENDS products.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a finished tobacco product is offered for sale, sold, or otherwise distributed to consumers (this is also referred to as final package or final packaging), or in which a bulk tobacco product is offered for sale, sold, or otherwise distributed (including commercial distribution and interplant transfers).

Personnel means all persons, including managers, staff, consultants, contractors, and third-party entities, performing services for the manufacturer subject to this part. This definition includes independent contractors performing services for the manufacturer.

Relabeling means operations in which the labeling of a finished tobacco product is subsequently changed or replaced.

Repackaging means operations in which the packaging of a finished tobacco product is subsequently changed or replaced.

Representative sample means a sample that consists of a number of units that are drawn based on a valid scientific rationale (such as random sampling) and intended to ensure that the sample accurately reflects the material being sampled.

Reprocessing means using a tobacco product that has been previously recovered from manufacturing in the subsequent manufacture of a finished or bulk tobacco product.

Returned tobacco product means a commercially distributed finished or bulk tobacco product returned to the tobacco manufacturer by any person not under the control of the tobacco product manufacturer, including a wholesaler/distributor, retailer, consumer, or a member of the public.

Rework means action taken on a nonconforming or returned tobacco product to ensure the product meets the specifications and other requirements of the MMR of a subsequently manufactured tobacco product before it is released for further manufacturing or distribution.

Small tobacco product manufacturer means a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer.

Specification means any requirement with which a product, process, service, or other activity must conform.

Tobacco product means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that is a drug under section 201(g)(1) (21 U.S.C. 321(g)(1)), a device under section 201(h) (21 U.S.C. 321(h)), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)). The term ''tobacco product'' does not mean an article that is a food under section 201(f) (21 U.S.C. 321(f)), if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

Tobacco product-contact surface means a surface that comes into contact with a tobacco product and a surface from which drainage (or other transfer) ordinarily occurs onto the tobacco product or onto surfaces that come into contact with the tobacco product during the normal course of operations. For example, tobacco product-contact surfaces include surfaces of equipment that come into contact with the tobacco product.

Tobacco product manufacturer means any person(s), including a repacker or relabeler, who: manufactures, fabricates, assembles, processes, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States. Tobacco product manufacturer includes any person(s) establishing specifications for a tobacco product.

Unique identifier means information, such as a code or number, that is maintained for each accepted incoming tobacco product that would enable the tobacco product manufacturer and FDA to identify the supplier and unique shipment of the incoming product.

Validation means confirmation by examination and objective evidence that the particular requirements can be consistently fulfilled.

Verification means confirmation by examination and objective evidence that specified requirements have been fulfilled.

Subpart B—Management System Requirements

§ 1120.12 Organization and personnel.

(a) *Organization.* Each finished and bulk tobacco product manufacturer must establish and maintain an organizational structure to ensure that manufacturing operations meet the requirements of this part.

(b) *Personnel qualifications.* Each finished and bulk tobacco product manufacturer must have sufficient personnel to carry out the requirements of this part. Personnel must have the background, education, training, and experience, or any combination thereof, needed to carry out the requirements under this part. Each manufacturer must maintain appropriate written records of the background, education, training, and experience of its personnel.

(c) *Responsibility.* Each finished and bulk tobacco product manufacturer must designate, in writing, appropriate responsibility and authority for all personnel who perform an activity subject to this part.

(d) *Management with executive responsibility.* Each finished and bulk tobacco product manufacturer must designate, in writing, management with executive responsibility that has the duty, power, and responsibility to implement the requirements under this part. Management with executive responsibility must establish and maintain required processes and procedures to ensure compliance with the requirements under this part. Management with executive responsibility must ensure the requirements of this part are communicated, understood, implemented, and followed at all levels of the organization.

(e) *Training.* Each finished and bulk tobacco product manufacturer must establish and maintain training procedures for identifying training needs and establishing training frequency for personnel based on the work the employee performs. The manufacturer must train personnel on their assigned responsibility and on the tobacco product manufacturing practice requirements relevant to their responsibility.

(f) *Records.* The training records required under § 1120.12(b) must include:

(1) The type and description of the training;

(2) The training date;

(3) The names of parties performing and taking the training; and

(4) Documentation supporting completion.

§ 1120.14 Tobacco product complaints.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the receipt, evaluation, investigation, and documentation of all complaints. The procedure must ensure that all complaints are:

(1) Processed upon receipt in a uniform and timely manner;

(2) Evaluated and, if necessary, investigated with any followup action taken, according to paragraphs (b) and (c) of this section; and

(3) Documented according to paragraph (e) of this section.

(b) *Evaluation.* All complaints must be evaluated to determine whether the complaint could be related to:

(1) A nonconforming tobacco product;

(2) A product design issue; or

(3) Any adverse experience that is required to be reported under a regulation promulgated under section 909(a) of the Federal Food, Drug, and Cosmetic Act.

(c) *Investigation.* (1) If the evaluation determines that the complaint could be related to paragraphs (b)(1) through (3) of this section, an investigation must be performed except as provided in paragraph (d) of this section.

(2) The investigation must include:

(i) The scope and cause of the issue;

(ii) The risk of illness or injury posed by the issue;

(iii) Whether any other followup action is necessary, including whether a corrective and preventative action is necessary under § 1120.16.

(d) *Exception.* An investigation required under paragraph (c) of this section must be completed unless an investigation has already been performed for a similar complaint and the tobacco product manufacturer determines and documents that the previous investigation results apply and another investigation is not necessary.

(e) *Complaint records.* Each finished and bulk tobacco product manufacturer must maintain complaint records. The record documenting the complaint, including all evaluation, investigation, and any followup action, must be maintained according to the procedures identified under paragraph (a) of this section. Complaints received that could be related to a nonconforming tobacco product, design issues, or any adverse experience that is required to be reported under a regulation promulgated under section 909(a) of the Federal Food, Drug, and Cosmetic Act, and that may result in a risk of illness, injury, or death not normally associated with the use of tobacco products must be clearly identified or separated. Complaint records must include the following information, if available:

(1) Name of the product, including brand and sub-brand;

(2) Description of the product;

(3) Manufacturing code;

(4) Date complaint received;

(5) Format of complaint (*i.e.,* oral or written);

(6) Name, address, and phone number of complainant;

(7) Nature and details of complaint, including how the product was used;

(8) Identification of individual(s) receiving complaint;

(9) Record of evaluation by the manufacturer including the name of the individual(s) performing the evaluation;

(10) If no investigation is undertaken, the name of the individual(s) responsible for that decision and the rationale for the decision;

(11) Investigation date(s);

(12) Record of investigational activities performed and who performed the activity;

(13) Results of investigation; and

(14) Followup action taken, including any reply to the complainant or any corrective and preventive action.

(f) *Unavailable complaint records.* If information identified under paragraph (e) of this section is unavailable, the record must include:

(1) Documentation of the attempt(s) to obtain the information; and

(2) Why the information is not included.

§ 1120.16 Corrective and preventive actions.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for implementing corrective and preventive actions. The procedures must include requirements for:

(1) Reviewing and analyzing processes, process control records, complaints, production records, returned products, reprocessed products, reworked products, and other sources of data to identify existing and potential causes of nonconforming tobacco product and design problems. Appropriate statistical methodology must be employed where necessary to detect recurring problems;

(2) Investigating the cause of design problems or nonconformities relating to the product or manufacturing process;

(3) Identifying and taking the action needed to correct and prevent the recurrence of design problems and nonconformities and other related problems;

(4) Verifying or validating the corrective and preventive action to ensure that the action taken is effective and does not adversely affect the tobacco product;

(5) Implementing and documenting changes to tobacco product specifications, manufacturing methods and production process procedures, and packaging, labeling, and labels needed to correct and prevent identified causes of the design problem or nonconformity; and

(6) Disseminating information related to the design problem or nonconforming product and the corrective and preventive action taken to:

(i) Management with executive responsibility;

(ii) Those responsible for acceptance activities of a tobacco product; and

(iii) Personnel responsible for identifying training needs in accordance with § 1120.12(e).

(b) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities conducted under this section. Records must include the date and time, individual performing the activity, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

Subpart C—Buildings, Facilities, and Equipment

§ 1120.32 Personnel practices.

Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the cleanliness, personal practices, and apparel of personnel. Such procedures must include requirements to ensure that contact between the personnel and the tobacco product or the environment would not result in contamination of the tobacco product.

§ 1120.34 Buildings, facilities, and grounds.

(a) *Buildings and facilities.* Each finished and bulk tobacco product manufacturer must ensure that any buildings and facilities used in or for the manufacture, packaging, or storage of a tobacco product are of suitable construction, design, and location to facilitate cleaning and sanitation, maintenance, and proper operations. Each building and facility must be maintained in an appropriate condition to prevent contamination. Buildings and facilities must have adequate:

(1) Lighting;

(2) Heating, ventilation, and cooling;

(3) Plumbing (including control of drainage, backflow, sewage, and waste) to avoid being a source of contamination or creating insanitary conditions;

(4) Waste collection, storage, and disposal (including not creating malodors that contaminate tobacco products or result in an attraction, harborage, or breeding place for animals and pests); and

(5) Readily accessible handwashing and toilet facilities. The facilities must provide for water at suitable temperatures and appropriate cleaning and sanitation materials.

(b) *Grounds.* Each finished and bulk tobacco product manufacturer must maintain facility grounds in a condition to prevent contamination.

(c) *Water.* Each finished and bulk tobacco product manufacturer must ensure water used in the manufacturing process, including water that is or may become part of the tobacco product (*e.g.,* water used as an ingredient or water used on tobacco product-contact surface) is potable, will not contaminate the tobacco product, is maintained under positive pressure, and is supplied from sources that comply with all applicable Federal, State, and local requirements.

(d) *Cleaning and sanitation.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the cleaning and sanitation of buildings, facilities, and grounds, including procedures for the use of any cleaning compounds, sanitizing agents, pesticide chemicals, rodenticides, insecticides, fungicides, fumigating agents, and other toxic materials.

(1) These procedures must detail the cleaning schedules, equipment, and materials to be used in the cleaning and sanitizing, as appropriate, of the buildings, facilities, and grounds.

(2) The procedures must include measures to ensure that materials used for cleaning and sanitation are identified, held, used, and stored in a manner to protect against contamination of tobacco products and tobacco product-contact surfaces.

(3) The use of cleaning and sanitation materials must also comply with all applicable Federal, State, and local requirements related to their application, use, or storage.

(e) *Animal and pest control.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for monitoring, controlling, and minimizing the presence of animals and pests in the buildings, facilities, and grounds to protect against contamination of tobacco products. These procedures must include requirements for establishing threshold criteria for animals and pests. The procedures also must include requirements that any pesticide used in the buildings, facilities, and grounds be registered in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135) and used in accordance with its label, as applicable, and used in a manner that protects against contamination of the tobacco product.

(f) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of cleaning and sanitation, and animal and pest control activities required under this section. These records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.36 Equipment.

(a) *Design and construction.* Each finished and bulk tobacco product manufacturer must ensure that all equipment is appropriately designed and constructed and is suitable for its intended purpose.

(b) *Maintenance.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures, including the methods and schedules, for the routine cleaning and maintenance of equipment, to ensure proper performance of equipment and prevent contamination. The procedures must provide for any change over of tobacco product and account for changes, limitations, or adjustment to the equipment.

(c) *Identification.* Each finished and bulk tobacco product manufacturer must identify (electronically, by signage, or other method of identification), if applicable, all processing lines and major equipment to be used during manufacturing to prevent mixups and contamination.

(d) *Testing, monitoring, and measuring equipment.* (1) Each finished and bulk tobacco product manufacturer must establish and maintain procedures for all testing, monitoring, and measuring equipment to ensure the equipment is capable of producing accurate and reliable results.

(2) All testing, monitoring, and measuring equipment must be identified and disabled, removed, replaced, or

repaired when it is no longer suitable for its intended purpose or when it is no longer capable of producing accurate and reliable results.

(3) Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the routine calibration of testing, monitoring, and measuring equipment. These procedures must describe an appropriate reference standard and include specific directions and acceptance criteria for the limits of accuracy and precision. Equipment must be calibrated:

(i) Before its first use;

(ii) Thereafter, at a frequency determined by the equipment manufacturer or at intervals necessary to ensure accurate and reliable results; and

(iii) After repair or maintenance.

(e) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. These records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.38 Environmental controls.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures to adequately control environmental conditions, where appropriate. Environmental control systems must be maintained and monitored to verify that the environmental controls, including necessary equipment, are adequate and functioning properly.

(b) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section, including maintenance and monitoring. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

Subpart D—Design and Development Controls

§ 1120.42 Design and development activities.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures to control the design and development of each finished and bulk tobacco product and its package, including the control of risks associated with the product, production process, packing, and storage. These procedures must include the following requirements:

(1) *Risk management process.* These procedures must use a risk management process that includes the following:

(i) *Risk assessment.* Each finished and bulk tobacco product manufacturer must perform a risk assessment that includes risk identification, risk analysis, and risk evaluation. Risk identification is identification of all known or reasonably foreseeable risks associated with the tobacco product and its package, as well as its production process, packing, and storage. Risk identification must include risks that may occur with normal use and with reasonably foreseeable misuse of a tobacco product. Risk analysis is an analysis of the nature and level of risk for each identified known or reasonably foreseeable risk that takes into account the likelihood of occurrence of the risk and the consequences of occurrence of the risk (*i.e.,* severity of the potential harm). Risk evaluation is a determination of the significance of the risk and what type of risk treatment is needed.

(ii) *Risk treatment.* Each finished and bulk tobacco product manufacturer must treat all identified risks, including risks addressed in applicable tobacco product standards. Risk treatment must significantly minimize or prevent risks:

(A) That are reasonably likely to occur and that may cause serious illness, injury, or death not normally associated with the use of the tobacco product, or

(B) That the manufacturer determines constitute an unacceptable level of risk. Risks addressed in any applicable tobacco product standards must be treated in a manner that ensures the tobacco product will conform to the specifications and requirements established in the tobacco product standard.

(iii) *Reassessment.* Each finished and bulk tobacco product manufacturer must reassess the risks whenever the manufacturer becomes aware of new information that could change the risk assessment and risk treatment, including information about previously unidentified risks or the adequacy of risk treatment measures, in accordance with paragraphs (a)(1)(i) and (ii) of this section.

(2) *Design verification and validation.* For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, each finished and bulk tobacco product manufacturer must perform design verification to confirm that the tobacco product and its package meet specifications and design validation to assess the performance of the tobacco product;

(3) *Design approval.* For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, each finished and bulk tobacco product manufacturer must ensure the product and package design is approved by a designated, authorized individual;

(4) *Design transfer.* For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, each finished and bulk tobacco product manufacturer must transfer the approved product and package specifications to the master manufacturing record; and

(5) *Design changes.* Each finished and bulk tobacco product manufacturer must, where appropriate, utilize the processes under paragraphs (a)(2) to (4) of this section for design changes before the changes are implemented.

(b) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.44 Master manufacturing record.

(a) Each tobacco product manufacturer must establish and maintain a master manufacturing record (MMR) for each finished and bulk tobacco product they manufacture for distribution. The MMR must include the following information:

(1) Tobacco product specifications (including any physical, chemical, and biological specifications) and acceptance criteria for those specifications. The tobacco product specifications must include:

(i) The identity and amount of any components or parts, ingredients, additives, and materials in the finished or bulk tobacco product;

(ii) The finished or bulk tobacco product design, an identification of the product's heating source (if any), a discussion of intended user operation, and any relevant product drawings or schematics;

(iii) Any specification necessary to ensure that the tobacco product meets any applicable product standard established under section 907 of the Federal Food, Drug, and Cosmetic Act; and

(iv) Specification(s) for pesticide chemical residue(s) for raw tobacco.

(2) All relevant manufacturing methods and production process procedures. The manufacturing methods

and production process procedures must include any process controls, process specifications with relevant acceptance criteria, and monitoring and acceptance activities (inspections, testing, evaluation, and other verification activities); and

(3) All packaging, labeling, and labels approved by the tobacco product manufacturer for use with the finished or bulk tobacco product.

(b) Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the review and approval of the MMR, including any changes made to the MMR after initial approval. Under these procedures, a designated, qualified individual must review and approve all MMR information before it is implemented in the manufacture of finished and bulk tobacco products for distribution. The designated, qualified individual's approval of the MMR must be documented by date, name, and signature of the individual(s) approving the document. The procedures for MMR review and approval must ensure that the designated, qualified individual confirms that any design activities conducted to support the tobacco product specifications have been completed in accordance with the product design and development procedures established by the manufacturer under § 1120.42 and that the resulting production specifications are correctly transferred into the MMR.

(c) The MMR must describe which methods and procedures established under paragraph (a)(2) of this section and related sections, including §§ 1120.62 (Purchasing controls), 1120.64 (Acceptance activities), 1120.66 (Production processes and controls), and 1120.68 (Laboratory controls), are used to ensure that the tobacco product is in conformance with each tobacco product specification established under paragraph (a)(1) of this section.

Subpart E—Process Controls

§ 1120.62 Purchasing controls.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures to ensure that each purchased or otherwise received product or service related to the manufacture of a finished or bulk tobacco product is from a qualified supplier and conforms to established specifications.

(b) *Qualification.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for qualifying its suppliers. These procedures must include the following requirements for qualification of suppliers:

(1) Evaluating and selecting potential suppliers based on their ability to meet written requirements set by the manufacturer (*e.g.,* past history, onsite audits, test results);

(2) Defining the type and extent of control to be exercised over selected suppliers and their product or service, based on evaluation results;

(3) Developing a list of qualified suppliers and the product(s) or service(s) they provide, and updating this information periodically; and

(4) Monitoring qualified suppliers to ensure they meet specified requirements and performing reevaluations as needed.

(c) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities conducted under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. These records also must include a written agreement that the supplier will notify the manufacturer of any change in the product or service so that the manufacturer can determine whether the change may affect the specifications of the finished or bulk tobacco product established in accordance with § 1120.44(a)(1).

§ 1120.64 Acceptance activities.

(a) *General.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for acceptance activities, including acceptance criteria, in accordance with paragraphs (b) through (d) of this section.

(b)(1) *Incoming acceptance activities.* The acceptance activities procedures must address the acceptance activities for all incoming products to ensure that any specifications established under § 1120.44 or through purchasing controls under § 1120.62 are met and that such products are not contaminated or deteriorated. The incoming acceptance procedures must ensure that each accepted incoming tobacco product is designated by a unique identifier, which must be maintained throughout manufacturing and documented in accordance with § 1120.70(b)(5). For incoming finished or bulk tobacco product, the unique identifier must include or be traceable to the manufacturing code on the packaging or label of the finished or bulk tobacco product. The results of incoming acceptance activities must be reviewed and approved to ensure the incoming tobacco product specifications established under § 1120.44 or through purchasing controls under § 1120.62 are met, and that such products are not contaminated or deteriorated.

(2) *Pesticide chemical residue.* The acceptance activities procedures must address the testing and acceptance of raw tobacco to ensure that it meets established specifications for pesticide chemical residue set by the manufacturer and complies with any applicable tolerance under Federal law.

(3) *Contamination.* All incoming tobacco products must be evaluated for contamination or deterioration.

(c) *In-process and final acceptance activities.* The acceptance activities procedures must address in-process and/or final acceptance activities to ensure that each finished or bulk tobacco product meets the specifications established under § 1120.44. The results of these acceptance activities must be reviewed and approved to ensure the finished and bulk tobacco product specifications established under § 1120.44 are met.

(d) *Acceptance status.* Each finished and bulk tobacco product manufacturer must identify by suitable means the acceptance status of a tobacco product, indicating whether the tobacco product is a conforming or nonconforming tobacco product. The identification of the acceptance status must be maintained from receipt of incoming products throughout manufacturing and until the finished or bulk tobacco product passes required acceptance activities and is released for distribution.

(e) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, acceptance criteria, any information that demonstrates the requirement was met, equipment used if applicable, and any data or calculations necessary to reconstruct the results.

§ 1120.66 Production processes and controls.

(a) *General.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for production processes, including process controls, to ensure that tobacco products conform to the requirements established in the MMR in accordance with § 1120.44. Production process procedures must address the following:

(1) Production process specifications with relevant acceptance criteria.

(2) Relevant process controls, such as any monitoring and acceptance activities (inspection, testing, evaluation, and other verification activities).

(3) Any deviations from the production process specifications and established acceptance criteria, or from relevant process controls, must be investigated to determine if they result in a nonconforming tobacco product. The disposition of any product affected by a deviation must be documented.

(4) All changes to production processes, including process controls, must be evaluated to determine their impact on the tobacco product specifications in the MMR. If any production process changes result in a change to the tobacco product specifications, the manufacturer must ensure that procedures applicable to changes in tobacco product specifications are followed in accordance with §§ 1120.42 and 1120.44 and update the tobacco product specifications in the MMR as needed. Changes to validated processes must be revalidated before implementation, where appropriate.

(b) *Process validation.* In addition to the requirements in paragraph (a) of this section, the production process procedures must include the following requirements for process validation, if applicable. If the results of a process, including automated processes, cannot be fully verified, a manufacturer must validate the process to demonstrate that it will produce a tobacco product that conforms to the specifications established under § 1120.44(a)(1). Process validation must use appropriate objective measures and valid scientific tools and analyses to maintain the process in a state of control. The process validation must include the following:

(1) *Process design.* Each finished and bulk tobacco product manufacturer must design a production process for the manufacture of its tobacco products. The process design must address the capability and functionality of the production process and establish a strategy for process control.

(2) *Process qualification.* Each finished and bulk tobacco product manufacturer must perform:

(i) Process qualification to determine if the process is capable of reproducible manufacturing; and

(ii) Process performance qualification to confirm the process design and demonstrate that the manufacturing process performs as expected in accordance with established criteria, which must be documented in a written protocol.

(3) *Continued process verification.* Each finished and bulk tobacco product manufacturer must monitor the production process using data collected from records required under this part and valid scientific tools to detect variability and ensure that the process remains in a state of control.

(c) *Additional requirements.* In addition to the requirements in paragraph (a) of this section, the production process procedures must include the following requirements, if applicable:

(1) *Manual methods.* If a production process includes a manual method or process, the production process procedures must describe the manual method or process in sufficient detail to ensure that the tobacco product meets established specifications and include if applicable, the criteria for workmanship using a standard or approved model sample.

(2) *Manufacturing material.* The production process procedures must address the use and removal of manufacturing material if such material could reasonably be expected to contaminate the tobacco product or otherwise result in a nonconforming tobacco product.

(d) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.68 Laboratory controls.

(a) *Competency.* When using a laboratory to conduct activities under this part, each finished and bulk tobacco product manufacturer must demonstrate, through appropriate documentation, the laboratory's competence to perform laboratory activities associated with the manufacture of finished and bulk tobacco products.

(b) *Controls.* Each finished and bulk tobacco product manufacturer must establish and maintain laboratory control procedures for any laboratory activities that are conducted under this part. Laboratory control procedures must include the following requirements:

(1) Use of scientifically valid laboratory methods that are accurate, precise, and appropriate for their intended purpose;

(2) Use of representative samples in accordance with § 1120.72; and

(3) Demonstration of analytical control.

(c) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.70 Production record.

(a) *Production record.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures to ensure that a production record is prepared for each batch of finished or bulk tobacco product to demonstrate conformity with the requirements established in the MMR in accordance with § 1120.44. Designated personnel must review and approve the production record for release of each batch of finished or bulk tobacco product into distribution.

(b) *Production record content.* The production record must include, or refer to the location of:

(1) The manufacturing code;

(2) The quantity of finished or bulk tobacco product manufactured in the batch;

(3) Identification of major equipment and processing lines used in manufacturing the batch of finished or bulk tobacco product;

(4) Records of any activities performed under this part necessary to demonstrate that the batch of finished or bulk tobacco product was manufactured to conform with requirements established in the MMR under § 1120.44;

(5) All unique identifiers of all accepted incoming tobacco products, including components or parts, ingredients, additives, and materials, used in the manufacture of the batch of finished or bulk tobacco product;

(6) If any finished or bulk tobacco product was used in the manufacturing of the batch, the manufacturing code for that finished or bulk tobacco product;

(7) Actual or copies of the packaging, labeling, and labels used with the finished or bulk tobacco product; and

(8) The name(s) and signature(s) of the designated individual(s) reviewing and approving the production record for release of the batch of finished or bulk tobacco product into distribution.

§ 1120.72 Sampling.

For any sampling performed under this part, each tobacco product manufacturer must establish and maintain an adequate sampling plan

using representative samples. The sampling plan must include:

(a) The intended purpose of the sampling;

(b) The scientific technique or method used to establish the sample size, including an explanation of how the sample size is representative of the material being sampled; and

(c) The method of sampling.

§ 1120.74 Nonconforming tobacco product.

Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the control and disposition of nonconforming tobacco product. The procedures must include the following requirements:

(a) *Identification and segregation.* Each finished and bulk tobacco product manufacturer must identify and segregate potential nonconforming product in a manner that prevents mixups and use of potential nonconforming product prior to investigation and disposition.

(b) *Investigation.* Each finished and bulk tobacco product manufacturer must investigate all potential nonconforming tobacco products.

(1) To determine if the product is nonconforming, the investigation must include an examination of relevant production processes and controls, laboratory testing, complaints, and any other relevant records and sources of information.

(2) For products determined to be nonconforming, the investigation must also determine:

(i) The scope and cause of the nonconformance; and

(ii) The risk of illness or injury posed by the nonconformance.

(c) *Disposition and followup.* Each finished and bulk tobacco product manufacturer must determine the disposition of all nonconforming tobacco products and conduct any necessary followup. If the disposition decision is that the tobacco product can be released for distribution without rework, an adequate written justification must be provided. An adequate written justification must address why releasing the nonconforming product would not result in an increased risk of illness or injury or in the tobacco product being adulterated or misbranded. Nonconforming product cannot be released for distribution without rework or an adequate justification.

(d) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time of the activity, the individual performing the activity, the type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.76 Returned tobacco product.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for the control and disposition of returned tobacco product. The procedures must include the following requirements:

(1) *Identification.* Each finished and bulk tobacco product manufacturer must identify returned tobacco product with the product name, manufacturing code, quantity returned, date the manufacturer received the returned product, and reason for the return.

(2) *Segregation.* Each finished and bulk tobacco product manufacturer must segregate identified returned tobacco product in a manner that prevents mixups and use of returned product prior to evaluation and disposition.

(3) *Evaluation and disposition.* Each finished and bulk tobacco product manufacturer must evaluate identified returned tobacco product and determine its disposition. The returned tobacco product must be discarded unless the manufacturer determines that it can be reworked under § 1120.78 or released for distribution based on an adequate written justification.

(b) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. Records of evaluation and disposition must include the product name, manufacturing code, quantity returned, date the manufacturer received the returned product and reason for the return, disposition decision and any justification, and the name of the individual making the decision.

§ 1120.78 Reprocessing and rework.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures for reprocessing and reworking tobacco products. The procedures must include:

(1) Evaluation of the tobacco product to determine whether the product is appropriate for reprocessing or rework and authorization of any reprocessing or rework by a designated individual. Tobacco product is appropriate for reprocessing if it is uncontaminated and has the same specifications as those in the MMR of the subsequently manufactured tobacco product. Tobacco product is appropriate for rework if further manufacturing can correct the nonconformity and the product can meet specifications and other requirements in the MMR of the subsequently manufactured tobacco product.

(2) Production processes, including process controls, in accordance with § 1120.66(a), and acceptance activities, in accordance with § 1120.64(c), used to ensure the reprocessed or reworked tobacco product conforms to the requirements established under § 1120.44 for the subsequently manufactured tobacco product.

(b) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results. The production record of any finished or bulk tobacco product that includes reprocessed or reworked product must include the amount, any unique identifier(s) assigned under § 1120.64(b), any batch number, and any manufacturing code associated with the reprocessed or reworked product.

Subpart F—Packaging and Labeling Controls

§ 1120.92 Packaging and labeling controls.

(a) *Procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures to control packaging and labeling activities to prevent mixups and to ensure that all packaging and labeling are approved for use by the manufacturer and comply with all requirements of the MMR as well as all other applicable requirements of the Federal Food, Drug, and Cosmetic Act, the Comprehensive Smokeless Tobacco Health Education Act, and the Federal Cigarette Labeling and Advertising Act and their implementing regulations. The procedures must address the following:

(1) *Label integrity.* Labels must be indelibly printed on or permanently affixed to finished and bulk tobacco product packages, so they remain legible, prominent, and conspicuous during the customary conditions of processing, packing, storage, handling, distribution, and use.

(2) *Design and construction.* Each finished and bulk tobacco product manufacturer must ensure that:

(i) Packaging and labeling used do not contaminate or otherwise render the tobacco product adulterated or misbranded; and

(ii) Storage and shipping cases or containers of finished or bulk tobacco products are designed and constructed to protect against contamination and adulteration of the products during the customary conditions of storage, handling, and distribution.

(b) *Records.* Each finished and bulk tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.94 Repackaging and relabeling.

(a) *Procedures.* Each finished tobacco product manufacturer must establish and maintain procedures to control repackaging and relabeling activities. The procedures must address all requirements described in § 1120.92.

(b) *Records.* Each finished tobacco product manufacturer must maintain records of all activities required under this section. Records must include the date and time, individual performing the activity, type of activity performed, any information that demonstrates the requirement was met, and any data or calculations necessary to reconstruct the results.

§ 1120.96 Manufacturing code.

(a) Each finished and bulk tobacco product manufacturer must apply a manufacturing code to the packaging or label of all finished and bulk tobacco products. For a finished tobacco product, the manufacturing code must be applied in a manner that assures it will remain on the packaging or label through the expected duration of use of the tobacco product by the consumer. For a bulk tobacco product, the manufacturing code must be applied in a manner that assures it will remain on the packaging or label until the product is received by the finished tobacco product manufacturer, including a packager or labeler.

(b) The manufacturing code for each finished and bulk tobacco product must be permanently affixed, legible, conspicuous, and prominent.

(c) The manufacturing code must contain the following information listed in the following order:

(1) The manufacturing date in 2-digit numerical values in the month-day-year format (MMDDYY); and

(2) The finished or bulk tobacco product batch number.

§ 1120.98 Warning plans.

(a) Each finished tobacco product manufacturer required to comply with a warning plan for tobacco product packaging must establish and maintain procedures to implement the requirements of such warning plan. Such procedures must include requirements for inspection of packaging before distribution to ensure that the finished tobacco product labels bear the required warning statements in accordance with the warning plan.

(b) Each finished tobacco product manufacturer required to comply with a warning plan for tobacco product packaging must maintain records that demonstrate that the manufacturer is in compliance with the warning plan.

Subpart G—Handling, Storage, and Distribution

§ 1120.102 Handling and storage.

Each finished and bulk tobacco product manufacturer must establish and maintain procedures to ensure that tobacco products are handled and stored under appropriate conditions to prevent nonconforming products as well as mixups, deterioration, contamination, adulteration, and misbranding of tobacco products.

§ 1120.104 Distribution.

(a) *Distribution procedures.* Each finished and bulk tobacco product manufacturer must establish and maintain procedures to ensure the following:

(1) Finished and bulk tobacco products are distributed to the initial consignee under appropriate conditions to prevent nonconforming products as well as mixups, deterioration, contamination, adulteration, and misbranding of tobacco products; and

(2) Only those finished and bulk tobacco products approved for release are distributed.

(b) *Distribution records.* Each finished and bulk tobacco product manufacturer must maintain distribution records that include:

(1) The name and address of the initial consignee;

(2) The identification and quantity of finished or bulk tobacco products shipped;

(3) The date shipped; and

(4) The manufacturing code(s).

(c) *Records of direct accounts.* Each finished and bulk tobacco product manufacturer must maintain a list of direct accounts (including wholesalers, distributors, and retailers), including their name, address, and contact information.

Subpart H—Recordkeeping and Document Controls

§ 1120.122 Recordkeeping and document control requirements.

(a) All documents and records required by this part must comply with the following requirements:

(1) All documents and records must be written in English, or an accurate English translation must be made available upon request.

(2) All documents and records that are associated with a batch of finished or bulk tobacco product must be retained for a period of not less than 4 years from the date of distribution of the batch or until the product reaches its expiration date if one exists, whichever is later. Documents and records that are not associated with a batch of finished or bulk tobacco product must be retained for a period of not less than 4 years from the date they were last in effect.

(3) All documents and records must be maintained at the manufacturing establishment or another location that is readily accessible to responsible officials of the tobacco product manufacturer and to FDA. These documents and records, including those not stored at the establishment, must be made readily accessible to FDA during the retention period for inspection and photocopying or other means of reproduction. Original or true copies of documents and records that can be immediately retrieved from another location, including by computer or other electronic means, meet the requirements of this paragraph.

(b)(1) All records required by this part, regardless of storage medium, must be attributable, legible, contemporaneously recorded, original, and accurate.

(2) For the purposes of this subpart, these terms are defined as the following:

(i) *Attributable.* Attributable means that the data in a record is traceable to its source. This means it should be attributable to the originator of the data, whether that source is an individual, an automated piece of equipment, or individual operating equipment.

(ii) *Legible.* Legible means the record is permanently recorded in a readable format. A legible record prevents loss and preserves traceability of changes without obscuring the original entry or subsequent additions or deletions.

(iii) *Contemporaneously recorded.* Contemporaneously recorded means

that data is recorded at the time the procedure, assessment, observation, or other activity is performed.

(iv) *Original.* Original means the record reflects the first capture of the data and all information related to all subsequent changes required to fully reconstruct the TPMP activities. An original record preserves the record content and the meaning of the data, including associated metadata. Original records may be static or dynamic. A static record, such as a paper record, is fixed and allows little or no interaction between the user and record content. Records in a dynamic state allow the user to interact with the information.

(v) *Accurate.* Accurate means that the data in a record is correct, truthful, complete, valid, and reliable. All records required under this part, including the associated data and metadata, must be accurate.

(c) Each finished and bulk tobacco product manufacturer must establish and maintain procedures to control all documents established to meet the requirements of this part. The procedures must provide for the following:

(1) *Document approval and distribution.* Each finished and bulk tobacco product manufacturer must review and approve all documents established to meet the requirements of this part before implementation. The approval must include the date, name, and signature of the individual(s) approving the document. Documents established to meet the requirements of this part must be available at all locations for which they are designated, used, or otherwise necessary, and all such documents that are superseded and obsolete documents must be promptly removed from all points of use or otherwise prevented from unintended use.

(2) *Document changes.* Before implementation, changes to documents established to meet the requirements of this part must be reviewed and approved by an individual(s) in the same function or part of the organization that performed the original review and approval. Approved changes must be communicated to the appropriate personnel in a timely manner. Superseded and obsolete documents established to meet the requirements of this part must be archived. Each tobacco product manufacturer must maintain records of changes to documents established to meet the requirements of this part. Change records must include:

(i) A description of the change;

(ii) Identification of the affected documents;

(iii) The name and signature of the approving individual(s);

(iv) The approval date; and

(v) The date the change becomes effective.

Subpart I—Small Tobacco Product Manufacturers

§ 1120.130 Compliance date for small tobacco product manufacturers.

Small tobacco product manufacturers of finished and bulk tobacco products shall not be required to comply with the requirements in this part until [DATE 4 YEARS AFTER EFFECTIVE DATE OF FINAL RULE].

Subpart J—Exemptions and Variances

§ 1120.140 Exemptions and variances.

Under section 906(e)(2) of the Federal Food, Drug, and Cosmetic Act, any person subject to any requirement prescribed in this part may petition FDA for a permanent or temporary exemption or variance from such requirement. The petitioner remains subject to the relevant requirement unless FDA grants the petition for an exemption or variance under § 1120.146. To petition for an exemption or variance, the petitioner must submit all information supporting the petition in an electronic format that FDA can process, review, and archive. If the petitioner is unable to submit a petition in an electronic format, the petitioner may submit a written request to FDA requesting FDA allowance of an alternative format and explaining in detail why the petitioner cannot submit the petition in an electronic format. Such request must include an explanation of why an alternative format is necessary. All petitions for exemptions or variances, including all supporting information, and all requests to submit petitions in an alternate format must be legible and in the English language.

§ 1120.142 Petition for an exemption or variance.

A petition for an exemption or variance from a requirement in this part must contain:

(a) The petitioner's name, address, and contact information;

(b) Identification of the tobacco product(s);

(c) The requirement(s) in this part for which an exemption or variance is requested;

(d) A detailed explanation of why the exemption or variance is requested, including why the tobacco product manufacturer is not able to comply with the requirement(s) of this part;

(e) The duration of the proposed exemption or variance;

(f) For a petition for a variance, a detailed explanation setting forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the requirement(s) in this part, as well as the basis for the petitioner's determination that the proposed methods will be sufficient to assure that the public health is protected, the tobacco product(s) will be in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act;

(g) For a petition for an exemption, a detailed explanation setting forth the basis for the petitioner's determination that compliance with the requirement(s) is not required to assure that: the public health is protected, the tobacco product will be in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act;

(h) Any other information justifying the exemption or variance;

(i) A statement certifying that, to the best of the petitioner's knowledge and belief, the information provided in the petition includes all information and views on which the petition relies, including representative data, and any information known to the petitioner that is unfavorable to the petition; and

(j) An environmental assessment under part 25 of this chapter prepared in accordance with the requirements of § 25.40 of this chapter.

§ 1120.144 Referral to the Tobacco Products Scientific Advisory Committee.

FDA may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under § 1120.142. The Tobacco Products Scientific Advisory Committee must report its recommendations to FDA with respect to a petition referred to it within 60 days after the date of the petition's referral.

§ 1120.146 Petition determination.

(a) *Petition for an exemption.* Upon review of the information submitted and any recommendation from the Tobacco Products Scientific Advisory Committee:

(1) FDA may approve the petition for an exemption from a requirement if it determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act.

(2) FDA may request additional information if necessary to make a determination. FDA may consider the exemption request withdrawn if the information is not received by the time specified in the request.

(b) *Petition for a variance.* Upon review of the information submitted and any recommendation from the Tobacco Products Scientific Advisory Committee:

(1) FDA may approve the petition for a variance if it determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirements in this part are sufficient to assure that the tobacco product will be in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act.

(2) FDA may request additional information if necessary to make a determination. FDA may consider the variance request withdrawn if the information is not received by the time specified in the request.

(c) *Timeframe.* FDA will either grant or deny the petition within 60 days after:

(1) The date the complete petition was submitted to FDA under § 1120.142; or

(2) The day after FDA referred the petition to the Tobacco Products Scientific Advisory Committee under § 1120.144, whichever is later.

(d) *Order granting a petition for variance.* An order from FDA granting a variance will prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product as may be necessary to assure that the tobacco product will be in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act.

§ 1120.148 Hearing.

After the issuance of an order under § 1120.146 respecting a petition, the petitioner will have an opportunity for a hearing under part 16 of this chapter.

Dated: February 28, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

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