

Power Generating Stations,” with some exceptions and clarifications. Specifically, this revision removes the previous SDOE guidance from this guide and instead endorses, with clarifications, the SDOE criteria within IEEE Std 7–4.3.2–2016. This revision also includes additional guidance for fault detection and self-diagnostics, if used, in Digital Instrumentation and Control systems. In addition, this revision endorses Annex D of IEEE Std 7–4.3.2–2016 and clarifies the applicability of the control of access guidance for safety-related PDDs.

The staff is also issuing for public comment a draft regulatory analysis (ADAMS Accession No. ML22132A293). The staff developed a regulatory analysis to assess the value of issuing or revising a regulatory guide as well as alternative courses of action.

As noted in the **Federal Register** on December 9, 2022 (87 FR 75671), this document is being published in the “Proposed Rules” section of the **Federal Register** to comply with publication requirements under 1 CFR chapter I.

### III. Backfitting, Forward Fitting, and Issue Finality

If finalized, the NRC staff may use this DG as a reference in its regulatory processes, such as licensing, inspection, or enforcement. However, the NRC staff does not intend to use the guidance in this DG to support NRC staff actions in a manner that would constitute backfitting as that term is defined in Section 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR), “Backfitting,” and as described in NRC Management Directive (MD) 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” nor does the NRC staff intend to use the guidance to affect the issue finality of an approval under 10 CFR part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” The staff also does not intend to use the guidance to support NRC staff actions in a manner that constitutes forward fitting as that term is defined and described in MD 8.4. If a licensee believes that the NRC is using this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfitting or forward fitting appeal with the NRC in accordance with the process in Management Directive 8.4.

### IV. Submitting Suggestions for Improvement of Regulatory Guides

A member of the public may, at any time, submit suggestions to the NRC for improvement of existing RGs or for the

development of new RGs. Suggestions can be submitted on the NRC’s public website at <https://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html>. Suggestions will be considered in future updates and enhancements to the “Regulatory Guide” series.

Dated: March 3, 2023.

For the Nuclear Regulatory Commission.

**Meraj Rahimi,**

*Chief, Regulatory Guide and Programs Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.*

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## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 51

[NRC–2018–0296]

RIN 3150–AK32

### Renewing Nuclear Power Plant Operating Licenses—Environmental Review

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed rule; public meetings and request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) plans to hold comment-gathering public meetings on a proposed rule to amend its environmental protection regulations by updating the Commission’s 2013 findings on the environmental effect of renewing the operating license of a nuclear power plant. The purpose of the meetings is to provide information and receive public comments on the proposed changes to NRC regulations, draft Revision 2 to NUREG–1437, “Generic Environmental Impact Statement for License Renewal of Nuclear Plants” (LR GEIS), and associated guidance.

**DATES:** The NRC plans to hold public meetings in March and April 2023 during the 60-day public comment period. See Section III, “Request for Comments and Public Meetings,” of this document for more information on the meetings.

**ADDRESSES:** Please refer to Docket ID NRC–2018–0296 when contacting the NRC about the availability of information regarding this public meeting. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2018–0296. Address

questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: [Dawn.Forder@nrc.gov](mailto:Dawn.Forder@nrc.gov). For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Email comments to:*

[Rulemaking.Comments@nrc.gov](mailto:Rulemaking.Comments@nrc.gov). If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.

- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

#### FOR FURTHER INFORMATION CONTACT:

Yanely Malave-Velez, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–1519, email: [Yanely.Malave-Velez@nrc.gov](mailto:Yanely.Malave-Velez@nrc.gov); Jennifer Davis, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–3835, email: [Jennifer.Davis@nrc.gov](mailto:Jennifer.Davis@nrc.gov); or Kevin Folk, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–6944, email: [Kevin.Folk@nrc.gov](mailto:Kevin.Folk@nrc.gov). All are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

#### SUPPLEMENTARY INFORMATION:

#### I. Obtaining Information and Submitting Comments

##### A. Obtaining Information

Please refer to Docket ID NRC–2018–0296 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2018–0296.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to [PDR.Resource@nrc.gov](mailto:PDR.Resource@nrc.gov).

- *NRC’s PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC’s PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville,

Maryland 20852. To make an appointment to visit the PDR, please send an email to [PDR.Resource@nrc.gov](mailto:PDR.Resource@nrc.gov) or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

### B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC-2018-0296 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

## II. Background

On March 3, 2023, the NRC published a proposed rule in the **Federal Register** for a 60-day public comment period (88 FR 13329). The NRC proposes to amend its environmental protection regulations by updating the Commission's 2013 findings on the environmental effect of renewing the operating license of a nuclear power plant in part 51 of title 10 of the *Code of Federal Regulations* (10 CFR), "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," subpart A, "National Environmental Policy Act—Regulations Implementing Section 102(2)." Additionally, the NRC proposes to revise NUREG-1437, "Generic Environmental Impact Statement for

License Renewal of Nuclear Plants" (LR GEIS), which is intended to streamline the NRC's license renewal environmental review by documenting a systematic approach that the NRC uses to evaluate the environmental impacts of renewing the operating licenses of commercial nuclear power plants. The LR GEIS also provides the technical basis for Table B-1, in appendix B to subpart A of 10 CFR part 51, "Environmental Effect of Renewing the Operating License of a Nuclear Power Plant." Among other things, these proposals will update 10 CFR part 51 and the LR GEIS to fully account for subsequent license renewal as well as initial license renewal. The NRC will solicit comments at each meeting for consideration in the development of the final rule, LR GEIS, and associated guidance.

## III. Request for Comments and Public Meetings

The NRC staff plans to hold the following comment-gathering public meetings during the 60-day public comment period to present an overview of the proposed changes to the environmental protection regulations and the LR GEIS.

- March 16, 2023, at the Bethesda North Marriott Hotel & Conference Center; First Meeting: Open House from 1:30 p.m.–2 p.m. and Public Meeting from 2 p.m.–4 p.m. (local time).
- Second Meeting: Open House from 5:30 p.m.–6 p.m. and Public Meeting from 6 p.m.–8 p.m. (local time).
- March 28, 2023, at the Marriott Chicago Naperville; 1801 N Naperville Boulevard, Naperville, IL 60563. Open House from 5:30 p.m.–6 p.m. and Public Meeting from 6 p.m.–8 p.m. (local time).
- March 30, 2023, at the Marriott Dallas/Ft. Worth Westlake; 1301 Solana Boulevard, Building 3, Westlake, Texas 76262. Open House from 5:30 p.m.–6 p.m. and Public Meeting from 6 p.m.–8 p.m. (local time).
- April 4, 2023, at the Alloy King of Prussia; 301 West DeKalb Pike, King of Prussia, Pennsylvania 19406. Open House from 5:30 p.m.–6 p.m. and Public Meeting from 6 p.m.–8 p.m. (local time).
- April 6, 2023, at the Courtyard by Marriott Atlanta Decatur Downtown/Emory; 130 Clairemont Avenue,

Decatur, GA 30303. Open House from 5:30 p.m.–6 p.m. and Public Meeting from 6 p.m.–8 p.m. (local time).

Interested stakeholders also may attend by telephone or online webinar. The public meetings will be transcribed and will include a presentation of the contents of the draft LR GEIS and proposed rule; and an opportunity for government agencies, organizations, and individuals to provide comments. No oral comments on the draft LR GEIS or proposed rule will be accepted during the open house sessions. To be considered, oral comments must be presented during the transcribed portion of the public meeting. The NRC staff also will accept written comments at any time during the public meetings. Persons interested in presenting oral comments at any of the six public meetings are encouraged to pre-register. Information for the teleconference and online webinar will be available in the meeting notices, which can be accessed through the NRC's Public Meeting Schedule at <https://www.nrc.gov/pmns/mtg>.

Members of the public also may register to provide oral comments in-person at each meeting. Individual oral comments may be limited by the time available, depending on the number of persons who register.

If special equipment or accommodations are needed to attend or present information at a public meeting, please contact Yanely Malave-Velez, telephone: 301-415-1519, email: [Yanely.Malave-Velez@nrc.gov](mailto:Yanely.Malave-Velez@nrc.gov), no later than 10 days before the designated scheduled meeting to provide the NRC staff adequate notice to determine whether the request can be accommodated.

The NRC requests that comments that are not provided during the meeting be submitted as noted in Section I, "Obtaining Information and Submitting Comments," of this document in writing by May 2, 2023.

## IV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No. 1 Federal Register citation
Proposed Rule: Renewing Nuclear Power Plant Operating Licenses—Environmental Review, March 3, 2023 .....	88 FR 13329
<b>Draft Generic Environmental Impact Statement for License Renewal of Nuclear Power Plants</b>	
Draft NUREG–1437, “Generic Environmental Impact Statement for License Renewal of Nuclear Power Plants,” Volume 1, Revision 2.	ML23010A078
Draft NUREG–1437, “Generic Environmental Impact Statement for License Renewal of Nuclear Power Plants,” Volume 2, Revision 2.	ML23010A086
<b>Draft Guidance Documents</b>	
Draft NUREG–1555, Supplement 1, Revision 2, “Standard Review Plans for Environmental Reviews for Nuclear Power Plants, Supplement 1: Operating License Renewal”.	ML22165A070
Draft Regulatory Guide DG–4027, “Preparation of Environmental Reports for Nuclear Power Plant License Renewal Applications” (also referenced as Regulatory Guide (RG) 4.2, Supplement 1).	ML22165A072

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at <https://www.regulations.gov> under Docket ID NRC–2018–0296. The Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. The following actions are needed to subscribe: (1) navigate to the docket folder NRC–2018–0296, (2) click the “Subscribe” link, and (3) enter an email address and click on the “Subscribe” link.

Dated: March 7, 2023.

For the Nuclear Regulatory Commission.

**Patricia K. Holahan,**

*Director, Subsequent License Environmental Directorate, Office of Nuclear Material Safety and Safeguards.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 14 and 1120

[Docket No. FDA–2013–N–0227]

#### **Proposed Requirements for Tobacco Products Manufacturing Practice; Tobacco Products Scientific Advisory Committee; Notice of Meeting; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee

(TPSAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues related to tobacco products. This meeting will be held to discuss and provide an opportunity for recommendations on the Requirements for Tobacco Product Manufacturing Practice (TPMP) proposed rule. The meeting will be open to the public.

**DATES:** The meeting will be held on May 18, 2023, from 9 a.m. to 2 p.m. Eastern Time.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993–0002. For those unable to attend in person, the meeting will also be webcast and will be available at the following link: <https://fda.zoomgov.com/j/1600966352?pwd=bmRrRlp1MlUrdWVmR095KzN3eWV1UT09;Passcode:Y=Sw4a>. Answers to commonly asked questions including information regarding special accommodations due to disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA has established a docket for public comment (Docket No. FDA–2013–N–0227). Please note that late, untimely filed comments will not be considered by the committee. Either electronic or written comments on this public advisory committee meeting must be submitted by May 11, 2023, for consideration by the committee. The <https://www.regulations.gov> electronic filing system will accept comments on this public advisory committee meeting until 11:59 p.m. Eastern Time at the end of May 11, 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.

Comments received on or before May 11, 2023, will be provided to the committee and become part of the docket. Comments received after May 11, 2023, and prior to September 6, 2023, will also become part of the docket, but will not be considered by the committee. In the event that the meeting is canceled, FDA will continue to evaluate any relevant information and consider any comments submitted to the docket for the TPSAC meeting, as appropriate. FDA also reminds the public that commenters may submit either electronic or written comments on the proposed rule published elsewhere in this issue of the **Federal Register** by September 6, 2023.

You may submit comments as follows:

#### *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