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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 439

[Docket No. FSIS–2021–0013]

RIN 0583–AD70

Changes to Accreditation of Non-Federal Analytical Testing Laboratories

AGENCY: Food Safety and Inspection Service (FSIS), Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: FSIS is revising the regulations prescribing the statistical methods used in measuring the performance of chemistry laboratories in its voluntary Accredited Laboratory Program (ALP) and expanding the scope of accreditations offered by the program. Currently, participants in the ALP are accredited for the analysis of food chemistry (moisture, protein, fat, and salt), specific chemical residues, and classes of chemical residues. FSIS also is providing for the ALP to accredit non-Federal laboratories for microbiological indicator organisms and pathogen testing. FSIS is changing the statistical method the ALP uses to evaluate laboratory proficiency testing (PT). Additionally, FSIS is making various minor edits and changes to the regulation for the sake of clarity and to incorporate all sample types under the jurisdiction of FSIS.

DATES: This rule is effective October 24, 2022.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture; Telephone: (202) 720–0399.

SUPPLEMENTARY INFORMATION:

Background

FSIS accredits non-Federal analytical laboratories under its Accredited Laboratory Program (ALP). Under this voluntary program, FSIS accredits laboratories to conduct analyses of official meat and poultry samples for food chemistry (moisture, protein, fat, and salt), specific chemical residues, and classes of chemical residues. In response to the meat and poultry industries' need for more rapid analytical results as food testing expanded, and because of limitations in FSIS laboratory capacity at the time of this need, these programs were established to accredit non-Federal laboratories for certain tests of both meat and poultry products.

The ALP monitors each non-Federal laboratory currently accredited under the program to ensure that these laboratories are operating at a level of quality that produces reliable results that can be used to support decisions in establishments' food safety systems. The Proficiency Testing (PT) program administered by the ALP supports this effort. Monitoring is achieved by evaluating PT results for acceptable analytical performance and assessing quality assurance through on-site reviews of each laboratory's management system and facility assets.

On December 14, 2020, FSIS proposed changes to its ALP regulations (85 FR 80668). Specifically, FSIS proposed to change the statistical method it uses to evaluate laboratory PT sample results to the *z* score approach for those accreditations that are currently evaluated by Cumulative Summation (CUSUM). FSIS also proposed to accredit non-Federal laboratories for microbiological indicator organisms and pathogen testing, in response to industry interest. This second change will allow ALP-accredited laboratories to support statistical process control testing. FSIS intends to announce additional criteria for submitting test results in a future **Federal Register** document. Additionally, FSIS proposed to make various minor edits and changes to the regulations for the sake of clarity and to incorporate all sample types under the jurisdiction of FSIS (*e.g.,* to include egg products), as appropriate for the associated analyte, and to improve program flexibility.

The comment period ended on February 12, 2021. After reviewing comments, FSIS is finalizing the rule as proposed.

Comments and Responses

FSIS received seven comments on the proposed rule. Commenters included representatives from laboratories, an association of laboratory scientists, a State Department of Agriculture, a nationwide laboratory network, and a trade association. Four of the seven commenters expressed overall support for the proposed rule. Some commenters raised questions and made suggestions, and two of the commenters expressed concern with making International Organization for Standardization (ISO) 17025 accreditation a prerequisite to participation in the program, a possibility upon which FSIS requested comment in the proposal. No commenter expressed broad opposition to the proposal, as a whole, for updating the statistical PT scoring and expanding the program to include accreditations for microbiological indicator organisms and pathogen testing.

The following is a discussion of the relevant issues raised in the comments.

Statistical Methods

Comments: All commenters generally agreed with the proposed change from CUSUM to *z* scores. One commenter from a State Department of Agriculture asked at which point a lab would be considered on probation under the new statistical analysis using *z* scores; how grading will be applied; and whether a *z* score will be determined per event.

Response: Per 9 CFR 439.20 and ISO 13528, the PT scoring changes will be applied per event. The ALP will also monitor laboratory performance over time. After adopting the proposed changes, probation imposed for performance issues will be administered the same way it has with CUSUMs, but assessment will rely instead on unacceptable *z* scores and monitoring for persistent bias. Unacceptable *z* scores are greater than 3 and less than −3. FSIS intends to determine probation for PT performance issues as follows.

- A laboratory will be placed on probation for having two *z* scores that exceed the action level of $|z| \geq 3.0$ for the same analyte or class of analytes within six consecutive PT events.
- A laboratory may be placed on probation for having a persistent bias of an analyte or class of analytes compared

to the accepted values of ALP PT samples. As a general practice under ISO 13528, FSIS intends that the ALP will use control charts to monitor for this aspect of performance. Bias occurs once eight or more consecutive values fall above or below the center or mean line. Under the ALP, FSIS reserves the right to consider other factors (such as magnitude or significance) when determining the impact of bias.

Management of Associated Data

Comments: Two commenters stated that ALP data should be managed through a website portal or other similar option. One commenter representing an association of scientists strongly supported the FSIS vision of utilizing the ALP to allow regulated establishments to voluntarily submit test results to FSIS. Another commenter representing a nationwide laboratory network suggested that accredited laboratories should maintain complete records of all aspects of the testing process and that the records should be securely maintained in an electronic format that is adequately backed up. In addition, the commenter recommended that key components of ALP data should be clearly defined to assure proper data interpretation and that definitions used by ISO13528:2015(E) should be consistent with USDA to assure uniformity.

Response: FSIS intends to develop a web-based platform for ALP test result submissions to FSIS. FSIS will announce the availability of the web-based platform in a future *Constituent Update.* Per 9 CFR 439.20, the FSIS ALP regulations require a secure management system that is adequate for tracking samples and related analyses and test results. The ALP does allow, but does not require, electronic records, and it does require that records be secure. Test result definitions used by the ALP are consistent with ISO 13528:2015(E). Any electronic system for submitting test results to FSIS will have to be compatible with FSIS data management systems.

Desired Food Matrix and Analyte Pairs

*Comment*s: One commenter representing a laboratory did not see the benefit of adding pathogens and indicator organism constituents to the ALP. Five commenters recommended that FSIS expand the ALP offerings to include such items as pH in meat, beta-agonists in beef/pork muscle/organs, *Campylobacter* in chicken, *Salmonella* in meat products, *Listeria spp.* in swabs/sponges, *Listeria monocytogenes* in meat products, *Escherichia coli* in carcass swabs, Enterobacter in swabs/sponges, Shiga toxin-producing *Escherichia coli* in meat products, generic *Escherichia coli,* total coliform, Aerobic Plate Count, and drug residues in animal products, including antibiotics and pesticides. Other commenters recommended the ALP include microbiology qualitative and quantitative testing and requested that FSIS revisit approved analytes in the ALP on a systematic basis.

Response: Per 9 CFR 439.1 and 439.10, FSIS will consider all requests for accredited matrix and analyte pairs for the ALP that are within FSIS's jurisdiction. FSIS will also consider qualitative and quantitative testing for chemical and microbiological components under the ALP. Finally, FSIS will routinely examine the ALP offerings when appropriate.

ISO Accreditation

Comments: Two commenters representing laboratories did not support making ISO 17025 accreditation a prerequisite to participating in the ALP and stated such a requirement could cause an undue burden on smaller laboratories wishing to join the ALP. Two commenters representing a laboratory association and a laboratory network supported making ISO 17025 accreditation a prerequisite to participating in the ALP but also stated that the requirement may be unnecessary. One of these commenters suggested that laboratories not accredited to ISO 17025 should operate under a robust quality management system or ''ISO-like'' environment. One commenter representing a laboratory network supported the rule and stated that ISO 17025 accreditation should be a prerequisite to membership in the ALP.

Response: This final rule expands the ALP in a way that is inclusive for all interested laboratories and establishments that can successfully meet the program requirements and, per 9 CFR 439.20, the ALP will require participating laboratories to have a management system in place that includes traceability, document control, and secure record retention. Laboratories may choose whether to be accredited to the ISO 17025 standard; however, FSIS will not require ISO 17025 accreditation under the ALP. Laboratories seeking ALP accreditation without ISO 17025 accreditation are often very small and conduct meat and poultry analyses only. In these cases, the ALP accreditation provides value by affirming that the lab can do independent PT analysis with those PT samples made by and coming from the ALP.

Comments: Three commenters responded that if a laboratory is accredited to ISO 17025, the FSIS ALP audit should be streamlined to account for this and offer fee discounts. One commenter representing a network of laboratories responded that the ALP proficiency testing program should be accredited to the ISO 17043 standard if it is to attract members from the governmental sector. One commenter representing an association of laboratories stated that a reduction in fees would be welcomed by laboratories interested in the ALP, but the best way to incentivize laboratories to become ALP members is to expand the scope of testing. The commenter pointed out that most laboratories providing services to meat and poultry companies are focused on supporting their clients' food safety programs. The commenter stated that laboratories' clients view their being an FSIS ALP laboratory as positive, which is beneficial to the laboratory.

Response: FSIS will continue to accept the management systems of laboratories that are accredited to ISO 17025 by an International Laboratory Accreditation Cooperation recognized accrediting body as meeting ALP requirements. The laboratories must be in good standing with their ISO accreditation for the ALP to accept the management systems. The ALP performs onsite reviews of participating laboratories to ensure they are following management system requirements, as well as the technical and method requirements for participation in the program. FSIS estimates that the ALP review for ISO 17025 accredited laboratories will be reduced by a range of 0.5 to 1 hour. The ALP has been ISO 17043 accredited as a proficiency testing provider since 2015. The ALP has also been ISO 17034 accredited as a reference material producer since 2017. Both accreditations are kept current. Because comments have been supportive of expanding the ALP offerings, FSIS intends to develop new offerings from the ALP. The new offerings may be found on the ALP website as they are developed and available.

Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs

and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated as a ''non-significant'' regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Need for the Rule

There were approximately 55 food chemistry laboratories participating in the ALP in 2012. Since then, participation has declined to 34 laboratories in 2021. Of those laboratories, 25 were accredited for food chemistry, 13 for chemical residue chlorinated pesticides analysis, and 4 for chemical residue PCBs analysis (some laboratories have multiple accreditations).[1] Participation in the ALP will likely be bolstered by expanding the ALP to include additional analytes, such as indicator organisms and foodborne pathogens. In addition, switching from the CUSUM PT sample scoring system currently used by the ALP to *z score*-based statistics should simplify the accreditation process for both the laboratories and FSIS. The program generally facilitates industry testing to verify that food is safe and properly labeled.

Expected Industry Costs and Savings

Although the final rule does not change the current accreditation fee structure,[2] it will reduce the number of samples non-Federal food chemistry laboratories will have to analyze to attain and maintain food chemistry accreditation. Based on industry data, non-ALP laboratories charge approximately $108 [3] per sample. Current criteria for obtaining accreditation (9 CFR 439.10(d)(2)(i)) require that laboratories analyze a set of 36 samples (9 CFR 439.1(k) ''Initial accreditation check sample'') for food chemistry to obtain initial accreditation or to remove probationary status in food chemistry. The estimated cost for analyzing the sample set (also known as qualification set) is approximately $3,888 (36 × $108 = $3,888). This number of samples is not necessary to statistically evaluate laboratory performance for admittance to the program. Under this final rule, FSIS removed the requirement for the set of 36 samples. This will permit the ALP to offer laboratories smaller sets for food chemistry accreditation. The smaller qualification sets will reduce costs for laboratories and still be large enough to evaluate laboratory performance. FSIS experts provided an estimated cost of analysis of approximately $1,512 when using 14 samples per set (14 × $108 = $1,512), a reduction of $2,376 ($3,888 − $1,512 = $2,376) per qualification set for food chemistry. This analysis assumes that between 1 and 6 establishments will have to complete qualification sets in any given year.[4] Based on this assumption the annual savings ranges from $2,376 (1 × $2,376) to $14,256 (6 × $2,376), with a mid-point of $8,316 (3.5 × $2,376).

Additionally, the changes to the accreditation process (9 CFR 439.10(d)(4)(ii)) are also expected to reduce industry costs. Current criteria state that if a laboratory's second set of qualification samples do not meet the criteria for obtaining accreditation, laboratories must submit a new application, all fees, and all documentation of corrective action required for accreditation. FSIS will no longer require food chemistry laboratories to reapply and pay the fees again before receiving the third qualification sample set. Instead, fees will be paid after the third set or if the initial accreditation process is not completed within eleven months (per 9 CFR 439.10(c)). This is expected to reduce an applicable laboratory's accreditation cost by between $2,100 and $5,000.

Regulatory Flexibility Analysis

The FSIS Administrator (Administrator) has made a determination that this final rule will not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). First, this rule's impact is limited to a small number of entities and participation in the program is voluntary. Second, while the changes are expected to reduce accreditation costs, these cost savings are not anticipated to be significant and will apply to accredited laboratories regardless of size.

Paperwork Reduction Act

FSIS has reviewed this rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and has determined that there is no new information collection related to this final rule. FSIS collects information for the ALP under Office of Management and Budget (OMB) approval numbers 0583–0082 and 0583–0163.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *https://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *https://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

[1] A list of current FSIS Accredited Laboratories can be found at *https://www.fsis.usda.gov/science-data/laboratories-procedures/accredited-laboratory-program* (last accessed on June 22, 2021). PCBs stands for Polychlorinated Biphenyls.

[2] Fees and charges for laboratory accreditation are provided in 9 CFR part 391.

[3] This cost is based on publicly listed industry prices in 2021 charged by N.P Analytical Laboratories, Great Lakes Scientific, New Jersey Feed Laboratory Inc (NJFL), and Analytical Feed and Food Lab accessed on June 22, 2021.

[4] For instance, in 2016, there were 2 new applicants and 4 probation applicants and, in 2021, there are no new applicants and 1 probation applicant.

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Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible FSIS or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632–9992.

Submit your completed form or letter to USDA by: (1) mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: *program.intake@usda.gov.*

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List of Subjects in 9 CFR Part 439

Laboratories, Meat inspection, Poultry and poultry products.

For the reasons discussed in the preamble, FSIS revises 9 CFR part 439 to read as follows:

PART 439—ACCREDITATION OF NON-FEDERAL LABORATORIES FOR ANALYTICAL TESTING OF MEAT, POULTRY, AND EGG PRODUCTS

Sec.

AUTHORITY: 7 U.S.C. 138f, 450, 1901–1906, 1622(o); 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

§ 439.1 Definitions.

(a) *Accredited Laboratory Program (ALP).* The voluntary Food Safety and Inspection Service (FSIS) program in which non-Federal laboratories are accredited as capable of performing analyses with the level of quality that is necessary to maintain accreditation in the program, on samples of raw or processed meat, poultry, and egg products, and through which a proficiency testing sample program for quality assurance is conducted.

(b) *Food chemistry.* Analysis of raw or processed meat or poultry products for the components moisture, protein, fat, and salt.

(c) *Initial accreditation proficiency testing sample.* A sample provided by the FSIS ALP to a non-Federal laboratory to determine whether the laboratory's analytical capability meets the standards for acceptance into the program. The concentration or presence of the targeted analyte(s) and the composition of the components in the sample is unknown to the laboratory.

(d) *Inter-laboratory accreditation maintenance proficiency testing sample.* A sample provided by the FSIS ALP to an accredited laboratory to assist in determining whether the laboratory is maintaining acceptable analytical performance for a given analyte or component. The concentration or presence of the targeted analyte(s) and the composition of the components in the sample is unknown to the laboratory.

(e) *International Organization for Standardization (ISO) 13528.* ISO 13528:2015(E) Corrected version 2016, ''Statistical methods for use in proficiency testing by interlaboratory comparison,'' October 15, 2016, or updated versions.

(f) *Probation.* The period commencing with official notification to an accredited laboratory that it no longer satisfies the ALP performance requirements specified in this part and ending with official notification that accreditation is fully restored, is suspended, or is revoked.

(g) *Refusal of accreditation.* An action taken by FSIS when a laboratory that is applying for accreditation is denied the accreditation.

(h) *Responsibly connected.* Any individual, or entity, that is a partner, officer, director, manager, or owner of 10 percent or more of the voting stock of the applicant or recipient of accreditation or an employee in a managerial or executive capacity or any employee who conducts or supervises the analysis of FSIS samples.

(i) *Revocation of accreditation.* An action taken by FSIS against a laboratory thereby removing the laboratory's certification of accreditation and participation in inter-laboratory accreditation maintenance proficiency testing sample events.

(j) *Suspension of accreditation.* An action taken by FSIS against a laboratory thereby temporarily removing the laboratory's certification of accreditation and participation in the inter-laboratory accreditation maintenance proficiency testing sample events. Suspension of accreditation ends when accreditation either is fully restored or is revoked.

(k) *z score.* A statistically derived number representing a laboratory's performance for analyzing quantitative proficiency testing samples. The ALP calculates and interprets *z* scores consistent with the ISO 13528 standard.

§ 439.5 Applications for accreditation.

(a) Participation in the ALP is voluntary. Application for accreditation must be made on designated paper or electronic forms provided by FSIS, or otherwise in writing, by the owner or manager of a non-Federal analytical laboratory. Application forms may be obtained by contacting the ALP at *ALP@usda.gov.* The forms must be sent to the ALP or may be submitted electronically. The application must specify the kinds of accreditation sought by the owner or manager of the laboratory. A laboratory whose accreditation has been refused or revoked for performance reasons may reapply for accreditation after 60 days from the effective date of that action and must provide written documentation specifying what corrections were made and illustrate to FSIS that the corrections are effective or would reasonably be expected to be effective.

(b) At the time that an application for accreditation is filed with the ALP, the laboratory must submit fees payable to the U.S. Department of Agriculture by check, bank draft, money order, or other form of payment accepted by the U.S. Department of Agriculture, in the amount specified by FSIS as directed in 9 CFR 391.5, along with the completed application for the accreditation(s).

(c) An application for accreditation will not be processed or allowed to advance, without further procedure, if the accreditation fee(s) is delinquent.

(d) FSIS will issue a bill annually in the amount specified by FSIS in 9 CFR 391.5 for each accreditation held and are due by the date required. Bills are payable to the U.S. Department of Agriculture by check, bank draft, money order, or other form of payment accepted by the U.S. Department of Agriculture.

§ 439.10 Criteria for obtaining accreditation.

(a) Analytical laboratories may be accredited for the analyses of foodborne indicator and pathogen analytes, or a specified chemical residue or a class of chemical residues, in raw or processed meat, poultry, and egg products. Analytical laboratories also may be accredited for the analyses of food chemistry components in raw or processed meat and poultry products.

(b) Accreditation will be granted only if the applying laboratory successfully satisfies FSIS requirements that are stated in this part.

(c) To obtain FSIS accreditation, an analytical laboratory must:

(1) Be supervised by a person holding, at a minimum, a bachelor's degree in biology, chemistry, microbiology, food science, food technology, or a related field.

(i) For food chemistry accreditation, the supervisor must also have one year of experience in food chemistry analysis, or equivalent qualifications.

(ii) For chemical residue accreditation, either the supervisor or the analyst assigned to analyze the sample must also have three years of experience determining analytes at or below part per million levels, or equivalent qualifications.

(iii) For indicator organisms or pathogen accreditation, either the supervisor or the analyst assigned to analyze the sample must also have three years of experience in foodborne pathogen analyses or equivalent qualifications.

(2) Demonstrate the capability to achieve quality assurance levels that are within acceptable limits as determined by evaluation that is consistent with ISO 13528 for the analysis of initial accreditation proficiency testing samples, in the analyte category for which accreditation is sought. FSIS and some Association of Official Analytical Collaboration (AOAC) International analytical test procedures are acceptable for use in this program. FSIS procedures may be found on the U.S. Department of Agriculture (USDA) FSIS website at *www.fsis.usda.gov.* AOAC procedures may be found on the AOAC website at *www.aoac.org.*

(3) Complete a second set of proficiency testing samples if the results of the first set of proficiency testing samples are unsuccessful.

(i) The second set of proficiency testing samples will be provided within 30 days following the date of receipt by FSIS of a request from the applying laboratory. The second set of proficiency testing samples will be analyzed only for the analyte(s) or analyte classes for which unacceptable initial results had been obtained by the laboratory.

(ii) If the results of the second set of proficiency testing samples are unsuccessful, the laboratory may request a third set of proficiency testing samples after a 60-day waiting period, commencing from the date of notification by FSIS of unsuccessful results. The third set of proficiency testing samples will be analyzed only for the analyte(s) or analyte classes for which unacceptable initial results had been obtained by the laboratory.

(iii) If the laboratory is unsuccessful for the third set and still wishes to pursue accreditation, the ALP will require a new application and an application fee if the initial accreditation process is not completed within eleven months. Documentation of corrective action(s) related to the previous unsuccessful accreditation attempt must be submitted to and accepted by the ALP.

(4) Allow inspection of the laboratory facility and pertinent documents by FSIS officials prior to the determination of granting accredited status.

(5) Pay the accreditation fee by the date required.

§ 439.20 Criteria for maintaining accreditation.

(a) *Criteria.* To maintain accreditation, an analytical laboratory must fulfill the requirements of this section.

(b) *Records.* To demonstrate traceable and appropriate application of equipment, standards, procedures, analysts, and approvals related to accreditation, an accredited laboratory must:

(1) Maintain laboratory quality control records for the most recent three years that samples have been analyzed.

(2) Maintain complete records of the receipt, analysis, and disposition of samples for the most recent three years that samples have been analyzed.

(3) Maintain in a secure electronic format or in a standards book, all records, readings, and calculations for prepared standards. Entries are to be dated and the analyst identified at the time of the entry, and manual calculations verified and documented by the supervisor, or by the supervisor's designee, before use of the standard. The standards records are to be retained for three years after the last recorded entry. The certificates of analysis are to be kept on file for purchased standards for at least the period of time that the materials are in use.

(4) Maintain records of instrument maintenance and calibration. The records are to be retained for three years after the last recorded entry.

(5) As provided in paragraph (e) of this section, records are to be made available for review by any duly authorized representative of the Secretary of Agriculture, including ALP personnel or their designees.

(c) *Inter-laboratory accreditation maintenance proficiency testing sample.* (1) An accredited laboratory must analyze inter-laboratory accreditation maintenance proficiency testing samples and return the results to the ALP by the due date, which is usually within approximately three weeks of sample receipt. This must be done whenever requested by FSIS and at no cost to FSIS.

(2) Results must be those of the accredited laboratory. Analyses of proficiency testing samples must not be contracted out by the accredited laboratory.

(d) *Corporate changes.* The ALP must be informed within 30 days of any change of address or in the laboratory's ownership, officers, directors, supervisory personnel, or other responsibly connected individual or entity.

(e) *On-site review.* An accredited laboratory must permit any duly authorized representative of the Secretary to perform both announced and unannounced on-site laboratory reviews of facilities and records, both hard copy and electronic, during normal business hours, and to copy any records pertaining to the laboratory's participation in the ALP.

(f) *Analytical test procedures.* An accredited laboratory must use analytical test procedures designated by the FSIS ALP as being acceptable. FSIS and some AOAC analytical test procedures are acceptable.

(g) *Quality assurance levels.* An accredited laboratory must demonstrate the capability to maintain quality assurance levels that are within acceptable limits as evaluated by the ALP in the analysis of inter-laboratory accreditation maintenance proficiency testing samples for the analyte category for which accreditation was granted. An accredited laboratory will successfully demonstrate the maintenance of these capabilities if its results from inter-

laboratory accreditation maintenance proficiency testing samples satisfy ALP evaluation criteria based on the ISO 13528 standard, to include performance evaluation by *z* score statistics.

(h) *Fees.* An accredited laboratory must pay the annual required accreditation fee when it is due.

(i) *Probation.* If placed on probation, an accredited laboratory must meet the ALP requirements as prescribed in this section in order to remove the probation status.

(1) The laboratory must successfully analyze a set of initial accreditation proficiency testing samples for the analyte(s) that triggered the probation and submit the analytical results to FSIS by the due date, which is typically within approximately three weeks of receipt of the samples.

(2) Similarly satisfy criteria for accreditation maintenance proficiency testing samples specified by the ALP in this part.

(3) Provide written corrective action documentation, related to the issue that triggered the probation, to the ALP by the date required.

(j) *Suspension.* If placed on suspension, an accredited laboratory must meet the ALP requirements as prescribed in this section in order to remove the suspension status. If the laboratory is unsuccessful in meeting the requirements to remove the suspension status, accreditation will be revoked.

(1) Laboratories that are suspended due to performance or response issues enter a waiting period of 60 days from the effective date of that action. After the 60-day period has passed, if the laboratory wishes to pursue reinstatement to the ALP, the laboratory must submit a written corrective action plan specifying what corrections were made and illustrate to FSIS that the corrections are effective or would reasonably be expected to be effective.

(i) After the corrective action plan has been accepted by the ALP, the laboratory must successfully analyze a set of initial accreditation proficiency testing samples for the analyte(s) that triggered the suspension and meet all other program requirements including payment of any annual fees that are due. The ALP may perform an on-site inspection at the laboratory's facility and/or require the laboratory to provide documentation to confirm that it meets the requirements of the program.

(ii) The suspended laboratory is allowed two attempts to successfully analyze the initial accreditation proficiency testing set(s) of samples.

(2) Laboratories that are suspended due to indictment or charges as described in § 439.52 may not seek removal of suspension status until being cleared of said indictment or charges.

§ 439.50 Refusal of accreditation.

Upon a determination by the FSIS Administrator (Administrator), a laboratory will be refused accreditation for the following reasons:

(a) A laboratory will be refused accreditation for failure to meet the requirements of the ALP as stated in this part.

(b) A laboratory will be refused accreditation if the laboratory or any individual or entity responsibly connected with the laboratory has been convicted of, or is under indictment for, or has charges on any information brought against them in a Federal or State court concerning any of the following violations of law:

(1) Any felony.

(2) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(3) Any misdemeanor based upon a false statement to any governmental agency.

(4) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

(5) Altering any official sample or analytical finding; or substituting any analytical result from any other laboratory and representing the result as its own.

§ 439.51 Probation of accreditation.

Upon a determination by the Administrator, a laboratory will be placed on probation for the following reasons:

(a) If the laboratory fails to complete more than one inter-laboratory accreditation maintenance proficiency testing sample analysis within 12 consecutive months, unless written permission is granted by the Administrator.

(b) If the laboratory does not respond to ALP inquiries related to its participation in the program or fails to meet any of the requirements or criteria set in this part.

(c) If the laboratory does not successfully demonstrate the maintenance of quality assurance capabilities including its results from inter-laboratory accreditation maintenance proficiency testing samples. ALP evaluation criteria are based on the ISO 13528 standard, to include performance evaluation by *z* score statistics.

§ 439.52 Suspension of accreditation.

A laboratory will be suspended from the program if probation status is not rectified according to program requirements stated in this part. The accreditation of a laboratory will be immediately suspended if the laboratory or any individual or entity responsibly connected with the laboratory is indicted or has charges on information brought against them in a Federal or State court for any of the following violations of law. A laboratory must notify the ALP within 30 calendar days if any of these situations occur.

(a) Any felony.

(b) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(c) Any misdemeanor based upon a false statement to any governmental agency.

(d) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

(e) Altering any official sample or analytical finding; or substituting any analytical result from any other laboratory and representing the result as its own.

§ 439.53 Revocation of accreditation.

A laboratory will have its accreditation revoked from the program if suspension status is not rectified. The accreditation of a laboratory will also be revoked for the following reasons:

(a) An accredited laboratory will have its accreditation revoked if the Administrator determines that the laboratory or any responsibly connected individual or any agent or employee has:

(1) Altered any official sample or analytical finding; or

(2) Substituted any analytical result from any other laboratory and represented the result as its own.

(b) An accredited laboratory will have its accreditation revoked if the laboratory or any individual or entity responsibly connected with the laboratory is convicted in a Federal or State court of any of the following violations of law. A laboratory must notify the ALP within 30 calendar days if any of these situations occur.

(1) Any felony.

(2) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(3) Any misdemeanor based upon a false statement to any governmental agency.

(4) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

§ 439.60 Notifications and hearings.

Accreditation of any laboratory will be refused, suspended, or revoked under the conditions previously described in this part. The owner or operator of the laboratory will be sent written notice of the refusal, suspension, or revocation of accreditation by the Administrator. In such cases, the laboratory owner or operator will be provided an opportunity to present, within 30 days of the date of the notification, a statement challenging the merits or validity of such action and to request an oral hearing with respect to the denial, suspension, or revocation decision. An oral hearing will be granted if there is any dispute of material fact joined in such responsive statement. The proceeding will be conducted thereafter in accordance with the applicable rules of practice, which will be adopted for the proceeding. Any such refusal, suspension, or revocation will be effective upon the receipt by the laboratory of the notification and will continue in effect until final determination of the matter by the Administrator.

Paul Kiecker,

Administrator.

[FR Doc. 2022–18274 Filed 8–23–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0244; Airspace Docket No. 20–AWP–9]

RIN 2120–AA66

Modification of Class D and Class E Airspace and Establishment of Class E Airspace; Camarillo, CA

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This action modifies the Class E airspace, designated as an extension to a Class D or Class E surface area, at Camarillo Airport, Camarillo, CA. This action also removes the Camarillo very high frequency omnidirectional range (VOR)/distance measuring equipment (DME) from the airspace's legal description. Additionally, this action establishes Class E airspace extending upward from 700 feet above the surface. Lastly, this action makes administrative changes to the Class D and Class E legal descriptions. These actions would ensure the safety and management of visual flight rules (VFR) and instrument flight rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, November 3, 2022. The Director of the Federal Register approves this incorporation by reference under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11, Airspace Designations and Reporting Points, and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Nathan A. Chaffman, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3460.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would modify the Class D and Class E airspace at Camarillo Airport, Camarillo, CA, to support VFR and IFR operations at the airport.

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** for FAA–2021–0244 (87 FR 34595; June 7, 2022) to modify the Class E airspace designated as an extension to a Class D or Class E surface area, establish Class E airspace beginning at 700 feet above the surface, remove the Camarillo VOR/DME from the airspace's legal description, and make administrative changes to the Class D and Class E legal descriptions at Camarillo Airport, Camarillo, CA. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Class D, Class E4, and Class E5 airspace designations are published in paragraphs 5000, 6004, and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending 14 CFR part 71 by modifying the Class E airspace, designated as an extension to a Class D or Class E surface area. This airspace area is east of the airport and is reduced to properly contain IFR aircraft descending below 1,000 feet above the surface. This action also removes the Camarillo VOR/DME navigational aid (NAVAID) from the airspace's legal description. The NAVAID is not required to define the airspace and removal of the NAVAID simplifies the airspace's description.

Additionally, this action establishes Class E airspace extending upward from 700 feet above the surface. This airspace is designed to contain arriving IFR aircraft descending below 1,500 feet above the surface and departing IFR aircraft until they reach 1,200 feet above the surface. Lastly, this action also makes several administrative modifications to the Class D and Class E airspace's legal descriptions. To match the FAA database, the geographic coordinates in the third line of the Class E4 airspace's text header are modified to read lat. ''34°12′50″ N, long. 119°05′40″ W.'' Also, since Camarillo Airport's Class D airspace abuts the Class D areas for Point Mugu Naval Air Station and Oxnard Airports, the geographic coordinates at Camarillo Airport's Class