



DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-2006 (Proposed New Regulatory Guide)

PREPARATION OF UPDATED FINAL SAFETY ANALYSIS REPORTS FOR NON-POWER PRODUCTION OR UTILIZATION FACILITIES

A. INTRODUCTION

Purpose

This regulatory guide (RG) provides licensees of non-power production or utilization facilities (NPUFs) with a method that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for use in updating facility final safety analysis reports (FSARs).

Applicability

This RG applies to NPUFs licensed under the authority of Section 103, Section 104a, or Section 104c of the Atomic Energy Act of 1954, as amended (AEA), and sections 50.22, 50.21(a), or 50.21(c) of part 50, “Domestic Licensing of Production and Utilization Facilities,” of Title 10 of the *Code of Federal Regulations* (10 CFR) (Ref. 1).

Applicable Regulations

- 10 CFR part 50, “Domestic Licensing of Production and Utilization Facilities”
 - Section 50.71(e)(3)(iv) states, “For non-power production or utilization facility licenses issued after [EFFECTIVE DATE OF FINAL RULE], a revision of the original FSAR must be filed within 5 years of the date of issuance of the operating license. The revision must bring the FSAR up to date as of a maximum of 6 months prior to the date of filing the revision.”
 - Section 50.71(e)(4)(ii) states, “Non-power production or utilization facility licensees shall file subsequent FSAR updates at intervals not to exceed 5 years. Each update must

This regulatory guide is being issued in draft form to involve the public in the development of regulatory guidance in this area. It has not received final staff review or approval and does not represent an NRC final staff position. Public comments are being solicited on this draft guide and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Comments may be submitted through the Federal-rulemaking Web site, <http://www.regulations.gov>, by searching for Docket ID NRC-2011-0087. Alternatively, comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments must be submitted by the date indicated in the *Federal Register* notice.

Electronic copies of this draft regulatory guide, previous versions of this guide, and other recently issued guides are available through the NRC’s public Web site under the Regulatory Guides document collection of the NRC Library at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/>. The draft regulatory guide is also available through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML15323A054. The regulatory analysis may be found in ADAMS under Accession No. ML15323A058.

reflect all changes made to the FSAR up to a maximum of 6 months prior to the date of filing the update.”

Related Guidance

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content” (Ref. 2), provides guidance for applicants preparing license applications for NPUFs.
- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria” (Ref. 3), provides guidance on the NRC’s review of license applications.

Purpose of Regulatory Guides

The NRC issues RGs to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions that differ from those set forth in RGs will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This RG contains and references information collections covered by 10 CFR part 50 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), control number 3150-0011.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

Reason for Issuance

This RG provides implementing guidance for a rulemaking that established a requirement for NPUF licensees to submit an updated FSAR every five years. The NRC experienced a persistent backlog of license renewal applications for licensed facilities beginning in 2001. To minimize the potential reoccurrence of this backlog, the NRC revised 10 CFR parts 2, 50, and 51 to establish a more efficient, effective, and focused regulatory framework. This framework included periodic updates to FSARs, which created a mechanism for incorporating design and operational changes into the licensing basis as they occur. As a result, NPUF licensees will routinely update their licensing bases, and NRC staff will be made aware of changes to the licensing bases more frequently than prior to the rulemaking.

Background

This RG describes the information that should be included in submittals of FSAR revisions for NPUFs to comply with the applicable parts of 10 CFR 50.71(e). Each submittal serves to reflect changes and the effects of changes to the design basis and to assure that the information included in the FSAR contains the latest information developed by the licensee. The FSAR (as updated) helps both the NPUF licensee and the NRC ensure that the facility design and licensing bases are current. This also helps provide reasonable assurance that a facility will continue to operate without undue risk to public health and safety or the environment.

Role of the FSAR (as updated)

Once the NRC issues a license for a nuclear facility, the licensee must operate the facility in compliance with its license. Because the facility's design and operation are not static, certain changes may be necessary over the course of facility life. Licensees are required to follow NRC regulations to justify and implement any changes and the effects of changes to the design basis and licensing basis. The FSAR (as updated) provides the NRC with current design and licensing bases for a facility that is needed by the NRC in its regulatory oversight of NPUF licensees, including its use as a reference for evaluating license amendment requests and in preparation for and conduct of inspection and operator examination activities.

The NRC licensee has primary responsibility for operating its facility safely and in compliance with its license. This responsibility includes maintaining an up to date facility design basis and facility licensing basis. The FSAR (as updated) also serves to provide the general public a description of the facility and its operation.

Harmonization with International Standards

The International Atomic Energy Agency (IAEA) has established a series of specific safety guides (SSG) and Technical Documents (TECDOC) promoting a high level of safety for protecting people and the environment. These documents present international good practices and increasingly reflect best practices to help users striving to achieve high levels of safety. With respect to this RG, IAEA Specific Safety Guide, No. SSG-10, "Aging Management for Research Reactors" (Ref. 4), addresses aging considerations in different stages of the lifetime of a research reactor. The IAEA TECDOC-792, "Management of Research Reactor Aging" (Ref. 5), provides to research reactor operators a guide to understanding the behavior and influence of aging mechanisms on reactor structures, systems and components; how to detect and assess the effects of aging; and preventive and corrective measures to mitigate these effects. While the NRC has an interest in facilitating the harmonization of standards used

domestically and internationally, the agency does not specifically endorse SSG-10 or TECDOC-792 and is only acknowledging that these documents may be a useful reference for general information. The NRC could consider the use of international standards in a licensing action following adequate justification by a licensee or applicant and technical review by the NRC.

C. STAFF REGULATORY GUIDANCE

1. Content of the FSAR (as updated)
 - a. The scope of information provided through the update process should be guided by requirements for establishing the original safety analysis report in 10 CFR 50.34 and submitting periodic updates to the FSAR in 10 CFR 50.71, as augmented by the guidance of NUREG-1537, Part 1. The updated information should include all the changes necessary to reflect information and analyses prepared by the licensee since submittal of the original FSAR or, as appropriate, the last update to the FSAR. This includes any information provided in the special reports and annual reports to the NRC that requires changes to the FSAR and any information and analysis that support a licensing action (e.g., a license amendment) during the 5-year period between FSARs (as updated), such as:
 - i. Changes to the facility or facility operations resulting from new or amended regulatory requirements.
 - ii. Changes and the effects of changes to the facility or procedures and new experiments to assure the information included in the FSAR (as updated) contains the latest information developed. NPUF licensees are required by Technical Specification to make operating reports (annually) and special reports (as required). These reports should be reviewed by the licensee to determine what information should be included in the FSAR revisions submitted to the NRC to meet the requirements of 10 CFR 50.71(e). Examples include:
 1. Licensee evaluations performed under 10 CFR 50.59, “Changes, tests, and experiments,” which result in changes to the FSAR. For example:
 - a. Evaluation of major preventive or corrective maintenance operations to safety-related items that may have required facility modifications (e.g., replacing a safety-related analog meter with a digital readout; replacing a safety-related pump with one with increased flow when the flow is an analyzed condition in the FSAR; or changes to electrical and instrumentation and control drawings in the FSAR); or
 - b. Evaluation of changes in the facility and procedures, new tests or classes of experiments not previously analyzed or described in the FSAR.
 2. Licensee evaluations performed under 10 CFR 50.90, “Application for amendment of license, construction permit, or early site permit.”
 3. Licensee responses to NRC requests for additional information (RAI) which result in changes to the FSAR (e.g., during license renewal, relicensing or the amendment process).
 4. Evaluations of significant changes in the nature and amount of radioactive effluents released or discharged beyond the effective control of the licensee that effect the conclusions in the NRC’s Environmental Impact Statement (EIS) or Environmental Assessment (EA) for the facility.
 5. Evaluations of environmental surveys performed outside the facility for significant trends that affect the conclusions in the NRC’s EIS or EA for the facility.

6. Evaluations of potential facility aging to safety-related items and any aging management actions taken (e.g., repair of pool liner leakage, abandonment of underground piping).
 7. Evaluations of changes in the facility site environs (e.g., new industrial, transportation or residential facilities near the facility site or changes in the population potentially exposed to facility releases).
 8. Any licensee regulatory commitment made in licensee special reports that requires changes to the FSAR.
- b. Licensees are generally not expected to update historical information unless the licensee becomes aware of significant changes in the facility site environs. Historical information includes such material as data obtained to support or develop the original facility design basis related to natural phenomena such as geography, meteorology, geology, and seismology.
 - c. As part of the FSAR update process, licensees should remove obsolete information from the FSAR, such as structures, systems and components that are no longer installed in the facility and evaluations or other descriptions that no longer apply to the facility as described in the FSAR. The information removed from the FSAR as part of the update process should be identified and reported to the NRC with a basis for the licensee's determination that such information should be removed.
 - d. Pending licensing actions (e.g., approval of a license amendment request) need not be included if the licensing action requested has not been completed within 6 months of the date the FSAR (as updated) is required to be filed.
 - e. The NRC staff will review the updates to the FSAR in accordance with the criteria contained in NUREG-1537, Part 2.
2. Format of the FSAR (as updated)
 - a. The format of the FSAR (as updated) is at the discretion of the licensee and should generally follow the format guidance in NUREG-1537, Part 1.
 - b. The FSAR (as updated) should highlight the changed portion on each page, including the contents page. A summary of changes should accompany the FSAR (as updated).

3. Submittal of the FSAR (as updated)

- a. The FSAR (as updated) shall be submitted in accordance with 10 CFR 50.71(e)(2) which requires that the submitted FSAR include: (1) a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and (2) an identification of changes made under the provisions of Section 50.59 but not previously submitted to the Commission.
- b. The FSAR (as updated) must be submitted in accordance with 10 CFR 50.4, “Written communications.” Where practicable, licensees should electronically submit the entire document, for example via Electronic Information Exchange, e-mail, or CD-ROM. As specified in paragraph (a), “General requirements,” of 10 CFR 50.4, “Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC’s Web site at <http://www.nrc.gov/site-help/e-submittals.html>; by e-mail to MSHD.Resource@nrc.gov; or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.”
- c. Information included in the FSAR (as updated) that is considered sensitive or proprietary, that the licensee seeks to have withheld from the public, must be marked in accordance with 10 CFR 2.390, “Public inspections, exemptions, requests for withholding” (Ref. 6). Any information related to security must be submitted in accordance with 10 CFR 73.21, “Protection of Safeguards Information: Performance Requirements” (Ref. 7).

D. IMPLEMENTATION

The purpose of this section is to provide information on how applicants and licensees may use this guide and information regarding the NRC's plans for using this RG.

Applicants and licensees may use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this RG may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees may continue to use guidance that the NRC has found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.

Licensees may use the information in this RG for actions that do not require NRC review and approval. Licensees may use the information in this RG or applicable parts to resolve regulatory or inspection issues.

The NPUF licensees are not protected by the backfitting provisions in 10 CFR 50.109. The NRC staff may discuss with licensees various actions consistent with staff positions in this RG, as one acceptable means of meeting the underlying NRC regulatory requirement. However, unless this RG is part of the licensing basis for a facility, the NRC staff may not represent to the licensee that the licensee's failure to comply with the positions in this RG constitutes a violation.

GLOSSARY

Notwithstanding the definitions in 10 CFR Chapter I, for the purposes of this guide, the following definitions (derived from the referenced documents) apply:

- aging** Aging is the general process in which characteristics of structures, systems or components (SSC) change with use or time which eventually leads to degradation of materials subjected to normal service conditions, including normal operation and transient conditions under which the SSC is required to operate (derived from Ref. 5).
- aging management** Aging management is engineering, operations, and maintenance actions to control, within acceptable limits, aging degradation and wear of SSCs, including timely detection and mitigation (derived from Ref. 4).
- change** Change means a modification or addition to, or removal from the facility or procedures, that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished (derived from Ref. 8).
- design bases** Design bases means that information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be (1) restraints derived from generally accepted "state of the art" practices for achieving functional goals, or (2) requirements derived from analysis (based on calculation and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals (derived from Ref. 9).
- effects of changes** Effects of changes include appropriate revisions of descriptions in the final safety analysis report (FSAR) such that the FSAR (as updated) is complete and accurate (derived from Ref. 10).
- facility** Facility as described in the FSAR (as updated) means:
(i) The SSCs that are described in the FSAR (as updated);
(ii) The design and performance requirements for such SSCs described in the FSAR (as updated); and
(iii) The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished (derived from Ref. 11).
- FSAR (as updated)** FSAR (as updated) means the final safety analysis report (or Final Hazards Summary Report) submitted in accordance with 10 CFR 50.34, as amended and supplemented, and as updated per the requirements of Section 50.71(e) (derived from Ref. 12).
- historical information** Historical information is the information that was accurate at the time the licensee facility was originally licensed that is not expected to be updated for the life of the facility; information that is not affected by changes to the licensee facility or its operation; or information that does not change with time (derived from Ref. 13).
- licensing basis** The licensing basis for a facility is comprised of selected information exchanged between a licensee and the NRC relating to design features, equipment descriptions, operating practices, site characteristics, programs and procedures, and other factors that describe a facility's design, construction, maintenance and operation. Licensing basis information is contained in a variety of document types (e.g., final safety

analysis report, license amendments). Each licensing basis document has certain characteristics in terms of change control mechanisms, reporting of changes to the NRC, dealing with discrepancies, and possible involvement of the public (derived from Ref. 14).

non-power production or utilization facility A non-power production or utilization facility (NPUF) means a non-power reactor, testing facility, or other production or utilization facility, licensed under 10 CFR 50.21(a), 50.21(c) or 50.22 that is not a nuclear power reactor.

obsolete information Obsolete information is information about safety-related items that has been removed from the licensee facility; programs or procedures which are no longer in effect; or design information, evaluations and FSAR descriptions that no longer apply to the facility (derived from Ref. 12).

safety-related items Safety-related items are those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public; and to control or mitigate the consequences of such accidents (derived from Ref. 15).

REFERENCES¹

1. *U.S. Code of Federal Regulations (CFR)*, “Domestic Licensing of Production and Utilization Facilities,” part 50, Chapter I, Title 10, “Energy.”
2. U.S. Nuclear Regulatory Commission (NRC), “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,” NUREG-1537, Part 1, February 1996, Agencywide Document Access and Management System (ADAMS) accession number ML042430055.
3. NRC, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,” NUREG-1537, Part 2, February 1996, ADAMS accession number ML042430048.
4. International Atomic Energy Agency (IAEA), “Aging Management for Research Reactors,” Specific Safety Guide No. SSG-10, Vienna, Austria, 2010.²
5. IAEA, “Management of Research Reactor Aging (TECDOC-792),” Vienna, Austria, 1995.
6. *CFR*, “Agency Rules of Practice,” part 2, Chapter 1, Title 10, “Energy,” Section 2.390, “Public inspections, exemptions, requests for withholding.”
7. *CFR*, “Physical Protection of Plants and Materials,” part 73, Chapter 1, Title 10, “Energy,” Section 73.21, “Protection of Safeguards Information: Performance Requirements.”
8. *CFR*, “Domestic Licensing of Production and Utilization Facilities,” part 50, Chapter 1, Title 10, *Energy*, Section 50.59(a)(1).
9. *CFR*, “Domestic Licensing of Production and Utilization Facilities,” part 50, Chapter 1, Title 10, “Energy,” Section 50.2, “Definitions.”
10. *CFR*, “Domestic Licensing of Production and Utilization Facilities,” part 50, Chapter 1, Title 10, *Energy*, Section 50.71, “Maintenance of records, making of reports,” Footnote 1.
11. *CFR*, “Domestic Licensing of Production and Utilization Facilities,” part 50, Chapter 1, Title 10, “Energy,” Section 50.59(a)(3).
12. *CFR*, “Domestic Licensing of Production and Utilization Facilities,” part 50, Chapter 1, Title 10, “Energy,” Section 50.59(a)(4).

¹ Publicly available NRC documents are available electronically through the NRC Library on the NRC’s public Web site at <http://www.nrc.gov/reading-rm/doc-collections/> and through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>. The documents can also be viewed online or printed for a fee in the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD. For problems with ADAMS, contact the PDR staff at 301-415-4737 or (800) 397-4209; fax (301) 415-3548; or e-mail pdr.resource@nrc.gov.

² Copies of International Atomic Energy Agency (IAEA) documents may be obtained through their Web site: www.iaea.org/ or by writing the International Atomic Energy Agency, P.O. Box 100 Wagramer Strasse 5, A-1400 Vienna, Austria.

13. Electric Power Research Institute (EPRI) Nuclear Energy Institute (NEI) EPRI/NEI Report No. 98-03, Rev. 1, "Guidance for Updating Final Safety Analysis Reports," Palo Alto, CA, June 1999.³
14. EPRI/NEI Report No. 07-06, "Nuclear Regulatory Process," Palo Alto, CA, March 2007.
15. American Nuclear Society, "Quality Assurance Program Requirements for Research Reactors," ANSI/ANS 15.8-1995, LaGrange Park, IL.⁴

³ Copies of Electric Power Research Institute (EPRI) standards and reports may be purchased from EPRI, 3420 Hillview Ave., Palo Alto, CA 94304; telephone (800) 313-3774; fax (925) 609-1310.

⁴ Copies of American National Standards (ANS) may be purchased from the American National Standards Institute (ANSI), 1819 L Street, NW, 6th floor, Washington, DC 20036; telephone: (202) 293-8020). Purchase information is available through the ASCE Web site at <http://webstore.ansi.org/ansidocstore/>.