AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

violation, the DOE contractor identifies other examples of the violation with the same root cause, DOE may refrain from initiating an additional enforcement action. In determining whether to exercise this discretion, DOE will consider whether the DOE contractor acted reasonably and in a timely manner appropriate to the security significance of the initial violation, the comprehensiveness of the corrective action, whether the matter was reported, and whether the additional violation(s) substantially change the security significance or character of the concern arising out of the initial violation.

h. The preceding paragraphs are solely intended to be examples indicating when enforcement discretion may be exercised to forego the issuance of a civil penalty or, in some cases, the initiation of any enforcement action at all. However, notwithstanding these examples, a civil penalty may be proposed or notice of violation issued when, in DOE's judgment, such action is warranted on the basis of the circumstances of an individual case.

[70 FR 3607, Jan. 26, 2005, as amended at 71 FR 68733, Nov. 28, 2006; 74 FR 66033, Dec. 14, 2009; 79 FR 19, Jan. 2, 2014; 81 FR 41795, June 28, 2016]

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*.

SOURCE: 85 FR 66205, Oct. 19, 2020, unless otherwise noted.

§ 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: (i) DOE–STD–3009, Change Notice No. 1, January 2000, or successor document, or (ii) DOE–STD–3011–94 or successor document.
(5) The decommissioning of a DOE nuclear facility.	(i) Using the method in DOE–STD–1120–98, Integration of Environment, Safety, and Health into Facility Disposition Activities, May 1998, or successor document; (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 (iii) Deriving hazard controls based on the Safety and Health Programs, the Work Plans, the Health and Safety Plans, and the Emergency Response Plans.
(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.	(i) Using the method in DOE–STD–1120–98 or successor document, and (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).
(7) A DOE nuclear explosive facility and the nuclear explosive operations conducted therein.	Developing its documented safety analysis in two pieces: (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 (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.
(8) A DOE Hazard Category 3 nonreactor nuclear facility.	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: (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.
(9) Transportation activities	(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.
(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.	(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.
(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 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.
(2) Operating limits	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.

TABLE 3—Continued

As appropriate for a particular DOE nuclear facility, the section of the technical safety requirements on:	Will provide information on:
(3) Limiting control settings	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.
(4) Limiting conditions for operations	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 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.
(5) Surveillance requirements	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.
(6) Administrative controls	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.
(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.

PART 835—OCCUPATIONAL RADIATION PROTECTION

Subpart A—General Provisions

Sec.

835.1 Scope.
835.2 Definitions.
835.3 General rule.
835.4 Radiological units.

Subpart B—Management and Administrative Requirements

835.101 Radiation protection programs.
835.102 Internal audits.
835.103 Education, training and skills.
835.104 Written procedures.

Subpart C—Standards for Internal and External Exposure

835.201 [Reserved]
835.202 Occupational dose limits for general employees.
835.203 Combining internal and external equivalent doses.
835.204 Planned special exposures.
835.205 Determination of compliance for non-uniform exposure of the skin.
835.206 Limits for the embryo/fetus.
835.207 Occupational dose limits for minors.
835.208 Limits for members of the public entering a controlled area.
835.209 Concentrations of radioactive material in air.

Subpart D [Reserved]

Subpart E—Monitoring of Individuals and Areas

835.401 General requirements.
835.402 Individual monitoring.
835.403 Air monitoring.
835.404 [Reserved]
835.405 Receipt of packages containing radioactive material.

Subpart F—Entry Control Program

835.501 Radiological areas.
835.502 High and very high radiation areas.

Subpart G—Posting and Labeling

835.601 General requirements.
835.602 Controlled areas.
835.603 Radiological areas and radioactive material areas.
835.604 Exceptions to posting requirements.
835.605 Labeling items and containers.
835.606 Exceptions to labeling requirements.

Subpart H—Records

835.701 General provisions.
835.702 Individual monitoring records.
835.703 Other monitoring records.
835.704 Administrative records.

Subpart I—Reports to Individuals

835.801 Reports to individuals.

Subpart J—Radiation Safety Training

835.901 Radiation safety training.
835.902–835.903 [Reserved]

Subpart K—Design and Control

835.1001 Design and control.
835.1002 Facility design and modifications.
835.1003 Workplace controls.

Subpart L—Radioactive Contamination Control

835.1101 Control of material and equipment.
835.1102 Control of areas.

Subpart M—Sealed Radioactive Source Control

835.1201 Sealed radioactive source control.
835.1202 Accountable sealed radioactive sources.