



The Secretary of Energy

Washington, DC 20585

October 18, 2014

The Honorable Peter S. Winokur
Chairman
Defense Nuclear Facilities Safety Board
625 Indiana Avenue, NW, Suite 700
Washington, DC 20004-2901

Dear Mr. Chairman:

In the Department's Implementation Plan (IP) to the Board's Recommendation 2010-1, *Safety Analysis Requirements for Defining Adequate Protection for the Public and the Workers*, we committed to analyzing potential changes to the Department of Energy's (DOE's) regulatory framework for developing and reviewing nuclear facility documented safety analyses (DSAs).

We have completed this analysis (enclosed) and have determined that, although no change to DOE's nuclear safety management rule, Title 10 Code of Federal Regulations (C.F.R.) 830, is needed, the following changes to DOE Order 420.1C, *Facility Safety*, are warranted to improve the DOE framework for developing and reviewing nuclear facility DSAs:

- Addition of a requirement for program offices to use revised DOE Standard (STD) 1104, *Review and Approval of Nuclear Facility Safety Basis and Safety Design Basis Documents*, for review and approval of DSAs.
- Addition of a requirement to implement the new revision of DOE-STD-3009, *Preparation of Nonreactor Nuclear Facility Documented Safety Analysis*, applicable to (1) new facilities, (2) major modifications to existing facilities unless determined otherwise by the Program Offices, and (3) existing facilities where estimated off-site doses from postulated accidents have not been mitigated to less than 25 Rem. This requirement will apply whenever the DOE-STD-3009 method is being used to satisfy 10 C.F.R. 830 requirements.

In addition, as stated in Section 6.2 of the Department's 2010-1 IP, the evaluation of DSAs for existing defense nuclear facilities relative to the new revision of DOE-STD-3009 will be performed consistent with the current regulatory process for developing and maintaining DSA updates. This evaluation will look for and implement enhancements that can be made based upon lessons learned and best practices that have been incorporated in the revised DOE-STD-3009, related to protection of the public



from nuclear hazards. The Department is in the process of developing its approach for this evaluation.

If you have any questions, please contact Dr. James O'Brien, Director, Office of Nuclear Safety, at (301) 903-1408.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ernest J. Moniz', with a stylized flourish at the end.

Ernest J. Moniz

Enclosure

**REGULATORY ANALYSIS
OF POTENTIAL CHANGES TO REQUIREMENTS DOCUMENTS
TO INVOKE DOCUMENTED SAFETY ANALYSIS
DEVELOPMENT AND REVIEW CRITERIA**

1. PURPOSE

This regulatory analysis identifies and analyzes potential changes to Title 10 of the Code of Federal Regulations (C.F.R.) Part 830, *Nuclear Safety Management*, and other Department of Energy (DOE) requirement documents in regards to methods for developing and reviewing Documented Safety Analyses (DSAs) for DOE nuclear facilities. This regulatory analysis fulfills commitments made in Section 6.5 of DOE's Implementation Plan (IP) for Defense Nuclear Facilities Safety Board (DNFSB) Recommendation 2010-1, *Safety Analysis Requirements for Defining Adequate Protection for the Public and the Workers*, which was issued by Secretary Chu on September 26, 2011.

This analysis addresses three specific regulatory issues:

- Potential Changes to DSA Development Requirements;
- Changes to Invoke DOE Standard (STD) 1104, *Review and Approval of Nuclear Facility Safety Basis and Safety Design Basis Documents*, for reviewing and approving DSAs; and
- Review of Existing DSAs to new DSA Development Standard.

This analysis was focused on the issues associated with DNFSB Recommendation 2010-1 and did not evaluate some other regulatory options for DOE nuclear safety regulatory infrastructure such as an analysis of converting to applicable Nuclear Regulatory Commission regulations.

This regulatory analysis follows the general approach in the Office of Management and Budget's (OMB's) guidance to Federal agencies on the development of regulatory analysis (OMB Circular A-4). As stated in OMB guidance, a regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of Rules. It provides a formal way of organizing the evidence on key effects, good and bad, of the various alternatives that should be considered in developing regulations. The OMB Guidance identifies three basic elements of a good regulatory analysis: (1) a statement of the need for proposed action; (2) an examination of alternative approaches; and (3) an evaluation of the benefits and costs, both quantitative and qualitative, of the proposed action and the main alternatives identified by the analysis.

Consistent with OMB guidance, this evaluation discusses the following:

- Proposed action;
- Alternatives;
- Benefits (e.g., potential improvements in DSA development);
- Costs (e.g., resources to implement changes); and
- Preferred alternative(s).

2. BACKGROUND

2.1 2010-1 Implementation Plan Commitment

Section 6.5 of DOE's IP for DNFSB Recommendation 2010-1, states that:

“DOE will evaluate its regulatory framework (and modify as needed) to ensure that essential elements of the safety analysis and hazard control identification are performed during the development of facility DSAs. The options that will be considered include:

- *Continuing with the current safe harbor approach with clarification on the need for incorporation of revisions to standards identified as a safe harbor;*
- *Direct incorporation of the Standard revision citation into the body of 10 C.F.R. Part 830;*
- *Direct incorporation of key criteria from the Standard into the body of 10 C.F.R. Part 830 with the remainder of the Standard being either included as a safe harbor or as a non-mandatory standard. [DOE 2010-1 Implementation Plan, Section 6.5].”*

Section 6.5 of the 2010-1 IP also stated that DOE would:

- *“Evaluate its regulatory framework for review of DSAs and determine whether a new requirement in 10 CFR Part 830 or in a DOE Directive (such as DOE Integrated Safety Management Order) to require use of [DOE-STD-1104, Review and Approval of Nuclear Facility Safety Basis and Safety Design Basis Documents] for the review of DSAs, and to set limits on the delegation of authority to approve DSAs in certain circumstances is needed.”; and*
- *“Address the process for review of existing DSAs to new DSA development criteria in DOE Standards including backfit considerations (including need for development of backfit requirements, standards, or criteria). [DOE 2010-1 Implementation Plan, Section 6.5]”*

2.2 Nuclear Safety Rule

Title 10 C.F.R. Part 830 establishes nuclear safety management requirements for DOE nuclear facilities. Title 10 C.F.R. Part 830, Subpart B, *Safety Basis Requirements*, was issued on January 10, 2001, and became effective on February 9, 2001, to establish safety basis requirements for hazard category 1, 2, and 3 DOE nuclear facilities. Title 10 C.F.R. Part 830, Subpart B, includes requirements to: (1) work within safety basis controls (10 C.F.R. § 830.201); (2) establish and maintain the safety basis of facilities, including identifying, analyzing, and controlling hazards to ensure adequate protection of workers, the public, and the environment (10 C.F.R. § 830.202); (3) prepare DSAs which address a prescribed set of elements (10 C.F.R. § 830.204); and (4) either use the methodologies that are set forth in Appendix A, Table 2 (i.e., the safe harbor methodologies) in preparing DSAs or obtain DOE approval of the methodologies used (10 C.F.R. § 830.204).

Title 10 C.F.R. Part 830, Appendix A, Table 2 identifies different types of nuclear facilities (such as DOE reactors, DOE nonreactor nuclear facilities, and transportation activities) and identifies acceptable (i.e., pre-approved or “safe harbor”) methods that may be used to prepare DSAs for these types of facilities. Table 2 identifies “DOE-STD-3009, Change Notice No. 1, *Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Safety Analysis Reports*, July 1994, or successor document” as a safe harbor method for DOE nonreactor nuclear facilities. Regardless of the safe harbor method used to prepare a DSA, 10 C.F.R. Part 830 provides enforceable requirements for contractors to operate DOE hazard category 1, 2, and 3 nuclear facilities within the approved DSA limits and controls.

3. ANALYSIS OF POTENTIAL CHANGES TO DSA DEVELOPMENT REQUIREMENTS

The issue being analyzed is whether the current DOE regulatory framework for developing DSAs ensures that essential elements of the safety analysis and hazard control identification are performed and reflected in DSAs.

3.1 Identification of Options Related to Development of Facility DSAs

- Option 1: Continue with current 10 C.F.R. Part 830 safe harbor methodology without change.
- Option 2: Continue with current 10 C.F.R. Part 830 safe harbor methodology with clarification on the need to incorporate revisions to safe harbor standards.
- Option 3: Revise 10 C.F.R. Part 830 to directly incorporate a citation to DOE-STD-3009 into the body of 10 C.F.R. Part 830.
- Option 4: Revise 10 C.F.R. Part 830 to directly incorporate key performance criteria from DOE-STD-3009 into the body of 10 C.F.R. Part 830.

3.2 Evaluation of Options

3.2.1 Option 1: **Continue with current 10 C.F.R. Part 830 safe harbor methodology without change.**

This option would retain the current regulatory framework as described in 10 C.F.R. Part 830 without changes.

The original basis for using safe harbor methods, as described in the Preamble of the Interim Final Rule (65 Fed. Reg. 60292, 60300-60201, October 10, 2000), was that these methods were: (1) already approved as acceptable for use; (2) based on many years of experience with the types of facilities to which they may be applied; and (3) expected to streamline the safety basis process for both DOE and contractors as they were already familiar with the safe harbor methods. This original basis for the safe harbor methods remains valid.

An advantage of this option is that DOE would continue to identify “what” needs to be accomplished with respect to nonreactor nuclear facility safety without dictating exactly “how” that is to be accomplished as part of the regulation. This provides the necessary flexibility across the Department to effectively and efficiently accomplish the diverse nuclear missions of the Department. DOE would retain the authority to direct specific contractors (using contractual vehicles) to use specific revisions of the safe harbor standards listed in the Rule, as appropriate, for the facility being evaluated. Thus, if an existing facility would not benefit from using a new revision of a safety analysis methodology, DOE would have the flexibility to continue to allow the use of the previous version, avoiding unnecessary administrative costs.

A potential disadvantage of this option is that DOE would not be mandating in a Rule which version of the standard must be implemented or what key DSA development or hazard control criteria must be met (beyond the general requirements already identified in 10 C.F.R. Part 830). DOE would continue to rely upon contract vehicles to do so where needed; no negative impacts have been identified for this approach.

The current process for developing DSAs is performance based and provides an appropriate and useful approach for allowing the detailed criteria and guidance to be provided via safe harbor DSA standards specific for the type of facility/situation being evaluated. The safe harbor method has served the Department well and has supported development and approval of DSAs for all existing DOE hazard category 1, 2, and 3 nuclear facilities. Further, the current approach recognizes and allows for successor versions of safe harbor standards without the need for rulemaking. This provides flexibility regarding the specific version to be applied and permits DOE and its contractors to apply the most appropriate version. Furthermore, if needed, DOE can mandate the specific version be implemented via other mechanisms (such as a DOE directive or contractual vehicles).

3.2.2 Option 2: Continue with current 10 C.F.R. Part 830 Safe Harbor Methodology with Clarification on the Need to Incorporate Revisions to Safe Harbor Standards.

This option is to revise Table 2 of Appendix A of 10 C.F.R. Part 830 to reflect the most recent approved versions of safe harbor standards (for example, DOE-STD-3009-201x, when published). Specifically, Table 2 would be revised to reflect DOE-STD-3009-201x, as well as other updated versions of safe harbor standards.

Another potential approach for this option might be to provide a general requirement in 10 C.F.R. Part 830 to implement the latest version of identified safe harbor standards, and not cite a specific version of such standards as the required version. However, this approach is not legally permitted.

The chief benefit of this option is that it would provide clear direction regarding the specific version of safe harbor standards to be used. This option would formally adopt enhancements that are captured in updates to safe harbor standards, and exclude use of predecessor standards. This option would ensure that all facilities use the most recent version of safe harbor methods, and would provide a more consistent basis for developing, reviewing, and approving DSAs.

The main disadvantage with this option would be a reduction in the flexibility for program offices and contractors to manage and operate the facilities most efficiently in a risk informed manner. This option could cause low-risk facilities to perform unnecessary reviews, re-analysis, and re-formatting consistent with the latest version of safe harbor standards without real nuclear safety benefits. Another disadvantage of this option is the resources and expenses associated with the rulemaking process that would be incurred every time a safe harbor DSA standard is updated. This could be a disincentive to making improvements to the safe harbor standards compared to the current practice (Option 1).

When 10 C.F.R. Part 830, Subpart B, was promulgated, it anticipated that future revisions to safe harbor standards would be issued and accommodated by allowing “or successor document” in Appendix A, Table 2. Title 10 C.F.R. Part 830, Subpart B, requirements provided adequate protection to the workers and the public at the time of its promulgation through use of safe harbor standards identified. While enhancements and improvements to DOE-STD-3009 and other safe harbor standards have been and continue to be pursued, the core 10 C.F.R. Part 830 DSA requirements are unchanged. The original safe harbor standards continue to provide appropriate means for ensuring DSAs developed from them will provide for adequate protection.

DOE has mechanisms other than changes to 10 C.F.R. Part 830 that it can use to provide DOE-wide direction for implementation of updates to safe harbor standards, if needed. For example, DOE program offices can provide specific direction to applicable contractors for each facility or DOE can issue a Notice or Order to provide direction for all facilities.

3.2.3 Option 3: Revise 10 C.F.R. Part 830 to Directly Incorporate All DOE-STD-3009 Requirements (or a Citation to a specific version of DOE-STD-3009) Into 10 C.F.R. Part 830

This option is to revise 10 C.F.R. Part 830, Subpart B, by incorporating the requirements from the most recent version of DOE-STD-3009 into the body of 10 C.F.R. Part 830. Alternatively, a simpler approach would be to include a citation to the most recent version of DOE-STD-3009 to be applied to all DOE hazard category 1, 2, and 3 nonreactor nuclear facilities.

One advantage of this option is that all hazard category 1, 2, and 3 nonreactor nuclear facilities would use the same DSA development criteria method and the same version of that method for developing DSAs. This option would provide a consistent basis for DOE's DSAs and ensures that all improvements in DSA development criteria would be implemented for all DOE nuclear facilities. Any relief from this approach would require a formal exemption from the Rule requirements.

The primary disadvantage of this option is that it is likely to cause a significant amount of work for existing facilities to comply with the detailed criteria identified in the new draft revision of DOE-STD-3009, with no identified safety improvements. Although the safety analysis approach in the new standard did not change, the structure changed and level of detail increased.

A substantial effort may be needed to revise a facility DSA to reflect the new standard without any anticipated changes to the hazard controls (which is the main purpose of the DSA effort). This option is a significant philosophical change from the original 10 C.F.R. Part 830, Subpart B, requirements because it abandons the safe harbor concept. Further, the relationship to the other safe harbor methods (such as DOE-STD-1120, *Integration of Environment, Safety and Health into Facility Disposition Activities*, for decommissioning a DOE nuclear facility, DOE-STD-3016, *Hazard Analysis Reports for Nuclear Explosive Operations*, for nuclear explosive operations, and DOE-STD-3011, *Guidance for Preparation of Basis for Interim Operations (BIO) Documents*, for limited operational life facilities) will have to be carefully examined. DOE-STD-3009 is broadly applicable to all hazard category 2 and 3 nuclear facilities and activities, whereas all other sets of facility or activities types identified in Table 2 are focused sub-sets of the broader set of all nuclear facilities and activities.

This option would reduce flexibility for DOE program offices and contractors to make facility-specific implementation decisions regarding updates to DOE-STD-3009 or use of other methodologies for DSA development. It would also add an extra burden of formal exemptions for any relief from safe harbor methods, whereas the current approach permits these to be addressed as part of DOE review and evaluation of DSAs. Another disadvantage of this option is that it would require the expenditure of resources and expenses on the rulemaking process every time a DSA development improvement is made. Furthermore, since the current standard provides guidance as well as DSA development criteria, a new guidance document would need to be developed to incorporate the guidance.

When 10 C.F.R. Part 830, Subpart B, was promulgated, it allowed use of multiple safe harbor methods and did not invoke use of any specific method as a requirement. It anticipated that future revisions to safe harbor standards would be issued, and it accommodated this by allowing

use of “successor document[s].” Title 10 C.F.R. Part 830, Subpart B, requirements provided adequate protection to the workers and the public through use of the core DSA requirements and safe harbor standards identified at the time of promulgation. While enhancements and improvements to DOE-STD-3009 and other safe harbor standards have been and continue to be pursued, the core 10 C.F.R. Part 830 DSA requirements remain unchanged. The original safe harbor standards continue to provide adequate protection.

As discussed under the other options above, DOE has mechanisms other than changes to 10 C.F.R. Part 830 that it can use to provide facility-specific or DOE-wide direction for implementation of updates to safe harbor standards.

3.2.4 Option 4: Revise 10 C.F.R. Part 830 to Directly Incorporate Key Performance Criteria from DOE-STD-3009 into the 10 C.F.R. Part 830

This option would require a major revision to 10 C.F.R. Part 830 to incorporate a different approach for identifying key performance criteria into the Rule. Examples of potential criteria that could be incorporated into the Rule are identified below:

For new facilities and major modifications to existing facilities, engineered controls, administrative controls, or both, shall be applied to the extent needed to reduce the likelihood of occurrence of the event so that, upon implementation of such controls, the event is highly unlikely or its consequences are less severe than:

- *A dose of 25 rem total effective dose to an individual located outside the site boundary;*
- *A co-located worker dose of 100 rem total effective dose to an individual located at 100 meters from a facility; or*
- *An acute chemical exposure to an individual from hazardous chemicals that could endanger the life of a facility worker, or lead to irreversible or other serious, long-lasting health effects to any individual located outside the site boundary.*

The benefit of this option would be that it would highlight the key DSA development performance criteria and make them broadly applicable to all safe harbor methods. This option provides added clarity on the performance criteria to be met and on the exemption process that must be pursued if not met. It is also consistent with the approach taken by Nuclear Regulatory Commission in 10 C.F.R. Part 70, *Domestic Licensing of Special Nuclear Material*.

One disadvantage of this change is the resources and expenses needed to develop and finalize an amendment to the Rule. Further, this change would establish the 25 rem and 100 rem criteria as “bright lines,” which is not consistent with current practice or current calculation methodologies. Changing these values to “bright lines” may misrepresent the nature of what is being calculated and how this calculation is being used.

DOE has had very good success with the use of the current safe harbor methodology for ensuring DSAs are effectively developed for identifying the key hazard controls (safety class and safety significant) and for ensuring adequate protection of the public, workers, and the environment. But, as identified in DNFSB Recommendation 2010-1, DOE has had several facilities for which the mitigated off-site dose estimates for plausible accident scenarios exceeded the Evaluation Guideline of 25 rem. In each case, the risk to the public remained well below expectations established in the DOE nuclear safety policy. Interim direction provided by the Deputy Secretary of Energy, in a memorandum, "*Adequate Protection*," dated September 17, 2012, ensures senior-level DOE approval of the safety analyses if a situation were to occur where no viable control strategy exists to prevent or mitigate the consequences in one or more accident scenarios from exceeding the Evaluation Guideline. This direction is currently being incorporated into revisions to applicable Departmental requirements documents.

3.2.5 Conclusion/Recommendation

Based on the analysis above, DOE's recommended course of action is Option 1: Continue with current 10 C.F.R. Part 830 safe harbor methodology without change. This option retains the current regulatory framework as described in 10 C.F.R. Part 830 without change. The analysis did not identify any significant benefits to safety or improvements to regulatory stability that would justify the cost of revising the Rule. However, improvements are warranted in DOE-STD-3009 to enhance its use in developing applicable DSAs by clearly identifying those criteria that must be met to ensure the Standard is properly used as a safe harbor methodology for DSA development.

4. ANALYSIS OF CHANGES TO INVOKE DOE STANDARD 1104 FOR REVIEW OF DSAs

DOE stated in its Recommendation 2010-1 IP that it would evaluate its regulatory framework for review of DSAs and determine whether a new requirement in 10 C.F.R. Part 830 or in a DOE Directive (such as DOE Integrated Safety Management Order) to require use of DOE-STD-1104 for the review of DSAs, and to set limits on the delegation of authority to approve DSAs in certain circumstances, is needed.

4.1 Background

DOE-STD-1104 contains the Department's method and criteria for reviewing and approving a nuclear facility's documented safety analysis (DSA). The Department's review and approval of the DSA formally documents the basis for DOE concluding that a facility can be operated safely in a manner that adequately protects workers, the public, and the environment. Therefore, it is important to clearly identify expectations for use of the review methodology and criteria contained in DOE-STD-1104.

Currently, DOE program offices use DOE-STD-1104 as intended, but there is no formal requirement to do so.

4.2 Options Evaluated

The following options were evaluated:

- Option 1: Maintain the current status quo of not invoking DOE-STD-1104 in any existing DOE Order or Rule.
- Option 2: Invoke DOE-STD-1104 via 10 C.F.R. Part 830, *Nuclear Safety Management*, Subpart B, *Safety Basis Requirements*.
- Option 3: Convert DOE-STD-1104 into a stand-alone DOE Order.
- Option 4: Invoke DOE-STD-1104 in a new or existing DOE Order.

4.3 Evaluation of Options

4.3.1 Option 1: Maintain Status Quo

Maintaining the status quo will continue DOE's practice of relying on voluntary use of the Standard by the program offices. Although there is no formal requirement for using the methods and processes in DOE-STD-1104, the Standard is broadly applied and used. However, good regulatory processes would have the critical criteria for review and approval of safety basis documents clearly identified and clearly invoked by a requirements document.

4.3.2 Option 2: Invoke DOE-STD-1104 Via Requirement in 10 C.F.R. Part 830

DOE contractors are required by 10 C.F.R. Part 830, Subpart B, to obtain DOE safety basis approval prior to facility operation, but 10 C.F.R. Part 830 does not contain specific requirements addressing how DOE review and approval is to be made. To make DOE-STD-1104 the required method for DOE review and approval of safety bases DOE-wide, it must be invoked by an appropriate means within the DOE system of rules and directives, or its requirements must be incorporated into formal requirements within the DOE system. As 10 C.F.R. Part 830 generally addresses DOE review and approval, one option evaluated was to revise 10 C.F.R. Part 830, Subpart B, to invoke DOE-STD-1104 or to establish requirements on methods or approvals for reviewing and approving safety basis documents. However, this option is not preferred because DOE does not typically use rules to establish requirements on DOE Federal personnel because it is unnecessary and creates rigidity. Further, a revision to 10 C.F.R. Part 830 would be a substantial undertaking, requiring significant resources and time that are not warranted if preferable alternatives exist. In addition, any future changes made to DOE-STD-1104 to address improvements in review and approval of safety basis documents would have to be processed as a rule change.

4.3.3 Option 3: Convert DOE-STD-1104 into a stand-alone DOE Order

Another approach considered was conversion of DOE-STD-1104 to a new stand-alone directive. A DOE Order is the preferred method to establish formal and enduring process requirements and responsibilities for Federal personnel related to DOE Federal review and approval of contractor documents. However, DOE-STD-1104 has a long history, being established in 1996; its use is supported by a specific training program; and it is already in wide use throughout the DOE community. Anticipated changes to DOE-STD-1104, in accordance with the Department's 2010-1 IP, can be accommodated without significant revisions to the DOE-STD-1104 content. In contrast, conversion of the Standard to a new stand-alone DOE Order would require significant rework of DOE-STD-1104 to meet the Order format requirements (per DOE Order (O) 251.1C, *Departmental Directives Program*, and would likely need to also include a supporting guide or new standard to include some of the details that would not be appropriate to include in an order.

The detailed technical criteria and review methodology make the content of the document better suited for a Standard rather than an Order. To ensure continuity of DOE-STD-1104 and its technical focus, and to avoid a significant work effort that provides minimal or questionable added value, this option is not preferred.

4.3.4 Option 4: Invoking DOE-STD-1104 in a New or Existing DOE Order

This option involves invoking DOE-STD-1104 as a required method in either a new or existing DOE Order. DOE does not have an Order focused on review and approval of safety basis documents or development of DOE Safety Evaluation Reports. A new Order to invoke the Standard could be developed; however, such an Order would contain a single requirement to implement DOE-STD-1104. This approach is not recommended.

In looking at existing DOE Orders, the one that most closely aligns with the development and approval of safety basis documents is DOE O 420.1C, *Facility Safety*. In fact, this Order includes requirements for the use and development of safety basis documents (in accordance with DOE-STD-1189-2008, *Integration of Safety into the Design Process*). Adding a short phrase or sentence invoking DOE-STD-1104 into DOE O 420.1C requirements and responsibilities should be relatively straightforward and efficient; and could be accomplished by a Page Change to DOE O 420.1C rather than a full revision. It preserves DOE-STD-1104 and its technical nature, and uses a DOE Order as the most appropriate means for establishing formal and enduring requirements and responsibilities for DOE Federal personnel. It is the most efficient method for achieving the objective of formalizing the DOE-STD-1104 requirements. Also, a well-understood and well-established relief process is established by using the relief mechanism in DOE O 420.1C for exemptions and equivalencies (consistent with DOE O 251.1C, therefore, this is the preferred approach.

4.4 Conclusion/Recommendation

Based on evaluation of regulatory options described above, the preferred approach is to invoke DOE-STD-1104 via a concise, simple Page Change to DOE Order 420.1C. The development of

a revision to DOE-STD-1104 and the Page Change to DOE Order 420.1C are ongoing, and the Page Change will not be issued until the revision of DOE-STD-1104 is finalized. This action is expected to have no impact on DSA development or review costs because DOE reviews will be essentially the same as those that have been applied for many years, with the exception that additional review and documentation requirements will be applied to identified situations where offsite mitigated dose estimates exceed the 25 rem Evaluation Guideline.

5. ANALYSIS OF REVIEW OF EXISTING DSAs TO NEW DSA DEVELOPMENT STANDARD

This part of the regulatory analysis evaluates which, if any, existing facilities DSAs should be reviewed and revised using the new DOE-STD-3009 criteria and guidance, and what is the appropriate mechanism for directing this review to occur. It is based upon the premise that recommended actions would be taken under the current DOE regulatory framework. Options for changing the framework were discussed in Section 3.

5.1 Background

DOE stated, in its Recommendation 2010-1 IP, that it would address the process for review of existing DSAs using the new DSA development criteria in DOE Standards, including the need for development of backfit requirements, standards, or criteria.

Title 10 C.F.R. Part 830 does not require any facilities to use any specific version of DOE STD-3009. Current practice in most cases is to use the latest version when developing a new DSA and to incorporate any specific new features (such as specific administrative controls) identified in a new version of DOE-STD-3009 via periodic DSA updates.

The new revision of DOE-STD-3009 is an update to: (1) reflect best practices and lessons learned in application of the Standard over the last 20 years; (2) clarify which elements of DOE-STD-3009 must be met to fully implement the safe harbor methodology; (3) clearly address the use of the 25 rem Evaluation Guideline and provide requirements if mitigated offsite dose estimates exceed the Evaluation Guideline; and (4) make it consistent with the criteria and guidance for development of a Preliminary DSA identified in DOE-STD-1189.

5.2 Options for Applying New Standard 3009 to Existing Facilities

The following options were evaluated regarding the mechanism to drive implementation:

Implementation Mechanism Options

- Option 1: Allow Program Secretarial Officers (PSOs) to decide which contractors and facilities should apply the new version of DOE-STD-3009.
- Option 2: Issue a top-level DOE memorandum, from the Deputy Secretary or Secretary, to direct Program Secretarial Officers (PSO) to apply the DOE-STD-3009 revision to appropriate facilities and contracts.

Option 3: Issue a DOE directive (Order or Notice or Order change) to direct PSOs to apply the DOE-STD-3009 revision to appropriate facilities and contracts.

The following options were evaluated regarding the scope of facilities to implement the DOE-STD-3009 revision:

Scope of Facilities Options

- Option A: Every DOE hazard category 2 and 3 nuclear facility with mitigated offsite dose estimates exceeding the 25 rem Evaluation Guideline.
- Option B: Every DOE hazard category 2 and 3 nuclear facility.
- Option C: Every DOE hazard category 2 nuclear facility.
- Option D: Every DOE hazard category 2 and 3 nuclear facility, as determined based on evaluation by the responsible PSOs.
- Option E: Every DOE hazard category 2 and 3 nuclear facility that designs a “major modification,” as determined in accordance with DOE-STD-1189.
- Option F: A combination of the above options.

5.3 Evaluation of Options

5.3.1 Implementation Mechanisms

Title 10 C.F.R. Part 830 allows use of any applicable safe harbor, including any approved successor version of the Standards listed in the safe harbor table, and allows the use of alternate methods for DSA development, if approved by DOE. The only way to make a specific standard or a specific version of a standard into a requirement for a given facility is to make it a contract requirement (for example, via contract clause, contract commitment, or addition to the contract’s List of Applicable Directives). Such a contract requirement would need to be drafted so that it would not conflict with the Rule requirements; it would merely limit the flexibilities allowed by the Rule. This approach is consistent with DOE practice in other areas where applicable DOE or Federal rules and regulations exist. Contract requirement changes can be affected by contracting officer direction, program office direction to the contracting officer, Deputy Secretary direction to the program office (such as by memorandum), or incorporation of a Contractor Requirements Document from a DOE Directive (Notice or Order) into the contract. Such contract changes are routinely accommodated through established processes, such as those in place to implement Department of Energy Acquisition Regulation (DEAR) clause 970.5204-2, “Laws, regulations, and DOE directives.”

For enduring requirements (such as the ongoing application of DOE-STD-3009 to emergent facilities), a DOE Order is the most appropriate and efficient way to issue clear DOE

requirements to ensure the required evaluation is performed. A change to existing DOE O 420.1C is the preferred implementation mechanism because: (1) an Order change ensures full DOE-wide review and comment; (2) DOE O 420.1C already contains nuclear design and safety bases requirements; and (3) development of a stand-alone Order is not justified.

For one-time or temporal requirements (such as the one-time evaluation of a set of existing facilities), a DOE Notice or Deputy Secretary memorandum is the most appropriate implementation mechanism. The choice between a Notice and a Deputy Secretary memorandum should depend on the scope of the facilities involved. For a small number of facilities, and a limited number of affected program offices, a Deputy Secretary memorandum is fully adequate to accomplish clear DOE direction on short-term requirements.

5.3.2 Scope of Facilities

The Department's DNFSB Recommendation 2010-1 IP specifies the priority with which Departmental facilities would be evaluated using the new DOE-STD-3009 and DOE-STD-1104 stating:

“Once the revised DOE Standards 3009 and 1104 are issued, DOE will evaluate the DSAs for all defense nuclear facilities as part of the required periodic update process. This evaluation will be prioritized such that the small number of defense nuclear facilities where mitigated doses exceed the 25 rem Evaluation Guideline for one or more of their DBAs, are evaluated utilizing the new standards as soon as practicable, with the expectation that the evaluations will be performed at the first annual update initiated six months after issuing the revision to the standard on which the safety analysis is based. [DOE 2010-1 Implementation Plan, Section 6.2]”

The IP calls for application of the new Standards to existing facilities where mitigated doses exceed the 25 rem Evaluation Guideline. In such cases, the new DOE-STD-3009 standard would only be applied to those facilities for which DOE-STD-3009 is an applicable safe harbor standard. So, for example, the new DOE-STD-3009 would not be applied to activities related to packaging and transportation of nuclear materials of national security interest, which use DOE O 461.1 and DOE Manual 461.1-1, *Packaging and Transfer of Materials of National Security Interest Manual*, or successor documents as their safe harbor methods; however, the new DOE-STD-1104 would apply for DOE review and approval of all DSA revisions, regardless of safe harbors used.

The 2010-1 implementation plan states:

“The evaluations will focus on implementation of changes to the standards in regards to the accident analysis and identification of hazard controls, in particular as related to situations where controls have not been identified that mitigate offsite doses from DBAs to below 25 rem. [DOE 2010-1 Implementation Plan, Section 6.2]”

The safety rationale for addressing existing facilities that do not mitigate offsite dose estimates to below the Evaluation Guideline is to provide added visibility and assurance to the rationale for accepting such conditions.

Beyond these prioritized facilities, immediate application of the standard¹ to every other existing DOE hazard category 2 and 3 nuclear facility is not a preferred option because:

- (1) Although DOE-STD-3009 has been updated to improve its clarity, maintainability, and consistency in developing DSAs, its methodology for hazard analysis, accident analysis and hazard controls has not fundamentally changed; and
- (2) The hazards of existing facilities have been evaluated per 10 C.F.R. 830 and the existing DOE-STD-3009 methodology and an effective set of safety controls have been established in existing DSAs and approved by DOE.

Consequently, it would not be prudent to require other-than-high-priority nuclear facilities to immediately implement the revised Standard. It would be beneficial to learn from implementation of the new Standard at the high priority facilities to determine whether the benefits of revising the safety analyses more broadly (e.g., in regards to having a consistent set of DSAs) would outweigh the cost of implementation. It is important to understand the cost and benefits so that program offices can make informed evaluations and decisions on how best to allocate their limited resources to safety and mission related facility improvements.

Note, although new facilities are not within the scope of this regulatory analysis, one set of facilities that offers relatively straightforward application of the new DOE-STD-3009 will be those new DOE facilities and major modifications that have been designed in accordance with DOE-STD-1189. For new facilities designed in accordance with DOE-STD-1189, the criteria for developing the preliminary DSA, in accordance with DOE-STD-1189, are well aligned with the DSA requirements in the new DOE-STD-3009. For new major modifications to existing DOE nuclear facilities designed in accordance with DOE-STD-1189, the major modification will have been designed and analyzed in a manner consistent with the requirements of the revised DOE-STD-3009 and the major modification represents a good opportunity to upgrade the existing safety analysis and DSA for the remainder of the existing facility.

Facilities that change mission could reasonably be included in the identified scope of facilities whenever the associated changes involve a major modification that is designed in accordance with DOE-STD-1189, and DOE-STD-3009 is used as the safe harbor method. The revision to DOE-STD-3009 is only considered for application where DOE-STD-3009 is the applicable safe harbor standard currently in use. For certain sets of facilities, such as nuclear reactors, transportation activities, and environmental restoration activities, DOE-STD-3009 is not identified in 10 C.F.R. Part 830 as an acceptable safe harbor methodology.

¹ Note: This regulatory analysis does not address the method for performing an “evaluation” of existing facilities to elements of the new Standard 3009 (that is called for in Section 6.2.1 of the Department’s IP).

5.3.3 Backfit Considerations

The Department's DNFSB Recommendation 2010-1 IP identified that backfit considerations (including need for development of backfit requirements, standards, or criteria) would be included to its review of existing DSAs to the new DSA development standard. "Backfit" is generally understood to be the application of new requirements to existing facilities, and can be addressed in two steps: (1) the establishment of new DOE requirements, and (2) the application of new DOE requirements to existing DOE facilities. Where new requirements are incorporated into DOE directives, backfit considerations (i.e., consideration of the relative costs and benefits of application of new requirements to existing facilities) can be adopted in individual directives through the "Applicability" section; the "Equivalencies/Exemptions" provisions; and the "Responsibilities" section, as it pertains to Contracting Officers' responsibilities; and are reflected in the Department's process for incorporating requirements into contracts (DEAR 970.5204-2, *Laws, Regulations, and DOE Directives*). The Department's directives process (DOE O 251.1C, *Departmental Directives Program*) also includes considerations of costs and benefits in establishing and applying new requirements. Development and application of a specific DOE Directive regarding the use of DOE-STD-3009 revision will be subject to these processes.

In addition, DOE has established a working group to evaluate the broad question of whether it would benefit from further development of a specific policy, requirements, and/or processes for use and conduct of cost-benefit analysis. This study is ongoing and outside the scope of this analysis.

5.4 Conclusion/Recommendation

Based on evaluation of regulatory options, the preferred approach is to use a Deputy Secretary memorandum to communicate direction to apply the DOE-STD-3009-201x revision for any existing DOE nuclear facilities with calculated mitigated offsite dose estimates greater than the 25 rem Evaluation Guideline. This would apply only to those existing DOE nuclear facilities for which DOE-STD-3009 is the applicable safe harbor standard per 10 C.F.R. Part 830. Currently there is only one existing facility that meets this criteria (exceeds the 25 rem Evaluation Guideline) and efforts are underway to reduce the calculated dose to below 25 rem via inventory reductions. If no existing facilities with approved DSAs have offsite dose estimates greater than 25 rem at the time that DOE-STD-3009-201x is issued, then no Deputy Secretary memorandum will be required.

In addition, and outside the scope of this regulatory options paper, a DOE Order (e.g., change to DOE O 420.1C) should be used to direct the use of the new DOE-STD-3009-201x revision for new DOE nuclear facilities and for new major modifications to existing DOE nuclear facilities, except in cases approved by the applicable PSO and concurred upon by the applicable Central Technical Authority. The Order change will clarify the cut-off point for application to ongoing projects (i.e., related to design maturity).

It is preferable that program offices continue to have flexibility in applying the new Standard for

all other applicable (per 10 C.F.R. Part 830, Subpart B, Appendix A, Table 2) existing nuclear facilities that are not undergoing major modification. Decisions on whether or not to apply the new Standard for these existing facilities will be made by the responsible PSOs. DOE remains confident that its DSAs for existing nuclear facilities include appropriate hazard and accident analyses, and appropriate sets of hazard controls.