

issued August 5, 1998, are adopted as a final rule with the following change:

PART 1446—PEANUTS

1. The authority citation for part 7 CFR part 1446 continues to read as follows:

Authority: 7 U.S.C. 7271; 15 U.S.C. 714b and 714c.

2. Paragraph (c) of § 1446.102 is amended by adding a new sentence to the end of the paragraph to read as follows:

§ 1446.102 Administration.

* * * * *

(c) *Supervisory authority.* * * * Further, the Director of TPD, FSA, may authorize the wavier or modification of deadlines and other requirements, except statutory deadlines or requirements, in cases where lateness or the failure to meet such other requirements does not adversely affect operation of the program.

3. Paragraph (3) of the definition of "Segregations" in § 1446.103 is revised to read as follows:

§ 1446.103 Definitions.

* * * * *

(3) *Segregation 3.* Segregation 3 peanuts are farmers stock peanuts which, upon visible inspection, are found to contain *Aspergillus flavus* mold: *Provided further, however,* That, in accordance with such written instructions as the Director may issue, the Director shall permit producers at approved buying points as specified by the Director to have the Segregation 3 lot reconditioned, one time only, and then reinspected visually. If the buying point where the peanuts were initially delivered does not have adequate cleaning facilities, CCC may approve an alternative buying point for cleaning and reinspection. The visual reinspection may not occur more than 72 hours from the initial inspection except as permitted by the Director and the second grade shall be considered the final grade for the farmers stock peanuts.

§ 1444.307 [Amended]

4. Section 1444.307 is amended by removing paragraph (g) from that section.

Signed at Washington, D.C., on January 3, 2001.

Keith Kelly,

Executive Vice President, Commodity Credit Corporation.

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DEPARTMENT OF ENERGY

10 CFR Part 830

RIN 1901-AA34

Nuclear Safety Management

AGENCY: Department of Energy

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE) adopts, with minor changes, the interim final rule published on October 10, 2000, to amend the DOE Nuclear Safety Management regulations.

EFFECTIVE DATE: This final rule is effective on February 9, 2001.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Introduction and Summary

On October 10, 2000, the Department of Energy (DOE) published an interim final rule in the **Federal Register** (65 FR 60291) that amended DOE's nuclear safety regulations in 10 CFR Part 830 (Interim Final Rule). DOE provided a 30-day public comment period for the Interim Final Rule and subsequently received comments to the rule from over 30 parties. As a result of the comments that were received to that Interim Final Rule, DOE became aware of a number of minor errors in the published version of the rule and the preamble, as well as a number of minor changes to the rule that would clarify and simplify implementation of the amended rule. We are republishing the rule as a final rule with those changes. Finally, we are summarizing the issues raised in the comments to the Interim Final Rule and providing DOE's responses to the major issues. Many of the comments concerned rule implementation issues that will be addressed in the rule implementation guides.

II. Discussion of Changes to the Rule

The following changes to 10 CFR Part 830 are being made in response to comments to the Interim Final Rule.

A. Changes to § 830.2, Exclusions

We are amending paragraph 830.2(d) to exclude the mixed oxide fuel fabrication and irradiation facilities that the Nuclear Regulatory Commission (NRC) has the authority to license and regulate under § 3134 of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999 (Public Law 105-261). Section 3134

amends the Energy Reorganization Act of 1974 to add § 202(5) (42 U.S.C. 5842). This exclusion will make clear that these facilities will be licensed by the NRC and must be designed and constructed to meet NRC regulations. Thus, these facilities are excluded from the requirement to meet 10 CFR Part 830 before and after a license is issued by the NRC.

B. Changes to § 830.3, Definitions.

We are revising the following definitions in § 830.3:

1. Safety Class Structures, Systems, and Components

We are revising the words "identified by the documented safety analysis" to "determined from safety analyses" to make the definition consistent with those for "safety structures, systems, and components" and "safety significant structures, systems, and components."

2. Technical Safety Requirements (TSRs)

We are revising the definition of TSRs to express it more clearly. As revised, the definition of TSRs means the limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and the hazards identified in the documented safety analysis for the facility: Safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix. The documented safety analysis identifies the need for TSRs, but the actual limits are identified in the TSRs. The revisions make clear that the TSRs address the specific numerical limits and related actions necessary for safe operation of a nuclear facility. Because the TSRs identify the limits and actions necessary in specific situations, it is not appropriate to use the graded approach to justify the use of different limits and actions than those set forth in the TSRs. The change made to the graded approach section is consistent with this change.

C. Changes to § 830.7, Graded Approach

We received a number of comments requesting us to clarify where a contractor must use a graded approach and how the graded approach documentation should be submitted. We are revising the language in § 830.7 to clarify that a contractor may not use a graded approach in implementing the unreviewed safety question (USQ)

process or in implementing the technical safety requirements. We are addressing the documentation question in Section III. I of this preamble.

D. Changes to Subpart B, Safety Basis

1. Section 830.203 Unreviewed Safety Question Process

a. Unreviewed safety question (USQ) procedure. In § 830.203 of the Interim Final Rule we stated that the contractor must submit a USQ "process." In fact, the document that specifies how the USQ process is to be performed is the USQ "procedure." We are changing the rule language in § 830.203 to reflect that a contractor is to submit "a procedure for its USQ process," rather than a "USQ process." Conforming changes are being made in Appendix A to Subpart B as well. These changes should be considered when reading the USQ discussions in the preamble to the Interim Final Rule.

b. Existing USQ procedure. In § 830.203, we deleted the words "DOE-approved" from the requirement for contractors to continue to use their existing USQ procedure pending approval of the USQ procedure to be submitted under the rule by April 10. This will ensure that contractors who have not received DOE-approval for their current USQ procedures will continue to use their existing USQ procedures.

c. Editorial changes. We made some editorial changes to § 830.203 to make it easier to read.

2. Section 830.206 Preliminary Documented Safety Analysis

We received a number of comments on the application of the requirements for a preliminary documented safety analysis to new nuclear facilities and major modifications to nuclear facilities that were nearly ready to operate. We agree that the purpose of the requirement is to ensure that DOE and the contractor agree on design considerations during the design and early construction phases of the modification, and that the final documented safety analysis will document those considerations during the final construction efforts. Consequently, we are revising § 830.206 to apply to hazard category 1, 2, and 3 new nuclear facilities and major modifications for which construction begins after December 11, 2000.

3. Section 830.207 DOE Approval of Safety Basis

We are adding the words, "or as approved by DOE on a later date," to paragraph 830.207(b) to clarify that the

contractor must perform work to the approved safety basis in effect on October 10, 2000 unless there is a more recent DOE-approved safety basis. The applicable safety basis for the nuclear facility is the latest DOE-approved safety basis.

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

1. We are adding two "safe harbor" provisions for transportation activities in Table 2. This change is discussed in more detail in the response to comments.

2. We are making conforming changes in the appendix to be consistent with the change to the definition of TSRs.

3. Editorial Changes.

a. We are adding a reference to Table 1 in paragraph C in Appendix A to Subpart B, Scope.

b. We are revising language in paragraph C in Appendix A to Subpart B to read, "all DOE nuclear facilities, including radiological facilities,* * *" to clarify that radiological facilities are considered to be a subset of nuclear facilities.

c. We are adding a "3" to the last item of Table 1 in Appendix A to Subpart B where it was inadvertently omitted.

d. We are editing Table 2 in Appendix A to Subpart B to correct the alignment and to correct language in paragraph (6)(2) of the table.

e. We are changing the reference to "DOE-STD-3009-94" to read "DOE-STD-3009, Change Notice 1, January 2000," throughout the rule.

III. Response to Comments on the Interim Final Rule

DOE received written comments from over 30 interested organizations (primarily DOE contractors) and individuals on the amendments in the Interim Final Rule for the DOE Nuclear Safety Management requirements of 10 CFR Part 830. You may examine written comments between 9 AM and 4 PM 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.

This section of the Supplementary Information summarizes the issues raised in the comments and gives DOE's response. Many of the comments raised questions and positions related to the implementation of the requirements. These comments will be considered in the development of the implementation guides that were discussed in the preamble to the Interim Final Rule.

Preamble

A. *Comment:* In the Summary of Changes in the preamble to the Interim Final Rule, paragraph G, several commentors noted that the paragraph that reads "The USQ process has two steps * * *" is incorrect and should be entirely deleted.

Response: We agree.

B. *Comment:* Several commentors provided editorial corrections.

Response: We agree with the following editorial corrections to the preamble:

1. In the "Summary of Changes" in the preamble to the Interim Final Rule, paragraph II.D.f, "Existing DOE nuclear facility and new DOE nuclear facility," the date for new nuclear facilities was erroneously listed as April 9, 2000. The correct date is April 9, 2001.

2. In the "Summary of Changes" in the preamble to the Interim Final Rule, paragraph II.D.2.d.vi, on page 60297, "electronic microscopes" should be "electron microscopes."

830.1, Scope

C. *Comment:* A number of commentors objected to expanding the scope of the rule to cover activities performed offsite. One commentor suggested limiting the offsite applicability by setting a dollar threshold for procurement actions, exempting procurement of commercial items, limiting the applicability to components having nuclear safety significance, or reducing fines for offsite work.

Response: We have considered the suggestions for limiting the applicability of the rule offsite and do not agree that such limitations should be adopted. In 1995, we gave notice that we were considering an option that would expand the scope of Part 830 to cover conduct that could affect the safe management of nuclear facilities without any limitation that such conduct must occur at nuclear facilities. See the Notice of Limited Reopening of the Comment Period, 60 FR 45381, 45384 (Aug. 31, 1995). In adopting this option to cover offsite activities, we noted that the scope of the rule would 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 may affect, nuclear safety of DOE nuclear facilities. Thus, the provision of items and services taking place offsite which affect

nuclear safety would be covered by the rule. DOE expects that contractors will establish specifications and standards in their procurement documents and flow them down to all tiers of subcontractors and suppliers, regardless of whether items will be provided or services will be performed onsite or offsite.

We also recognize that in some cases contractors may not flow down specifications but may choose to procure commercial grade items and materials and to perform the tests or other actions that are necessary to upgrade these materials or items to allow them to be used as items important to nuclear safety. Contractors may choose to perform the required actions to upgrade these materials or items either for economic reasons or because qualified vendors cannot be found. In these cases, the supplier is responsible for meeting the requirements for commercial grade materials or items as specified in the procurement documents and the contractor is responsible for ensuring the requirements are met for using these materials or items as items important to nuclear safety.

We believe that the alternatives suggested for limiting the offsite application of the rule are not necessary or advisable. Commercial products as well as small dollar purchases may affect nuclear safety of DOE nuclear facilities depending on their intended use. All the facts and circumstances involved in the failure of an item procured from an offsite vendor or supplier will be looked at in any subsequent enforcement action. Civil penalties can be appropriately mitigated or adjusted in accordance with the enforcement discretion in 10 CFR Part 820.

D. *Comment:* A number of commentors questioned how they should apply the requirements of this rule to transportation activities not regulated by the Department of Transportation (DOT).

Response: We are amending the rule to add two additional "safe harbor" methods in Table 2 of Appendix A to Subpart B for transportation activities covered by this rule. The new safe harbor methods will endorse the methods and processes described in DOE-O-460.1A, Packaging and Transportation Safety, and its associated guide and DOE-O-461.1, Packaging and Transportation of Materials of National Security Interest, and its associated manual, as acceptable ways to satisfy the rule requirements for transportation activities covered by the provisions of this rule.

830.2, Exclusions

E. *Comment:* A commentor stated that an exclusion to the requirements of this rule should be provided for the mixed plutonium-uranium oxide fuel fabrication and irradiation facilities for the period prior to licensing by the Nuclear Regulatory Commission (NRC).

Response: We already exclude any activity licensed by the NRC in paragraph 830.2(a). The NRC has licensing and related regulatory authority for any facility under contract with DOE that is used for the express purpose of fabricating mixed plutonium-uranium oxide nuclear reactor fuel for use in a commercial nuclear reactor licensed under the AEA, other than any such facility that is utilized for research, development, demonstration, testing or analysis purposes. See Section 3134(a) of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999 (Pub. L. 105-261) which amends the Energy Reorganization Act of 1974 to add Section 202(5) (42 U.S.C. 5842). The design and construction of these facilities will be required to meet NRC nuclear safety regulations and, therefore, we are revising § 830.2 to make clear that we are excluding these facilities from the provisions of 10 CFR Part 830. This exclusion is similar to the exclusion for activities under the Nuclear Waste Policy Act.

830.3, Definitions

F. *Comment:* A commentor stated that the terms "safety analysis," "documented safety analyses," and "hazard analyses" are used inconsistently in the definitions of "safety class structures, systems, and components;" "safety significant structures, systems, and components;" and "safety structures, systems, and components."

Response: We are revising the words "Documented safety analysis" to "safety analyses" to make the definition consistent with those for "safety structures, systems, and components" and "safety significant structures, systems, and components."

G. *Comment:* A number of commentors noted that some terms used in the rule, such as the terms "limited operational life" and "short remaining operational period" are not defined in the rule and guidance should be provided on what these terms mean.

Response: We agree with the comment and we will address these and other terms in the implementation guides for this rule.

830.7, Graded Approach

H. *Comment:* A number of commentors raised questions regarding the use of the graded approach and the appropriate place to document it.

Response: We received a number of comments requesting us to clarify where a contractor must use a graded approach and how the graded approach documentation should be submitted. As stated in the preamble to the Interim Final Rule, contractors are already required to implement the quality assurance requirements using a graded approach. In the appendix, we stated that DOE expects a contractor to use a graded approach to develop a documented safety analysis and describe how the graded approach was applied. The preamble provided that use of the graded approach is not appropriate in implementing the USQ process or in implementing technical safety requirements. We are revising the requirements in § 830.7 to add a sentence to clarify that the graded approach is not appropriate in implementing the USQ process or in implementing technical safety requirements. The graded approach remains applicable to the implementation of quality assurance and to the documented safety analysis.

We also received comments concerning the documentation requirements explaining how the graded approach was applied. Section 830.7 requires a contractor to document the basis of the graded approach used and to submit that documentation to DOE. While the rule does not prescribe when and where such documentation should be submitted, it is expected that the documentation and justification for grading would be submitted in the documents in which it is used. Grading methodology and its application would then be reviewed by the DOE officials who have the authority to approve the documents. Grading approaches for site-wide programs or facility-specific applications are explained further in guidance documents.

Subpart A, Quality Assurance

I. *Comment:* Several comments expressed concern that failure to perform work consistent with all "contract" requirements might be subject to enforcement actions under the provisions of the Price-Anderson Amendments Act of 1988 (PAAA).

Response: Paragraph 830.122(e)(1) of Subpart A of the rule requires contractors to: "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." However, both this rule and the DOE PAAA enforcement process in 10 CFR Part 820 are limited to contractor activities that affect, or may affect, the safety of DOE nuclear facilities. Thus, contract requirements that do not have an effect on nuclear safety are not subject to the work process provisions of Subpart A of this rule and will not be subject to PAAA enforcement. DOE has other contract remedies to address noncompliance with contract requirements and work processes that have no effect on nuclear safety.

J. *Comment:* A number of comments questioned how the work process requirements apply to subcontractors and suppliers.

Response: Section 830.121(a) is explicit that all contractors, including subcontractors and suppliers, must conduct work in accordance with the quality assurance criteria listed in § 830.122, including the work processes criteria in paragraph 830.122(e). Moreover, the general rule in paragraph 830.4(a) is clear that subcontractors and suppliers may not take any action inconsistent with the requirements in Part 830. In addition to these direct requirements, paragraph 830.121(c)(4) makes the prime contractor responsible for ensuring subcontractors and suppliers satisfy the quality assurance criteria of paragraph 830.122(e). DOE expects that in most cases, prime contractors would satisfy this requirement through the flowdown of requirements and standards in procurement documents. The prime contractor will be subject to regulatory enforcement if a subcontractor or supplier does not meet the quality assurance criteria when providing items and services that could affect nuclear safety of DOE nuclear facilities. This responsibility of the prime contractor, however, does not relieve the subcontractors and suppliers from the requirements imposed directly upon them.

K. *Comment:* A number of commentors asked why DOE is requiring contractors to identify consensus standards that are used in the Quality Assurance Program (QAP).

Response: DOE has a long history of requiring the use of appropriate national and international standards for implementing its quality assurance requirements. DOE is strongly committed to this philosophy to ensure that its contractors develop and implement effective and efficient QAPs. Each DOE quality assurance criterion is stated as a performance expectation and

does not specify the methods to achieve the desired performance result. National and international standards (e.g., ASME NQA-1, ASQ E-4, or ISO 9001) and their supplemental guidance include a number of proven methods for achieving DOE's performance expectations. DOE has found cases where failure to use these standards to develop implementing processes has led to noncompliance with the DOE quality assurance criteria. DOE is concerned that all of its contractors are not taking full advantage of the benefits standards offer. Use of national and international standards will help contractors to develop effective and efficient QAPs that are also aligned with their customer's and supplier's QAPs. The DOE implementation guide for the quality assurance requirements in the rule (DOE-G-414.1-2) includes a discussion of standards use and references to the most widely accepted national and international standards for quality assurance. Contractor use of this implementation guide and the clear identification and the documented use of standards will also help DOE meet its responsibilities to review contractor QAPs to ensure that they meet the rule requirements and to oversee contractors to ensure that they fully implement their DOE-approved QAPs.

Subpart B, Safety Basis

L. *Comment:* A commentor stated that § 803.201 does not add to the rule's substantive requirements, and because the word "work" is not defined, it could lead to unjustified applications or too narrow interpretations.

Response: Other sections of the safety basis requirements (Subpart B) define the requirements for derivation and documentation of the safety basis for a nuclear facility. Section 803.201 requires that the activities within them must be conducted in accordance with the safety basis. It is essential to have this element for the safety basis requirements be more than a paper exercise.

M. *Comment:* Several commentors asked how the authorization basis is different from the safety basis.

Response: The rule defines the safety basis as the documented safety analysis and the hazard controls that provide reasonable assurance that a DOE nuclear facility can be operated safely and in a manner that adequately protects workers, the public, and the environment. The authorization basis is defined in DOE-G-450.4-1A, Integrated Safety Management System Guide for Use with Safety Management System Policies (DOE-P-450.4, DOE-P-450.5, and DOE-P-450.6); the Functions,

Responsibilities, And Authorities Manual (DOE-M-411.1-1B); and the Department of Energy Acquisition Regulation (DEAR) 48 CFR 970.5223-1, as safety documentation that supports the decision to allow a process or facility to operate. Included are corporate operational and environmental requirements as found in regulations and specific permits, and, for specific activities, work packages or job safety analyses. In general, the safety basis as defined in the rule is a subset of the authorization basis as the authorization basis includes documents relating to environmental issues, such as permits, as well as safety documentation.

N. *Comment:* Several commentors asked why DOE-STD-1027 is listed as a requirement for hazard categorization, instead of a safe harbor method.

Response: In general, each of the safe harbor standards listed in Table 2 of Appendix A to Subpart B of the rule can be effectively applied to specified types of facilities and activities. In allowing the contractor to choose the appropriate safe harbor standard for developing the safety basis, DOE expects the contractor to select the standard that best fits the application. However, DOE wants contractors to be consistent when determining the hazard classification for its nuclear facilities; hence we are requiring the consistent use of DOE-STD-1027 which has an established history for this purpose.

O. *Comment:* A commentor asked what is a "below hazard category 3" nuclear facility.

Response: In DOE-STD-1027, these facilities are categorized as having no potential for significant offsite, onsite, or localized consequences. A "below hazard category 3" nuclear facility is a DOE facility or activity that meets the definition of a nuclear facility but does not meet the threshold in DOE-STD-1027 for a hazard category 3 nuclear facility. These facilities are sometimes referred to as "radiological facilities." See also Table 1 in Appendix A to Subpart B of the rule.

P. *Comment:* Two commentors questioned a statement in the preamble to the Interim Final Rule, in paragraph III.D on segmentation that said "If a 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 the purposes of this rule."

Response: We agree that the statement could be misleading and the individual circumstances would need to be evaluated to determine the effect on operations in the other segment before

making the determination of whether segmentation would be permitted for purposes of categorizing the facility and establishing an appropriate safety basis. Additional discussion on segmenting nuclear facilities can be found in DOE-STD-1027.

We emphasize, however, that in considering segmentation a contractor must be mindful of its overriding obligation to ensure adequate protection of workers, the public, and the environment. A contractor will have the burden of proof to demonstrate that segmentation is appropriate.

Q. Comment: A commentor stated that USQ determinations related to potential inadequacies of the safety analysis (PISA) are not always done in a timely manner and a definite time period for the performance of a USQ determination should be provided in paragraph 830.203(e)(3).

Response: The implementation guide for the USQ requirements of the rule (DOE-G-424.X) will provide DOE's expectation that the contractor's USQ procedure should define the period for the performance of a USQ determination related to a PISA and that this time period should be on the order of days, not weeks or months.

R. Comment: Several commentors asserted that a PISA should not be classified as a USQ until a USQ determination confirms that the safety analysis is inadequate.

Response: The fact that the safety analysis could be inadequate, either because of a deficiency in the analysis or because of an as-found condition, indicates that there is a safety question that has not yet been reviewed (in other words, a USQ). When a contractor discovers a PISA, DOE requires the contractor to take action to place the facility in a safe condition and to notify DOE of the potential inadequacy. The performance of a subsequent USQ determination is to confirm a positive USQ determination or a negative USQ determination through the application of the risk-related criteria for a USQ. If the finding is negative, this would support a request to DOE to remove any operational restrictions imposed when the PISA was discovered.

S. Comment: Section 830.203 requires contractors for existing nuclear facilities to continue to use their existing DOE-approved USQ procedure. One commentor asked what it should do if DOE has not yet approved its USQ procedure.

Response: We have deleted the word "DOE-approved" from the requirement. Contractors are expected to continue to use their existing USQ procedures pending DOE approval of the USQ

procedure to be submitted to DOE for approval by April 10, 2001 under the rule.

T. Comment: The definition of a USQ in § 830.3 of the rule states that a situation involves a USQ if a margin of safety could be reduced. A commentor proposed that the margins of safety described in the bases appendix to be considered should be limited to the margins of safety described in the bases section of the technical safety requirements.

Response: Not all nuclear facilities are required to have technical safety requirements. For example, certain environmental restoration activities are not required to develop technical safety requirements. The safety basis implementation guides will clarify how the margin of safety criterion should be implemented.

U. Comment: A commentor stated that paragraph 830.204(b)(2), should specify that the documented safety analysis must address both hazards for the facilities and the activities therein, instead of just the hazards associated with the facility.

Response: We agree. In fact, the definition for a nonreactor nuclear facility includes facilities, activities, and operations. No change to the rule is necessary.

V. Comment: Several commentors questioned why a contractor must submit a preliminary documented safety analysis for a major modification rather than using the USQ process to address the changes.

Response: Several commentors recommended that contractors use the USQ process and modify an existing documented safety analysis, rather than submitting a preliminary documented safety analysis for a major modification. This suggestion would defeat the purpose of the review and approval of the safety aspects of design of the modification prior to procurement and construction, which is to ensure that DOE agrees with the design before the modification is implemented. If the contractor proceeded to modify the existing documented safety analysis for the facility and submit it for approval, prior to design and construction, the documented safety analysis would be instantly out of compliance because it would no longer reflect the current configuration of the nuclear facility.

W. Comment: Several commentors indicated that by tying the definition for a major modification to the initial operation date, rather than the design date, contractors could be required to develop preliminary documented safety analyses for major modifications that were already designed by now and

possibly under construction, and for which documented safety analysis would also be required. A commentor recommended that the requirement for a preliminary documented safety analyses for a major modification or new facility be linked to the initiation of conceptual design.

Response: The purpose of the preliminary documented safety analysis is to ensure that DOE and the contractor agree on design considerations during the design and early construction phases of the modification. We are, therefore, amending § 830.206 to apply to hazard category 1, 2, and 3 new DOE nuclear facilities and major modifications for which construction begins after December 11, 2000.

X. Comment: A commentor stated that the preliminary documented safety analysis should identify safety systems in addition to safety programs.

Response: Safety systems will, of necessity, be identified as part of the safety analysis that derives the aspects of design that are necessary to satisfy the nuclear safety design criteria. This is expressed in the definition of preliminary documented safety analysis.

Y. Comment: Several commentors asked if a preliminary documented safety analysis is needed for environmental restoration, and decontamination and decommissioning?

Response: As stated in paragraph F.6 of Appendix A to Subpart B of the rule, 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 explosives operations, or transition surveillance and maintenance activities.

Z. Comment: One commentor stated that we should discuss how the integrated safety management principles would be used for design.

Response: The implementation guide for the documented safety analysis (DOE-G-421.X, Implementation Guide for Use in Developing Documented Safety Analyses to Meet Subpart B of 10 CFR Part 830) specifies that a preliminary documented safety analysis should show how the nuclear safety design criteria of DOE Order 420.1 (DOE-O-420.1), Facility Safety, will be satisfied. The implementation guide for DOE-O-420.1 says that an iterative process between safety analysis and design should begin as early as possible so safety is integrated into the design process as early as possible. This is consistent with the integrated safety management system process.

AA. *Comment:* A number of commentors asked how contractors should address normal and abnormal conditions in a documented safety analysis.

Response: Contractors should refer to DOE implementation guides for additional information on how to meet DOE's expectations regarding the requirements in this rule. In particular, contractors should refer to DOE-STD-3009, section 3.3, page 35 for additional information on how to address normal and abnormal conditions in the documented safety analysis. This section of the standard describes how all modes of normal operation are to be considered.

BB. *Comment:* Several commentors asked how a contractor should ensure that a safety basis contains all the required contents of the rule when using a "safe harbor" standard to prepare a documented safety analysis.

Response: In general, "safe harbor" standards listed in Table 2 of Appendix A to Subpart B of the rule are the standards currently used in the DOE complex to develop documented safety analyses and they reflect years of experience developing adequate documented safety bases. DOE is confident that these standards provide good methods for developing a documented safety analysis. If a contractor uses a "safe harbor" methodology, that methodology should result in a contractor satisfying the regulatory requirements for a documented safety analysis. However, the contractor is responsible for meeting the requirements of the rule, even if it uses a safe harbor standard to prepare its documented safety analysis.

CC. *Comment:* A commentor asked what a contractor should do if it developed a documented safety analysis using a safe harbor method, but did not meet every criterion of a safe harbor method.

Response: As discussed in the preamble to the Interim Final Rule, if a contractor uses a method other than a safe harbor method it must obtain DOE approval of the method before developing the documented safety analysis. If a contractor uses a safe harbor method to develop the documented safety analysis, but does not follow the method completely, the contractor should request DOE approval of the method with the specific deviations identified.

DD. *Comment:* Section 830.204 of the rule does not limit the documented safety analysis to only nuclear hazards. Several commentors asked if controls for non-nuclear hazards are enforceable.

Response: As stated in paragraph V.F of the preamble to the Interim Final Rule, we expect our contractors to address all radioactive and nonradioactive hazards, as well as the controls necessary to provide adequate protection to the public, the workers, and the environment from these hazards, in the documented safety analysis for category 1, 2, or 3 nuclear facilities. However, as stated in the General Statement of Enforcement Policy (Appendix A to 10 CFR Part 820), we will only pursue enforcement actions through the procedures in Part 820 for those noncompliances that have nuclear safety significance.

EE. *Comment:* A commentor asked why DOE listed criticality safety requirements separately in § 830.204.

Response: DOE chose to specifically call out certain content requirements for the documented safety analysis in the rule because of their importance to nuclear safety. Among these are the criticality safety requirements. The criticality safety requirements in § 830.204 are consistent with the current criticality safety requirements in DOE-O-420.1 which is listed as a safe harbor method for the design criteria for a new nuclear facility. In addition, DOE-G-421.X, Implementation Guide for Use in Developing Documented Safety Analyses to Meet Subpart B of 10 CFR Part 830, will address the role of criticality safety.

FF. *Comment:* A commentor stated that we should specifically incorporate the criticality standards identified in DOE-O-420.1 in the requirements for the documented safety analysis in § 830.204.

Response: The rule addresses this issue in several ways. First, DOE-O-420.1 is invoked in § 830.206 relative to the design criteria to be used for the preliminary documented safety analysis. DOE-O-420.1 addresses the design features important for criticality safety. Second, Appendix A to Subpart B invokes DOE-O-420.1 in two places: (1) paragraph F.6 of the appendix describes the design criteria for a preliminary documented safety analysis and (2) section G of the appendix states that "Order 420.1 provides DOE's expectations with respect to fire protection and criticality safety." DOE-G-421.X will provide additional discussion of the importance of DOE-O-420.1 with respect to criticality safety standards. We believe these requirements and associated guidance provide sufficient direction to contractors regarding DOE's expectations for criticality safety.

GG. *Comment:* A commentor asked if the rule permits a documented safety

analysis to reflect a final categorization that would permit segmentation or the application of unmitigated release parameters more appropriate to the actual situation.

Response: Yes. Several commentors misinterpreted the requirement in § 830.202 for classification according to DOE-STD-1027 as not allowing for documented safety analysis to contain a final categorization that would permit segmentation or the application of unmitigated release parameters more appropriate to the actual situation. The suggestion was made to allow for these modifications as part of the initial categorization. However, no change to the rule is needed because DOE-STD-1027 does permit these modifications as part of a safety analysis, and DOE-STD-3009 calls for final categorization as part of the documented safety analysis.

HH. *Comment:* Paragraph 830.205(c) should include reference to DOE-STD-1120.

Response: Section 830.205 does not reference DOE-STD-1120. However, DOE-STD-1120 is referenced in Table 2 of Appendix A to Subpart B to the rule as a safe harbor for environmental restoration activities. We believe that this is the appropriate reference to DOE-STD-1120 for the rule.

II. *Comment:* Several commentors stated that including design features as a section in the technical safety requirements, instead of allowing the design features to be included in the documented safety analysis, is expensive and provides no safety benefit.

Response: It is important that certain design features be included in the technical safety requirements. The design features to be included in a section of the technical safety requirements are those which are regarded as important in establishing the safety basis. These design features should not be changed without DOE approval. Since changes to the technical safety requirements must be approved by DOE, any changes to design features identified as technical safety requirements would require prior DOE approval. If these important design features are just included in the description of the facility in the documented safety analysis, alterations would be subject to the USQ process. If the contractor determines that the change does not involve a USQ, then the change may not be submitted for prior DOE approval.

JJ. *Comment:* Several commentors asked why a contractor is required to submit the annual update of the documented safety analysis to DOE for approval when DOE will have already

approved any changes to be incorporated in the documented safety analysis through the USQ process.

Response: DOE requires contractors to obtain DOE approval of the annual update of the documented safety analysis to assure that both the changes made pursuant to the USQ process and any changes not covered by the USQ process have been properly included in the update. If the USQ process has been followed properly, the annual approval of the documented safety analysis should require minimal effort. The annual update will not require DOE to review USQs already approved by DOE.

KK. Comment: A commentator asked if DOE has already approved a safety basis, does the contractor need to resubmit the safety basis for approval.

Response: Yes. However, if a contractor determines that its current safety basis meets the requirements of the rule, it may request DOE to approve that safety basis under the rule through the provisions in paragraph 830.207(c).

LL. Comment: A commentator asked what safety basis applies if a contractor has submitted a new safety basis to DOE for approval as of October 10, 2000, but DOE has not yet approved it.

Response: The effective safety basis is the DOE-approved safety basis. When DOE approves a new safety basis, that becomes the new effective safety basis as of the date of the approval. We are adding the words, "or as approved by DOE at a later date," to paragraph 830.207(b) to clarify that a safety basis may be superseded by later revisions with DOE approval.

MM. Comment: Paragraph 830.207(c) states that if a contractor believes that its current safety basis meets the rule, it should notify DOE by April 9, 2001 and request DOE to approve the safety basis under the rule. Further, it states that if DOE does not issue a safety evaluation report (SER) by October 10, 2001, a contractor must submit a safety basis to DOE for approval. Several commentators suggested that existing safety bases which are asserted to be compliant with the rule should be assumed to be approved by DOE if DOE does not issue an SER by October 10, 2001, instead of being assumed to be deficient. A commentator also suggested that DOE might not approve the safety basis within 6 months because of lack of resources.

Response: It is desired that both the contractor and DOE take positive action in establishing safety bases under the rule. The contractor should maintain cognizance of the status of DOE reviews and work with DOE to resolve the status of the safety basis submitted in a timely fashion. If the safety basis was originally

developed using one of the safe harbors of the rule, the safety evaluation report for the safety basis was issued approving the safety basis and the safety basis and the safety evaluation report are current, then the DOE effort to verify compliance with rule provisions should be small.

Appendix A to Subpart B

NN. Comment: A commentator stated that in Appendix A, paragraph G should refer to "requirements" in DOE-O-420.1, not "expectations."

Response: We agree that the provisions in DOE-O-420.1 are requirements if the order is included in a contract for the facility or if the order is adopted by the contractor in its work processes. If not, the order still provides DOE's expectations.

OO. Comment: A commentator noted that the sentence preceding Table 3 in Appendix A to Subpart B of the rule says that Table 3 defines the specific nuclear facilities referenced in Table 2 that are not defined in § 830.3; however, Table 3 defines both facilities and activities. Consequently, the commentator stated that the reference should state it defines "facilities or activities."

Response: The commentator is correct that the table refers to both facilities and activities. However, the term used is "nuclear facilities." Nuclear facilities, as defined in the rule, includes both reactor and nonreactor nuclear facilities. The definition of "nonreactor nuclear facilities" includes facilities, operations, and activities. Therefore, no change is required.

PP. Comment: One commentator stated that DOE should make the safety bases documents available to the public and a second commentator expressed concern that DOE protect classified documents from being released.

Response: As stated in the last paragraph of Appendix A to Subpart B, 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. In accordance with applicable laws, regulations, and directives, DOE will not release classified documents to the public. However, many of the safety basis documents are not classified and, therefore, can be made available to the public.

General

QQ. Comment: A commentator asked, if there is no single contractor responsible for a facility, who is responsible to

ensure the requirements of the rule are met?

Response: At some DOE sites, management and operating (M&O) contractors or management and integration (M&I) contractors are responsible for ensuring that the responsibilities of an activity are properly integrated. In such cases, the M&O contractor or the M&I contractor, respectively, would be responsible for ensuring the requirements at a facility, including the safety bases requirements of Subpart B of 10 CFR Part 830 are met. For other facilities, DOE may have assumed the role of the integrator and may be responsible to ensure that the requirements are met. During an enforcement action, DOE will weigh the facts and circumstances surrounding an action to determine the responsible party.

RR. Comment: A commentator asked if DOE expects contractors to modify contracts and Safety Management Systems to include the new requirements in the rule.

Response: Regulatory requirements are legal requirements and they apply whether or not they are incorporated in contracts or Safety Management Systems. In addition, Department of Energy Acquisition Regulation (DEAR) 48 CFR 970.5204-2 (Laws Clause) states that a contractor is obligated to comply with applicable Federal, state, and local laws and regulations, unless relief has been granted in writing by the appropriate regulatory agency and to flow down applicable regulations to subcontractors and suppliers. It further states that omission of any applicable law or regulation from List A does not affect the obligation of the contractor to comply with such law or regulation.

SS. Comment: A commentator asked if contractors and subcontractors are required to report defects and operational events through the Occurrence and Processing Reporting System (ORPS).

Response: DOE expects its prime contractors to continue to report defects and operational events through ORPS, as required by contracts. Use of this system may be enforceable through the quality assurance requirements of Subpart A, but the particular circumstances of the situation would need to be assessed. Subcontractors will continue to report through the prime contractors. Both DEAR 48 CFR 970.5223-1 and the procurement requirements of Subpart A, require prime contractors to flowdown requirements to subcontractors.

TT. Comment: A commentator asked if exemptions granted to contractors under

DOE order requirements would be automatically continued under the rule.

Response: No. New exemptions will need to be requested under the provisions of Subpart E of 10 CFR Part 820.

IV. Regulatory and 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 regulatory action has been determined not to be "a significant

regulatory action" under Executive Order 12866, "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Accordingly, this action was not subject to review under that Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB).

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

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform" (61 FR 4729, February 7, 1996) imposes on Executive agencies the general duty to (1) eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. 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 January 4, 2001.

T. J. Glauthier,

Deputy Secretary, 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.

Accordingly, the interim final rule for 10 CFR Part 830 which was published at 65 FR 60291 on October 10, 2000 is adopted as a final rule with minor changes as set forth below.

1. 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

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

§ 830.1 Scope.

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

§ 830.2 Exclusions.

This part does not apply to:
(a) Activities that are regulated through a license by the Nuclear Regulatory Commission (NRC) or a State under an Agreement with the NRC, including activities certified by the NRC under section 1701 of the Atomic Energy Act (Act);

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

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

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

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

§ 830.3 Definitions.

(a) The following definitions apply to this part:

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

Basis 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 determined from safety analyses.

Safety evaluation report means the report prepared by DOE to document

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

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

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

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

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

Safety management system means an integrated safety management system established consistent with 48 CFR 970.5223-1.

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

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

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

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

Technical safety requirements (TSRs) means the limits, controls, and related actions that establish the specific

parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and the hazards identified in the documented safety analysis for the facility: Safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix.

Unreviewed Safety Question (USQ) means a situation where

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

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

(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. The graded approach may not be used in implementing the unreviewed safety question (USQ) process or in implementing technical safety requirements.

Subpart A—Quality Assurance Requirements

§ 830.120 Scope.

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

§ 830.121 Quality Assurance Program (QAP).

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

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

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

(2) Modify the QAP as directed by DOE.

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

(4) Conduct work in accordance with the QAP.

(c) The QAP must:

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

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

(3) Use voluntary consensus standards in its development and implementation, where practicable and consistent with

contractual and regulatory requirements, and identify the standards used.

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

§ 830.122 Quality assurance criteria.

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

(a) Criterion 1—Management/Program.

(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

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

(b) Criterion 2—Management/Personnel Training and Qualification.

(1) Train and qualify personnel to be capable of performing their assigned work.

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

(c) Criterion 3—Management/Quality Improvement.

(1) Establish and implement processes to detect and prevent quality problems.

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

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

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

(d) Criterion 4—Management/Documents and Records.

(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.

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

(e) Criterion 5—Performance/Work Processes.

(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.

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

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

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

(f) Criterion 6—Performance/Design.

(1) Design items and processes using sound engineering/scientific principles and appropriate standards.

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

(3) Identify and control design interfaces.

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

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

(g) Criterion 7—Performance/Procurement.

(1) Procure items and services that meet established requirements and perform as specified.

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

(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.

§ 830.202 Safety basis.

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

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

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

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

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

(4) Prepare a documented safety analysis for the facility; and (5) Establish the hazard controls upon which the contractor will rely to ensure adequate protection of workers, the public, and the environment.

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

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

(2) Annually 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.

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

(b) The contractor responsible for a hazard category 1, 2, or 3 DOE existing nuclear facility must submit for DOE approval a procedure for its USQ process by April 10, 2001. Pending DOE approval of the USQ procedure, the contractor must continue to use its existing USQ procedure. If the existing procedure 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 procedure.

(c) The contractor responsible for a hazard category 1, 2, or 3 DOE new nuclear facility must submit for DOE approval a procedure for its USQ process on a schedule that allows DOE approval in a safety evaluation report issued pursuant to section 207(d) of this Part.

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

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

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

(3) Test or experiment not described in the existing documented safety analysis; or (4) Potential inadequacy of the documented safety analysis because the analysis potentially may not be bounding or may be otherwise inadequate.

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

(f) The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must annually submit to DOE a summary of the USQ determinations performed since the prior submission.

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

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

(2) Notify DOE of the situation;

(3) Perform a USQ determination and notify DOE promptly of the results; and (4) Submit the evaluation of the safety of the situation to DOE prior to removing any operational restrictions initiated to meet paragraph (g)(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.

If construction begins after December 11, 2000, 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, or as approved by DOE at a later date, 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 (see Table 1). 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 facilities (including 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 3 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 970.5223-1, Integration of Environment, Safety and Health into Work Planning and Execution) and the DEAR clause on laws, regulations, and DOE directives (48 CFR 970.5204-2, Laws, Regulations and DOE Directives), the contractor will have established the foundation to meet the safety basis requirements.

2. The processes embedded in a safety management system should lead to a contractor establishing adequate safety bases and safety management programs that will meet the safety basis requirements of this Subpart. Consequently, the DOE expects if a contractor has adequately implemented integrated safety management, few additional requirements will stem from this Subpart and, in such cases, the existing safety basis prepared in accordance with integrated safety management provisions, including existing DOE safety requirements in contracts, should meet the requirements of this Subpart.

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

E. Enforcement of Safety Basis Requirements

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

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

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

4. A documented safety analysis must address all hazards (that is, both radiological and nonradiological hazards) and the controls necessary to provide adequate protection to the public, workers, and the environment from these hazards. Section 234A of the Atomic Energy Act, 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 by * * * |
|---|--|
| (1) A DOE reactor | Using the method in U.S. Nuclear Regulatory Commission Regulatory Guide 1.70, Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants, or successor document. |
| (2) A DOE nonreactor nuclear facility | Using the method in DOE-STD-3009, Change Notice No. 1, January 2000, Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Safety Analysis Reports, July 1994, or successor document. |
| (3) A DOE nuclear facility with a limited operational life | Using the method in either: (1) DOE-STD-3009-, Change Notice No. 1, January 2000, 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, Change Notice No. 1, January 2000, 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, Integration of Environment, Safety, and Health into Facility Disposition Activities, May 1998, or 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 29 CFR 1926.65 for construction activities) for developing a Safety and Health Program and a site-specific Health and Safety Plan (including elements for Emergency Response Plans, conduct of operations, training and qualifications, and maintenance management). |
| (7) A DOE nuclear explosive facility and the nuclear explosive operations conducted therein. | Developing its documented safety analysis in two pieces: (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, Change Notice No. 1, January 2000, 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, Change Notice No. 1, January 2000, 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. |
| (9) Transportation activities | (1) Preparing a Safety Analysis Report for Packaging in accordance with DOE-O-460.1A, Packaging and Transportation Safety, October 2, 1996, or successor document and (2) Preparing a Transportation Safety Document in accordance with DOE-G-460.1-1, Implementation Guide for Use with DOE O 460.1A, Packaging and Transportation Safety, June 5, 1997, or successor document. |
| (10) Transportation and onsite transfer of nuclear explosives, nuclear components, Naval nuclear fuel elements, Category I and Category II special nuclear materials, special assemblies, and other materials of national security. | (1) Preparing a Safety Analysis Report for Packaging in accordance with DOE-O-461.1, Packaging and Transportation of Materials of National Security Interest, September 29, 2000, or successor document and (2) Preparing a Transportation Safety Document in accordance with DOE-M-461.1-1, Packaging and Transfer of Materials of National Security Interest Manual, September 29, 2000, or successor document. |

5. Table 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. If construction begins after December 11, 2000, the contractor responsible for the design and construction of a new DOE nuclear facility or 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 actions necessary for the safe operation of a nuclear facility. The exact form and contents of technical safety requirements will depend on the circumstances of a particular nuclear facility as defined in the documented safety analysis for the nuclear facility. As appropriate,

technical safety requirements may have sections on (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 analysis shows that they are relied upon to mitigate or prevent an accident. The limited control settings section also identifies the protective actions to be taken at the specific settings chosen in order to correct a situation automatically or manually such that the related safety limit is not exceeded. Protective actions may include maintaining the variables within the requirements and repairing the automatic device promptly or shutting down the affected part of the process and, if required, the entire facility. |
| (4) Limiting conditions for operations | The limits that represent the lowest functional capability or performance level of safety structures, systems, and components required to perform an activity safely. The limiting conditions for operation section describes, as precisely as possible, the lowest functional capability or performance level of equipment required for continued safe operation of the facility. The limiting conditions for operation section also states the action to be taken to address a condition not meeting the limiting conditions for operation section. Normally this simply provides for the adverse condition being corrected in a certain time frame and for further action if this is impossible. |
| (5) Surveillance requirements | Requirements relating to test, calibration, or inspection to assure that the necessary operability and quality of safety structures, systems, and components is maintained; that facility operation is within safety limits; and that limiting control settings and limiting conditions for operation are met. If a required surveillance is not successfully completed, the contractor is expected to assume the systems or components involved are inoperable and take the actions defined by the technical safety requirement until the systems or components can be shown to be operable. If, however, a required surveillance is not performed within its required frequency, the contractor is allowed to perform the surveillance within 24 hours or the original frequency, whichever is smaller, and confirm operability. |
| (6) Administrative controls | Organization and management, procedures, recordkeeping, assessment, and reporting necessary to ensure safe operation of a facility consistent with the technical safety requirement. In general, the administrative controls section addresses (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. |
| (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. |

TABLE 4—Continued

| | |
|---|--|
| As appropriate for a particular DOE nuclear facility, the section of the technical safety requirements on * * * | Will provide information on * * * |
| (9) Bases appendix | The reasons for the safety limits, operating limits, and associated surveillance requirements in the technical safety requirements. The statements for each limit or requirement shows how the numeric value, the condition, or the surveillance fulfills the purpose derived from the safety documentation. The primary purpose for describing the basis of each limit or requirement is to ensure that any future changes to the limit or requirement is done with full knowledge of the original intent or purpose of the limit or requirement. |

H. Unreviewed Safety Questions

1. The USQ process is an important tool to evaluate whether changes affect the safety basis. A contractor must use the USQ process to ensure that the safety basis for a DOE nuclear facility is not undermined by changes in the facility, the work performed, the associated hazards, or other factors that support the adequacy of the safety basis.

2. The USQ process permits a contractor to make physical and procedural changes to a nuclear facility and to conduct tests and experiments without prior approval, provided these changes do not cause a USQ. The USQ process provides a contractor with the flexibility needed to conduct day-to-day operations by requiring only those changes and tests with a potential to impact the safety basis (and therefore the safety of the nuclear facility) be approved by DOE. This allows DOE to focus its review on those changes significant to safety. The USQ process helps keep the safety basis current by ensuring appropriate review of and response to situations that might adversely affect the safety basis.

3. DOE Guide 424.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 its procedure used to implement the 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.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000-CE-81-AD; Amendment 39-12068; AD 2000-26-18]

RIN 2120-AA64

Airworthiness Directives; Stemme GmbH & Co. KG Models S10 and S10-V Sailplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to certain Stemme GmbH & Co. KG (Stemme) Models S10 and S10-V sailplanes. This AD requires you to replace the eyebolts on the airbrake, inspect the airbrake sheets for proper clearance and adjust as necessary, and inspect for damage to the landing gear doors and replace any damaged parts. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Germany. The actions specified by this AD are intended to prevent aerodynamic flutter of the upper covering straps on the airbrake cover caused by the current design airbrake eyebolts, which could result in damage to the airbrake system and landing gear doors. Continued operation with such damaged components could result in loss of control of the sailplane.

DATES: This AD becomes effective on February 2, 2001.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulation as of February 2, 2001.

The Federal Aviation Administration (FAA) must receive any comments on this rule on or before February 15, 2001.

ADDRESSES: Submit comments in triplicate to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000-CE-81-AD, 901

Locust, Room 506, Kansas City, Missouri 64106.

You may get the service information referenced in this AD from Stemme GmbH & Co. KG, Gustav-Meyer-Allee 25, D-13355 Berlin, Germany; telephone: 49.33.41.31.11.70; facsimile: 49.33.41.31.11.73. You may examine this information at FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000-CE-81-AD, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4144; facsimile: (816) 329-4090.

SUPPLEMENTARY INFORMATION:

Discussion

What Events Have Caused This AD?

The Luftfahrt-Bundesamt (LBA), which is the airworthiness authority for Germany, recently notified FAA that an unsafe condition may exist on certain Stemme Model S10 and S10-V sailplanes. The LBA reports that the current design airbrake eyebolts could cause aerodynamic flutter of the upper airbrake straps at high airspeeds. This can cause damage to the airbrake system.

One reported occurrence resulted in flutter of the upper covering straps on the airbrake cover, which resulted in an uncommanded yawing condition and separation of the landing gear door from the sailplane. This caused damage to the horizontal stabilizer.

What Are the Consequences If the Condition Is Not Corrected?

This condition, if not corrected, could result in aerodynamic flutter of the upper covering straps on the airbrake cover and damage to the airbrake system and landing gear doors. Continued operation with such damaged components could result in loss of control of the sailplane.