

The Secretary of Energy

Washington, DC 20585 March 8, 2023

The Honorable Joyce Connery Chair Defense Nuclear Facilities Safety Board 625 Indiana Avenue, NW, Suite 700 Washington, DC 20004-2901

Dear Chair Connery:

In Milestone 5.2.1. of the Department of Energy's (DOE) Implementation Plan (IP) to Recommendation 2020-1, *Nuclear Safety Requirements*, DOE stated that it would complete a regulatory analysis of possible regulatory approaches to enhancing the current hazard categorization requirements under 10 Code of Federal Regulation (CFR) Part 830, Subpart B, Section 830.202, *Safety Basis*, Subsection (b)(3).

DOE has completed this analysis (enclosed) and determined that the most prudent regulatory approach is to develop a single, updated, and consolidated hazard categorization standard, and to properly incorporate by reference and codify this standard into 10 CFR Part 830.202(b)(3). The updated standard will represent the acceptable methodology for future and updated hazard categorizations of DOE nuclear facilities and be properly cited under the updated Rule.

The Department agrees that improvements to hazard categorization requirements under 10 CFR Part 830.202(b)(3) have the potential to improve clarity and enhance regulatory outcomes for the categorization of DOE nuclear facilities. However, the Department remains confident that its existing framework provides reasonable assurance of adequate protection.

If you have any questions, please contact Mr. Garrett Smith, Director, Office of Nuclear Safety, who is also the Department's Responsible Manager for the IP, at (301) 903-7440.

Sincerely,

Jennifer Granholm

Enclosure

Department's Implementation Plan, Milestone 5.2.1 to the Board's Recommendation 2020-1, *Nuclear Safety Requirements*

REGULATORY ANALYSIS OF POTENTIAL CHANGES TO DEPARTMENT OF ENERGY HAZARD CATEGORIZATION REQUIREMENTS



February 2023

U.S. Department of Energy Washington, D.C. 20585

Executive Summary

On February 21, 2020, the Defense Nuclear Facilities Safety Board (DNFSB or the Board) issued Recommendation 2020-1, *Nuclear Safety Requirements*, to the Department of Energy (DOE or the Department). The DNFSB recommended in part that the Department revise Title10 Code of Federal Regulation (CFR) Part 830, *Nuclear Safety Management*, Subpart B, *Safety Basis Requirements*, to mandate the use of a single version of DOE-Standard (STD)-1027, *Hazard Categorization of DOE Nuclear Facilities*, when performing nuclear facility hazard categorizations. Subsequently, on January 19, 2021, the DNFSB issued a letter transmitting their October 5, 2020, Staff Report, entitled *Review of DOE Nuclear Facility Hazard Categorization Standards*. This report details the DNFSB staff's review of the three approved hazard categorization methodologies that the Department currently allows its contractors to use when performing nuclear facility hazard categorization. In its letter, the DNFSB identified technical findings with these hazard categorization standards that they consider to be safety findings and recommended that the Department:

(1) discontinues the use of the NNSA-SD-1027 because its methodology is not technically justified and is superseded by DOE Standard 1027-2018, (2) updates DOE Standard 1027-2018 to address deficiencies described in the enclosure to [the January 21, 2021] letter, and (3) ensures that the changes in methodology introduced in Standard 1027-2018 and NNSA-SD-1027 have not caused hazard category 3 and below hazard category 3 facilities to be inappropriately categorized. ¹

On June 1, 2021, the DNFSB transmitted to the Secretary of Energy (Secretary) a revised and reaffirmed Recommendation 2020-1. On September 8, 2021, the Secretary corresponded with the DNFSB Chair and accepted the DNFSB's recommendation, as detailed in the letter's enclosure. Subsequently, the Secretary transmitted the Department's Implementation Plan (IP) to the DNFSB on June 27, 2022, detailing the approach and actions the Department intends to take with respect to Recommendation 2020-1. These actions include a regulatory analysis of the issues identified by the DNFSB related specifically to the Department's hazard categorization requirements under 10 CFR Part 830, Subpart B, Section 830.202(b)(3), *Safety Basis*. Among other actions, the IP states that:

...[a]t a minimum, the Department will initiate a rulemaking in the Federal Register which will propose to formally incorporate the Department's hazard categorization Standard into the rule. (Implementation Plan, p.8)

¹ National Nuclear Security Administration (NNSA) SD 1027, *Guidance on Using Release Fraction and Modern Dosimetric Information Consistently with DOE-STD-1027-92, Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports, Change 1.*

The primary purpose of this regulatory analysis is to implement this action by analyzing the benefits and drawbacks of the spectrum of possible regulatory approaches to enhancing the current hazard categorization requirements. Ultimately, the Department's final recommendation (Section 6) is to develop a single, updated, and consolidated hazard categorization standard, and to properly incorporate by reference (IBR) this standard into 10 CFR Part 830, Subpart B, Section 830.202(b)(3) (see Section 4.4). The updated standard will represent the acceptable methodology for future and updated hazard categorizations of DOE nuclear facilities and be properly cited under the updated Rule.

While the options presented in this analysis, and the final recommended approach, are expected to be applicable to all existing and new DOE nuclear facilities, none of the proposed options will require existing facilities to change or update their established hazard categorization, unless the facility significantly changes the material at risk or meets other criteria to be determined in later phases of the IP process.

The Department did not see evidence in the DNFSB's review pointing towards systemic or immediate safety issues resulting from their findings. The Department remains confident that the existing hazard categorization framework provides reasonable assurance of adequate protection and can continue to be used effectively to meet the requirements of 10 CFR Part 830. However, the items identified by the Board in Recommendation 2020-1 warrant consideration. Moving forward, the Department is comfortable assessing these findings within the larger scope of regulatory updates to enhance the current nuclear safety and hazard categorization frameworks.

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1. <u>Purpose and Approach</u>

The purpose of this document is to analyze the benefits and drawbacks of potential regulatory approaches to enhancing the current hazard categorization requirements at Department of Energy (DOE or the Department) nuclear facilities. The analysis presented in this report is intended to be process-oriented and not to solve or otherwise evaluate technical items.

This report executes Implementation Plan (IP) Milestone 5.2.1, *Regulatory Analysis*, in two main evaluation phases. First, by evaluating the existing hazard categorization and nuclear safety regulatory framework, including the currently applicable rule, standards, and directives. This evaluation considers the ramifications of the current framework based on stakeholder recommendations, e.g., the Defense Nuclear Facilities Safety Board (DNFSB or the Board), the Office of the Federal Register (OFR), and internal DOE feedback. Finally, the second evaluation phase of this report considers the results of the evaluation to inform the possible regulatory options moving forward, including a recommended approach.

This document is consistent with the Action Items contained in the IP to systematically:

- Evaluate the existing framework of hazard categorization and use of multiple standards (Section 3), and options going forward for categorizing new and existing defense nuclear facilities (Section 4);
- Evaluate the nuclear safety framework (e.g., DOE directives and technical standards) to determine the best approach to proposing requirements that would provide greater clarity in the categorization of defense nuclear facilities, including those facilities below hazard category 3 (Section 3);
- Present options for proposed new standard(s) (Section 4 and 5), including an evaluation of DOE-Standard (STD)-1027-2018, *Hazard Categorization of DOE Nuclear Facilities*, to determine potential changes. This includes consideration of the concerns identified in the DNFSB's letter dated January 19, 2021, and the need for a revision of the standard (Section 3); and
- Present options for revising the Title10 Code of Federal Regulation (CFR) Part 830, *Nuclear Safety Management*, to incorporate the standard(s) used by the Department for hazard categorization (Section 4 and 5).

In addition to the commitments made to the DNFSB, this analysis re-asserts the Department's desire to clarify the current hazard categorization language in 10 CFR Part 830.202(3). Key to this analysis is the critical assessment of the regulatory and administrative impacts of using multiple approved standards for hazard categorization.

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 analyses (OMB Circular A-4, *Regulatory Analysis*). As stated in OMB Circular A-4, a regulatory analysis is a tool for

regulatory agencies to use to anticipate and evaluate the likely consequences of rules. It provides a formal way of organizing the evidence on key effects of the various alternatives that should be considered in developing regulations. The OMB Guidance emphasizes that a regulatory analysis should provide examination of alternative approaches, and an evaluation of the benefits and drawbacks of the proposed action and the main alternatives identified by the analysis.

2. <u>Introduction</u>

Improvements to hazard categorization requirements under 10 CFR Part 830.202(b)(3), *Safety Basis*, have the potential to improve clarity for the categorization of DOE nuclear facilities. However, as discussed in Section 3.2, the Department remains confident that its existing framework provides reasonable assurance of adequate protection. The Department is assured that current methodologies can be used effectively to meet the requirements of 10 CFR Part 830 but agrees that the process may benefit from improvements and clarification.

For facility hazard categorization, 10 CFR Part 830.202 (b)(3), states that DOE nuclear facilities must:

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 (CN) 1, September 1997). [emphasis added].

The Department cites the language "consistent with", quoted above, as part of the basis for allowing the use of multiple hazard categorization standards documents. Currently, the Department has authorized the use of the following standards and supplemental guides as effective in fulfilling the requirements of 10 CFR Part 830.202(b)(3):

- 1. DOE-STD-1027-1992, CN 1, Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports;
- 2. DOE-STD-1027-2018, CN 1, Hazard Categorization of DOE Nuclear Facilities; and
- 3. NA-SD-1027, CN 2, Guidance on Using Release Fraction and Modern Dosimetric Information Consistently With DOE-STD-1027-92, Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports, CN No. 1.

2.1. <u>Regulatory Background</u>

Title 10 CFR Part 830 establishes nuclear safety management requirements for DOE nuclear facilities. Title 10 CFR 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 (HC) -1, -2, and -3 DOE nuclear facilities. Title 10 CFR Part 830, Subpart B, includes requirements to:

- (1) perform work at HC-1, -2, and -3 facilities in accordance with the safety basis (10 CFR Part 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 CFR Part 830.202);
- (3) prepare documented safety analyses (DSAs) which address a prescribed set of elements (10 CFR Part 830.204); and
- (4) either use the methodologies that are set forth in Appendix A, Table 1 (i.e., the safe harbor methodologies) in preparing DSAs or obtain the Department's approval of the methodologies used (10 CFR Part 830.204).

Title 10 CFR Part 830, Appendix A to Subpart B, Table 1, identifies different types of nuclear facilities and DOE-accepted methodologies (also referred to as "safe harbors") that may be used to prepare DSAs for these types of facilities. Table 1 identifies "DOE-STD-3009, CN No. 1, *Preparation Guide for U.S. DOE 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 CFR Part 830 provides enforceable requirements for contractors to operate DOE HC 1, 2, and 3 nuclear facilities within the approved DSA limits and controls. Nuclear facilities below HC-3 are not required to meet 10 CFR Part 830, Subpart B.

DOE-STD-1027-92 was developed in 1992 under DOE Order (O) 5480.23, *Nuclear Safety Analysis Reports*, prior to the issuance of the Rule. This Standard provides methodologies to meet the requirements contained in DOE O 5480.23, including a uniform methodology for determining hazard categories, as well as insights into the graded approach for conducting safety analyses. In 1997, CN 1 was issued to DOE-STD-1027-92 and served as a routine update to the standard. Then in 2001, DOE issued 10 CFR Part 830, Subpart B, *Safety Basis Requirements*. DOE O 5480.23 was subsequently cancelled, and the Rule instead provides acceptable and approved ("safe harbor") methodologies for meeting the requirements of the Rule.

In 2011, the National Nuclear Security Administration (NNSA) issued the supplemental directive, NNSA-SD-1027. The supplemental directive is used across several facilities in the Department for final hazard categorizations. It relies on the methodology in DOE-STD-1027-92, CN 1. In 2018, DOE-STD-1027-1992, CN 1, was updated to incorporate previously issued guidance, more recent consensus standards, and update mathematical determinations. This update retained the methodology used in DOE-STD-1027-1992, CN 1. The Department considers both DOE-STD-1027-92, CN1, DOE-STD-1027-2018, and NNSA-SD-1027 acceptable approaches for facility categorization and compliant with the requirements of the 10 CFR Part 830.202(b)(3).

3. Evaluation of Existing Hazard Categorization and Nuclear Safety Frameworks

This section assesses the existing hazard categorization and nuclear safety frameworks outlined in 10 CFR Part 830.202(b)(3) and includes those standards and directives the Department has deemed "consistent with" DOE-STD-1027-92, CN1 (refer to Section 2). This evaluation forms part of the basis for the recommended regulatory options presented in Section 4 and assessed in Sections 5 and 6 of this report.

The assessment in this section provides the regulatory and administrative context of the current frameworks, as well as insights into the Department's plans to address potential technical inconsistencies identified by the DNFSB through Recommendation 2020-1, and items internally identified through Department activities. The evaluation of technical items in this report is not intended to provide a technical resolution since this document remains a regulatory analysis. The technical analysis explores the extent of issues identified to determine whether updates to the standard(s) are warranted.

3.1. <u>Regulatory Evaluation of Existing Hazard Categorization and Nuclear Safety</u> <u>Frameworks</u>

This section provides the regulatory and administrative evaluation of the existing hazard categorization and nuclear safety frameworks. This includes items identified by the DNFSB through Recommendation 2020-1, as well as items internally identified through Department activities. The existing hazard categorization framework remains adequate and facilities operating under the current framework are safe and continue to meet the requirements of 10 CFR Part 830. However, the manner that DOE-STD-1027-92, CN1, is referenced in 10 CFR Part 830.202(b)(3) supports the need for a regulatory update.

The current hazard categorization requirement under 10 CFR Part 830.202(b)(3) requires a contractor responsible for a DOE nuclear facility to:

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". CN 1, September 1997) [emphasis added]

The Administrative Procedure Act (APA) requires federal agencies to publish the contents of their rules in the Federal Register [see U.S.C. 552(a)]. However, certain material that is not actually written into an agency rule (such as an industry standard), but nonetheless, referenced by the rule, may be deemed "published" in the Federal Register if the material is "incorporated by reference" with the approval of the Director of the Federal Register.

When the reference to DOE-STD-1027-92, CN1, in 10 CFR Part 830.202 was added in 2001, DOE did not receive approval from the Director of OFR to incorporate the material by reference. Although the reference to the standard was ultimately published in the CFR, that publication

does not constitute approval by the Director of OFR. See 1 CFR Part 51, *Incorporation by Reference*, at Part 51.1(e). Furthermore, other requirements of OFR for the IBR process, such as using the words "incorporated by reference" or referring to 5 U.S.C. Part 552(a) in the regulatory text, were not followed. See 1 CFR Part 51.9(a), and (b).

Additionally, even if DOE-STD-1027-92, CN1, had been "incorporated" properly in 2001, neither DOE-STD-1027-2018 nor NNSA-SD-1027 would be included in that reference. As provided by 1 CFR Part 51.1:

An incorporation by reference of a publication is limited to the edition of the publication that is approved. Future amendments or revisions of the publication are not included [in the incorporation by reference].

Although the hazard categorizations in DOE-STD-1027-2018 and NNSA-SD-1027 may be "consistent with" DOE-STD-1027-1992, those standards should have been approved by the Director of the OFR and would have needed to be incorporated individually into the Rule. These concerns support the need for a rulemaking to revise 10 CFR Part 830 to properly cite and codify approved hazard categorization methodology in accordance with OFR's requirements. Section 4 of this report outlines possible approaches to updating the Rule and standard(s) to best address this issue.

3.2. <u>Technical Evaluation of Existing Hazard Categorization and Nuclear Safety</u> <u>Frameworks</u>

This section provides a technical evaluation of the existing hazard categorization and nuclear safety framework at the process-level and identifies relevant technical items to determine whether updates to existing standards and guides are warranted. This includes items identified by the DNFSB through Recommendation 2020-1, as well as items internally identified by the Department. The Department did not see evidence in the DNFSB's review pointing towards systemic or immediate safety issues resulting from their findings. As such, the Department believes it can assess these findings within the larger scope of regulatory updates to enhance and consolidate the current nuclear safety and hazard categorization frameworks.

During its review of the three approved hazard categorization methodologies, the DNFSB identified what they consider safety items with the three currently approved hazard categorization standards. The most significant was with the use of NNSA-SD-1027, which NNSA subsequently addressed in an administrative update. In their January 19, 2021, letter to DOE, the DNFSB asserted that:

...[NNSA-SD-1027] is not technically justified, is not conservative, and is inconsistent with 10 CFR 830 and other versions of the standard. Its use may result in inappropriate facility hazard categorization, which could potentially lead to inadequate controls for protection of workers and members of the public.

In their October 5, 2020, Staff Report, *Review of DOE Nuclear Facility Hazard Categorization Standards*, associated with their January 19, 2021, letter, the DNFSB identified safety concerns regarding DOE's hazard categorization requirements including the following major concerns:

[1. The] Use of NNSA-SD-1027 May Lead to Facility Under-Categorization... [2. The] Change in Methodology for Deriving Hazard Category 3 Threshold Quantities... non-conservatively increased the HC-3 TQ values for many radionuclides... [3.] More Clarity is Needed in DOE Hazard Categorization Documents... [4.] [The] Inappropriate Use of "Should" Statements.

This section explores the nature of these findings to consider how they may be addressed through potential regulatory updates. Again, it is not intended for technical items to be solved in this analysis, but rather considered within the scope of larger regulatory updates.

3.2.1. Use of NNSA-SD-1027 May Lead to Facility Under-Categorization

This section explores the nature of the following findings from the DNFSB to consider how they may be addressed through potential regulatory updates. As stated in their October 5, 2020, Staff Report, *Review of DOE Nuclear Facility Hazard Categorization Standards*:

Use of NNSA-SD-1027 May Lead to Facility Under-Categorization - For hazard category 2 threshold quantity (TQ) values, DOE-STD-1027-92 and DOE-1027-2018 make conservative assumptions with respect to lung absorption class, while NNSA-SD-1027 does not... Further, the staff team concludes that the use of nonconservative lung absorption classes in NNSA-SD-1027 constitutes a change in methodology from DOE Standard 1027-92, which makes NNSA-SD-1027 inconsistent with 10 CFR 830. Use of NNSA-SD-1027 may result in a less conservative facility hazard categorization compared to what would result from using DOE Standard 1027-2018...

Both NNSA-SD-1027 and DOE-STD-1027-2018 rely on the recommendations of the International Commission on Radiological Protection (ICRP) Publication 60. Since NNSA-SD-1027 was published before DOE-STD-1027-2018 there is not a clear description of how the two documents complement each other. In their Staff Report from October 5, 2020, the DNFSB identified that in developing its Hazard Category 2 threshold quantities tables, NNSA-SD-1027 uses the ICRP's recommended default values (and if no such value was recommended the most conservative value was selected).

In response to this feedback, NNSA made an administrative change dated May 10, 2021, to NNSA-SD-1027 which added clarifying text to NNSA-SD-1027 to ensure that appropriately conservative values are used. This appropriate conservatism allows for the use of the default value when technically defensible, based on material form. This

additional guidance brings the use of the NNSA-SD-1027 closer into alignment with the language in DOE-STD-1027-2018, which allows for the use, where appropriate, of the ICRP recommended default values, even if the initial conservative values were the initial assumption.

There is no evidence that any facility has been or could be under-categorized by using the default TQ values instead, therefore the Department does not consider the approaches to be inconsistent. However, on an administrative level this brings into question the clarity of the applicable requirements outlined in the rule, and a revision of the nuclear safety framework would improve clarity and ensure a single methodology for future and updated categorizations across DOE nuclear facilities.

3.2.2. <u>Change in Methodology for Deriving Hazard Category 3 Threshold</u> <u>Quantities</u>

This section will explore the nature of the following findings from the DNFSB, to consider how they may be addressed through potential regulatory updates. As stated in their October 5, 2020, Staff Report, *Review of DOE Nuclear Facility Hazard Categorization Standards*:

Change in Methodology for Deriving Hazard Category 3 Threshold Quantities - DOE changed the quantitative methodology used to derive the HC-3 TQ values in DOE-STD-1027-2018 and [NNSA-SD-1027] compared to what was used in DOE-STD-1027-92. This change in methodology non-conservatively increased the HC-3 TQ values for many radionuclides. As a result, the newer hazard categorization documents may be considered inconsistent with 10 CFR 830.

The methodology in DOE-STD-1027-1992 for calculating threshold quantities in existing hazard categorization standards is based on a methodology from the Environmental Protection Agency's document, *Technical Background Document to Support Final Rulemaking Pursuant to Section 102 of the Comprehensive Environmental Response, Compensation, and Liability Act: Radionuclides, a Report to the Emergency Response Division, Office of Emergency and Remedial Response (1989).* The DNFSB identified an issue with the use of this methodology that supports the need to update to the current hazard categorization framework.

DOE-STD-1027-1992 selects threshold quantities based upon the most conservative value between the committed dose equivalent to any organ or the whole body total effective dose equivalent limit. However, DOE-STD-1027-1992 incorrectly states its threshold quantities are based only on a whole body total effective dose equivalent limit. DOE-STD-1027-2018 and NNSA-SD-1027, however use only a 10-rem whole body total

effective dose limit, resulting in methodological differences compared to the equivalent table in DOE-STD-1027-1992.

The DNFSB expressed concern that the newer hazard categorization standards are inconsistent with 10 CFR Part 830 due to this change. While the Department has seen no evidence of non-conservative increases in the HC-3 TQ values, this finding supports the need to revise the current methodology. Potential differences in future hazard categorization could be avoided with a single updated standard and clarification in the rule.

3.2.3. Below HC-3 Nuclear Facilities

DOE agrees that consideration is warranted regarding the classification of facilities, including below HC-3 facilities. Through the analysis of technical items identified in this section, at future phases of the IP, the Department intends to provide increased clarity in the categorization of DOE facilities. The Department also plans to assess the implications of requiring contractors at a subset of below HC-3 facilities at a higher risk of breaching the HC-3 threshold (criteria to be defined later) to maintain current hazard categorization determinations and provide them to the Department upon request. This would not apply to existing facilities, except under certain circumstances (see Section 4.1).

Based on the evidence provided in both the regulatory and technical evaluations of this report, it is recommended that this proposal be considered while implementing IP milestone 5.2.5. This milestone states that DOE will perform an evaluation of the use of previous methodologies at existing defense nuclear facilities, including HC-3 and below HC- 3 facilities.

3.2.4. More Clarity is Needed in DOE Hazard Categorization Documents

This section explores the nature of the following findings from the DNFSB, to consider how they may be addressed through potential regulatory updates. As stated in their October 5, 2020, Staff Report, *Review of DOE Nuclear Facility Hazard Categorization Standards*:

More Clarity is Needed in DOE Hazard Categorization Documents - The DNFSB's staff team identified that DOE's hazard categorization documents need more clarity regarding adjusting hazard categorization release fractions, evaluating new information that impacts Below HC-3 facilities, criticality exclusions, and material-at-risk exclusions. The lack of clarity could result in a defense nuclear facility being undercategorized.

The Department agrees with the DNFSB that continuous improvements in clarity provides increased regulatory certainty and uniformity in implementation therefore the Department will seek to identify potential improvements and clarity through our existing processes for developing technical standards.

3.2.5. Inappropriate Use of "Should" Statements

This section explores the nature of the following findings from the DNFSB to consider the potential for regulatory changes to address those concerns. As stated in their October 5, 2020, Staff Report, *Review of DOE Nuclear Facility Hazard Categorization Standards*:

Inappropriate Use of "Should" Statements - The DNFSB's staff team identified multiple instances where DOE Standard 1027-2018 uses a "should" statement where a "shall" statement is appropriate. Analysts are allowed to treat "should" statements as guidance rather than requirements. If these statements are taken as guidance rather than requirements, it may result in analysts under-categorizing DOE's defense nuclear facilities.

While the Department has not identified any "should" statements that have or would result in facility under-categorization, the Department agrees that a review and update of the current language in the standards would be beneficial in providing clarity and consistency across DOE nuclear Facilities. This supports the recommendation for a single standard, as this would improve future uniformity of interpretation. Under the current regulatory framework, DOE determined that maintaining a version consistent with DOE-STD-1027-92 CN1 meant stability between what is a requirement ("shall") and what is guidance ("should"). This regulatory analysis evaluates the options available (Section 4) to DOE that will allow DOE the appropriate flexibility to assess the need for requirement statements in an updated hazard categorization process and will establish those through the Department's standard development process.

3.3. Assessment of the Evaluation of Regulatory and Technical Findings

This section discusses the technical and regulatory issues within the nuclear safety and hazard categorization frameworks which could use further investigation and disposition. Based upon the scope and nature of the findings presented here, the Department concludes that the technical and regulatory issues identified warrant a revision and update to the current methodology for hazard categorization. However, the Department did not identify any immediate or systemic safety issues which would warrant an expedited or otherwise atypical regulatory approach.

4. **Options for Proposed New Standard and Rule Update**

This section satisfies DOE's Recommendation 2020-1 IP commitment to consider options for a proposed new standard, including an evaluation of DOE-STD-1027-2018, to determine potential

changes and the need for a revision of the Standard. This section also considers options for proposed revisions to 10 CFR Part 830 to incorporate the standard(s) used by the Department for hazard categorization.

The justification for the options evaluated here is derived from the evaluation of the hazard categorization and nuclear safety frameworks provided in Section 3 of this report. The options are inclusive of all reasonable approaches available to the Department within the scope of their current regulatory and administration framework. The options presented in this section are intended to provide the complete spectrum of approaches. This allows for a systematic analysis of the level of effort, benefits, and drawbacks of each scenario, and culminates in Sections 5 and 6, with a conclusion and final recommended approach.

4.1. <u>Applicability</u>

While the options presented in this section, and the final recommended approach, will be applicable to all existing and new DOE nuclear facilities, none of the proposed options will require existing facilities to change or update their established hazard categorization unless the facility significantly changes the material at risk or meets any other criteria that may be established for reevaluating hazard categorizations in later phases of the implementation process.

It is assumed that an updated rule will include a regulatory mechanism allowing existing facilities with an established DOE hazard categorization, developed prior to the promulgation of the rule update, to continue operating under that existing categorization. This will be the case unless, during future phases of the IP, the Department identifies any significant safety issue with current methodologies. The definitions and applicability of an updated standard will be further explored in future phases of the IP (e.g., development of a standard, development of a draft rule).

4.2. Option 1: Status Quo

The Department could take no action and retain the current hazard categorization framework. However, this option does not address technical issues identified by the Department in the 2018 revision of DOE-STD-1027 or address regulatory and administrative issues identified internally and by OFR to properly update the reference to DOE-STD-1027-92, CN1, in the current hazard categorization requirements within 10 CFR Part 830.202(b)(3), as discussed in Section 3.1. Therefore, DOE does not believe this option is justified, based on this regulatory analysis.

4.3. Option 2: Incorporate by Reference DOE-STD-1027-18 and NNSA-SD-1027

The Department could decide to forgo any technical updates recommended by the DNFSB or identified in Section 3 of this report and seek permission from the Director of the OFR to IBR DOE-STD-1027-2018 and NNSA-SD-1027 into 10 CFR Part 830, Subpart B. However, there is a possibility that the Director of the OFR will not approve incorporating these standards by reference because OFR rules include a presumption against approving a standard published by the agency seeking to incorporate the standard by reference. See 1 CFR Part 51.7(b):

The Director [of OFR] will assume that a publication produced by the same agency that is seeking its approval is inappropriate for incorporation by reference. A publication produced by the agency may be approved, if, in the judgment of the Director, it meets the requirements of paragraph (a) [of 1 CFR Part 51.7] and possesses other unique or highly unusual qualities. A publication may be approved if it cannot be printed using the Federal Register/Code of Federal Regulations printing system.

If the Department, including NNSA, chooses to pursue this option, the Department would need to overcome this presumption, either by proving that the standards possess unique or highly unusual qualities or otherwise cannot be printed using the CFR printing system. See 1 CFR Part 51.7(b).

Assuming the Director of the OFR approves incorporating each standard by reference, this approach would resolve regulatory concerns stemming from the improper IBR, discussed in Section 3.1. Furthermore, it would result in a shorter and more streamlined rule than the codification approach discussed in Option 4. Additionally, the IBR process has been utilized by the Department in the past and is therefore a more familiar and culturally acceptable approach internally. Finally, incorporating both DOE-STD-1027-2018 and NNSA-SD-1027 could minimize the negotiations between DOE entities to reach a consensus on a single standard.

On the other hand, this approach would not incorporate the beneficial technical updates discussed earlier in this paper and would allow differing approaches in future and updated hazard categorizations. Furthermore, updating an existing standard or adding a new standard would require DOE to restart the IBR process and seek new approval from the Director of the Federal Register each time.

4.4. <u>Option 3: Update DOE-STD-1027-2018 and Incorporate by Reference the Updated</u> <u>Standard into 10 CFR Part 830</u>

DOE, including NNSA, could choose to update DOE-STD-1027-2018 in accordance with the discussion included in Section 3 of this report and then incorporate, by reference only, the updated standard in the CFR. Like Option 2, this approach would resolve regulatory concerns identified in Section 3.1. However, unlike Option 2, the updated standard produced through this process could thoroughly consider the technical information presented in Section 3.2 of this report. Furthermore, incorporating one standard by reference into DOE rules is simpler than incorporating multiple standards, and ensures a consistent approach to future hazard categorization.

On the other hand, this approach may take longer to effectuate than Option 2 because revising DOE-STD-1027-2018 and reaching an agreement between the various DOE program offices responsible for managing DOE nuclear facilities may be a lengthy process. Finally, as discussed

in Option 2, the Department could have trouble securing permission from the Director of the OFR to incorporate the Department's own standard into the rule.

4.5. <u>Option 4: Revise DOE-STD-1027-2018 and Codify the Updated Standard in an</u> <u>Appendix to 10 CFR Part 830</u>

The Department could update DOE-STD-1027-2018 in accordance with the discussion included in Section 3 of this report and then publish the content of the standard directly into an appendix to 10 CFR Part 830, as opposed to incorporating the standard by reference, as presented in Options 2 and 3. Under this option, compliance with the provisions of the appendix would be required for DOE contractors that operate HC -1, -2, or -3 DOE nuclear facilities.

Like Options 2 and 3, this approach would resolve any regulatory concerns with the IBR discussed in Section 3.1, and like Option 3, the updated standard produced through this process would reflect the technical considerations presented in Section 3 of this report, by evaluating the DNFSB's concerns.

However, unlike Options 2 and 3, a key benefit of this option is that it does not require approval by the Director of OFR. Therefore, the standard could be updated by regular notice and comment rulemaking under the APA without having to undertake the IBR process with the OFR. This option is the most consistent with the practice of other federal agencies and ensures future updates are streamlined and straight-forward.

A downside to this option is that this approach is less familiar within the Department and therefore, may encounter increased resistance internally and be met with a longer implementation time. Additionally, as discussed in Option 3, this approach may take longer to effectuate because revising DOE-STD-1027-2018 and reaching an agreement within the Department, including NNSA, may be a lengthy process.

4.6. <u>Option 5: Revise DOE-STD-1027-2018 and Include the Hazard Categorization</u> <u>Requirement as a Safe Harbor or Invoked Standard</u>

The Department could update DOE-STD-1027-2018 in accordance with the discussion included in Section 3 of this report and then adopt an approach for its hazard categorization requirement similar to the approach the Department currently uses for DSAs for HC- 1, 2, or 3 nuclear facilities.

Currently, 10 CFR Part 830.202(b)(4) and (5) require a contractor to prepare a DSA for HC-1, 2, or 3 facilities and establish the hazard controls upon which the contractor will rely to ensure adequate protection of workers, the public, and the environment. Section 830.204(a) provides that the contractor must either obtain approval from the Department for the methodology used to prepare the DSA or use a methodology set forth in Table 1 of Appendix A to subpart B of 10 CFR Part 830. Table 1, in turn, lists methodologies that DOE has approved for specific types of facilities, which includes references to outside standards.

The Department could approach hazard categorization similarly by updating 10 CFR Part 830 to provide that a contractor must categorize a nuclear facility and obtain approval from the Department for the methodology used to categorize the facility or otherwise use a methodology set forth in an appendix to 10 CFR Part 830. Additionally, 10 CFR 830 could provide high-level requirements that must be followed for hazard categorization. These high-level requirements would be developed during a future IP phase.

As in Options 3 and 4, the accompanying updated standard produced through this process could reflect the technical considerations presented in Section 3.2 of this report, including evaluating the DNFSB's concerns. Furthermore, it would not require the Department to undertake a rulemaking or go through the IBR processes to update the standard.

A drawback to this approach is that it would not require Department contractors to use a particular hazard categorization methodology. Rather, the approach would allow the use of the Department's pre-approved standard by requiring a contractor obtain the Department's approval for any other methodology. This approach would permit the use of multiple hazard categorization methodologies and an approval criterion for alternative methodologies would need to be developed. This option would also not ensure a uniform methodology for future and updated hazard categorizations, and it limits the public's opportunities for participation in rulemaking.

4.7. <u>Option 6: Revise DOE-STD-1027-2018 and Produce Hazard Categorization</u> <u>Requirements as an Order</u>

The Department, including NNSA, could update DOE-STD-1027-2018 in accordance with the discussion included in Section 3.2 of this report and then require Department contractors to use the updated standard to categorize facilities through a DOE Order. Additionally, under this option, the Department would revise 10 CFR Part 830, subpart B, to remove specific reference to hazard categorization standards, and instead include generic high-level requirements such as "develop a hazard categorization and obtain the Department's approval."

As in Options 3, 4, and 5, the updated requirements produced through this process could reflect the technical considerations presented in Section 3.2 of this report, including the DNFSB's concerns. However, the Department cannot enforce requirements if they are not codified or properly incorporated into the Rule which would fundamentally question the Department's regulatory structure. Further, this option opens the possibility of numerous hazard categorization methodologies being used throughout the Department's directives system's equivalencies/exemptions process and therefore may not be responsive to the recommendation for a single methodology for hazard categorization.

Furthermore, this approach would not be able to use mechanisms found in the Department's rules to enforce contractor compliance with the new standard. Rather, the Department could require use of the standard by including it in its contracts, and if a contractor did not adhere to

the standard, the Department would be limited to the remedies available under contract law. This could also result in inconsistent application across facilities.

5. <u>Assessment of Options</u>

The regulatory evaluation of the current framework for hazard categorization and nuclear safety (Section 3.1) provided sufficient regulatory and administrative arguments supporting the need to update the existing rule. Further, based on the technical evaluation of the current hazard categorization and nuclear safety framework (Section 3.2) it is reasonable to conclude there is a need to update DOE-STD-1027-2018, as well as clarify and consolidate the existing methodologies into a single source. Based on these evaluations, input from the DNFSB, and the Secretary's Final Decision on Recommendation 2020-1, DOE concludes that the proposed regulatory approach presented in Option 3, *Update DOE-STD-1027-2018 and Incorporate by Reference the Updated Standard into 10 CFR Part 830* (Section 4.4), will most effectively balance the needs of stakeholders and ensure a robust regulatory framework for hazard categorization of DOE nuclear facilities.

Option 3 presents the approach to update and consolidate DOE-1027-2018 and NNSA-SD-1027 into a single standard for hazard categorization requirements and incorporates this standard by reference into an update to 10 CFR Part 830, Subpart B. While some of the goals discussed in Section 3 are achieved through the other options presented, maintaining the rule in its current form, or selecting an option which allows for future or updated categorizations to be based upon one of multiple standards presents too many drawbacks and does not meet the Secretary's commitments.

A drawback to Option 3 is that to update 10 CFR Part 830 to incorporate a DOE standard by reference (as discussed in Options 2, 3, and 4), the Department would need to receive approval by the Director of OFR for each standard that the agency seeks to incorporate. This would require overcoming the presumption in 1 CFR Part 51.7(b) that incorporation of standards published by the agency seeking incorporation is inappropriate. To do this, the Department will need to show that the standard possesses unique or highly unusual qualities to any other existing publication (see 1 CFR Part 51.7(b)). Additionally, each time that the Department wants to update the standard, the Department will need to seek a new approval from the Director of OFR and repeat the IBR process again.

6. <u>Final Recommendation</u>

If approved by the Secretary, the Department will develop a single, updated, and consolidated hazard categorization standard and seek to properly incorporate it by reference in 10 CFR Part 830 (Option 3). The Department will conduct a rulemaking to address the administrative and legal gaps currently in 10 CFR Part 830 830.202 (b)(3) (identified in Section 3.1 of this report). The updated standard will represent the single, acceptable methodology for future or updated hazard categorizations of DOE nuclear facilities and will be properly cited under the updated

rule. The new standard will be applicable to all existing and new DOE nuclear facilities. However, it is expected that the updated rule will only require existing facilities to change or update their established hazard categorization when certain criteria are met. These criteria and other applicability considerations will be further explored in future phases of the IP (e.g., development of a standard, development of a draft rule).

The updated content will reflect the actions identified by the Secretary in response to Recommendation 2020-1 and other planned updates. It will also consider the input provided by the DNFSB in its communications, as well as relevant aspects of NNSA's Supplemental Directive. Finally, Section 3 of this report will be used as a roadmap to frame technical updates and ensure a structured technical debate.