



[6450-01-P]

DEPARTMENT OF ENERGY

10 CFR Part 830

RIN 1992-AA57

Nuclear Safety Management

AGENCY: Office of Environment, Health, Safety and Security, U. S. Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE or the Department) is amending its regulations concerning nuclear safety management. These regulations govern the conduct of DOE contractors, DOE personnel, and other persons conducting activities (including providing items and services) that affect, or may affect, the safety of DOE nuclear facilities. The revisions reflect the experience gained in the implementation of the regulations over the past seventeen years, with specific improvements to the unreviewed safety question (USQ) process and the review and approval of safety documentation. The revisions are intended to enhance operational efficiency while maintaining robust safety performance.

DATES: This rule is effective [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***].

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I. Introduction and Background

A. Introduction

Pursuant to the Atomic Energy Act of 1954, as amended (the AEA), the Energy Reorganization Act of 1974, and the Department of Energy Organization Act of 1977, the Department of Energy (DOE or the Department) owns and leases nuclear and non-nuclear facilities at various locations in the United States. These facilities are operated either by DOE or by contractors with DOE oversight. Activities at these facilities include, but are not limited to: research, testing, production, disassembly, or transporting nuclear materials. DOE rules governing nuclear safety at these facilities are set forth in the Nuclear Safety Management rule (10 CFR part 830). The regulations were issued in response to external assessments from the National Academy of Sciences (NAS), the enactment of the Price-Anderson Amendments Act of 1988 (PAAA), and DOE efforts to improve safety at DOE nuclear facilities. Aspects of 10 CFR part 830 were finalized and

issued from 1994 to 2001, covering core safety requirements for quality assurance and facility safety basis. Over the past 17 years, DOE has gained considerable experience in the implementation of 10 CFR part 830, and is modifying the requirements to incorporate that experience and help ensure more effective safety performance.

B. Procedural History of the Rule

On December 9, 1991, DOE published an Notice of Proposed Rulemaking and Public Hearing proposing “Procedural Rules for DOE Nuclear Activities” (56 FR 64290) and a Notice of Proposed Rulemaking and Public Hearing proposing “Nuclear Safety Management” (1991 Notice, 56 FR 64316) to add Parts 820 and 830, respectively, to Title 10 of the Code of Federal Regulation (CFR).¹ Title 10 CFR part 830 was proposed to establish safety management requirements for DOE nuclear facilities. DOE issued, as final, the sections of 10 CFR part 830 related to the initial provisions (§§830.1–830.7) and Subpart A - General Provisions (§§830.100-830.120) on April 5, 1994 (1994 Notice, 59 FR 15843).

The Department issued a Notice of Limited Reopening of Comment Periods for the remaining topics to be addressed in 10 CFR part 830 on August 31, 1995 (Reopening Notice, 60 FR 45381).

On October 10, 2000, the Department published an Interim Final Rule and Opportunity for Public Comment (65 FR 60291) which amended the nuclear safety regulations to (1) establish and maintain safety bases for Hazard Category 1, 2, and 3

¹ The Department proposed 10 CFR part 820 (Part 820), *Procedural Rules for DOE Nuclear Activities*, to establish the procedural requirements for enforcement activities in accordance with PAAA. On August 17, 1993, the Department issued the Final Rule for 10 CFR part 820, *Procedural Rules for DOE Nuclear Activities* (58 FR 43680). Part 820 establishes the procedures for DOE enforcement actions and for issuing civil and criminal penalties for contractor, subcontractor, and supplier violations of DOE nuclear safety requirements. Part 820 was most recently amended on December 27th, 2016 to clarify what constitutes nuclear safety requirements.

DOE nuclear facilities and perform work in accordance with safety bases, and (2) clarify that the quality assurance work process requirements apply to standards and controls adopted to meet regulatory or contract requirements that may affect nuclear safety (Interim Final Rule). The Interim Final Rule was also issued to provide further opportunity for public comment on the rule.

Following the public comment period, the Department issued a Final Rule on January 10, 2001 (66 FR 1810).

To incorporate the past 17 years of experience into its implementation of nuclear safety management, DOE issued a Notice of Proposed Rulemaking (NPR) on 10 CFR part 830 on August 8, 2018 (83 FR 38982). The NPR proposed amending 10 CFR part 830 to: facilitate the improvement of facility hazard categorization, modify the process for defining USQs, improve DOE's approval process for facility modifications, and update definitions related to new and existing facilities. The final rule is incorporating the changes to the definition of USQs, the improvement of DOE's approval process for facility modifications, and updates to certain definitions, described in greater detail below. The final rule is not incorporating the proposed change that would have added "or successor document" to 10 CFR 830.202(b)(3), which pertains to facility hazard categorization. Further details on the changes are included in Section III. Description of the Final Rule.

II. Summary of Public Comments and Responses

DOE issued a NPR on August 8, 2018 (83 FR 38982), inviting public comment. The 60-day public comment period also included a series of four public meetings to provide additional opportunities for public input. DOE received public comments from

multiple individuals and one entity. For those comments relevant to the proposed changes, DOE provides responses and describes changes from the NOPR in the paragraphs that follow.

DOE did not finalize the proposed language regarding successor versions of hazard categorization standards. Instead, DOE intends to incorporate any future changes to hazard categorization through the rulemaking process. DOE received comments directed toward the recommendation to remove this proposed change, which have been addressed through DOE's decision on this issue.

1. Commenters indicated concern about the proposed deletion of Table 1 in Appendix A to Subpart B, which incorporated a qualitative conceptualization of the methodology for defining hazard categorization from DOE-STD-1027-92, CN1. The comments expressed concern that this proposed change, in conjunction with the proposed addition of "or successor document" to the version of DOE-STD-1027 would potentially allow for DOE to change the hazard categorization methodology without public comment.

Response: DOE maintains the removal of Table 1 in this final rule. 10 CFR part 830 continues to require categorization consistent with a specific quantitative process that is unchanged by the removal. DOE-STD-1027-92, CN1 also continues to provide multiple qualitative concepts to illuminate hazard categorization. In addition, DOE notes that if substantive changes are made to DOE-STD-1027-92, CN1, DOE would conduct a rulemaking to update the reference to DOE-STD-1027-92, CN1, in 10 CFR part 830.

2. Commenters expressed concern that the proposed removal of the approval process for annual updates in §830.202(c)(2) would make it more difficult for DOE to

exercise its authority and responsibility to protect health and minimize danger to life or property. The comments also expressed concern that DOE has not adequately assessed the nature of the problem and therefore, it was unclear if the proposed solution would suffice. The comments noted that the proposed change would place an increased emphasis on the effective implementation of the USQ process and DOE's ability to assess cumulative changes.

Response: DOE agrees that the proposed change increases the importance of an effectively implemented process for USQs. In fact, this increased importance is an intended aspect of the change, as it allows DOE to emphasize the central role the USQ process plays in gaining DOE's approval for changes. The shift to having DOE's approval occur in direct association to proposed changes is intentional and beneficial, and does not preclude DOE from directing changes nor does it present challenges to DOE in exercising its authority. The periodicity of documented safety analysis examinations is based on risk rather than rote annual reviews of changes that have already been approved. Changes to documented safety analyses as a result of positive USQ determinations will continue to be required to be submitted to DOE for review and approval.

3. Commenters expressed concern that the proposed change to the annual approval process would create gaps in how DOE approves the incorporation of changes into the safety basis with regard to Justification for Continued Operations (JCO) and Evaluation of the Safety of the Situation (ESS). In particular, comments were addressed regarding the concern that JCO's and ESS's could represent changes that would not be approved by DOE.

Response: The proposed rule provides in §830.203(d) that “A contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must obtain DOE approval prior to taking any action determined to involve a USQ.” The text has not changed from the current Rule (in §830.203(e)). While JCOs are not explicitly discussed in the Rule, DOE’s process for reviewing and approving facility safety bases (DOE-STD-1104-2016) indicates that JCOs, documents that result from positive USQ determinations, are “mechanism[s] by which a contractor may request that DOE review and approve a temporary change to the facility safety basis” and that a “JCO is associated only with situations where the PISA [Potential Inadequacy of the Safety Analysis] USQD is positive.” Given that DOE, pursuant to §830.203(d), must approve any action determined to involve a USQ, control over significant changes (JCO’s or ESS’s with a positive USQ determination) is maintained. It is understood that current DOE guidance (DOE G 424.1-1B Chg 2) and practice have frequently used the annual update to process the approval of these changes. This guidance will be updated to reflect the changes in 10 CFR part 830, but the requirement for DOE’s approval will not change.

4. Commenters were concerned with language proposed to be added to Appendix A to Subpart B that included statements that could be viewed as requirements, despite the disclaimer that the appendix does not create any new requirements. Specifically, questions were raised about the addition of the statement, “If additional changes are proposed by the contractor and included in the annual update that have not been previously approved by DOE or have not been evaluated as a part of the USQ process, DOE must review and approve these changes.”

Response: Commenters are correct that the appendix does not create new requirements. The statement referenced by the commenter restates a requirement established in the main body of the Rule. Specifically, the new addition to the appendix restates the core requirements already established in §830.203(c) and §830.203(d). It is DOE’s position that such changes should be evaluated as part of the USQ process, but this statement was included in the appendix to ensure that the past practice of using the annual update as a vehicle for DOE’s initial approval would not create confusion regarding the requirement to obtain DOE approval before taking any action DOE determined to involve a USQ.

5. Comments indicated concern that removing the requirement for DOE to approve the annual update would negatively impact DOE’s ability to review and direct changes to safety analysis documents.

Response: As stated in §830.202(c)(3), the contractor responsible for the facility must “[i]ncorporate in the safety basis any changes, conditions, or hazard controls directed by DOE”. There are no limitations placed on DOE’s review or direction. To reflect the changes in the annual update process, DOE will revise DOE-STD-1104-2016, *Review and Approval of Nuclear Facility Safety Basis and Safety Design Basis Documents*, which contains the requirements and guidance for approval of safety basis documents. The revisions will incorporate the changes in requirements within 10 CFR part 830 and provide additional guidance for their implementation.

6. A comment noted that DOE proposed deletion from Appendix A to Subpart B, *A. Introduction*, the outdated reference to DOE Policy 450.2A, *Identifying, Implementing, and Complying with Environmental, Safety and Health Requirements*

rather than updating the reference to the newest version of the policy, DOE P 450.4A Chg 1, *Integrated Safety Management Policy*.

Response: The pertinent requirements related to the referenced policy document are already contained in 10 CFR part 830. The removal of the specific reference does not change any requirements in the regulation.

7. Comments were received that recommended an alternate approach to the proposed removal of the concept of a “margin of safety” from the definition of an USQ. The comments specifically note that the Nuclear Regulatory Commission (NRC) process that made a similar change also developed additional criteria during their rulemaking.

Response: There is a long history of the “margin of safety” criteria not providing a safety benefit. DOE has determined that the diversion of effort and attention to resolving the vague application of a criteria that does not result in independent positive determinations could be a net negative impact on the safety of DOE operations. While the NRC process for large reactors has maintained additional criteria that were determined to provide value, the process the NRC uses for non-reactor facilities does not contain these additional criteria. DOE will examine the benefit of additional guidance on the impact of cumulative changes in potential revisions to guidance associated with the USQ process and DOE approval of safety analysis changes.

8. Comments received noted a small number of grammatical improvements, word choice recommendations, and typographical errors.

Response: DOE acknowledges these comments and has made several editorial improvements in the final rule.

III. Description of the Final Rule

With the exception of the changes described below, the modifications to 10 CFR part 830 adopted in this Final Rule are described in the Discussion of Proposed Rule, Proposed Changes in Order of Appearance in Section II.B of DOE’s NOPR published August 8, 2018 (83 FR 38982).

1. In §830.3 Definitions, the definition for “*Hazard Category 1, 2, and 3 DOE nuclear facilities*” was modified to remove “or successor document” pursuant to DOE’s decision not to adopt that proposed change. The definition is now that Hazard Category 1, 2, and 3 DOE nuclear facilities are nuclear facilities that meet the criteria for their respective hazard category consistent with the provisions of DOE-STD-1027-92, Change Notice 1 and that Hazard Category 1, 2, and 3 DOE nuclear facilities are required to have safety bases established in accordance with Subpart B of this part. Hazard categories are based on their radioactive material inventories and the potential consequences to the public, workers, and the environment. Hazard Category 1 represents the highest potential consequence and Hazard Category 3 represents the lowest potential consequence of the facilities required to establish safety bases.

2. In §830.202, *Safety basis*, (b)(3) now reads identically to the previous text of the Rule, with the proposed insertion of the phrase “or successor document” rescinded pursuant to DOE’s decision not to adopt that proposed change.

3. Appendix A to Subpart B to Part 830— *General Statement of Safety Basis Policy*, Section C. Scope was changed by the inclusion of a comma to improve readability, but did not change intent.

4. In Appendix A to Subpart B to Part 830— *General Statement of Safety Basis Policy*, Section F. Documented Safety Analysis (3) was changed from “USQ” to “USQ

determination” to highlight that the modifier of “positive” is more appropriately applied to a USQ determination rather than a USQ.

5. In Appendix A to Subpart B to Part 830— *General Statement of Safety Basis Policy*, Section F. Documented Safety Analysis, Table 1 (10) was changed to correct a typographical error in the previous Rule.

6. In Appendix A to Subpart B to Part 830— *General Statement of Safety Basis Policy*, Section F. Documented Safety Analysis (5) was changed to more closely link the text discussing nuclear facilities with the formal definition established in this Rule.

IV. Regulatory Review

A. Review Under Executive Order 12866

This final rulemaking has been determined not to be a significant regulatory action under Executive Order (E.O.) 12866, “Regulatory Planning and Review,” 58 FR 51735 (Oct. 4, 1993). Accordingly, this Final Rule was not subject to review by the Office of Information and Regulatory Affairs of the Office of Management and Budget.

B. Review Under Executive Orders 13771 and 13777

On January 30, 2017, the President issued Executive Order 13771, “Reducing Regulation and Controlling Regulatory Costs.” That Order stated the policy of the executive branch is to be prudent and financially responsible in the expenditure of funds, from both public and private sources. The Order stated it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations. This Final rule is expected to be an E.O. 13771 deregulatory action. Additionally, on February 24, 2017, the President issued Executive Order 13777,

“Enforcing the Regulatory Reform Agenda.” The Order required the head of each agency designate an agency official as its Regulatory Reform Officer (RRO). Each RRO oversees the implementation of regulatory reform initiatives and policies to ensure that agencies effectively carry out regulatory reforms, consistent with applicable law. Further, E.O. 13777 requires the establishment of a regulatory task force at each agency. The regulatory task force is required to make recommendations to the agency head regarding the repeal, replacement, or modification of existing regulations, consistent with applicable law. At a minimum, each regulatory reform task force must attempt to identify regulations that:

- (i) Eliminate jobs, or inhibit job creation;
- (ii) Are outdated, unnecessary, or ineffective;
- (iii) Impose costs that exceed benefits;
- (iv) Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;
- (v) Are inconsistent with the requirements of Information Quality Act, or the guidance issued pursuant to that Act, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or
- (vi) Derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.

DOE concludes that this Final rule is consistent with the directives set forth in these executive orders. These provisions in this Final rule are intended, as described in section

II, to enhance operational efficiency while maintaining robust safety performance at DOE nuclear facilities.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, “Proper Consideration of Small Entities in Agency Rulemaking,” 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process (68 FR 7990). DOE has made its procedures and policies available on the Office of the General Counsel’s website (<http://energy.gov/gc/office-general-counsel>)

DOE has reviewed this Final rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. The Final rule will incorporate the experience of more than a decade of implementation to improve the effectiveness of the DOE nuclear safety regulatory framework while maintaining safety performance.

This Final rule is expected to reduce burden on affected DOE contractors. On this basis, DOE certified that this Final rule would not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking. DOE’s certification and supporting statement of factual basis were provided to the Chief Counsel for Advocacy of the Small Business Administration pursuant to 5 U.S.C. 605(b). DOE received no comments on the certification or the economic impact of the proposed rule.

D. Paperwork Reduction Act

The information collection necessary to administer DOE's nuclear safety program under 10 CFR part 830 is subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq. The information collection provisions of this Rule are included in the information collection requirements contained in DOE contracts with DOE prime contractors covered by this Rule and were previously approved by the Office of Management and Budget (OMB) and under OMB Control No. 1910-0300. Public reporting burden for the certification is estimated to average 1.91 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

E. National Environmental Policy Act

DOE has determined that this Final rule is covered under the Categorical Exclusion in DOE's National Environmental Policy Act regulations at paragraph A.5 of Appendix A to Subpart D, 10 CFR part 1021, which applies to rulemaking that interprets or amends an existing rule or regulation without changing the environmental effect of the rule or regulation that is being amended. The Final rule will amend DOE's regulations by removing duplicative approval requirements, updating definitions, and increasing the

efficiency of internal processes. These changes are primarily procedural and will not change the environmental effect of 10 CFR part 830. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

F. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Pub. L. 104-4, sec. 201 (codified at 2 U.S.C. 1531). For regulatory actions likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a),(b)) UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a “significant intergovernmental mandate,” and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA (62 FR 12820). (This policy is also available at <http://energy.gov/gc/office-general-counsel>.) DOE examined this Final rule according to UMRA and its statement of policy and has determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure by State,

local, and Tribal government, in the aggregate, or by the private sector, of \$100 million or more in any year. Accordingly, no further assessment or analysis is required under UMRA.

G. Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999, 5 U.S.C. 601 note, requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule that may affect family wellbeing. This Final rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

H. Review Under Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (Aug. 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined this Final rule and has determined that it would not preempt State law and would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

I. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, “Civil Justice Reform,” 61 FR 4729 (Feb. 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this Final rule meets the relevant standards of Executive Order 12988.

J. Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001, 44 U.S.C. 3516 note, provides for agencies to review most disseminations of information to the public

under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this Final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to the Office of Information and Regulatory Affairs (OIRA) a Statement of Energy Effects for any proposed significant energy action. A "significant energy action" is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. This regulatory action has been determined to not be a significant regulatory action, and it would not have an adverse effect on the supply, distribution, or use of energy. Thus, this action is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

L. Congressional Notification

As required by 5 U.S.C. 801, DOE will submit to Congress a report regarding the issuance of this final rule prior to the effective date set forth at the outset of this rulemaking. The report will state that it has been determined that the rule is not a “major rule” as defined by 5 U.S.C. 804(2).

V. Approval of the Office of the Secretary

The Secretary of Energy has approved the publication of this final rule.

List of Subjects in 10 CFR Part 830

Administrative practice and procedure, DOE contracts, Environment, Federal buildings and facilities, Government contracts, Nuclear materials, Nuclear power plants and reactors, Nuclear safety, Penalties, Public health, Reporting and recordkeeping requirements, and Safety.

Signing Authority

This document of the Department of Energy was signed on August 24, 2020, by Dan Brouillette, Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative

process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on August 27, 2020.

Treena V. Garrett
Federal Register Liaison Officer,
U.S. Department of Energy

For the reasons stated in the preamble, DOE revises part 830 of title 10 of the Code of Federal Regulations as set forth below:

PART 830—NUCLEAR SAFETY MANAGEMENT

Sec.

830.1 Scope.

830.2 Exclusions.

830.3 Definitions.

830.4 General requirements.

830.5 Enforcement.

830.6 Recordkeeping.

830.7 Graded approach.

Subpart A—Quality Assurance Requirements

830.120 Scope.

830.121 Quality Assurance Program (QAP).

830.122 Quality assurance criteria.

Subpart B—Safety Basis Requirements

830.200 Scope.

830.201 Performance of work.

830.202 Safety basis.

830.203 Unreviewed safety question process.

830.204 Documented safety analysis.

830.205 Technical safety requirements.

830.206 Preliminary documented safety analysis.

830.207 DOE approval of safety basis.

Appendix A to Subpart B to Part 830—General Statement of Safety Basis Policy

Authority: 42 U.S.C. 2201; 42 U.S.C. 7101 *et seq.*; and 50 U.S.C. 2401 *et seq.*

§ 830.1 Scope.

This part governs the conduct of DOE contractors, DOE personnel, and other persons conducting activities (including providing items and services) that affect, or may affect, the safety of DOE nuclear facilities.

§ 830.2 Exclusions.

This part does not apply to:

(a) Activities that are regulated through a license by the Nuclear Regulatory Commission (NRC) or a State under an Agreement with the NRC, including activities certified by the NRC under section 1701 of the Atomic Energy Act (Act);

(b) Activities conducted under the authority of the Director, Naval Nuclear Propulsion, pursuant to Executive Order 12344, as set forth in Public Law 106– 65;

(c) Transportation activities which are regulated by the Department of Transportation;

(d) Activities conducted under the Nuclear Waste Policy Act of 1982, as amended, and any facility identified under section 202(5) of the Energy Reorganization Act of 1974, as amended; and

(e) Activities related to the launch approval and actual launch of nuclear energy systems into space.

§ 830.3 Definitions.

(a) The following definitions apply to this part:

Administrative controls means the provisions relating to organization and management, procedures, recordkeeping, assessment, and reporting necessary to ensure safe operation of a facility.

Bases appendix means an appendix that describes the basis of the limits and other requirements in technical safety requirements.

Critical assembly means special nuclear devices designed and used to sustain nuclear reactions, which may be subject to frequent core and lattice configuration change and which frequently may be used as mockups of reactor configurations.

Criticality means the condition in which a nuclear fission chain reaction becomes self-sustaining.

Design features means the design features of a nuclear facility specified in the technical safety requirements that, if altered or modified, would have a significant effect on safe operation.

Document means recorded information that describes, specifies, reports, certifies, requires, or provides data or results.

Documented safety analysis means a documented analysis of the extent to which a nuclear facility can be operated safely with respect to workers, the public, and the environment, including a description of the conditions, safe boundaries, and hazard controls that provide the basis for ensuring safety.

Environmental restoration activities means the process(es) by which contaminated sites and facilities are identified and characterized and by which contamination is contained, treated, or removed and disposed.

Fissionable materials means a nuclide capable of sustaining a neutron-induced chain reaction (e.g., uranium-233, uranium-235, plutonium-238, plutonium-239, plutonium-241, neptunium-237, americium-241, and curium-244).

Graded approach means the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement in this part are commensurate with:

- (1) The relative importance to safety, safeguards, and security;
- (2) The magnitude of any hazard involved;
- (3) The life cycle stage of a facility;

- (4) The programmatic mission of a facility;
- (5) The particular characteristics of a facility;
- (6) The relative importance of radiological and nonradiological hazards; and
- (7) Any other relevant factor.

Hazard means a source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation).

Hazard Category 1, 2, and 3 DOE nuclear facilities means nuclear facilities that meet the criteria for their respective hazard category consistent with the provisions of DOE-STD-1027-92, Change Notice 1. Hazard Category 1, 2, and 3 DOE nuclear facilities are required to have safety bases established in accordance with Subpart B of this part. Hazard categories are based on their radioactive material inventories and the potential consequences to the public, workers, and the environment. Hazard Category 1 represents the highest potential consequence and Hazard Category 3 represents the lowest potential consequence of the facilities required to establish safety bases.

Hazard controls means measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment, including:

- (1) Physical, design, structural, and engineering features;
- (2) Safety structures, systems, and components;
- (3) Safety management programs;
- (4) Technical safety requirements; and
- (5) Other controls necessary to provide adequate protection from hazards.

Item is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, or support systems.

Limiting conditions for operation means the limits that represent the lowest functional capability or performance level of safety structures, systems, and components required for safe operations.

Limiting control settings means the settings on safety systems that control process variables to prevent exceeding a safety limit.

Low-level residual fixed radioactivity means the remaining radioactivity following reasonable efforts to remove radioactive systems, components, and stored materials. The remaining radioactivity is composed of surface contamination that is fixed following chemical cleaning or some similar process; a component of surface contamination that can be picked up by smears; or activated materials within structures. The radioactivity can be characterized as low-level if the smearable radioactivity is less than the values defined for removable contamination by 10 CFR part 835, Appendix D, Surface Contamination Values, and the hazard analysis results show that no credible accident scenario or work practices would release the remaining fixed radioactivity or activation components at levels that would prudently require the use of active safety systems, structures, or components to prevent or mitigate a release of radioactive materials.

Major modification means a modification to a DOE nuclear facility that substantially changes the existing safety basis for the facility.

New Hazard Category 1, 2, and 3 DOE nuclear facility means a Hazard Category 1, 2, or 3 DOE nuclear facility that is in design or under construction that does not yet have a DOE approved safety basis.

Nonreactor nuclear facility means those facilities, activities or operations that involve, or will involve, radioactive and/or fissionable materials in such form and quantity that a nuclear or a nuclear explosive hazard potentially exists to workers, the public, or the environment, but does not include accelerators and their operations and does not include activities involving only incidental use and generation of radioactive materials or radiation such as check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines.

Nuclear facility means a reactor or a nonreactor nuclear facility where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established by this Part.

Operating limits means those limits required to ensure the safe operation of a nuclear facility, including limiting control settings and limiting conditions for operation.

Preliminary documented safety analysis means documentation prepared in connection with the design and construction of a new Hazard Category 1, 2, or 3 DOE nuclear facility or a major modification to an existing Hazard Category 1, 2, or 3 DOE nuclear facility that provides a reasonable basis for the preliminary conclusion that the nuclear facility can be operated safely through the consideration of factors such as:

- (1) The nuclear safety design criteria to be satisfied;

(2) A safety analysis that derives aspects of design that are necessary to satisfy the nuclear safety design criteria; and

(3) An initial listing of the safety management programs that must be developed to address operational safety considerations.

Process means a series of actions that achieves an end or result.

Quality means the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality assurance means all those actions that provide confidence that quality is achieved.

Quality Assurance Program (QAP) means the overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Reactor means any apparatus that is designed or used to sustain nuclear chain reactions in a controlled manner such as research, test, and power reactors, and critical and pulsed assemblies and any assembly that is designed to perform subcritical experiments that could potentially reach criticality; and, unless modified by words such as containment, vessel, or core, refers to the entire facility, including the housing, equipment and associated areas devoted to the operation and maintenance of one or more reactor cores.

Record means a completed document or other media that provides objective evidence of an item, service, or process.

Safety basis means the documented safety analysis and hazard controls that provide reasonable assurance that a DOE nuclear facility can be operated safely in a manner that adequately protects workers, the public, and the environment.

Safety class structures, systems, and components means the structures, systems, or components, including portions of process systems, whose preventive or mitigative function is necessary to limit radioactive hazardous material exposure to the public, as determined from safety analyses.

Safety evaluation report means the report prepared by DOE to document:

(1) The sufficiency of the documented safety analysis for a Hazard Category 1, 2, or 3 DOE nuclear facility;

(2) The extent to which a contractor has satisfied the requirements of Subpart B of this part; and

(3) The basis for approval by DOE of the safety basis for the facility, including any conditions for approval.

Safety limits means the limits on process variables associated with those safety class physical barriers, generally passive, that are necessary for the intended facility function and that are required to guard against the uncontrolled release of radioactive materials.

Safety management program means a program designed to ensure a facility is operated in a manner that adequately protects workers, the public, and the environment by covering a topic such as: quality assurance; maintenance of safety systems; personnel training; conduct of operations; inadvertent criticality protection; emergency

preparedness; fire protection; waste management; or radiological protection of workers, the public, and the environment.

Safety management system means an integrated safety management system established consistent with 48 CFR 970.5223–1, *Integration of environment, safety, and health into work planning and execution*.

Safety significant structures, systems, and components means the structures, systems, and components which are not designated as safety class structures, systems, and components, but whose preventive or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses.

Safety structures, systems, and components means both safety class structures, systems, and components and safety significant structures, systems, and components.

Service means the performance of work, such as design, manufacturing, construction, fabrication, assembly, decontamination, environmental restoration, waste management, laboratory sample analyses, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

Surveillance requirements means requirements relating to test, calibration, or inspection to ensure that the necessary operability and quality of safety structures, systems, and components and their support systems required for safe operations are maintained, that facility operation is within safety limits, and that limiting control settings and limiting conditions for operation are met.

Technical safety requirements (TSRs) means the limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and the hazards identified in

the documented safety analysis for the facility: Safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix.

Unreviewed Safety Question (USQ) means a situation where:

(1) The probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the documented safety analysis could be increased;

(2) The possibility of an accident or malfunction of a different type than any evaluated previously in the documented safety analysis could be created; or

(3) The documented safety analysis may not be bounding or may be otherwise inadequate.

Unreviewed Safety Question process means the mechanism for keeping a safety basis current by reviewing potential unreviewed safety questions, reporting unreviewed safety questions to DOE, and obtaining approval from DOE prior to taking any action that involves an unreviewed safety question.

Use and application provisions means the basic instructions for applying technical safety requirements.

(b) Terms defined in the Act or in 10 CFR part 820 and not defined in this section of the rule are to be used consistent with the meanings given in the Act or in 10 CFR part 820.

§ 830.4 General requirements.

(a) No person may take or cause to be taken any action inconsistent with the requirements of this part.

(b) A contractor responsible for a nuclear facility must ensure implementation of, and compliance with, the requirements of this part.

(c) The requirements of this part must be implemented in a manner that provides reasonable assurance of adequate protection of workers, the public, and the environment from adverse consequences, taking into account the work to be performed and the associated hazards.

(d) If there is no contractor for a DOE nuclear facility, DOE must ensure implementation of, and compliance with, the requirements of this part.

§ 830.5 Enforcement.

The requirements in this part are DOE Nuclear Safety Requirements and are subject to enforcement by all appropriate means, including the imposition of civil and criminal penalties in accordance with the provisions of 10 CFR part 820.

§ 830.6 Recordkeeping.

A contractor must maintain complete and accurate records as necessary to substantiate compliance with the requirements of this part.

§ 830.7 Graded approach.

Where appropriate, a contractor must use a graded approach to implement the requirements of this part, document the basis of the graded approach used, and submit that documentation to DOE. The graded approach may not be used in implementing the unreviewed safety question (USQ) process or in implementing technical safety requirements.

Subpart A—Quality Assurance Requirements

§ 830.120 Scope.

This subpart establishes quality assurance requirements for contractors conducting activities, including providing items or services that affect, or may affect, nuclear safety of DOE nuclear facilities.

§ 830.121 Quality Assurance Program (QAP).

(a) Contractors conducting activities, including providing items or services, that affect, or may affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the Quality Assurance criteria in §830.122.

(b) The contractor responsible for a DOE nuclear facility must:

(1) Submit a QAP to DOE for approval and regard the QAP as approved 90 days after submittal, unless it is approved or rejected by DOE at an earlier date.

(2) Modify the QAP as directed by DOE.

(3) Annually submit any changes to the DOE-approved QAP to DOE for approval. Justify in the submittal why the changes continue to satisfy the quality assurance requirements.

(4) Conduct work in accordance with the QAP.

(c) The QAP must:

(1) Describe how the quality assurance criteria of §830.122 are satisfied.

(2) Integrate the quality assurance criteria with the Safety Management System, or describe how the quality assurance criteria apply to the Safety Management System.

(3) Use voluntary consensus standards in its development and implementation, where practicable and consistent with contractual and regulatory requirements, and identify the standards used.

(4) Describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of §830.122.

§ 830.122 Quality assurance criteria.

The QAP must address the following management, performance, and assessment criteria:

(a) *Criterion 1—Management/Program.* (1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

(2) Establish management processes, including planning, scheduling, and providing resources for the work.

(b) *Criterion 2—Management/Personnel Training and Qualification.* (1) Train and qualify personnel to be capable of performing their assigned work.

(2) Provide continuing training to personnel to maintain their job proficiency.

(c) *Criterion 3—Management/Quality Improvement.* (1) Establish and implement processes to detect and prevent quality problems.

(2) Identify, control, and correct items, services, and processes that do not meet established requirements.

(3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.

(4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

(d) *Criterion 4—Management/Documents and Records.* (1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.

(2) Specify, prepare, review, approve, and maintain records.

(e) *Criterion 5—Performance/Work Processes.* (1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.

(2) Identify and control items to ensure their proper use.

(3) Maintain items to prevent their damage, loss, or deterioration.

(4) Calibrate and maintain equipment used for process monitoring or data collection.

(f) *Criterion 6—Performance/Design.* (1) Design items and processes using sound engineering/scientific principles and appropriate standards.

(2) Incorporate applicable requirements and design bases in design work and design changes.

(3) Identify and control design interfaces.

(4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.

(5) Verify or validate work before approval and implementation of the design.

(g) *Criterion 7—Performance/ Procurement.* (1) Procure items and services that meet established requirements and perform as specified.

(2) Evaluate and select prospective suppliers on the basis of specified criteria.

Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

(h) *Criterion 8—Performance/ Inspection and Acceptance Testing.* (1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.

(2) Calibrate and maintain equipment used for inspections and tests.

(i) *Criterion 9—Assessment/ Management Assessment.* Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

(j) *Criterion 10—Assessment/ Independent Assessment.* (1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.

(2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments.

(3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.

Subpart B—Safety Basis Requirements

§ 830.200 Scope.

This Subpart establishes safety basis requirements for Hazard Category 1, 2, and 3 DOE nuclear facilities.

§ 830.201 Performance of work.

A contractor must perform work in accordance with the DOE-approved safety basis for a Hazard Category 1, 2, or 3 DOE nuclear facility and, in particular, with the

hazard controls that ensure adequate protection of workers, the public, and the environment.

§ 830.202 Safety basis.

(a) The contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must establish and maintain the safety basis for the facility.

(b) In establishing the safety basis for a Hazard Category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the facility must:

(1) Define the scope of the work to be performed;

(2) Identify and analyze the hazards associated with the work;

(3) Categorize the facility consistent with DOE–STD–1027–92 (“Hazard Categorization and Accident Analysis Techniques for compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports,” Change Notice 1, September 1997);

(4) Prepare a documented safety analysis for the facility; and

(5) Establish the hazard controls upon which the contractor will rely to ensure adequate protection of workers, the public, and the environment.

(c) In maintaining the safety basis for a Hazard Category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the facility must:

(1) Update the safety basis to keep it current and to reflect changes in the facility, the work and the hazards as they are analyzed in the documented safety analysis;

(2) Annually provide DOE the current documented safety analysis or a letter stating that there have been no changes in the documented safety analysis since the prior submittal; and

(3) Incorporate in the safety basis any changes, conditions, or hazard controls directed by DOE.

§ 830.203 Unreviewed safety question process.

(a) The contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must establish, implement, and take actions consistent with a DOE-approved USQ procedure that meets the requirements of this section.

(b) The contractor responsible for a new Hazard Category 1, 2, or 3 DOE nuclear facility must submit for DOE approval a procedure for its USQ process on a schedule that allows DOE approval in a safety evaluation report issued pursuant to §830. 207(a) of this part.

(c) The contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must implement the DOE-approved USQ procedure in situations where there is a:

(1) Temporary or permanent change in the facility as described in the existing documented safety analysis;

(2) Temporary or permanent change in the procedures as described in the existing documented safety analysis;

(3) Test or experiment not described in the existing documented safety analysis;

or

(4) Potential inadequacy of the documented safety analysis because the analysis potentially may not be bounding or may be otherwise inadequate.

(d) A contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must obtain DOE approval prior to taking any action determined to involve a USQ.

(e) The contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must annually provide to DOE a summary of the USQ determinations performed since the prior submittal.

(f) If a contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility discovers or is made aware of a potential inadequacy of the documented safety analysis, it must:

(1) Take action, as appropriate, to place or maintain the facility in a safe condition until an evaluation of the safety of the situation is completed;

(2) Notify DOE of the situation;

(3) Perform a USQ determination and notify DOE promptly of the results; and

(4) Submit the evaluation of the safety of the situation to DOE prior to removing any operational restrictions initiated to meet paragraph (f)(1) of this section.

§ 830.204 Documented safety analysis.

(a) The contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must obtain approval from DOE for the methodology used to prepare the documented safety analysis for the facility unless the contractor uses a methodology set forth in Table 1 of Appendix A to this part.

(b) The documented safety analysis for a Hazard Category 1, 2, or 3 DOE nuclear facility must, as appropriate for the complexities and hazards associated with the facility:

(1) Describe the facility (including the design of safety structures, systems and components) and the work to be performed;

(2) Provide a systematic identification of both natural and man-made hazards associated with the facility;

(3) Evaluate normal, abnormal, and accident conditions, including consideration of natural and man-made external events, identification of energy sources or processes that might contribute to the generation or uncontrolled release of radioactive and other hazardous materials, and consideration of the need for analysis of accidents which may be beyond the design basis of the facility;

(4) Derive the hazard controls necessary to ensure adequate protection of workers, the public, and the environment, demonstrate the adequacy of these controls to eliminate, limit, or mitigate identified hazards, and define the process for maintaining the hazard controls current at all times and controlling their use;

(5) Define the characteristics of the safety management programs necessary to ensure the safe operation of the facility, including (where applicable) quality assurance, procedures, maintenance, personnel training, conduct of operations, emergency preparedness, fire protection, waste management, and radiation protection; and

(6) With respect to a nonreactor nuclear facility with fissionable material in a form and amount sufficient to pose a potential for criticality, define a criticality safety program that:

(i) Ensures that operations with fissionable material remain subcritical under all normal and credible abnormal conditions;

(ii) Identifies applicable nuclear criticality safety standards; and

(iii) Describes how the program meets applicable nuclear criticality safety standards.

§ 830.205 Technical safety requirements.

(a) A contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must:

(1) Develop technical safety requirements that are derived from the documented safety analysis;

(2) Prior to use, obtain DOE approval of technical safety requirements and any change to technical safety requirements; and

(3) Notify DOE of any violation of a technical safety requirement.

(b) A contractor may take emergency actions that depart from an approved technical safety requirement when no actions consistent with the technical safety requirement are immediately apparent, and when these actions are needed to protect workers, the public or the environment from imminent and significant harm. Such actions must be approved by a certified operator for a reactor or by a person in authority as designated in the technical safety requirements for nonreactor nuclear facilities. The contractor must report the emergency actions to DOE as soon as practicable.

(c) A contractor for an environmental restoration activity may follow the provisions of 29 CFR 1910.120 or 29 CFR 1926.65 to develop the appropriate hazard controls (rather than the provisions for technical safety requirements in paragraph (a) of this section), provided the activity involves either:

(1) Work not done within a permanent structure, or

(2) The decommissioning of a facility with only low-level residual fixed radioactivity.

§ 830.206 Preliminary documented safety analysis.

Prior to construction of a new Hazard Category 1, 2, or 3 DOE nuclear facility or a major modification to an existing Hazard Category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the design and construction of the new facility or major modification must:

(a) Prepare a preliminary documented safety analysis for the facility, and

(b) Obtain DOE approval of:

(1) The nuclear safety design criteria to be used in preparing the preliminary documented safety analysis unless the contractor uses the design criteria in DOE Order 420.1, *Facility Safety*, or successor document; and

(2) The preliminary documented safety analysis before the contractor can procure materials or components or begin construction; provided that DOE may authorize the contractor to perform limited procurement and construction activities without approval of a preliminary documented safety analysis if DOE determines that the activities are not detrimental to public health and safety and are in the best interests of DOE.

§ 830.207 DOE approval of safety basis.

(a) With respect to a new Hazard Category 1, 2, or 3 DOE nuclear facility or a major modification to an existing Hazard Category 1, 2, or 3 DOE nuclear facility, a contractor may not begin operation of the facility or modification prior to the issuance of a safety evaluation report in which DOE approves the safety basis for the facility or modification.

(b) Pending issuance of a safety evaluation report in which DOE approves an updated or amended safety basis for an existing Hazard Category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the facility must continue to perform work in

accordance with the DOE-approved safety basis for the facility and maintain the existing safety basis consistent with the requirements of this Subpart.

Appendix A to Subpart B to Part 830— General Statement of Safety Basis Policy

A. Introduction

This appendix describes DOE’s expectations for the safety basis requirements of 10 CFR part 830, acceptable methods for implementing these requirements, and criteria DOE will use to evaluate compliance with these requirements. This appendix does not create any new requirements and should be used consistently with DOE’s policy that work be conducted safely and efficiently and in a manner that ensures protection of workers, the public, and the environment.

B. Purpose

1. The safety basis requirements of Part 830 require the contractor responsible for a DOE nuclear facility to analyze the facility, the work to be performed, and the associated hazards and to identify the conditions, safe boundaries, and hazard controls necessary to protect workers, the public and the environment from adverse consequences. These analyses and hazard controls constitute the safety basis upon which the contractor and DOE rely to conclude that the facility can be operated safely. Performing work consistent with the safety basis provides reasonable assurance of adequate protection of workers, the public, and the environment.

2. The safety basis requirements are intended to further the objective of making safety an integral part of how work is performed throughout the DOE complex.

Developing a thorough understanding of a nuclear facility, the work to be performed, the

associated hazards and the needed hazard controls is essential to integrating safety into management and work at all levels. Performing work in accordance with the safety basis for a nuclear facility is the realization of that objective.

C. Scope

1. A contractor must establish and maintain a safety basis for a Hazard Category 1, 2, or 3 DOE nuclear facility because these facilities have the potential for significant radiological consequences. DOE–STD–1027 sets forth the methodology for categorizing a DOE nuclear facility based on the inventory of radioactive materials.

2. Unlike the quality assurance requirements of Part 830 that apply to all DOE nuclear facilities, the safety basis requirements only apply to Hazard Category 1, 2, and 3 DOE nuclear facilities and do not apply to nuclear facilities below Hazard Category 3.

D. Integrated Safety Management

1. The safety basis requirements are consistent with integrated safety management. DOE expects that, if a contractor complies with the Department of Energy Acquisition Regulation (DEAR) clause on integration of environment, safety, and health into work planning and execution (48 CFR 970.5223–1, *Integration of Environment, Safety and Health into Work Planning and Execution*) and the DEAR clause on laws, regulations, and DOE directives (48 CFR 970.5204–2, *Laws, Regulations and DOE Directives*), the contractor will have established the foundation to meet the safety basis requirements.

2. The processes embedded in a safety management system should lead to a contractor establishing adequate safety bases and safety management programs that will meet the safety basis requirements of this Subpart. Consequently, the DOE expects if a

contractor has adequately implemented integrated safety management, few additional requirements will stem from this Subpart and, in such cases, the existing safety basis prepared in accordance with integrated safety management provisions, including existing DOE safety requirements in contracts, should meet the requirements of this Subpart.

3. DOE does not expect there to be any conflict between contractual requirements and regulatory requirements. In fact, DOE expects that contract provisions will be used to provide more detail on implementation of safety basis requirements such as preparing a documented safety analysis, developing technical safety requirements, and implementing a USQ process.

E. Enforcement of Safety Basis Requirements

1. Enforcement of the safety basis requirements will be performance oriented. That is, DOE will focus its enforcement efforts on whether a contractor operates a nuclear facility consistent with the safety basis for the facility and, in particular, whether work is performed in accordance with the safety basis.

2. As part of the approval process, DOE will review the content and quality of the safety basis documentation. DOE intends to use the approval process to assess the adequacy of a safety basis developed by a contractor to ensure that workers, the public, and the environment are provided reasonable assurance of adequate protection from identified hazards. Once approved by DOE, the safety basis documentation will not be subject to regulatory enforcement actions unless DOE determines that the information which supports the documentation is not complete and accurate in all material respects, as required by 10 CFR 820.11. This is consistent with the DOE enforcement provisions and policy in 10 CFR part 820.

3. DOE does not intend the adoption of the safety basis requirements to affect the existing quality assurance requirements or the existing obligation of contractors to comply with the quality assurance requirements. In particular, in conjunction with the adoption of the safety basis requirements, DOE revised the language in 10 CFR 830.122(e)(1) to make clear that hazard controls are part of the work processes to which a contractor and other persons must adhere when performing work. This obligation to perform work consistent with hazard controls adopted to meet regulatory or contract requirements existed prior to the adoption of the safety basis requirements and is both consistent with and independent of the safety basis requirements.

4. A documented safety analysis must address all hazards (that is, both radiological and nonradiological hazards) and the controls necessary to provide adequate protection to the public, workers, and the environment from these hazards. Section 234A of the Atomic Energy Act only authorizes DOE to issue civil penalties for violations of requirements related to nuclear safety. Therefore, DOE will impose civil penalties for violations of the safety basis requirements (including hazard controls) only if they are related to nuclear safety.

F. Documented Safety Analysis

1. A documented safety analysis must demonstrate the extent to which a nuclear facility can be operated safely with respect to workers, the public, and the environment.

2. DOE expects a contractor to use a graded approach to develop a documented safety analysis and describe how the graded approach was applied. The level of detail, analysis, and documentation will reflect the complexity and hazards associated with a particular facility. Thus, the documented safety analysis for a simple, low hazard facility

may be relatively short and qualitative in nature, while the documented safety analysis for a complex, high hazard facility may be quite elaborate and more quantitative. DOE will work with its contractors to ensure a documented safety analysis is appropriate for the facility for which it is being developed.

3. Because DOE has ultimate responsibility for the safety of its facilities, DOE will review each documented safety analysis:

(i) As part of the initial submittal;

(ii) When revisions are submitted as part of a positive USQ determination or major modification;

(iii) If DOE has reason to believe a portion of the safety basis to be inadequate, or;

(iv) If DOE has reason to believe a portion of the safety basis has substantially changed. DOE will review the documented safety analysis to determine whether the rigor and detail of the documented safety analysis are appropriate for the complexity and hazards expected at the nuclear facility. In particular, DOE will evaluate the documented safety analysis by considering the extent to which the documented safety analysis:

(A) Satisfies the provisions of the methodology used to prepare the documented safety analysis and

(B) Adequately addresses the criteria set forth in 10 CFR 830.204(b). DOE will prepare a Safety Evaluation Report to document the results of its review of the documented safety analysis. A documented safety analysis must contain any conditions or changes required by DOE in the Safety Evaluation Report. Generally, DOE's review of the annual submittal may be limited to ensuring that the results of USQs have been

adequately incorporated into the documented safety analysis. If additional changes are proposed by the contractor and included in the annual update that have not been previously approved by DOE or have not been evaluated as a part of the USQ process, DOE must review and approve these changes. DOE has the authority to review the safety basis at any time.

4. In most cases, the contract will provide the framework for specifying the methodology and schedule for developing a documented safety analysis. Table 1 sets forth acceptable methodologies for preparing a documented safety analysis.

Table 1

The contractor responsible for:	May prepare its document safety analysis by:
(1) A DOE reactor	Using the method in U.S. Nuclear Regulatory Commission Regulatory Guide 1.70, Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants, or successor document.
(2) A DOE nonreactor nuclear facility	Using the method in DOE–STD–3009, Change Notice No. 1, January 2000, Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Safety Analysis Reports, July 1994, or successor document.
(3) A DOE nuclear facility with a limited operational life	Using the method in either: (i)DOE-STD–3009-, Change Notice No. 1, January 2000, or successor document, or (ii)DOE-STD–3011–94, Guidance for Preparation of DOE 5480.22 (TSR) and DOE 5480.23 (SAR) Implementation Plans, November 1994, or successor document.
(4) The deactivation or the transition surveillance and maintenance of a DOE nuclear facility	Using the method in either:

	<p>(i)DOE-STD-3009, Change Notice No. 1, January 2000, or successor document, or</p> <p>(ii)DOE-STD-3011-94 or successor document.</p>
(5) The decommissioning of a DOE nuclear facility	<p>(i)Using the method in DOE-STD-1120-98, Integration of Environment, Safety, and Health into Facility Disposition Activities, May 1998, or successor document;</p> <p>(ii)Using the provisions in 29 CFR 1910.120 (or 29 CFR 1926.65 for construction activities) for developing Safety and Health Programs, Work Plans, Health and Safety Plans, and Emergency Response Plans to address public safety, as well as worker safety; and</p> <p>(iii)Deriving hazard controls based on the Safety and Health Programs, the Work Plans, the Health and Safety Plans, and the Emergency Response Plans.</p>
(6) A DOE environmental restoration activity that involves either work not done within a permanent structure or the decommissioning of a facility with only low-level residual fixed radioactivity	<p>(i)Using the method in DOE-STD-1120-98 or successor document, and</p> <p>(ii)Using the provisions in 29 CFR 1910.120 (or 29 CFR 1926.65 for construction activities) for developing a Safety and Health Program and a site-specific Health and Safety Plan (including elements for Emergency Response Plans, conduct of operations, training and qualifications, and maintenance management).</p>
(7) A DOE nuclear explosive facility and the nuclear explosive operations conducted therein.	<p>Developing its documented safety analysis in two pieces:</p> <p>(i)A Safety Analysis Report for the nuclear facility that considers the generic nuclear explosive operations and is prepared in accordance with DOE-STD-3009, Change Notice No. 1, January 2000, or successor document, and</p> <p>(ii)A Hazard Analysis Report for the specific nuclear explosive operations prepared in accordance with DOE-STD-3016-99, Hazards Analysis Reports for Nuclear Explosive Operations, February 1999, or successor document.</p>

<p>(8) A DOE Hazard Category 3 nonreactor nuclear facility</p>	<p>Using the methods in Chapters 2, 3, 4, and 5 of DOE-STD-3009, Change Notice No. 1, January 2000, or successor document to address in a simplified fashion:</p> <ul style="list-style-type: none"> (i)The basic description of the facility/activity and its operations, including safety structures, systems, and components; (ii)A qualitative hazards analysis; and (iii)The hazard controls (consisting primarily of inventory limits and safety management programs) and their bases.
<p>(9) Transportation activities</p>	<ul style="list-style-type: none"> (i)Preparing a Safety Analysis Report for Packaging in accordance with DOE-O-460.1A, Packaging and Transportation Safety, October 2, 1996, or successor document and (ii)Preparing a Transportation Safety Document in accordance with DOE-G-460.1-1, Implementation Guide for Use with DOE O 460.1A, Packaging and Transportation Safety, June 5, 1997, or successor document.
<p>(10) Transportation and onsite transfer of nuclear explosives, nuclear components, Naval nuclear fuel elements, Category I and Category II special nuclear materials, special assemblies, and other materials of national security</p>	<ul style="list-style-type: none"> (i)Preparing a Safety Analysis Report for Packaging in accordance with DOE-O-461.1, Packaging and Transportation of Materials of National Security Interest, September 29, 2000, or successor document and (ii)Preparing a Transportation Safety Document in accordance with DOE-M-461.1-1, Packaging and Transfer of Materials of National Security Interest Manual, September 29, 2000, or successor document.

5. Table 1 refers to specific types of nuclear facilities. These references are not intended to constitute an exhaustive list of the specific types of nuclear facilities. Part 830 defines nuclear facility broadly to include a reactor or a nonreactor nuclear facility where an activity is conducted for or on behalf of DOE and includes any related area, structure,

facility, or activity to the extent necessary to ensure proper implementation of the requirements established by this part. The only exceptions are those facilities specifically excluded such as accelerators. Table 2 defines the terms referenced in Table 1 that are not defined in 10 CFR 830.3.

Table 2

For purposes of Table 1:	Means:
(1) Deactivation	The process of placing a facility in a stable and known condition, including the removal of hazardous and radioactive materials.
(2) Decontamination	The removal or reduction of residual radioactive and hazardous materials by mechanical, chemical, or other techniques to achieve a stated objective or end condition.
(3) Decommissioning	Those actions taking place after deactivation of a nuclear facility to retire it from service and includes surveillance and maintenance, decontamination, and/or dismantlement.
(4) Environmental restoration activities	The process by which contaminated sites and facilities are identified and characterized and by which existing contamination is contained, or removed and disposed.
(5) Generic nuclear explosive operation	A characterization that considers the collective attributes (such as special facility system requirements, physical weapon characteristics, or quantities and chemical/physical forms of hazardous materials) for all projected nuclear explosive operations to be conducted at a facility.
(6) Nuclear explosive facility	A nuclear facility at which nuclear operations and activities involving a nuclear explosive may be conducted.
(7) Nuclear explosive operation	Any activity involving a nuclear explosive, including activities in which main-charge, high-explosive parts and pits are collocated.

For purposes of Table 1:	Means:
(8) Nuclear facility with a limited operational life	A nuclear facility for which there is a short remaining operational period before ending the facility’s mission and initiating deactivation and decommissioning and for which there are no intended additional missions other than cleanup.
(9) Specific nuclear explosive operation	A specific nuclear explosive subjected to the stipulated steps of an individual operation, such as assembly or disassembly.
(10) Transition surveillance and maintenance activities	Activities conducted when a facility is not operating or during deactivation, decontamination, and decommissioning operations when surveillance and maintenance are the predominant activities being conducted at the facility. These activities are necessary for satisfactory containment of hazardous materials and protection of workers, the public, and the environment. These activities include providing periodic inspections, maintenance of structures, systems, and components, and actions to prevent the alteration of hazardous materials to an unsafe state.

6. The contractor responsible for the design and construction of a new Hazard Category 1, 2, or 3 DOE nuclear facility or a major modification to an existing Hazard Category 1, 2, or 3 DOE nuclear facility must prepare a preliminary documented safety analysis. A preliminary documented safety analysis can ensure that substantial costs and time are not wasted in constructing a nuclear facility that will not be acceptable to DOE. If a contractor is required to prepare a preliminary documented safety analysis, the contractor must obtain DOE approval of the preliminary documented safety analysis prior to procuring materials or components or beginning construction. DOE, however, may authorize the contractor to perform limited procurement and construction activities without approval of a preliminary documented safety analysis if DOE determines that the

activities are not detrimental to public health and safety and are in the best interests of DOE. DOE Order 420.1, or successor document, sets forth acceptable nuclear safety design criteria for use in preparing a preliminary documented safety analysis. As a general matter, DOE does not expect preliminary documented safety analyses to be needed for activities that do not involve significant construction such as environmental restoration activities, decontamination and decommissioning activities, specific nuclear explosive operations, or transition surveillance and maintenance activities.

G. Hazard Controls

1. Hazard controls are measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment. They include:

- (i) Physical, design, structural, and engineering features;
- (ii) Safety structures, systems, and components;
- (iii) Safety management programs;
- (iv) Technical safety requirements; and
- (v) Other controls necessary to provide adequate protection from hazards.

2. The types and specific characteristics of the safety management programs necessary for a DOE nuclear facility will be dependent on the complexity and hazards associated with the nuclear facility and the work being performed. In most cases, however, a contractor should consider safety management programs covering topics such as quality assurance, procedures, maintenance, personnel training, conduct of operations, criticality safety, emergency preparedness, fire protection, waste management, and radiation protection. In general, DOE Orders set forth DOE's expectations concerning

specific topics. For example, DOE Order 420.1, or successor document provides DOE's expectations with respect to fire protection and criticality safety.

3. Safety structures, systems, and components require formal definition of minimum acceptable performance in the documented safety analysis. This is accomplished by first defining a safety function, then describing the structure, systems, and components, placing functional requirements on those portions of the structures, systems, and components required for the safety function, and identifying performance criteria that will ensure functional requirements are met. Technical safety requirements are developed to ensure the operability of the safety structures, systems, and components and define actions to be taken if a safety structure, system, or component is not operable.

4. Technical safety requirements establish limits, controls, and related actions necessary for the safe operation of a nuclear facility. The exact form and contents of technical safety requirements will depend on the circumstances of a particular nuclear facility as defined in the documented safety analysis for the nuclear facility. As appropriate, technical safety requirements may have sections on:

- (i) Safety limits;
- (ii) Operating limits;
- (iii) Surveillance requirements;
- (iv) Administrative controls;
- (v) Use and application; and
- (vi) Design features.

It may also have an appendix on the bases for the limits and requirements. DOE Guide 423.1-1B, Implementation Guide for Use in Developing Technical Safety

Requirements, or successor document, provides a complete description of what technical safety requirements should contain and how they should be developed and maintained.

5. DOE will examine and approve the technical safety requirements as part of preparing the safety evaluation report and reviewing updates to the safety basis. As with all hazard controls, technical safety requirements must be kept current and reflect changes in the facility, the work and the hazards as they are analyzed in the documented safety analysis. In addition, DOE expects a contractor to maintain technical safety requirements, and other hazard controls as appropriate, as controlled documents with an authorized users list.

6. Table 3 sets forth DOE’s expectations concerning acceptable technical safety requirements.

Table 3

As appropriate for a particular DOE nuclear facility, the section of the technical safety requirements on:	Will provide information on:
(1) Safety limits	The limits on process variables associated with those safety class physical barriers, generally passive, that are necessary for the intended facility function and that are required to guard against the uncontrolled release of radioactive materials. The safety limit section describes, as precisely as possible, the parameters being limited, states the limit in measurable units (pressure, temperature, flow, etc.), and indicates the applicability of the limit. The safety limit section also describes the actions to be taken in the event that the safety limit is exceeded. These actions should first place the facility in the safe, stable condition attainable, including total shutdown (except where such action might reduce the margin of safety) or should verify that the facility already is

	<p>safe and stable and will remain so. The technical safety requirement should state that the contractor must obtain DOE authorization to restart the nuclear facility following a violation of a safety limit. The safety limit section also establishes the steps and time limits to correct the out-of-specification condition.</p>
(2) Operating limits	<p>Those limits which are required to ensure the safe operation of a nuclear facility. The operating limits section may include subsections on limiting control settings and limiting conditions for operation.</p>
(3) Limiting control settings	<p>The settings on safety systems that control process variables to prevent exceeding a safety limit. The limited control settings section normally contains the settings for automatic alarms and for the automatic or non-automatic initiation of protective actions related to those variables associated with the function of safety class structures, systems, or components if the safety analysis shows that they are relied upon to mitigate or prevent an accident. The limited control settings section also identifies the protective actions to be taken at the specific settings chosen in order to correct a situation automatically or manually such that the related safety limit is not exceeded. Protective actions may include maintaining the variables within the requirements and repairing the automatic device promptly or shutting down the affected part of the process and, if required, the entire facility.</p>
(4) Limiting conditions for operations	<p>The limits that represent the lowest functional capability or performance level of safety structures, systems, and components required to perform an activity safely. The limiting conditions for operation section describes, as precisely as possible, the lowest functional capability or performance level of equipment required for continued safe operation of the facility. The limiting</p>

	<p>conditions for operation section also states the action to be taken to address a condition not meeting the limiting conditions for operation section. Normally this simply provides for the adverse condition being corrected in a certain time frame and for further action if this is impossible.</p>
(5) Surveillance requirements	<p>Requirements relating to test, calibration, or inspection to assure that the necessary operability and quality of safety structures, systems, and components is maintained; that facility operation is within safety limits; and that limiting control settings and limiting conditions for operation are met. If a required surveillance is not successfully completed, the contractor is expected to assume the systems or components involved are inoperable and take the actions defined by the technical safety requirement until the systems or components can be shown to be operable. If, however, a required surveillance is not performed within its required frequency, the contractor is allowed to perform the surveillance within 24 hours or the original frequency, whichever is smaller, and confirm operability.</p>
(6) Administrative controls	<p>Organization and management, procedures, recordkeeping, assessment, and reporting necessary to ensure safe operation of a facility consistent with the technical safety requirement. In general, the administrative controls section addresses (i) the requirements associated with administrative controls (including those for reporting violations of the technical safety requirement); (ii) the staffing requirements for facility positions important to safe conduct of the facility; and (iii) the commitments to the safety management programs identified in the documented safety analysis as necessary components of the safety basis for the facility.</p>

(7) Use and application provisions	The basic instructions for applying the safety restrictions contained in a technical safety requirement. The use and application section includes definitions of terms, operating modes, logical connectors, completion times, and frequency notations.
(8) Design features	Design features of the facility that, if altered or modified, would have a significant effect on safe operation.
(9) Bases appendix	The reasons for the safety limits, operating limits, and associated surveillance requirements in the technical safety requirements. The statements for each limit or requirement shows how the numeric value, the condition, or the surveillance fulfills the purpose derived from the safety documentation. The primary purpose for describing the basis of each limit or requirement is to ensure that any future changes to the limit or requirement is done with full knowledge of the original intent or purpose of the limit or requirement.

H. Unreviewed Safety Questions

1. The USQ process is an important tool to evaluate whether changes affect the safety basis. A contractor must use the USQ process to ensure that the safety basis for a DOE nuclear facility is not undermined by changes in the facility, the work performed, the associated hazards, or other factors that support the adequacy of the safety basis.
2. The USQ process permits a contractor to make physical and procedural changes to a nuclear facility and to conduct tests and experiments without prior approval, provided these changes do not cause a USQ. The USQ process provides a contractor with the flexibility needed to conduct day-to-day operations by requiring only those changes and tests with a potential to impact the safety basis (and therefore the safety of the nuclear facility) be approved by DOE. This allows DOE to focus its review on those changes

significant to safety. The USQ process helps keep the safety basis current by ensuring appropriate review of and response to situations that might adversely affect the safety basis.

3. DOE Guide 424.1-1B Chg 2, Implementation Guide for Use in Addressing Unreviewed Safety Question Requirements, or successor document provides DOE's expectations for a USQ process. The contractor must obtain DOE approval of its procedure used to implement the USQ process. The contractor is allowed to make editorial and format changes to its USQ procedure while maintaining DOE approval.

I. Functions and Responsibilities

1. The DOE Management Official for a DOE nuclear facility (that is, the Assistant Secretary, the Assistant Administrator, or the Office Director who is primarily responsible for the management of the facility) has primary responsibility within DOE for ensuring that the safety basis for the facility is adequate and complies with the safety basis requirements of Part 830. The DOE Management Official is responsible for ensuring the timely and proper --

(i) Review of all safety basis documents submitted to DOE; and

(ii) Preparation of a safety evaluation report concerning the safety basis for a facility.

2. DOE will maintain a public list on the internet that provides the status of the safety basis for each Hazard Category 1, 2, or 3 DOE nuclear facility and, to the extent practicable, provides information on how to obtain a copy of the safety basis and related documents for a facility.

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