

DEPARTMENT OF ENERGY**10 CFR Part 830**

RIN 1901-AA34

Nuclear Safety Management**AGENCY:** Department of Energy.**ACTION:** Interim final rule and opportunity for public comment.

SUMMARY: This interim final rule amends the Department of Energy's (DOE or the Department) nuclear safety regulations to (1) establish and maintain safety bases for hazard category 1, 2, and 3 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. The requirements in this rule apply to contractor-operated and government-operated nuclear facilities.

DATES: This rule is effective December 11, 2000. You may send comments for consideration until November 9, 2000.

ADDRESSES: Comments may be addressed to: Richard Black, Director, Office of Nuclear and Facility Safety Policy, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.

You may also email an electronic copy of your comments to Mary.Haughey@eh.doe.gov.

You may examine written comments between 9:00 a.m. and 4:00 p.m. at the U.S. Department of Energy Freedom of Information Reading Room, Room 1E-190, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-3142.

FOR FURTHER INFORMATION CONTACT: Richard L. Black, (See address above), (301) 903-3465, richard.black@eh.doe.gov.

SUPPLEMENTARY INFORMATION:**I. Introduction and Background***A. What Is the Procedural History of this Rule?*

On December 9, 1991, we published Procedural Rules for DOE Nuclear Activities (56 FR 64290) and a Notice of Proposed Rulemaking and Public Hearing (1991 Notice, 56 FR 64316) to add Parts 820 and 830 to Title 10 of the Code of Federal Regulation (CFR). We proposed 10 CFR Part 820 (Part 820), Procedural Rules for DOE Nuclear Activities, to establish the procedural requirements for enforcement activities in accordance with the Price-Anderson Amendments Act of 1988 (PAAA or Price-Anderson). On August 17, 1993, we issued the Procedural Regulations

for DOE Nuclear Activities in final form as 10 CFR Part 820 (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 830 was proposed to establish nuclear safety management requirements for DOE nuclear facilities. We issued as final the sections of the Nuclear Safety Management rule (Part 830) related to the general provisions (§§ 830.1-830.7) and the quality assurance requirements (§ 830.120) on April 5, 1994 (1994 Notice, 59 FR 15843).

We issued a Notice of Limited Reopening of the Comment Period for the remaining topics to be addressed in Part 830 on August 31, 1995 (Reopening Notice, 60 FR 45381). The comment period was reopened to solicit and consider comments on a number of issues which had been raised since the 1991 Notice. The Reopening Notice provided an opportunity for contractors and other members of the public to comment on the effect of recent Department initiatives, such as safe management systems, the revision of the related nuclear safety Orders, and the identification of tailored Work Smart Standards (WSS) through the Necessary and Sufficient Closure Process, and on the scope, level of detail, and implementation of the proposed rules. We also requested comments on whether there should be a threshold for the application of nuclear safety management requirements and whether all nuclear safety requirements could be implemented in an integrated fashion through, for example, the use of a site-wide implementation program or system.

B. Has the General Accounting Office (GAO) Made Recommendations About This Rule?

On June 10, 1999, the GAO issued a report entitled DOE's Nuclear Safety Enforcement Program Should Be Strengthened. On June 29, 1999, Assistant Secretary of Environment, Safety and Health, Dr. David Michaels testified before the House Committee on Commerce that DOE endorsed the overall GAO conclusion that DOE's enforcement program has been effective and should be further strengthened. The GAO made three recommendations which are that DOE:

- Expeditiously complete the process of issuing enforceable rules covering important nuclear safety requirements,
- Ensure that field locations are properly following DOE's guidance in

determining which facilities must comply with the nuclear safety rule on quality assurance, and

- Eliminate the administrative exemption from paying civil penalties for violations of nuclear safety rules that DOE granted to nonprofit educational institutions.

This rule completes DOE's rulemaking regarding nuclear safety management. This rule also reaffirms that the quality assurance requirements of this rule apply to contractors for all DOE nuclear facilities, including hazard category 1, 2, and 3 nuclear facilities and "below hazard category 3 nuclear facilities" (nuclear facilities whose hazards are less than hazard category 3) as defined in DOE Standard (STD) 1027, Change Notice 1, Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports, September 1997, U.S. Department of Energy, Washington, D.C. 20585.

The PAAA specifically excludes seven nonprofit contractors and their subcontractors and suppliers from civil monetary penalties for violations of the nuclear safety requirements. For consistency, 10 CFR 820.20(d) extends that exclusion to all nonprofit educational institutions. Those exclusions are not within the scope of this rule and therefore are not discussed in this rulemaking.

C. What Substantive Requirements Are Proposed in This Rule?

In the 1991 Notice, we proposed that the following nine topics be included in the nuclear safety management rules:

- Quality assurance requirements,
 - Safety analysis reports,
 - Technical safety requirements,
 - Unreviewed safety question (USQ),
 - Conduct of operations,
 - Maintenance management,
 - Training and certification,
 - Defect identification and reporting,
- and
- Occurrence reporting and processing.

The quality assurance requirements were published in 1994 and are revised in this Notice. The safety basis requirements being added address three of the topics from the 1991 Notice: safety analysis reports, technical safety requirements, and USQ. Three of the remaining five nuclear safety management topics from the 1991 Notice (conduct of operations, maintenance management, and training and certification) are expected to be addressed through the documented safety analysis required by the safety basis requirements and the work processes required by the quality

assurance requirements. Specifically, the documented safety analysis will establish what training, maintenance, and conduct of operations are required for safety. Compliance with the safety basis and quality assurance provisions of this rule will ensure that these safety functions are established, maintained, and implemented.

Defect identification and occurrence reporting and processing will continue to be addressed through contract provisions that require contractors to use the DOE Occurrence Reporting and Processing System (ORPS). We intend to maintain DOE Order 232.1A, Occurrence Reporting and Processing of Operations Information, and DOE Manual 232.1-1A, Occurrence Reporting and Processing of Operations Information, so that they can be adopted through contract requirements. Consequently, we believe that the nine topics proposed in the 1991 Notice are adequately covered through the combination of this rule and contract requirements.

D. Why Is DOE Issuing This Rule as an Interim Final Rule?

We are issuing this rule as an interim final rule to give the public further opportunity to comment. The public has until November 9, 2000 to submit comments on the rule. This regulation then becomes effective December 11, 2000. If DOE decides to amend this rule based on comments received, we will issue a **Federal Register** Notice to state those changes; otherwise this rule will become effective, as written, on December 11, 2000. Pending the effective date of this new rule, the quality assurance provisions of the current rule in 10 CFR 830.120 remain in effect and fully enforceable.

II. Summary of Changes

The changes to Part 830 are primarily to

- Convert the rule to “plain language”,
- Clarify the scope of the rule,
- Add provisions requiring the integration of quality assurance with the Safety Management System (SMS) [Part 830, Subpart A],
- Clarify that the work process provisions of quality assurance apply to standards and controls adopted to meet regulatory and contractual requirements relating to nuclear safety [Part 830, Subpart A], and
- Add provisions for nuclear facility safety bases [Part 830, Subpart B].

Plain Language

A. Why Is DOE Converting the Rule to Plain Language?

In 1998, President Clinton signed a presidential memo requiring agencies to use plain language principles for most of their written communications. While this memo does not require us to use plain language for regulations that were proposed before January 1, 1999, we chose to revise it in the plain language style because we were revising a substantial portion of Part 830. Plain language requirements vary depending upon the document, but the intent is to make the government language easier to understand. We are reformatting the rule to use

- Common, everyday words, except for necessary technical terms;
- Active voice; and
- Short sentences.

The word “shall” is being replaced with the word “must” to indicate an obligation. The word “may” is used for permission.

Because we are revising the text of the rule to the plain language format, we have rewritten the quality assurance requirements in this rule; however there are few significant changes. The significant changes are described in this summary.

General Sections

B. What Changes Are Made to § 830.1, Scope?

Section 830.1, Scope, is being revised to state that the rule 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. Previously, Part 830 only applied to activities conducted at a DOE nuclear facility. This change will ensure that Part 830 requirements are applicable to all activities performed for or on behalf of DOE that have the potential to affect nuclear safety. Some activities subject to Part 830 requirements may occur outside a nuclear facility and even may be conducted off a DOE site. The nuclear safety management requirements may apply to these activities. If a supplier furnishes safety items or services that either are, or will be, used at a nuclear facility, then that supplier falls within the scope of the rule provisions. Similarly, contractor activities performed in support of facility operations, such as training of operators or maintenance of safety equipment, fall under the scope of the rule to the extent the activities relate to nuclear safety.

Furthermore, a nonreactor nuclear facility is broadly defined to include not only buildings, but also activities and operations involving radioactive and/or fissionable materials in such form or quantity that a nuclear hazard or a nuclear explosive hazard potentially exists to workers, the public, or the environment.

We also are revising Paragraph 830.1 to add “DOE personnel.” This change is consistent with the change to paragraph 830.4(d).

C. What Changes Are Made to the Exclusions in § 830.2?

The exclusion for the Nuclear Explosives and Weapons Safety Program (weapons exclusion) is being deleted. Three new exclusions are being added relating to:

- Transportation;
- Facilities and activities conducted under the Nuclear Waste Policy Act of 1982, as amended (NWPAA); and
- Activities related to the launch approval and actual launch of nuclear energy systems into space.

In addition, the reference to the Public Law authorizing the Director Naval Nuclear Propulsion has been updated to Public Law 106-65. Public Law 106-65 also established the National Nuclear Security Administration in DOE.

Deletion

Nuclear Explosives and Weapons Safety Program. When we proposed the Nuclear Safety Management rule (Part 830) in the 1991 Notice and the Reopening Notice, we were concerned that conflicts could arise between nuclear safety requirements and the nuclear explosives weapons safety requirements. Today we are including specific methods by which nuclear explosive operations and their associated activities may meet Subpart B to Part 830 that are consistent with nuclear explosives safety. Therefore, we no longer need to exclude the Nuclear Explosives and Weapons Safety program, and we are deleting that exclusion. This change makes clear that this rule applies to nuclear explosives facilities and their associated nuclear explosive operations and activities.

Additions

1. *Transportation.* All transportation activities were excluded in the definition of nonreactor nuclear facility published in the 1994 Notice. The definition of nonreactor nuclear facility that we are publishing today does not exclude transportation activities. Instead, we are adding an exclusion for certain transportation activities to

§ 830.2. The exclusion for transportation activities in paragraph 830.2(d) is narrower than the exclusion for transportation activities previously contained in the definition for nonreactor nuclear facility. It only excludes transportation activities that are regulated by the Department of Transportation (DOT). We are excluding transportation activities that are regulated by DOT to avoid duplicate regulation by DOE and DOT. Transportation issues are discussed in greater detail in the discussion of responses to public comments.

2. *Activities conducted under the NWPA.* These activities are designated for licensing by the Nuclear Regulatory Commission (NRC), and the design and construction of these activities must meet NRC requirements in order for them to receive an NRC license. Facilities that are licensed by the NRC are already excluded from this Part following issuance of a license to operate by the NRC. This new exclusion will cover activities under the NWPA for the period of time preceding licensing by the NRC. An example of an activity conducted under NWPA is the Yucca Mountain Project. Activities conducted under NWPA should implement and comply with NRC regulations in anticipation of NRC licensing, not DOE nuclear safety regulations. Therefore, they are excluded from this rule.

3. *Activities related to the launch approval and actual launch of nuclear energy systems.* The new exclusion recognizes that some nuclear energy systems are developed and built by DOE contractors for missions to be launched into space. These missions are generally sponsored by the National Aeronautics and Space Administration. Safety analyses activities for such systems are conducted consistent with established executive policy and applicable DOE directives for systems and equipment developed for space launches, and the results of that analysis will be considered during launch decisions. Because these analyses are performed for other government agencies and approved by the Office of the President, they do not need to be governed by the requirements in Part 830. Manufacturing, assembly, and testing of these systems by DOE contractors are not excluded from this rule.

D. What Changes Are Made to § 830.3, Definitions?

We are adding, revising, and deleting a number of definitions in Part 830 to support new requirements or the formatting change to plain language.

• *Added Definitions.* We are adding the following definitions for use in Part 830: bases appendix; critical assembly; criticality; design features; documented safety analysis; environmental restoration activities; existing DOE nuclear facility; hazard controls; limiting conditions for operation; limiting control settings; low-level residual fixed radioactivity; major modification; new DOE nuclear facility; operating limits; preliminary documented safety analysis; safety basis; safety class structures, systems, and components; safety evaluation report; safety limits; Safety Management System; safety management program; safety significant structures, systems, and components; safety structures, systems, and components; surveillance requirements; technical safety requirements; Unreviewed Safety Question; Unreviewed Safety Question process; and use and application provisions. Additional discussion on these added definitions is provided in the following paragraphs.

a. *Basis appendix, design features, limiting conditions for operation, limiting control settings, operating limits, safety limits, surveillance requirements, and use and application provisions.* These are all terms that are used in Subpart B of Part 830 to describe the DOE requirements for hazard controls in the form of technical safety requirements. These terms are also currently used in DOE Order 5480.22, Technical Safety Requirements, and are intended to be consistent with that order.

b. *Critical assembly.* The term critical assembly is used in this rule to define the term reactor. Critical assembly was formerly defined within the definition for reactor. It is listed as a separate definition to simplify the definition of reactor.

c. *Criticality.* Criticality is the condition in which a nuclear fission chain reaction becomes self-sustaining. A contractor responsible for a nuclear facility with fissionable material in a form and amount sufficient to pose a potential for criticality is required to define their criticality safety program in their documented safety analysis.

d. *Documented safety analysis.* A documented safety analysis is a report that documents the adequacy of the analysis of a facility or activity to ensure that it can be constructed, operated, performed, maintained, shut down, and decommissioned safely and in compliance with applicable requirements. Depending upon the type of facility and the method approved by DOE to prepare a documented safety analysis for the facility, the documented

safety analysis might be in the form of a safety analysis report, a Basis for Interim Operation or BIO (prepared in accordance with DOE-STD-3011-94, Guidance for Preparation of DOE 5480.22 (TSR) and DOE 5480.23 (SAR) Implementation Plans, November 1994 or its successor document), a safety and health plan or HASP (as defined in 29 CFR 1910.120 or 1926.65), or a combination of a safety analysis report and a hazard analysis report (HAR). This term is used in the new safety basis requirements.

e. *Environmental restoration activities.* Environmental restoration activities are the processes by which contaminated sites and facilities are identified and characterized. It is also the process by which existing contamination is contained or removed. These activities include environmental remediation of contaminated soils. Environmental restoration activities are considered to be nuclear facilities if the activities involve radioactive and/or fissionable materials in such form and quantities that a nuclear hazard or a nuclear explosive hazard potentially exists. This term is used in the new safety basis requirements.

f. *Existing DOE nuclear facility and new DOE nuclear facility.* This rule imposes different safety basis requirements in Subpart B for new facilities versus existing facilities. The first difference is related to the development of a preliminary documented safety analysis for new nuclear facilities, which is not required for existing nuclear facilities. The second difference is with respect to schedules as specified in the rule. We consider an existing DOE nuclear facility to be a DOE nuclear facility that is or has been in operation prior to April 9, 2001. New nuclear facilities are facilities, activities and operations that begin operations on or after April 9, 2000.

For activities, such as decontamination or environmental restoration, for which the term "operate" is less clear, DOE intends the term to mean from the date a new decontamination or environmental restoration activity begins.

We consider new DOE nuclear facilities to include (1) construction of a new DOE facility which is intended to be used as a nuclear facility; (2) use of an existing non-nuclear DOE facility to possess, use or store radioactive or fissionable material in such form and quantity that a nuclear hazard potentially exists; and (3) initial possession, use, or storage of radioactive or fissionable material in such form and

quantity that a nuclear hazard potentially exists. We also consider the change from operation of a DOE nuclear facility to deactivation, decontamination, decommissioning, or environmental restoration to be a new DOE nuclear activity subject to the schedules for a new nuclear facility.

Many DOE nuclear facilities, particularly those that perform nuclear explosives operations, are designed to accommodate changing missions. These facilities and activities require both a generic form of documented safety analysis and an operation- or activity-specific form of documented safety analysis. One form of operation- or activity-specific documented safety analysis is defined in Appendix A, Table 3 as a specific nuclear explosive operation. We do not consider a specific nuclear explosive operation to be a "new DOE nuclear facility."

g. *Hazard controls.* 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. Although the hazard controls are required to address nonradiological hazards as well as radiological hazards, we will only pursue PAAA enforcement actions for noncompliances that have nuclear safety significance.

h. *Low-level residual fixed radioactivity.* Low-level residual fixed radioactivity is the radioactivity remaining following reasonable efforts to remove radioactive systems, components, and stored materials and is composed of:

- Surface contamination that remains 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.

Although the definition permits some smearable surface contamination (i.e., removable contamination), the smearable radioactivity must be less than the values defined for removable contamination by 10 CFR Part 835, Appendix D, Surface Contamination Values. In addition, the results of the hazard analysis must show that no credible accident scenario or work practices would release the fixed or activated components of remaining radioactivity at levels that would prudently require the use of active

safety systems, structures, or components to prevent or mitigate a release of radioactive materials.

This definition is generally consistent with the definition for this term in DOE-STD-1120-98, Integration of Environment, Safety and Health into Facility Disposition Activities, May 1998.

i. *Major modification.* A major modification means a modification to a DOE nuclear facility that is completed on or after April 9, 2001 and which substantially changes the existing safety basis for the facility. Because these changes have a significant effect on the safety basis of a nuclear facility, we expect contractors to develop a preliminary documented safety analysis that addresses these modifications and their impacts on the safety of the nuclear facility so DOE may review the proposed changes before they are implemented. Before operating the nuclear facility in the modified configuration or conducting modified operations, contractors must obtain approval of the upgraded safety basis from DOE and make any changes to the safety basis directed by DOE.

We treat major modifications to hazard category 1, 2, and 3 DOE nuclear facilities, such as the replacement of a major safety system, equivalent to the design, construction, and initial operation of a new facility. Because contractors for major modifications must revise their safety basis documents to reflect the major modifications and obtain DOE approval of the revised safety bases prior to making the modification, they do not need to assess major modifications under the USQ process of Subpart B.

j. *Preliminary documented safety analysis.* The preliminary documented safety analysis is the 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 a hazard category 1, 2, or 3 DOE nuclear facility. It is part of the safety basis requirements, and it serves as the principal safety basis for the DOE decision to authorize procurement, construction, or preoperational testing.

k. *Safety basis.* A safety basis for a DOE nuclear facility is documented in the documented safety analysis and the hazard controls for the nuclear facility. As changes are made or potential inadequacies of the safety analysis are discovered, contractors must perform USQ determinations. The results of the USQ determinations and any associated safety evaluations are part of the safety basis for the facility.

l. *Safety class structures, systems, and components.* Safety class structures, systems, and components means 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 identified by the safety analysis.

m. *Safety evaluation report or SER.* The SER is the documented safety evaluation performed by DOE on the safety basis documents for a facility that are developed by the contractor. It includes the reasons for approving the safety basis and any conditions for approval. Contractors are required by the safety basis requirements to meet any conditions stated in the SER.

n. *Safety Management System (SMS).* Safety Management System means an integrated safety management system established consistent with the Department of Energy Acquisition Regulation (DEAR) in 48 CFR 970.5204-2, Integration of Environment, Safety, and Health into Work Planning and Execution, or any successor regulation. Additional information on SMS may be found in DOE Policy 450.4, Safety Management System Policy; DOE Guide 450.4-1A, Integrated Safety Management System Guide.

o. *Safety management program.* Safety management programs are programs designed to ensure a facility is operated in a manner that adequately protects workers, the public, and the environment. Contractors may have already developed safety management programs to comply with contract requirements for Safety Management Systems. Subpart B of the rule requires contractors to define the characteristics of the safety management programs for the facility that are necessary for safe operations, including, where applicable, quality assurance, procedures, maintenance, personnel training, conduct of operations, emergency preparedness, fire protection, waste management, and radiation protection. They may also include criticality safety programs for nonreactor nuclear facilities with fissionable material in a form or amount sufficient to pose a potential for criticality. Rather than repeating or reinventing these programs for the documented safety analysis, contractors may incorporate existing programs by reference into the documented safety analysis provided these programs are sufficient to provide adequate protection. Contractors may need to include a copy of documents that are incorporated by reference with the documented safety analysis when it

is submitted to DOE for review and approval.

p. *Safety significant structures, systems, and components.* Safety significant structures, systems, and components means systems, structures, and components which are not designated as safety class systems, structures, and components, but whose preventive or mitigative function is a major contributor to defense in depth (*i.e.*, prevention of uncontrolled material release) and/or worker safety as determined from hazard analyses.

q. *Safety structures, systems, and components.* Safety structures, systems, and components are the combination of safety class systems, structures, and components and safety significant systems, structures, and components.

r. *Technical safety requirements.* Technical safety requirements are the limits, controls and related requirements necessary for the safe operation of a nuclear facility that are appropriate for the work and the hazards. Technical safety requirements include safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix. These requirements are also consistent with the criteria for technical safety requirements in DOE Order 5480.22 which generally have been implemented by contractors for DOE hazard category 1, 2, and 3 nuclear facilities.

s. *Unreviewed Safety Question (USQ).* A situation involves a USQ if (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; (3) a margin of safety could be reduced; or (4) the documented safety analysis may not be bounding or may be otherwise inadequate. If a situation involves a USQ, the contractor must use the USQ process to determine if the change or the potential inadequacy of the documented safety analysis needs to be submitted to DOE for review and approval.

t. *Unreviewed Safety Question Process.* The USQ process permits a contractor to make physical and procedural changes to a nuclear facility and to conduct tests and experiments without prior DOE approval, provided these changes do not explicitly or implicitly affect the safety basis of the nuclear facility. The USQ process

provides a contractor with the flexibility needed to conduct day-to-day operations by requiring that only those changes and tests with a potential to impact the safety basis (and therefore the safety of the nuclear facility) be brought to the attention of DOE. This allows DOE to focus its review on those changes significant to safety. The USQ process is an important tool for keeping the safety basis current by ensuring changes are appropriately reviewed and incorporated into the safety basis. The USQ process provides a method for contractors to determine if a USQ is involved and the actions to take if the situation involves a USQ. DOE approval is required before a change is made that affects the safety basis of a DOE nuclear facility.

2. Revised Definitions

The following terms are continued in this Part, but their definitions are revised:

a. *Document.* The second sentence of this definition regarding when a document is a record is being deleted as unnecessary to the definition. This change does not affect the meaning of the terms document and record.

b. *Graded Approach.* The definition of graded approach is being revised to include an additional condition for grading: "the relative importance of radiological and nonradiological hazards."

c. *Hazard.* Minor editorial changes were made that do not affect the meaning.

d. *Nonreactor nuclear facility.* We are making the following changes to the definition for nonreactor nuclear facility.

i. *Facilities.* We are adding the word "facilities" in the definition so that it reads "Nonreactor facilities means those facilities, operations and activities * * *" to make it clear that facilities are included in the definition. The word "facility" as it is used in this term is broadly defined to include buildings, operations, and activities and, in some cases, the surrounding area.

ii. *Nuclear explosive hazard.* We are adding the words "* * * or a nuclear explosive hazard * * *" to clarify that nuclear explosive facilities, and the nuclear explosive operations conducted therein, are included in the definition of nonreactor nuclear facility.

iii. *Transportation exclusion.* We are deleting the exclusion of transportation activities from the definition, but we are continuing to exclude transportation activities regulated by DOT from the scope of Part 830 through an added exclusion in § 830.2. This narrows the exclusion for transportation activities

and is discussed in greater detail in the response to public comments.

iv. *Examples.* The definition of nonreactor nuclear facility previously listed six examples of facilities and activities to be included in the definition. Some persons took these examples to mean that nonreactor nuclear facilities were limited to the specific examples stated. We are deleting the six examples because we do not want to imply that this is a definitive list. Except for the change relating to services to nuclear facilities, which is discussed in the next paragraph, the deletion of the six examples is not intended to change the scope of the definition of nonreactor nuclear facilities.

v. *Services.* The previously listed examples of nonreactor nuclear facilities included design, manufacturing, and assembly. While we continue to consider design, manufacturing, and assembly to be important to the safe operation of a nuclear facility, under the revised definition for a nonreactor nuclear facility, unless the facility where these activities occur also involves, or will involve, radioactive and/or fissionable materials in such form and quantity that a nuclear hazard potentially exists, it is no longer considered to be a nuclear facility. Rather, these activities are considered to be services. Furthermore, we have clarified the requirements in the rule relating to services which are provided to nuclear facilities.

The change relating to services provided to a nuclear facility will affect the application of the rule to facilities which provide services to nuclear facilities, but do not use, possess, or store radioactive or fissionable materials. Under this change, contractors for facilities which provide items and services that may affect nuclear safety, but do not use, store, or possess radioactive or fissionable materials (now or at a later date), must perform their activities in accordance with the quality assurance criteria of Subpart A of this rule, but are not required by this rule to submit a Quality Assurance Program (QAP) to DOE for approval. They may, however, have separate contract requirements for a QAP that they will need to meet. In addition, facilities that provide services or items, but do not expect to use, store, or possess radioactive or fissionable material now or in the future, are not required to meet the safety basis requirements of Subpart B. This change is consistent with the changes to the scope (§ 830.1) relating to items and services that may affect nuclear safety.

vi. *Incidental Use.* We are continuing to exclude incidental use from the definition of nonreactor nuclear facility, however we are making a minor revision to one of the examples. We are adding the word "radiation" to read "Incidental use and generation of radioactive materials or radiation including . . ." This change is to acknowledge that the use of X-ray machines and electronic microscopes does not involve radioactive materials but does produce radiation. This exclusion is for activities that involve such insignificant amounts of radioactive materials or radiation (e.g., X-ray machines, check and calibration sources, electron microscopes, use of radioactive sources in research, experimental, and analytical laboratory activities) that the amounts do not warrant consideration as a nuclear facility and their use does not need to be regulated by this rule. However, some of the uses would still be subject to the radiation protection requirements in 10 CFR Part 835 (Part 835), Occupational Radiation Protection. Other applications of this rule to incidental uses will be handled by DOE on a case-by-case basis.

e. *Nuclear facility.* We are revising the definition of nuclear facility to make it clear that nuclear facilities include any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established by Part 830. The nuclear facility may be on or off a DOE site. The facility may be wholly or partially owned or controlled by DOE. This change was made, in part, to address concerns stated in the GAO report that the term nuclear facility was being interpreted too narrowly for purposes of applying the Part 830 requirements.

Nuclear facilities include facilities, operations, and activities whose intended use will require them to possess, use, or form radioactive or fissionable materials. Many activities performed at or for facilities where fissionable material will be stored, used, or formed take place before the introduction of these materials at the facility. Consequently, nuclear facilities also include facilities that will use, store, or possess radioactive or fissionable material in a form or quantity that a nuclear hazard potentially exists to workers or the public.

Nuclear facilities include both reactors and nonreactor nuclear facilities. A nonreactor nuclear facility is broadly defined to include facilities, activities, and operations involving the possession, use, or formation of

radioactive or fissionable materials that are conducted by or on behalf of DOE regardless of whether they are conducted onsite or offsite. The term "DOE nuclear facility" and "nuclear facility" are used interchangeably in the rule because those terms relate to those activities conducted by or on behalf of DOE that affect or may affect the safety of DOE nuclear facilities. The use of the term "DOE nuclear facility" does not necessarily require the facility to be owned by DOE.

f. *Quality Assurance Program or QAP.* We are making a minor change to the definition of QAP to add the words "or management system" to clarify that the QAP is a management system.

g. *Reactor.* We are changing the definition of reactor to move the definition of critical assembly to a separate definition. The definition of reactor is also being revised to read more clearly. These changes do not affect the meaning of the definition.

h. *Service.* We are adding the following terms to the definition of service to make clear that these are services: manufacturing, assembly, decontamination, environmental restoration, waste management, and laboratory sample analyses.

3. Deleted Definitions

We are deleting the definitions for contractor, Department or DOE, and person from this rule and incorporating them by reference to the Atomic Energy Act (Act) and 10 CFR Part 820.

Paragraph 830.3(b) is revised to read "(b) Terms defined in the Act or in 10 CFR Part 820 and not defined in this section of the rule are used consistent with the meanings given in the Act or in 10 CFR Part 820." We are deleting the definition for Implementation Plan because the term is no longer used in Part 830.

E. What Changes are Made to § 830.4, General Requirements?

1. Changes to Paragraph 830.4(a)

We are deleting the language in paragraph 830.4(a) that referred to plans, programs, schedules, or other processes. This language is redundant to the requirement in 10 CFR 820.20(b)(3) and, therefore, is not needed.

2. Changes to Paragraph 830.4(b)

The contractor responsible for a nuclear facility is also expected to ensure compliance with the rule. We have simplified the language but there is no substantive change.

The "contractor responsible for a nuclear facility" is the "prime contractor" for the facility. The prime

contractor is the contractor whose work for the facility (including operations and activities) is contracted directly with DOE. The prime contractors include management and operating (M&O) contractors, management and integration (M&I) contractors, and environmental restoration contractors. DOE expects its prime contractors to implement mechanisms to oversee and ensure that subcontractors and suppliers comply with the nuclear safety management requirements.

Furthermore, prime contractors are expected to incorporate these expectations and the associated programs in contracts and other procurement documents with their subcontractors and suppliers. This requirement does not relieve subcontractors and suppliers from their responsibilities in accordance with this rule.

3. Changes to Paragraph 830.4(c)

We are rewriting paragraph 830.4(c) to state that the requirements of Part 830 must be implemented in a manner that provides reasonable assurance of adequate protection. This is consistent with DOE's statutory mandate under the Act. Paragraph 830.4(c) also requires contractors to implement the requirements in a manner that takes into account the work to be performed and the associated hazards. This is consistent with the principles of integrated safety management and the concept of grading.

4. Addition of Paragraph 830.4(d)

We are adding a new paragraph 830.4(d) to state where there is no contractor for a DOE facility, DOE must ensure implementation and compliance with the requirements of this Part. This amendment makes the requirements of this rule applicable to government-owned, government-operated (GOGOs) DOE nuclear facilities, as well as the nuclear facilities that are operated by contractors. Many of the requirements in this rule are addressed to contractors. Paragraph 830.4(d) makes clear that where DOE, rather than a contractor, is responsible for operating a nuclear facility, DOE must ensure that the activities and operations for that facility meet the requirements of this rule.

F. What Changes are Being Made to § 830.7, Graded Approach?

This section is being changed to state that, where appropriate, contractors must use a graded approach to implement the requirements of Part 830 and they must document the basis of the graded approach used. Contractors are already required to implement the

quality assurance requirements using a graded approach. The use of the graded approach is not appropriate in implementing the USQ process or in implementing technical safety requirements that establish clearly defined limits or actions.

Subpart A

Quality Assurance Requirements

G. What Changes are Being Made to the Scope and the Format of the Quality Assurance Requirements in Subpart A?

First, we are changing the numbering of the quality assurance requirements. Subpart A is being renamed to "Quality Assurance Requirements" and the requirements are contained in §§ 830.120, 830.121, and 830.122. Second, we are changing the format of the quality assurance requirements to read in plain language.

We are making conforming changes to the quality assurance requirements to agree with the changes made to the scope of Part 830 (§ 830.1) and to the definitions of contractor, nuclear facility, and services. We have revised the scope of the quality assurance rule to require contractors (including those responsible for supplying items and services) that conduct activities that affect, or may affect, the safety of a nuclear facility to conduct work in accordance with the quality assurance criteria of § 830.122. This makes clear that quality assurance requirements apply not only to prime contractors responsible for a nuclear facility, but also to subcontractors, suppliers, and other contractors, including those who provide items (such as pumps, valves, waste containers, piping, and electrical or mechanical devices) or services (such as design, engineering, maintenance, and welding) that affect, or could affect, nuclear safety. The quality of procured items such as fire suppression equipment may, or may not, affect nuclear safety depending upon the application of the equipment. DOE expects the contractor responsible for the nuclear facility (typically the prime contractor) to determine how to flow the quality assurance requirements down to subcontractors and suppliers, as well as the method for ensuring that procured items and services meet requirements and perform as expected. The contractor must also determine if the subcontractor or supplier is capable of providing items and services that meet the requirements including the quality assurance criteria. We have added a requirement for the QAP to describe how the contractor responsible for a nuclear facility ensures that subcontractors and suppliers satisfy the quality assurance criteria.

The scope of § 830.120 makes clear that the quality assurance criteria may apply to activities outside a nuclear facility, and even those conducted off a DOE site, if they can affect the safe operation of a DOE nuclear facility.

H. Are Subcontractors and Suppliers Expected To Submit a QAP to DOE for Approval?

As stated in the preamble to the 1994 Notice, subcontractors and suppliers are not expected to submit QAPs to DOE for review and approval. The requirement in the rule for contractors to submit QAPs to DOE for approval applies only to the contractors responsible for the nuclear facility (the prime contractors). However, while only contractors responsible for the nuclear facility are required by this rule to submit QAPs to DOE for approval, prime contractors are expected to use their contracts and other arrangements with subcontractors and suppliers to define what procured items or services are subject to quality assurance requirements (including QAPs) and how their subcontractors and suppliers are to comply with those requirements. Criterion 7 in the Quality Assurance Requirements requires contractors to (a) procure items and services that meet established requirements and perform as specified, (b) evaluate and select prospective suppliers on the basis of specified criteria, and (c) establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services. This criterion is meant to ensure that safety components do not fail while in service and that the fabrication or assembly of safety-related components and systems meet design specifications.

To the extent a contract or a related document states that a subcontractor or supplier must comply with a QAP, the subcontractor or supplier must meet that requirement. Any person, including subcontractors or suppliers subject to the requirements in a QAP, may be subject to enforcement actions under 10 CFR Part 820 if those requirements are violated.

I. What Changes Are Being Made to the Requirements for the QAP?

We are:

- Adding a requirement for contractors to identify and document the voluntary consensus standards they relied upon to develop and implement their QAP,
- Adding a requirement for contractors with an SMS to integrate the SMS with the QAP,
- Clarifying that the work process provision is to be read broadly to

include all standards and controls adopted to meet regulatory and contract requirements, and

- Making a number of format and plain language changes with no substantive effect.

J. Why Are We Requiring Contractors To Identify the Voluntary Consensus Standards They Use?

Most contractors use standards (e.g., American Society of Mechanical Engineers' NQA-1 standard) to develop their QAPs, but they have not always documented their use of these standards in the QAP. We are adding this requirement to ensure we clearly understand what voluntary consensus standards contractors are using to develop their QAPs. This is consistent with the requirement in the National Technology Transfer and Advancement Act of 1995 (Public Law 104-113) that government agencies adopt or use voluntary consensus standards when they are applicable and appropriate.

K. Why Is DOE Adding a Requirement for Contractors To Integrate Their QAP With Their SMS?

The Department expects that quality assurance criteria and practices will be embedded in all work processes, not just those that relate to nuclear safety. Therefore, the actions to implement the quality assurance criteria should be integrated with and consistent with the commitments in the SMS. This helps ensure that quality assurance criteria and practices will apply to all work processes that are implemented for safety management. For this reason, we are adding § 830.121(c)(2) to require contractors to integrate their QAP with their SMS. In addition, we wanted to provide a means for contractors to combine the two documents if they wished to reduce the paperwork burden so we have included an option that permits contractors to combine the QAP and the SMS into a single document. The two ways a contractor can document the integration of its QAP and its SMS are:

- The contractor may choose to retain its QAP and its SMS description as separate documents. If the contractor does this, its QAP must describe how the contractor applied the quality assurance criteria of § 830.122 to its integrated SMS; or
- The contractor may choose to integrate its QAP into its SMS description and not have a separate QAP. If the contractor does this, its SMS description must describe how the quality assurance criteria of § 830.122 are met.

If the contractor chooses to maintain a separate QAP and the DOE-approved QAP does not address SMS integration and standards identification, the contractor will need to revise its QAP. The contractor may wait and submit its revised QAP to meet the SMS integration requirement at the time of its next annual update of its QAP. We recently revised our Quality Assurance Management System Guide (DOE G 414.1-2) for use with 10 CFR 830.120. The guide provides information on how quality assurance integrates with and supports the Department's SMS policy.

Use of this guide will facilitate implementation of § 830.121(c)(2) and the effective integration of the quality and safety management systems.

This change is consistent with provisions of 48 CFR 970.5204-2 that state contractors are to provide SMS descriptions. If the contractor does not have a DOE-approved SMS, it is not required to integrate its QAP with its SMS.

L. Why Is DOE Deleting the Requirement for a Quality Assurance Implementation Plan?

Implementation plans were an option made available for contractors who needed a transition period for bringing existing facilities and activities into compliance with the quality assurance requirements. The regulatory requirements for a QAP were issued over six years ago and there is no longer any need for a transition period.

M. Why Is DOE Clarifying the Work Process Provision?

We are revising criterion 5 on work processes to make clear that work must be performed in accordance with standards and hazard controls adopted to meet contract or regulatory requirements. This clarification provides added emphasis that contractor work processes are very broadly interpreted under the quality assurance requirements and includes work-related standards, instructions, procedures, administrative controls, technical safety requirements, and other hazards controls.

Subpart B

N. What Changes Are Being Made to Subpart B?

We are adding §§ 830.201 through 830.207 to Subpart B of Part 830 to include requirements for contractors to develop safety basis documents for DOE hazard category 1, 2, and 3 nuclear facilities and comply with those documents. These changes are discussed in greater detail in the

Discussion of Safety Basis Requirements in Subpart B.

Subparts C and D

O. Is DOE Continuing to Reserve Subparts C and D?

Subparts C and D, which were reserved for future rulemaking are no longer needed and, consequently, are being deleted.

III. Discussion of Safety Basis Requirements in Subpart B

Section 830.200, Scope

A. Do the Safety Basis Requirements Apply to all DOE Nuclear Facilities?

No. The safety basis requirements of this Part only apply to DOE hazard category 1, 2, and 3 nuclear facilities. Unlike the general and quality assurance requirements of this rule, the safety basis requirements do not apply to contractors for "below hazard category 3" nuclear facilities. DOE expects its contractors to retain documentation for each of its nuclear facilities to support the determination that the nuclear facility is either a hazard category 1, 2, or 3 nuclear facility or below category 3.

In summary, using DOE-STD-1027, a hazard category 1 nuclear facility has the potential for significant offsite consequences. A hazard category 2 nuclear facility has the potential for significant on-site consequences beyond localized consequences. A hazard category 3 nuclear facility has the potential for only local significant consequences. A below hazard category 3 facility has the potential for consequences less than the other categories. Below category 3 facilities are sometimes referred to as "radiological facilities." While the safety basis provisions in Subpart B do not apply to below hazard category 3 nuclear facilities, the QA requirements in Subpart A and the occupational radiation protection requirements in 10 CFR Part 835 do apply.

Section 830.201, Performance of Work

B. What Are the "Performance of Work" Requirements for a Safety Basis?

Contractors must perform work in accordance with the DOE-approved safety basis for a DOE hazard category 1, 2, or 3 nuclear facility. This includes prime contractors to DOE, subcontractors, and suppliers. The definition of "work" as applied to this rule is very broad and encompassing. It includes any defined task or activity that may affect a safety basis for a facility. It includes such diverse activities as operations, research and

development, environmental restoration and remediation, maintenance and repair, design and construction, software development and use, inspection, data collection, administration, and analysis.

Section 830.202, Safety Basis

C. What Are the Requirements for Establishing a Safety Basis for a DOE Category 1, 2, or 3 Nuclear Facility?

The proper analysis of facility, operations, and activity hazards, the development of appropriate hazard controls for the work to be conducted, and the performance of work consistent with the approved safety basis are necessary for work at nuclear facilities to be performed safely. The safety basis requirements in this rule are derived from the proposal for requirements in the 1991 Notice and in the Reopening Notice under § 830.110, Safety Analysis Report, § 830.112, Unreviewed Safety Question Requirements, and § 830.310, Technical Safety Requirements, and are updated versions of the underlying requirements in DOE Orders on nuclear safety. While safety basis requirements already exist in DOE Orders and are imposed through contracts, we consider the requirements to be so fundamental to nuclear safety for DOE hazard category 1, 2, and 3 nuclear facilities that it is essential that these requirements be clearly enforceable under the PAAA. To properly establish a safety basis for a hazard category 1, 2, or 3 nuclear facility, a contractor must:

- Define the scope of work to be performed,
- Identify and analyze the hazards associated with the work,
- Categorize the facility consistent with DOE STD-1027,
- Prepare a documented safety analysis for the facility, and
- Establish the hazard controls upon which the contractor will rely to ensure adequate protection of workers, the public, and the environment.

D. Can a Facility Be Divided Into Compartments or "Segmented" for the Purpose of Facility Hazard Categorization?

The purpose of performing a hazard categorization and estimating the radiological and nonradiological hazardous material inventory is to understand the possible hazards and their potential interactions and to determine if they could cause harm to individuals or the environment. If there are facility features that prevent hazards from one process, operation, or activity from interacting with those of another, contractors may be able to address the

hazards separately. Therefore, in certain limited circumstances, contractors may be able to segment facilities (divide one facility into two or more facilities), provided the radiological or nonradiological hazardous materials in one segment cannot interact with radiological or nonradiological hazardous materials in other segments. If a contractor chooses to segment a facility, the burden of proof of the independence of the segments and the adequacy of the treatment of the hazards lies with the contractor.

The safety basis for each segmented facility must demonstrate that the hazards cannot interact with radiological or nonradiological hazardous materials in other segments of the physical structure. For example, if a fire causes the release of hazardous materials in one segment, it must be demonstrated that the materials are confined in that segment by the hazard controls or physical barriers that are not degraded by the fire. If the hazardous materials could be transported to other segments by common confinement systems or the lack of other physical barriers, the facility cannot be segmented for purposes of this rule.

Additional discussion on segmenting nuclear facilities can be found in DOE-STD-1027.

E. Is the Contractor Required To Incorporate Changes Directed by DOE Into the Safety Basis?

Yes. As stated in 830.202(c)(1), the contractor must incorporate in the safety basis for the facility, any changes, conditions, or hazard controls directed by DOE.

F. How Often Is the Contractor Required To Update the Documented Safety Analysis?

Each year, the contractor responsible for a DOE hazard category 1, 2, or 3 nuclear facility must update the documented safety analysis to reflect all changes to the nuclear facility, the hazards, and the work. The updated documented safety analysis must be submitted to DOE. If there were no changes to the nuclear facility or its activities or operations that affected the documented safety analysis over the previous year, the contractor may instead send DOE a letter confirming that there were no changes.

Section 830.203, Unreviewed Safety Question Process

G. When Must a Contractor Use a USQ Process To Evaluate if a Situation Involves a USQ?

Some changes to the nuclear facility can impact the safety basis. However, it

would be overly burdensome for a contractor to obtain DOE approval before making any changes to DOE hazard category 1, 2, or 3 nuclear facilities. Through the USQ process, contractors responsible for DOE hazard category 1, 2, or 3 nuclear facilities may make physical and procedural changes to a nuclear facility without DOE approval, provided those changes do not implicitly or explicitly affect the safety basis of the facility. The USQ process is also used to assess newly discovered situations that might involve a potential inadequacy of the safety basis.

The USQ process has two-steps. The contractor must first determine whether a situation involves a USQ. If it does, the contractor must inform DOE and then perform an evaluation to determine whether the existing safety basis is adequate to bound the situation.

A contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must use the USQ process for any of the following situations to determine if a USQ is involved:

- A temporary or permanent change in the facility as described in the existing documented safety analysis,
- A temporary or permanent change in the procedures as described in the existing documented safety analysis,
- A test or experiment not described in the existing documented safety analysis, or
- A potential inadequacy of the documented safety analysis is discovered for which the safety analysis may not be bounding or may be otherwise inadequate. In this case, the contractor must (1) take action to place the facility in a safe condition, (2) notify DOE of the situation, (3) perform a USQ evaluation, and (4) submit the USQ approval prior to removing any operational restrictions previously imposed.

H. What Is an Unreviewed Safety Question (USQ)?

A situation involves a USQ if

- the probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the facility documented safety analysis could be increased,
- the possibility of an accident or malfunction of a different type than any evaluated previously in the facility documented safety analysis could be created, or
- a margin of safety could be reduced.

A situation also involves a USQ if there is a potential inadequacy of the safety analysis.

I. Is the Contractor Required To Obtain DOE Approval of the USQ Process?

Yes. The contractor responsible for a hazard category 1, 2, or 3 existing DOE nuclear facility is required to submit the USQ process to DOE for approval by April 10, 2001. Pending DOE approval of the USQ process, the contractor must continue to use its existing DOE-approved USQ process. If the existing process already meets the requirements of this section, the contractor must notify DOE by April 10, 2001 and request DOE to issue an approval of the existing process. The USQ process for a hazard category 1, 2, or 3 new DOE nuclear facility must be submitted for DOE approval in the safety evaluation report issued pursuant to § 830.207(d) of the rule. In either case, we will notify the contractor if any changes to the process are required.

J. What Is a USQ Summary and How Often Must a Contractor Submit It to DOE?

Each year, when the contractor submits its updated documented safety analysis to DOE, the contractor must also submit a report which summarizes all situations for which the contractor performed a USQ determination since the prior submission. The report must summarize the results of those determinations.

Section 830.204 Documented Safety Analysis

K. Does the Rule Permit the Contractor To Use a Method To Develop the Documented Safety Analysis That Is Appropriate for the Hazards and the Work Involved?

Yes, this rule allows contractors to develop the documented safety analysis by a method that DOE has approved for the particular facility or activity and is appropriately graded for the work and the hazards. Contractors may either propose a method to prepare a documented safety analysis and obtain DOE approval, or use one of the safe harbor methods established for defined facilities and activities in Table 2 of Appendix A to Subpart B of Part 830—General Statement of Safety Basis Policy.

L. What Are “Safe Harbor” Methods?

Safe harbor methods are methods which we have already determined to be acceptable for use. They are standards or methods developed by DOE or NRC, or defined in regulations promulgated by the Occupational, Safety and Health Administration (OSHA). The safe harbor methods are based on many years of

experience with the types of facilities to which they may be applied.

Contractors who use safe harbor methods in accordance with the provisions in Table 1 of Appendix A to Subpart B of Part 830—General Statement of Safety Basis Policy, do not need to obtain DOE approval prior to preparing a documented safety analysis. They do need to get DOE approval to use a method other than a safe harbor method. Whether or not a contractor uses a safe harbor method to develop its documented safety analysis, the final documented safety analysis must be submitted to DOE for approval in accordance with the schedule contained in the rule. Because the safe harbor methods are already approved by DOE, use of these methods will streamline the safety basis process by reducing the amount of review that DOE will need to do. Most DOE contractors are familiar with DOE standards and NRC regulatory guides relating to the development of documented safety analyses that are in the form of a safety analysis report or a BIO. Safe Harbor methods listed in Table 1 of Appendix A to Subpart B of Part 830 include:

- NRC Regulatory Guide 1.70, Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants,
- DOE-STD-3009-94, Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Safety Analysis Reports,
- DOE-STD-3011-94, Guidance for Preparation of DOE 5480.22 (TSR) and DOE 5480.23 (SAR) Implementation Plans, and
- DOE-STD-3016-99, Hazards Analysis Reports for Nuclear Explosive Operations.

In addition, the safe harbor provisions in Appendix A to Subpart B of Part 830 also approve the use of selected provisions in OSHA regulation 29 CFR 1910.120 (or 29 CFR 1926.65 for construction activities) in conjunction with the methodology of DOE-STD-1120-98 (or its successor document) for the preparation of the documented safety analysis for DOE contractors conducting decommissioning or select environmental restoration activities of hazard category 1, 2, or 3 nuclear facilities.

The safe harbor methods listed are not the only methods that may be used. Contractors may propose other methods which they consider to be more effective. Provided they are approved by DOE, contractor-proposed methods may be used to prepare the facility safety basis. For example, the safe harbor method listed for reactors is NRC Regulatory Guide 1.70. That method

was developed primarily for power reactors and may be too onerous for certain types of research reactors. In such cases contractors should propose an alternate method for DOE approval.

M. What Are the Content Requirements for a Documented Safety Analysis?

The documented safety analysis must:

- Describe the facility and the work to be performed;
- Identify the hazards associated with the facility;
- Evaluate all accident conditions that are presented by natural and/or manmade hazards;
- Derive the hazard controls, including technical safety requirements, to eliminate, limit, or mitigate identified hazards, and define the process for maintaining the hazard controls current at all times and controlling their use;
- Define the characteristics of the safety management programs necessary to ensure the safe operation of the facility; and
- Define necessary criticality safety programs.

Requirements for a documented safety analysis are established in Section 830.204 and further guidance is available in the documented safety analysis implementation guide, DOE G 421.X, Implementation Guide for Use in Developing Documented Safety Analyses to Meet Subpart B of 10 CFR Part 830.

Section 830.205, Technical Safety Requirements

N. Why Is DOE Adding Requirements for Technical Safety Requirements?

The technical safety requirements are the hazard controls that define the conditions, safe boundaries, and the management or administrative controls necessary to ensure the safe operation of a nuclear facility. Technical safety requirements are part of the safety basis, as are other hazards controls necessary for adequate protection from all hazards, and are required to be approved by DOE. Contractors responsible for DOE hazard category 1, 2, and 3 nuclear facilities must ensure that the technical safety requirements are properly maintained and updated as operating conditions change or other situations arise that might not have been analyzed previously.

O. Are Contractors Required To Obtain DOE Approval of the Technical Safety Requirements?

Yes. Contractors are required to obtain DOE approval of their technical safety requirements. Section G of the Appendix A to Subpart B of Part 830

provides additional detail on DOE's expectations for technical safety requirements. These expectations are consistent with the criteria for technical safety requirements in DOE Order 5480.22 which are generally being implemented by contractors for DOE hazard category 1, 2, and 3 nuclear facilities.

P. Are Contractors for Environmental Restoration Facilities Who Follow the Provisions of 29 CFR 1910.120 or 29 CFR 1926.65 Required To Develop Technical Safety Requirements?

Rather than preparing technical safety requirements, a contractor for an environmental restoration activity that involves either (1) work not done within a permanent structure or (2) the decommissioning of a facility with only low-level residual fixed radioactivity may follow the provisions of 29 CFR 1910.120 or 1926.65 to develop its documented safety analysis and its appropriate hazard controls.

Q. Are Site Personnel Permitted To Take Actions That Do Not Meet the Technical Safety Requirements?

Site personnel may take emergency actions that depart from a technical safety requirement in rare circumstances when: (a) no actions consistent with the technical safety requirement are immediately apparent and (b) the departure from the technical safety requirements is needed to protect workers, the public, or the environment from imminent and significant harm. Such emergency 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. Contractors should report any emergency actions that depart from the technical safety requirements to DOE as soon as practicable in accordance with an appropriate, existing mechanism as incorporated into contracts, such as the Occurrence Reporting and Processing System.

Section 830.206, Preliminary Documented Safety Analysis

R. Who Must Prepare a Preliminary Documented Safety Analysis?

To ensure early agreement between DOE and its contractors regarding what safety design and systems are needed in new nuclear facilities, a contractor responsible for a new DOE nuclear facility that is hazard category 1, 2, or 3 must submit a preliminary documented safety analysis to DOE and obtain DOE approval prior to procuring materials or components, or beginning

construction. In addition, a contractor responsible for a major modification to a hazard category 1, 2, or 3 DOE nuclear facility must submit a preliminary documented safety analysis to DOE for approval.

The rule does not preclude contractors from using subcontractors to develop all or part of the preliminary documented safety analysis. Likewise, in cases where the contractor responsible for the design of, or modification to, a nuclear facility is not the contractor responsible for operation of the facility, the design contractor should generally prepare the preliminary documented safety analysis. Regardless of which contractor prepares the analysis, however, the contractor responsible for the nuclear activity is ultimately responsible for the analysis and must submit it to DOE for review and approval.

Section 830.207, DOE Approval of Safety Basis

S. By What Date Must a Contractor Submit a Safety Basis That Meets the Subpart B Requirements of This Rule for DOE Approval?

Contractors for hazard category 1, 2, and 3 existing DOE nuclear facilities must submit for DOE approval a safety basis that meets the requirements of Subpart B of this rule by April 10, 2003.

T. Pending DOE Approval of a Safety Basis That Meets This Rule, What Should a Contractor Do To Continue Operations and Work at a Hazard Category 1, 2, or 3 Existing Nuclear Facility?

Pending DOE approval of a safety basis that meets this rule, the contractor responsible for a hazard category 1, 2, or 3 existing DOE nuclear facility must continue to perform work in accordance with the safety basis for the facility in effect on October 10, 2000. The contractor must also maintain the safety basis consistent with the requirements of this rule pending DOE approval of the new safety basis.

U. What Should a Contractor Do if Its Current DOE-Approved Safety Basis Does Not Reflect Current Operations or Working Conditions?

If the current safety basis does not reflect current operations, the contractor should immediately inform DOE and request approval of any changes to the safety basis that are needed in the interim period while the safety basis is being upgraded to meet the safety basis requirements of this rule. It is essential that contractors establish technical standards, administrative controls,

hazard controls, and other work processes that reflect current operations and meet those work processes in accordance with the requirements of Subpart A. The implementation guides that support this rule provide further information on how contractors should establish interim and upgraded safety bases.

V. What Should a Contractor Do if It Already Has a DOE-Approved Safety Basis That Meets the Requirements of the Rule?

If the current, DOE-approved safety basis already meets the requirements of this Subpart and is consistent with current hazards and work at the nuclear facility, the contractor must: (1) Notify DOE by April 9, 2001, (2) document the adequacy of the existing safety basis, and (3) request DOE to issue a safety evaluation report that approves the existing safety basis. This is to ensure that both the contractor and DOE have verified the current safety basis against the requirements of this rule. If DOE does not issue a safety evaluation report by October 10, 2001, the contractor should assume that it has not adequately demonstrated or documented its safety basis against the requirements of this Subpart. In that case, the contractor should work with DOE to correct the deficiencies and resubmit the safety basis. In the interim, the contractor should continue to meet the existing safety basis in accordance with paragraph 830.207(b).

W. When Must a Contractor Have an Approved Safety Basis for a New DOE Hazard Category 1, 2, or 3 Nuclear Facility or a Major Modification to a DOE Hazard Category 1, 2, or 3 Nuclear Facility?

A contractor for a new nuclear facility or a major modification to a hazard category 1, 2, or 3 DOE nuclear facility must obtain DOE approval of the safety basis for the nuclear facility before beginning operation of the nuclear facility or implementing the major modification.

Safety Management Systems

X. May Contractors Use Safety Bases and Safety Management Programs Developed Consistent With Its Integrated Safety Management System To Meet the Rule?

Section 830.204 of the rule requires contractors to define the characteristics of the safety management programs for a nuclear facility that are necessary for safe operations. Many DOE contractors responsible for DOE hazard category 1, 2, or 3 nuclear facilities have already

developed safety management programs to comply with their contract requirements for Safety Management Systems. There should be no conflict between the requirements of this rule and the requirements for Safety Management Systems. Contractors who have developed safety management programs to meet contract requirements should use these programs as appropriate to meet the requirements of this rule. Contractors may incorporate existing programs by reference into the documented safety analysis provided these programs are sufficient to provide adequate protection. To aid the review process, they should also include a copy of any documents that are incorporated by reference with the documented safety analysis when it is submitted to DOE for review and approval.

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

Y. Why Did DOE Include an Appendix to Subpart B of Part 830?

DOE included the Appendix A to Subpart B of Part 830—General Statement of Safety Basis Policy, to provide information regarding DOE's expectations and criteria for the safety basis requirements of Part 830. The appendix does not create any new requirements. The appendix and the guidance documents referenced therein are intended to be read and applied consistent with DOE Policy 450.2A, "Identifying, Implementing and Complying with Environment, Safety and Health Requirements" (May 15, 1996).

IV. Discussion of Other General Topics Pertinent to the Rules

A. What Does DOE Intend To Do With Other DOE Directives That Relate to Nuclear Safety Management Topics?

We intend to maintain the DOE Quality Assurance Order (DOE O 414.1, Quality Assurance) so it may be applied through contracts to non-nuclear facilities. Other directives related to nuclear safety such as DOE Orders 5480.23 (Nuclear Safety Analysis Reports), 5480.22 (Technical Safety Requirements), and 5480.21 (Unreviewed Safety Questions) are incorporated in most DOE contracts where nuclear activities are involved, and work has begun using these orders for requirements. Those contract requirements are not changed by the issuance of this rule.

We will retain DOE Orders 5480.23, 5480.22, and 5480.21 during the transition period for this rule (approximately the next two and a half

years) while updated safety bases are established. After this transition period, we will consider canceling DOE Orders 5480.23, 5480.22, and 5480.21 and relying on this rule and its implementing guides for safety basis requirements. DOE contractors may also work with DOE to delete these orders from contracts where appropriate. DOE orders for other nuclear safety management topics such as maintenance, training, conduct of operations, defect identification, and occurrence reporting, will be retained so that the applicable and appropriate requirements of the orders can continue to be referenced in contracts.

B. What if There Is a Conflict Between Contract Requirements and Technical or Schedule Requirements in This Rule?

As previously noted, we expect the requirements in DOE Orders 414.1, 5480.23, 5480.22, and 5480.21 and other directives related to nuclear safety that are incorporated in contracts to be compatible with this rule. To the extent there are any conflicts between this rule and contract terms and conditions, the provisions of this rule take precedence. If the rule imposes more stringent requirements than the contract, the contractor must either meet the requirements in the rule or obtain an exemption from the rule in accordance with criteria in Subpart E of 10 CFR Part 820.

A contract or implementing document under a contract may specify details concerning how contractors will comply with the rule. For example, a project execution plan or similar project management planning document may provide for different contractors to design, construct, and operate a facility. In this regard, DOE may require the design contractor to prepare the documented safety analysis, and may require acceptance of the document by the operating contractor.

Also, a contract or implementing document under a contract may impose additional requirements beyond those imposed by the rule. For example, on a project specific basis, DOE might require by contract that a contractor meet a higher level of quality assurance than reflected in the rule as well as an enhanced USQ process. If a contract imposes more stringent requirements than imposed by this rule, the contract requirements would apply unless the contract is modified. Moreover, the contractor would be expected to develop work processes that address these contract requirements, and to the extent that these work processes address nuclear safety activities, they are

covered by the quality assurance provisions of 10 CFR 830.120.

C. What Should Contractors Do if They Have Completed Activities and Documents To Meet the Above DOE Orders?

We do not expect contractors to significantly modify documents or commitments already provided to meet similar commitments under contract. For example, existing documented safety analyses, technical safety requirements, and processes for USQs that meet the order requirements should meet the rule requirements. We do not expect contractors to reduce their commitments to protect health, safety, and the environment as a result of issuing this rule. If a contractor has previously submitted documents to meet contract requirements and they have been approved by DOE, the contractor should assess whether those documents meet the requirements of Part 830. If they do, the contractor should send a letter to DOE requesting that DOE extend its approval under the rule provisions. DOE will inform the contractor if they need to resubmit the documents for review.

If, on the other hand, a contractor determines that previously submitted documents do not meet the requirements of this rule, you should revise your documents to meet the requirements and submit them to DOE for approval. If the changes are minor, you should indicate what changes have been made to the documents since the DOE approval. This may help DOE to narrow its review.

D. How Are Nuclear Safety Requirements Imposed on Subcontractors and Suppliers?

Nuclear safety requirements can be imposed on subcontractors and suppliers through both regulations and contracts. The definition of contractor in 10 CFR 820.2 applies to Part 830. That definition includes "any person under contract (or its subcontractors or suppliers) with the Department of Energy." This definition includes those contractors, subcontractors, and suppliers that provide items and services to DOE nuclear facilities and activities. Therefore, requirements in Part 830 that are stated to apply to "contractors" apply to prime contractors, and can, as appropriate, apply to subcontractors, and suppliers.

Certain requirements in Part 830 are stated to apply to "a contractor responsible for a DOE nuclear facility." Such requirements only apply to prime contractors for DOE nuclear facilities. Regardless of the performer of the work,

the prime contractor bears responsibility for subcontractor and supplier compliance with appropriate nuclear safety requirements. DEAR clause 48 CFR 5204-78(d) (the Laws Clause) requires contractors to flow down necessary provisions in contracts to subcontractors at any tier to which the contractor determines such requirements apply. In addition, DEAR 48 CFR 5204-2 (the Integrated Safety Management Systems clause) states that contractors must include a clause substantially the same as the Laws Clause in subcontracts involving complex or hazardous work on the site at a DOE-owned or leased facility. Other DOE and federal procurement regulations require contractors to have a DOE-approved contractor purchasing system for subcontracting.

Many of the requirements that flow down to subcontractors and suppliers are quality assurance requirements that pertain to procured items and services. See discussion above in Section II. I. Enforcement actions may be brought against any subcontractor or supplier who fails to comply with requirements that are imposed for the performance of work and provision of items and services that could affect the safety of a DOE nuclear facility.

E. How Does This Amendment to Part 830 Affect the Positions in Ruling 1995-1?

Ruling 1995-1 interpreted certain provisions of Parts 830 and 835. 61 FR 4209 (Feb. 5, 1996). This interim final rule amends Part 830 in a manner that changes the interpretations relating to Part 830 in four of the ten questions presented in Ruling 1995-1. None of the changes affect the interpretations as they apply to Part 835. Each of the questions from the Ruling 1995-1 that are affected by this interim final rule is listed below, as well as the impacts of this amendment. The positions from Ruling 1995-1 that are not discussed remain unchanged.

Question 2. Do Parts 830 and 835 apply to government employees in general and to the Department's government-owned, government-operated (GOGO) facilities specifically?

Impact of this amendment: This amendment changes Ruling 1995-1 as it applies to DOE employees and GOGOs. Ruling 1995-1 indicated that Part 830, unlike Part 835, did not apply to NRC or DOE personnel and to DOE GOGO facilities. As discussed previously, the scope of Part 830 is being amended to cover the conduct of DOE personnel. In addition, the general requirements of Part 830 are being amended to cover GOGO facilities by providing that if

there is no contractor for a nuclear facility, DOE must ensure implementation of the requirements of Part 830.

Question 5. To what extent are activities performed on a DOE site subject to Parts 830 and 835 if they are regulated by the NRC (including activities certified by the NRC under section 1701 of the Atomic Energy Act) or by a State under an agreement with the NRC?

Impact of this amendment: Ruling 1995-1 indicated that Part 830 does not apply to activities that are regulated through a license by the NRC or under an Agreement with the NRC. This exclusion deals with the situation where the NRC has issued a license. As discussed previously, Part 830 is being amended to also exclude activities conducted under the NWPA. This new exclusion covers activities conducted under the NWPA for the period prior to the issuance of a license by the NRC.

Question 6. To what extent are DOE activities performed off a DOE site subject to Parts 830 and 835, and what is the effect if these activities are performed on a site regulated by the NRC or by an Agreement State?

Impact of this amendment: Ruling 1995-1 stated that because Part 830 applies only "at a DOE nuclear facility," Part 830 applies only at DOE operations and activities and would not apply, for example, at a supplier's facility. As discussed previously, the scope of Part 830 is being amended to remove this restrictive language. In particular, the amended scope governs the conduct of DOE contractors and other persons conducting activities (including providing items and services) that affect or may affect the safety of DOE nuclear facilities. The definition of a nuclear facility is amended to include activities conducted for or on behalf of DOE to include any related area, structure, facility, or activity. Furthermore, a nuclear facility is not limited to a facility located at a DOE site, and the nuclear facility may be wholly or partially owned or controlled by DOE.

Ruling 1995-1 indicated that Part 830 did not establish a threshold to exclude coverage of low hazard facilities. That continues to be the case. However, we have created a threshold for the new safety basis provisions in Subpart B of Part 830. Specifically, the safety basis provisions of Subpart B apply only to contractors responsible for hazard category 1, 2, and 3 nuclear facilities.

The discussion in Ruling 1995-1 relating to activities regulated by the NRC or an Agreement State is unchanged by this amendment.

Question 10. What is the purpose of the exclusion in Parts 830 and 835 for activities conducted under the Nuclear Explosives and Weapons Safety program relating to the prevention of accidental or unauthorized nuclear detonations, and what activities are intended to be included within the scope of this exclusion?

Impact of this amendment: Ruling 1995-1 indicated that the exclusion in Part 830 was drafted narrowly to cover only those activities necessary to prevent an accidental or unauthorized nuclear detonation. As discussed previously, the amended Part 830 does not contain this exclusion and, therefore this exclusion and the related interpretation no longer apply to Part 830. Further, the definition of nonreactor nuclear facility is amended to clarify that nuclear explosive hazards are included.

V. Summary and Discussion of Public Comments Received in Response to the December 9, 1991 and August 31, 1995 Notices of Proposed Rulemaking for Part 830

Many of the comments received on the 1991 Notice were responded to in the 1994 Notice, particularly those that related to general topics or quality assurance. Some of the outstanding issues from the 1991 Notice that were not addressed in the 1994 Notice, as well as additional issues raised in response to the Reopening Notice, are addressed below.

General Topics

A. Does the Rule Contain Detailed Criteria or Performance Objectives?

Many of the comments concerning the proposed Part 830 rule focused on whether the proposed rule should contain the detailed requirements in the existing DOE nuclear safety orders or performance objectives. Most of the comments stated that the rule should impose performance objectives, rather than specific requirements. In general, the commentors said that we should provide clear direction concerning what was expected as opposed to how it should be accomplished. However, there was some disagreement about the level of detail necessary to provide these clear expectations.

Today we are continuing requirements in Part 830 for quality assurance and adding requirements for a safety basis. However, in response to comments on the proposed rule, DOE decided not to include detailed requirements for training and certification, conduct of operation, maintenance management, defect

identification, and occurrence reporting which were included as rulemaking topics in the 1991 Notice.

We believe the combination of the safety basis requirements and the quality assurance requirements, along with contract provisions, provides sufficient nuclear safety management requirements to address the hazards at DOE nuclear facilities. Furthermore, rather than prescribing the method to be used to develop safety basis documents, the requirements in Subpart B of this rule allow the contractor to propose the method it intends to use to develop safety basis documents based upon the work to be performed and the hazards. DOE is responsible for approving safety basis documents appropriate to the hazards and facility or activity addressed.

Finally, the enforcement of the safety basis requirements will be performance-oriented. That is, DOE will focus its enforcement efforts on whether the contractor operates a nuclear facility and performs work consistent with its safety basis as approved by DOE.

B. How Do the Requirements of Part 830 Apply to Hazard Category 1, 2, and 3 Nuclear Facilities and Below Hazard Category 3 Nuclear Facilities?

We received a number of comments to the question in the Reopening Notice regarding limiting the application of Part 830 requirements to either hazard category 1, 2, and 3 nuclear facilities or only hazard category 1 and 2 nuclear facilities. The comments on this issue came mostly from DOE contractors or subcontractors and were almost equally divided on whether hazard category 3 nuclear facilities should be subject to the requirements in Part 830. In addition, those commentors who recommended limiting the rule to hazard category 1, 2, or 3 nuclear facilities or to hazard category 1 and 2 nuclear facilities generally focused their comments on the impacts of the safety basis requirements (safety analysis reports, technical safety requirements, and USQ) on low hazard facilities, not the impacts of the quality assurance requirements.

We have decided to continue to apply the general requirements of §§ 830.1 through 830.7 and the quality assurance requirements in Subpart A to Part 830 to all activities affecting nuclear safety. The quality assurance requirements apply for all DOE nuclear facilities, including hazard category 1, 2, and 3 nuclear facilities and below hazard category 3 nuclear facilities, except as excluded in § 830.2 or exempted in accordance with Subpart E of Part 820. The rule requires the implementation of

the quality assurance requirements to be graded so they may be appropriately applied at all DOE nuclear facilities. Safety basis requirements only apply to hazard category 1, 2, and 3 nuclear facilities. Furthermore, DOE has approved a simplified methodology for establishing a documented safety analysis for a hazard category 3 nuclear facility in Table 2 of Appendix A in recognition of the lesser hazards.

A number of the comments received to the Reopening Notice recommended using DOE-STD-1027, Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports, to define hazard categories for nuclear facilities. We are incorporating a requirement in § 830.202 for contractors to categorize their nuclear facilities consistent with DOE-STD-1027. DOE retains responsibility for approving the categorization as part of the safety basis.

C. How Do These Rules Apply to Transportation Activities?

The definition of nonreactor nuclear facility published in § 830.3 of the 1994 Notice excluded transportation of radioactive materials. This exclusion was added to avoid duplication of regulatory efforts because much of the transportation of radioactive materials occurs offsite where it is governed and regulated by DOT or NRC requirements. In the response to comments in the 1994 Notice, we indicated that we would add specific provisions to the rules to cover shipments wholly within DOE sites.

We have decided to amend the definition of nonreactor nuclear facility to delete the exclusion of transportation of radioactive materials and add new language to § 830.2 to exclude transportation of radioactive materials regulated by the DOT. This exclusion is more narrow than the previous exclusion in the definition of nonreactor nuclear facilities which excluded all transportation activities. We have determined that the applicable provisions of the Part 830 rules should apply to transportation activities which are not subject to DOT regulations.

The exclusion for activities regulated by DOT in Part 830 does not apply to either (1) non-transportation activities or (2) activities which do not need to meet the DOT regulations because they are specifically excluded from the DOT regulations. For example, 49 CFR 173.7(b) is a DOT regulation which excludes certain shipments of hazardous wastes which are made by or under the direction of DOE or the Department of Defense relating to national security. Excluding shipments

of hazardous materials which are covered by Paragraph 49 CFR 173.7(b) from Part 830 would result in them being excluded from both the DOT regulations and the DOE regulations. Thus, the exclusion for Part 830 only applies to transportation activities that are subject to DOT requirements.

Some commentors expressed concern that, in cases when the transportation exclusion does not apply, application of the Part 830 rules to transportation of radioactive materials onsite would require safety analysis reports to be prepared specifically for the transportation activities. While contractors may consider treating these activities as separate from the nuclear facilities and consequently prepare separate documented safety analyses (such as safety analysis reports), as well as plans and programs, a more cost effective way to apply the nuclear requirements to transportation requirements, and the one supported by the Department, would be to integrate those activities into existing site or facility analyses and plans.

D. What Are the Requirements for Nuclear Explosive and Weapons Activities?

The Reopening Notice indicated that comments received from the 1991 Notice requested that we clarify the exclusion of nuclear explosive and weapons surety activities from nuclear safety requirements. Then-proposed Parts 830 and 835 contained identical exclusions for activities conducted under the Nuclear Explosives and Weapons Surety program relating to the prevention of accidental or unauthorized nuclear detonations. This exclusion was drafted narrowly to exempt from the nuclear safety rules only those activities necessary to prevent an accidental or unauthorized nuclear detonation that might be in conflict with the nuclear safety requirements. The reason for this exclusion was the paramount importance of preventing accidental or unauthorized nuclear detonations and ensuring that the requirements in Parts 830 and 835 did not conflict with activities necessary to prevent any such detonation.

We have crafted the requirements of this rule to permit contractors to use methods to develop their safety basis documents that are based upon the work to be performed and the relevant hazards. Consequently, DOE contractors are expected to use methods that do not conflict with activities necessary to protect individuals from the risk of detonation or explosion. Nuclear Explosive and Weapons Surety

requirements are established in DOE Orders 452.1A and 452.2A, and they contain both nuclear and weapons safety requirements. Table 2 in Appendix A to Subpart B of this rule lists a safe harbor method for nuclear explosives facilities that has the same performance-based objectives as the Nuclear Explosive and Weapons Surety program requirements. As contractors now have the means to ensure there are no conflicts between weapons safety and nuclear safety, we determined that the weapons exclusion is no longer necessary and are deleting it from this rule.

The Integrated Weapons Activity Plan (IWAP) governs how and when the Nuclear Explosive and Weapons Surety requirements will be implemented. If a deviation or conflict exists between this rule and the IWAP, the IWAP can be used as a basis for requesting DOE to approve an exemption from rule requirements or schedules in accordance with Subpart E of Part 820.

E. Does the Rule Cover DOE Employees and DOE-Operated Facilities?

The Reopening Notice requested comments on the issue of extending applicability of Part 830 to cover DOE employees and DOE-operated facilities. Many commentors on this issue generally favored extending the nuclear safety requirements to DOE employees and DOE-operated nuclear facilities (referred to as GOGOs) where the facilities and hazards were comparable to DOE contractor operated nuclear facilities. The major concern expressed was with regard to application of PAAA civil penalties. DOE's authority to impose PAAA civil penalties only applies to indemnified contractors (including their subcontractors and suppliers), not DOE employees.

We believe that fundamental nuclear safety expectations should be applied to our GOGOs, as well as contractor-operated activities, and therefore the requirements of Part 830 should be applied to GOGOs. We are adding a new paragraph 830.4(d) to the rule to state that where there is no contractor for a DOE nuclear facility, DOE must ensure implementation and compliance with the requirements of this Part. This language is consistent with that in Part 835. It makes clear that where DOE, rather than a contractor, is responsible for the operation of a nuclear facility, DOE must ensure that the activities and operations of that facility meet the requirements of Part 830. However, as the authority to impose PAAA civil penalties for violations of nuclear safety requirements is limited to contractors,

we will not impose PAAA civil penalties on GOGOs.

F. Does the Rule Cover Nonradioactive Hazards?

The Reopening Notice proposed three options regarding the treatment of nonradioactive hazards in Part 830. Specifically, these were to address:

- Only radioactive hazards at a nuclear facility,
- Only radioactive hazards and those hazards which could cause or exacerbate an accident involving radioactivity or reduce the level of nuclear safety, or
- All substantial hazards at a nuclear facility.

The hazard categorization developed to meet § 830.202(b)(3) must be based on an inventory of all radioactive and nonradioactive hazardous materials within a nuclear facility. Further, we expect our contractors to address all hazards and the controls necessary to provide adequate protection to the public, workers, and the environment from these hazards in the documented safety analysis. Currently, a safety analysis report developed in accordance with DOE-STD-3009 would address these hazards. However, the AEA does not authorize DOE to issue civil penalties for violations of requirements not related to nuclear safety, and Price-Anderson enforcement is limited to violations of requirements related to nuclear safety. Therefore, we expect to limit our Price-Anderson enforcement actions to radiological hazards and those hazards which could cause or exacerbate an accident involving radioactivity or reduce the level of nuclear safety.

G. Does the Rule Apply to Non-Nuclear Facilities?

In the Reopening Notice, we requested comments on extending Part 830 to non-nuclear DOE facilities. A few commentors noted the advantage of seamless plans which would allow integrated and coordinated programs across sites. However, the majority of the comments, strongly recommended that Part 830 not be expanded to include non-nuclear facilities. We concluded that Part 830 should not be extended to apply to facilities or activities that do not affect safe operation of nuclear facilities. However, we have determined that Part 830 should be applied to activities which could affect the safe performance of a nuclear activity whether or not they are performed at a nuclear facility or on a DOE site.

Contractors are free to include non-nuclear activities together with nuclear activities within the scope of quality

assurance and safety management programs so that they are integrated and coordinated on a site-wide basis. In addition, where used, SMS descriptions will address the proper coordination of nuclear and non-nuclear activities. However, as we stated in the General Statement of Enforcement Policy in Part 820 (Appendix A to Part 820) and above, we will only pursue enforcement actions through the procedures in Part 820 for those noncompliances which have nuclear safety significance.

H. What Is the Role of Implementation Plans in Part 830?

In the Reopening Notice we requested comments on options to clarify the role of implementation plans for the Part 830 requirements. Implementation plans were an option made available for a contractor who needed a transition period for bringing existing facilities and activities into compliance with the nuclear safety requirements. One commentor to the Reopening Notice stated that deleting the requirement for implementation plans would permit contractors to apply their resources directly to implementing the nuclear safety programs.

DOE agrees. The regulatory requirements for a QAP were issued over six years ago. We expect that actions identified in the quality assurance implementation plans prepared at that time are completed and the implementation plans are superseded by final DOE-approved QAPs.

We also believe that implementation plans are not needed for safety basis requirements. Safety basis requirements have been imposed on contractors responsible for nuclear facilities for many years, consequently those contractors should be able to submit safety bases that meet the requirements of Part 830 by April 10, 2003.

We do not expect new contractors to need to prepare implementation plans. The DOE procurement process allows for ample notification and time for a new contractor either to accept and implement the existing nuclear safety documents and programs or to prepare new ones for DOE approval prior to beginning work. Consequently, the requirement to develop implementation plans should no longer be necessary, and we are deleting it from the rule.

I. How Does DOE Plan To Assess Compliance With the Requirements of Part 830?

A number of comments were received on what constitutes compliance with nuclear safety rules. Based on those comments, we have concluded that

more specificity as to what constitutes compliance would be useful. In order for a contractor to comply with a nuclear safety rule, it must fully implement the applicable requirements stated in the rule or have an approved exemption. Fully implementing the requirements includes:

- Ensuring that plans, programs, and procedures establish the criteria or define the actions to be taken to meet the requirements for a facility, activity, or operation, and
- Ensuring that actions, operations, and conditions at the site or facility are consistent with the plans, programs, and procedures.

Fully implementing the requirements also entails prime contractors ensuring that appropriate nuclear safety management requirements are imposed on and implemented by their subcontractors who perform work at nuclear facilities or suppliers who provide items and services that affect nuclear safety at these facilities.

J. Does DOE Plan To Issue Guidance Documents and Must Contractors Use Them?

We will issue guidance documents in the form of implementation guides and technical standards to help contractors determine what is needed to meet our expectations when implementing the requirements in Part 830. Guidance documents provide details about our expectations and suggest methods that may be used to meet them. DOE Policy 450.2A describes the role of guidance in implementing requirements. The primary implementation guides which define DOE's expectations for this rule are:

- DOE G 414.1-1: Implementation Guide for Use with Independent and Management Assessment Requirements of 10 CFR Part 830.120 and DOE 5700.6C Quality Assurance
- DOE G 414.1-2: Quality Assurance Management System Guide for Use with 10 CFR 830.120 and DOE O 414.1
- DOE G 421.X: Implementation Guide for Use in Developing Documented Safety Analyses to Meet Subpart B of 10 CFR Part 830
- DOE G 423.X: Implementation Guide for Use in Developing Technical Safety Requirements (TSRs)
- DOE G 424.X: Implementation Guide for Use in Addressing Unreviewed Safety Question (USQ) Requirements

Guides DOE G 414.1-1 and DOE G 414.1-2 are final guides already in use. Guides 421.X, 423.X, and 424.X are being made available for use and comment concurrent with the

publication of this rule. All of these guides, as well as DOE Policy 450.2A, are available through the DOE directives web page on <http://www.explorer.doe.gov:1776/htmls/directives.html>. Comments to Guides 421.X, 423.X, and 424.X may be submitted to Richard Black at the mailing address or email address provided at the beginning of this Notice.

K. To Whom in DOE Does a Contractor Submit Documents for DOE Approval?

The rule contains requirements for contractors to obtain approval from DOE, but does not specify who or what office in DOE will review and approve these documents. A number of commentors asked us to identify the specific DOE office or individual to whom documents are to be submitted or from whom approval is to be obtained. We chose not to specifically define individuals or offices for DOE responsibilities if they have the potential to be changed in future reorganizations. DOE M 411.1-1A, DOE Safety Management Functions, Responsibilities, and Authorities Manual (FRAM), explicitly defines current DOE responsibilities and authorities related to safety management that are established by DOE rules or Orders.

VI. Procedural Requirements

A. Review Under the National Environmental Policy Act

We have reviewed this amendment to 10 CFR Part 830 under the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. § 4321 *et seq.*) and the Council on Environmental Quality regulations for implementing NEPA (40 CFR Part 1500).

Prior to publishing the notice of proposed rulemaking to add Part 830 to Title 10 of the CFR, and under the NEPA procedures then in existence, we concluded that the potential environmental impacts of Part 830 would be clearly insignificant. We decided that neither an environmental impact statement nor an environmental assessment was required in connection with the promulgation of this rule. Since that time, we have issued regulations establishing implementing procedures for complying with NEPA's requirements [See 10 CFR Part 1021]. We have further considered Part 830 under these regulations. The regulations include a list of typical classes of actions, referred to as categorical exclusions, that normally do not require the preparation of either an environmental impact statement or an environmental assessment. Part 830 is

covered by several categorical exclusions including, among others, information gathering, data analysis, and document preparation (A9); training exercises and simulations (B1.2); routine maintenance activities and custodial services (B1.3); and site characterization and environmental monitoring (B3.1) [See 10 CFR Part 1021, Appendices A and B to Subpart D].

We have concluded that the amendment to 10 CFR Part 830 does not represent a major federal action having significant impact on the environment under NEPA (42 U.S.C. 4321 *et seq.* (1976)), the Council on Environmental Quality's regulations (40 CFR Parts 1500-08), and DOE's implementing regulations (10 CFR Part 1021). Therefore, the amendment to this rule does not require an environmental impact statement or an environmental assessment pursuant to NEPA.

B. Review Under Executive Order 12866

This rule is not a "significant regulatory action" within the scope of section 3(f) of the Executive Order 12866, "Regulatory Planning and Review" (58 FR 51735, October 4, 1993), and no formal assessment of costs and benefits was performed. DOE contracts already contain equivalent requirements for the safe management of nuclear activities to meet the Department's responsibilities under the Atomic Energy Act to protect workers, members of the public, and the environment. Thus, DOE concluded that this rulemaking would not result in any significant additional costs. The public comments submitted in response to the 1991 Notice of Proposed Rulemaking and the 1995 Reopening Notice, which contained similar requirements, provided no basis for DOE to change its view of the likely economic impact of a final rule. Further, we have determined that this rule will not (1) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (2) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or (3) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order 12866. Accordingly, this rule was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs in the Office of Management and Budget.

C. Review Under Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, requires that a Federal agency prepare a regulatory flexibility analysis for any rule for which the agency is required to publish a general notice of proposed rulemaking. The requirement to prepare an analysis does not apply, however, if the agency certifies that a rule will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). The impact of the changes to Part 830 are primarily with respect to major contractors. Subcontractors and suppliers are expected to satisfy the provisions of Part 830 primarily through the programs and procedures established by prime contractors. Consequently, the impacts to small entities with respect to changes to Part 830 are expected to be minor. The economic impact on contractors of this filing requirement is negligible. On this basis, DOE certifies that the rule will not have a significant economic impact on a substantial number of small entities and, therefore, no analysis has been prepared.

D. Review Under the Paperwork Reduction Act of 1995

The information collection provisions of this rule are not substantially different from those 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 assigned OMB Control No. 1910-0300. Accordingly, no additional Office of Management and Budget clearance is required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and the procedures implementing that Act, 5 CFR 1320.1 *et seq.*

E. Review Under Executive Order 13132

Executive Order 13132 (64 FR 43255, August 10, 1999), requires agencies to develop an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have "federalism implications." Policies that have federalism implications are defined in the Executive Order to include regulations that have substantial direct effects 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. DOE has examined the changes to Part 830 and determined that they do 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 various levels of government. No further action is required by Executive Order 13132.

F. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531 *et seq.*, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in an agency rule that may result in the expenditure by State, local, and tribal governments, in the aggregate or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This rule amends 10 CFR Part 830, and applies only to activities conducted by or for DOE. Any costs resulting from implementation of DOE's management, operation, and enforcement of its nuclear safety program are ultimately borne by the Federal government. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

G. Review Under Executive Order 12988, Civil Justice Reform

With respect to the review of existing regulations and the promulgation of new regulations, section 3 of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to eliminate drafting errors and ambiguity, write regulations to minimize litigation, provide a clear legal standard for affected conduct rather than a general standard, and promote simplification and burden reduction. 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. DOE has completed the required review and determined that, to the extent permitted by law, Part 830 meets the relevant standards of Executive Order 12988.

H. Review Under Small Business Regulatory Enforcement Fairness Act of 1996

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of the rule prior to its effective date. 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(3).

List of Subjects in 10 CFR Part 830

DOE contracts, Environment Federal buildings and facilities, Government contracts, Nuclear energy, Nuclear

materials, Nuclear power plants and reactors, Nuclear safety, Penalties, Public health, Reporting and recordkeeping requirements, and safety.

Issued in Washington, DC on September 28, 2000.

T. J. Glauthier,

Deputy Secretary of Energy, Department of Energy.

For the reasons set forth in the preamble, Part 830 of chapter III, title 10, of the Code of Federal Regulations is amended as set forth below.

PART 830—NUCLEAR SAFETY MANAGEMENT

1. The authority citation for part 830 is revised to read as follows:

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

2. Part 830—is revised to read as follows:

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

§ 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

(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.

Existing DOE nuclear facility means a DOE nuclear facility in operation before April 9, 2001.

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 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 is completed on or after April 9, 2001 that substantially changes the existing safety basis for the facility.

New DOE nuclear facility means a DOE nuclear facility that begins operation on or after April 9, 2001.

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 DOE nuclear facility or a major modification to a 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 identified by the documented safety analysis.

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 970.5204-2.

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 requirements necessary for the safe operation of a nuclear facility and, as appropriate for the work and the hazards identified in the documented safety analysis for the facility, includes 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;

(3) A margin of safety could be reduced; or

(4) 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.

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.

(3) 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 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.

§ 830.2021 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 submit to DOE either the updated documented safety analysis for approval or a letter stating that there have been no changes in the documented safety analysis since the prior submission; and

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

§ 830.203 Unreviewed safety question process.

The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must:

(a) Submit for DOE approval a USQ process that meets the requirements of this section:

(1) For an existing DOE nuclear facility, by April 10, 2001. Pending DOE approval of the USQ process, the contractor must continue to use its existing, DOE-approved USQ process. If the existing process already meets the requirements of this section, the contractor must notify DOE by April 10, 2001 and request that DOE issue an approval of the existing process; and

(2) For a new DOE nuclear facility, on a schedule that allows DOE approval in a safety evaluation report issued pursuant to section 207(d) of this Part.

(b) Implement the DOE-approved USQ process 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;

(c) Obtain DOE approval prior to taking any action determined to involve a USQ;

(d) Annually submit to DOE a summary of the USQ determinations performed since the prior submission; and

(e) If the contractor discovers or is made aware of a potential inadequacy of the documented safety analysis:

(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 (e)(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 2 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 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.

The contractor responsible for a hazard category 1, 2, or 3 new DOE nuclear facility or a major modification to a hazard category 1, 2, or 3 DOE nuclear facility 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; 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) By April 10, 2003, a contractor responsible for a hazard category 1, 2, or 3 existing DOE nuclear facility must submit for DOE approval a safety basis that meets the requirements of this Subpart.

(b) Pending issuance of a safety evaluation report in which DOE approves a safety basis for a hazard category 1, 2, or 3 existing DOE nuclear facility, the contractor responsible for the facility must continue to perform work in accordance with the safety basis for the facility in effect on October 10, 2000 and maintain the existing safety basis consistent with the requirements of this Subpart.

(c) If the safety basis for a hazard category 1, 2, or 3 existing DOE nuclear facility already meets the requirements of this Subpart and reflects the current work and hazards associated with the facility, the contractor responsible for the facility must, by April 9, 2001, notify DOE, document the adequacy of the existing safety basis and request DOE to issue a safety evaluation report that approves the existing safety basis. If DOE does not issue a safety evaluation report by October 10, 2001, the contractor must submit a safety basis pursuant to paragraph (a) of this section.

(d) With respect to a hazard category 1, 2, or 3 new DOE nuclear facility or a major modification to a 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.

**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 Policy 450.2A, "Identifying, Implementing and Complying with Environment, Safety and Health Requirements" (May 15, 1996).

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-1027-92 ("Hazard Categorization and Accident Analysis Techniques for compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports," Change Notice 1, September 1997) sets forth the methodology for categorizing a DOE nuclear facility. The hazard categorization must be based on an inventory of all radioactive materials within a nuclear facility.

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

TABLE 1

| | |
|---|---|
| A DOE nuclear facility categorized as * * * | has the potential for * * * |
| hazard category 1 | significant off-site consequences. |
| hazard category 2 | significant on-site consequences beyond localized consequences. |
| hazard category 3 | only local significant consequences. |
| below category 3 | only consequences less than those that provide a basis for categorization as a hazard category 1, 2, or nuclear facility. |

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 970.5204-2, Integration of Environment, Safety and Health into Work Planning and Execution) and the DEAR clause on laws, regulations, and DOE directives (48 CFR 970.5204-78, 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, however, 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 hazard 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 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 (1) satisfies the provisions of the methodology used to prepare the documented safety analysis and (2) 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.

4. In most cases, the contract will provide the framework for specifying the methodology and schedule for developing a documented safety analysis. Table 2 sets forth acceptable methodologies for preparing a documented safety analysis.

TABLE 2

| The contractor responsible for * * * | may prepare its documented safety analyses * * * |
|---|---|
| (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-3009-94, 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 limited operational life. | using the method in either: (1) DOE-STD-3009-94 or successor document or (2) 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: (1) DOE-STD-3009-94 or successor document or (2) DOE-STD-3011-94 or successor document. |
| (5) the decommissioning of a DOE nuclear facility | (1) using the method in DOE-STD-1120-98, May 1998, Integration of Environment, Safety, and Health into Facility Disposition Activities or nuclear successor document; (2) 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 (3) 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. | (1) using the method in DOE-STD-1120-98 or successor document and (2) using the provisions in 29 CFR 1910.120 (or activity that 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 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: (1) a Safety Analysis Report for the nuclear facility that considers the generic nuclear explosive operations and is prepared in accordance with DOE-STD-3009-94 or successor document and (2) 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-3009-94 or successor document to address in a simplified fashion: (1) the basic description of the facility/activity and its operations, including safety structures, systems, and components; (2) a qualitative hazards analysis; and (3) the hazard controls (consisting primarily of inventory limits and safety management programs) and their bases. |

5. Table 2 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 all 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 the employees or the general public, and to include any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements

established by Part 830. The only exceptions are those facilities specifically excluded such as accelerators. Table 3 defines the specific nuclear facilities referenced in Table 2 that are not defined in 10 CFR 830.3

TABLE 3

| For purposes of Table 2, * * * | 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 DOE nuclear facility or of a major modification to an existing 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, Facility Safety, 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 (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.

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 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 requirements 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 (1) safety limits, (2) operating limits, (3) surveillance requirements, (4) administrative controls, (5) use and application, and (6) design features. It may also have an appendix on the bases for the limits and requirements. DOE Guide 423.X, Implementation Guide for Use in Developing Technical Safety Requirements (TSRs) 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 4 sets forth DOE's expectations concerning acceptable technical safety requirements.

TABLE 4

| | |
|---|--|
| 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. |
| (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 nonautomatic initiation of protective actions related to those variables associated with the function of safety class structures, systems, or components if the safety analyses show 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. 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 (1) the requirements associated with administrative controls, (including those for reporting violations of the technical safety requirement); (2) the staffing requirements for facility positions important to safe conduct of the facility; and (3) the commitments to the safety management programs identified in the documented safety analysis as necessary components of the safety basis for the facility. |

TABLE 4—Continued

| | |
|---|--|
| As appropriate for a particular DOE nuclear facility, the section of the technical safety requirements on * * * | will provide information on * * * |
| (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 keeps the safety basis current by ensuring appropriate review of and response to situations that might adversely affect the safety basis.

3. DOE Guide 424.X, Implementation Guide for Addressing Unreviewed Safety Question (USQ) Requirements provides DOE's expectations for a USQ process. The contractor must obtain DOE approval of any USQ process.

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 (1) review of all safety basis documents submitted to DOE and (2) 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.

[FR Doc. 00-25453 Filed 10-6-00; 8:45 am]
BILLING CODE 6450-01-P