



Department of Energy

Washington, DC 20585

December 21, 2023

The Honorable Joyce L. Connery
Chair, Defense Nuclear Facilities Safety Board
625 Indiana NW, Suite 700
Washington, DC 20004

Dear Chair Connery:

This letter is to notify you that the Department of Energy has completed Deliverable 5.4.2, "Perform an Independent review of the submittal and approval of safety documents," of the Department's Implementation Plan, in response to the Defense Nuclear Facilities Safety Board Recommendation 2020-1, *Nuclear Safety Requirements*, dated June 27, 2022.

Enclosed is the "Independent Review of Safety Basis Development Processes at Defense Nuclear Facilities." The report documents the review led by the Office of Enterprise Assessments and provides recommendations for DOE program offices and field offices and for the DOE Office of Environment, Health, Safety and Security to enhance safety basis preparation, review, and approval processes across the complex.

If you or your staff have any questions, you may contact me at (301) 903-7440.

Sincerely,

A handwritten signature in black ink, appearing to read "Garrett Smith".

Garrett Smith
Director, Office of Nuclear Safety
Office of Environment, Health, Safety, and Security
Responsible Manager, Recommendation 2020-1,
Nuclear Safety Requirements, Implementation
Plan

Enclosure



Department of Energy

Washington, DC 20585

December 21, 2023

MEMORANDUM FOR WILLIAM "IKE" WHITE
SENIOR ADVISOR
OFFICE OF ENVIRONMENTAL MANAGEMENT

JILL HRUBY
UNDER SECRETARY FOR NUCLEAR SECURITY
ADMINISTRATOR
NATIONAL NUCLEAR SECURITY ADMINISTRATION

ASMERET A. BERHE
DIRECTOR
OFFICE OF SCIENCE

FROM: JOHN E. DUPUY 
DIRECTOR
OFFICE OF ENTERPRISE ASSESSMENTS

SUBJECT: *Independent Review of Safety Basis Development Processes at
Defense Nuclear Facilities - December 2023*

On September 8, 2021, DOE accepted the Defense Nuclear Facilities Safety Board's (DFNSB) Recommendation 2020-1 regarding nuclear safety requirements. On June 27, 2022, DOE issued an implementation plan that detailed the approach and actions to address the five categories and thirteen specific sub-recommendations contained in the Recommendation. The Office of Enterprise Assessments (EA) was identified as the lead organization responsible for completing section 5.4 of the plan to conduct an independent review of the safety basis development process.

EA conducted phase one of the review (data collection and analysis) from May 2017 to March 2023. This included a review of contractor procedures governing safety basis development, planning documents and schedules, field office procedures governing safety basis document review and approval, records of comments provided by DOE and their resolutions, results of assessment activities, and contractor and field office performance metrics addressing quality and timeliness of safety basis document submittals.

Based on the analysis of reviewed documents and knowledge obtained from other related EA assessments, EA revised the review plan in February 2023. The revised plan refined the scope of the review to exclude non-routine safety basis updates, such as those made to reflect facility major modifications performed in accordance with DOE-STD-1189-2016,



Integration of Safety into the Design Process, and new DSAs written to DOE-STD-3009-2014, *Preparation of Nonreactor Nuclear Facility Documented Safety Analysis*. Six sites were also selected for follow-up data collection, review, and interviews in phase two. These sites included Pantex Plant, Savannah River Site, Hanford Site, Los Alamos National Laboratory, Pacific Northwest National Laboratory and Lawrence Livermore National Laboratory.

The attached report details the results of the review. Overall, EA found the processes for preparing, reviewing, and approving submittals to change the safety basis of nuclear facilities are adequate and effective. The report includes recommendations for DOE program offices, field offices, and the Office of Environment, Health, Safety and Security on actions to consider which may enhance safety basis preparation, review, and approval processes across the complex.

We appreciate your continued support and cooperation as EA works with DOE line management in safely achieving its mission objectives. If you have any questions, comments, or feedback, please contact me at (202) 586-2730. Alternatively, your staff may contact Kevin Kilp, Director, Office of Environment, Safety and Health Assessments at (301) 903-5392.

Attachment: *Independent Review of Safety Basis Development Processes at Defense Nuclear Facilities - December 2023*

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Independent Review of Safety Basis Development Processes at Defense Nuclear Facilities

December 2023

Office of Enterprise Assessments
U.S. Department of Energy

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Acronyms

DNFSB	Defense Nuclear Facilities Safety Board
DOE	U.S. Department of Energy
DSA	Documented Safety Analysis
EA	Office of Enterprise Assessments
Hanford	Hanford Site
LANL	Los Alamos National Laboratory
LLNL	Lawrence Livermore National Laboratory
Pantex	Pantex Plant
PNNL	Pacific Northwest National Laboratory
SER	Safety Evaluation Report
SRS	Savannah River Site
USQ	Unreviewed Safety Question

INDEPENDENT REVIEW OF SAFETY BASIS DEVELOPMENT PROCESSES AT DEFENSE NUCLEAR FACILITIES

Executive Summary

The U.S. Department of Energy (DOE) Office of Environment, Safety and Health Assessments, within the Office of Enterprise Assessments (EA), conducted an independent review of safety basis development processes at defense nuclear facilities under the direction of the DOE Office of Environmental Management, the National Nuclear Security Administration, and the DOE Office of Science. The objective of this review was to evaluate the processes for preparing, reviewing, and approving submittals to change the safety basis of nuclear facilities. This report documents this review and fulfills the deliverable requirement for milestone 5.4.2 of DOE's *Implementation Plan for Defense Nuclear Facilities Safety Board Recommendation 2020-1: Nuclear Safety Requirements*.

Based on the information evaluated within the scope of this review, EA identified the following key conclusions:

- Despite wide variation in the extent and complexity of safety basis changes, 67% of the contractor change submittals were reviewed and approved by the responsible field office within four months, meeting the expectation suggested in DOE-STD-1104-2016, *Review and Approval of Nuclear Facility Safety Basis and Safety Design Basis Documents*. Project objectives and mission needs tend to be the primary drivers for review and approval duration. Where changes required significant time for field office review and approval, EA did not identify common causes for the delays.
- EA established no correlation between the perceived quality of change submittals and the time to review and approve the submittal. Field office personnel are generally satisfied with the level of quality provided in contractor submittals, and contractor personnel are generally satisfied with the level of feedback they receive.
- Annual update submittals were handled in different allowable ways among the reviewed sites. Some site contractors include multiple changes requiring DOE approval with the updates necessary to keep the safety basis current, often resulting in longer review and approval durations.
- Although annual update submittals are no longer required to be approved by DOE, most DOE field offices have instituted practices to document their reviews of these submittals as part of their operational awareness activities.
- Nuclear safety organizations at both the DOE and contractor level are experiencing staffing challenges. Organizations are managing the safety basis workload through careful planning, task prioritization, and feedback and improvement tools.
- In all cases reviewed by EA, contractors and DOE field offices worked together effectively to ensure that safety basis change submittals were approved in time to support mission activities.

As a result of this review, EA recommends the following actions to enhance safety basis preparation, review, and approval processes across the complex:

Recommendation for DOE program offices and field offices: Ensure that protocols to formally manage the safety basis change process are established and followed. To improve effectiveness, the protocols should include these common project management practices:

- Establish and document agreement between DOE and the contractor on the scope and schedule of anticipated submittals as soon as the need for changes is identified.
- Ensure that the scope of the change is aligned with the operational need.

- Identify key milestones for both the preparation and review processes, with interim review points as appropriate for the level of complexity of the planned changes.
- For submittals requiring DOE approval, establish the anticipated review period and incorporate it into the schedule.
- Conduct regular meetings to discuss progress and identify paths of resolution for technical and logistical issues.
- Develop and monitor metrics to understand the effectiveness of and bottlenecks in the processes for preparing, reviewing, and approving documented safety analyses (DSAs), including metrics that would demonstrate that quality objectives are being met.
- Document lessons learned from submittals considered to be either extremely successful or extremely unsuccessful and evaluate them on a periodic basis as part of the organization's feedback and improvement process.

Recommendation for the DOE Office of Environment, Health, Safety and Security: Include guidance in DOE-STD-1104-2016, or other documentation as appropriate, on how to handle annual update submittals that do not include changes requiring DOE approval. This guidance should include the following:

- Recommended practices for documenting receipt and review of annual update submittals.
- A recommendation to limit annual update submittals to changes resulting from negative unreviewed safety question determinations, such that DOE approval is not required.
- An explicit method for establishing the due date for an annual update submittal, based on the last approved version of the DSA.

INDEPENDENT REVIEW OF SAFETY BASIS DEVELOPMENT PROCESSES AT DEFENSE NUCLEAR FACILITIES

1.0 INTRODUCTION

The Office of Environment, Safety and Health Assessments, within the U.S. Department of Energy (DOE) Office of Enterprise Assessments (EA), conducted an independent review of safety basis development processes at defense nuclear facilities under the direction of the DOE Office of Environmental Management, the National Nuclear Security Administration, and the DOE Office of Science. The objective of this review was to evaluate the processes for preparing, reviewing, and approving submittals to change the safety basis of nuclear facilities. This report discusses the evaluation of practices at representative sites and facilities throughout the DOE complex and provides recommendations to improve safety basis preparation, review, and approval processes.

2.0 BACKGROUND

On June 1, 2021, the Defense Nuclear Facilities Safety Board (DNFSB or the Board) revised and reaffirmed Recommendation 2020-1, *Nuclear Safety Requirements*, which identified 13 sub-recommendations in 5 topical areas: aging infrastructure, hazard categories, DOE approvals, evaluation of documented safety analysis (DSA) preparation and review processes, and safety basis process and requirements. On September 8, 2021, DOE accepted the Recommendation, and on June 27, 2022, DOE issued the *Implementation Plan for Defense Nuclear Facilities Safety Board Recommendation 2020-1: Nuclear Safety Requirements*, which describes the approach and actions for addressing the sub-recommendations.

For the topical area pertaining to the evaluation of DSA preparation and review processes, the Board recommended that DOE “[c]onduct an independent review of contractor and federal processes to identify and evaluate the underlying issues that prevented the annual submittal and approval of high-quality safety basis documents, and use the findings to improve the relevant processes.” To address this sub-recommendation, this independent review focused on the contractor activities for preparing safety basis documents as well as the DOE activities for reviewing and approving them. Timelines, documents, and correspondence associated with the Board recommendation and DOE implementation plan are located on the [DNFSB website](#) or the [DOE Departmental Representative website](#).

The DOE implementation plan included two milestones for EA, both of which addressed the sub-recommendation on evaluating DSA preparation and review processes. Milestone 5.4.1 consisted of developing a review plan detailing the scope for an independent review of the safety basis development, review, and approval processes. EA issued the *Plan for the Independent Review of Safety Basis Development Processes* on September 19, 2022. Milestone 5.4.2 is the conduct of the review and is completed with issuance of this report.

3.0 METHODOLOGY

In accordance with the review plan, EA collected and analyzed more than 200 documents from across the DOE complex. The documents included safety basis submittal packages and the associated safety evaluation reports (SERs) from May 2017 to March 2023, contractor procedures governing safety basis development, planning documents and schedules, field office procedures governing safety basis document review and approval, records of comments provided by DOE and their resolution, results of assessment activities, and contractor and field office performance metrics addressing quality and timeliness of safety basis document submittals.

Based on the analysis of reviewed documents and knowledge obtained from other related EA assessments, EA revised the review plan in February 2023. The revised plan refined the scope of the review to exclude non-routine safety basis updates, such as those made to reflect facility major modifications performed in accordance with DOE-STD-1189-2016, *Integration of Safety into the Design Process*, and new DSAs written to DOE-STD-3009-2014, *Preparation of Nonreactor Nuclear Facility Documented Safety Analysis*. The preparation and review of these documents often require a higher level of effort due to the complexity of changes. As a result, the time required varies widely from document to document. EA determined that this information was not relevant to this review.

In the revised review plan, six sites were chosen for follow-up data collection, review, and interviews. These sites (Pantex Plant [Pantex], Savannah River Site [SRS], Hanford Site [Hanford], Los Alamos National Laboratory [LANL], Pacific Northwest National Laboratory [PNNL], and Lawrence Livermore National Laboratory [LLNL]) represent diverse nuclear facility safety bases across the program offices under the purview of the Board.

Queries were sent to the DOE office at each site (collectively referred to as “field offices”) to determine detailed information concerning safety basis change submittals and approvals. Figure 4-1 depicts an abbreviated example of a blank query sheet. Information was requested for annual updates, annual updates including changes, and changes submitted separately from annual updates (designated respectively as AU, AUC, and C in the query sheet). Based on responses to the queries, interview questions were tailored to each site. Initial interviews with field office personnel were done remotely, and more detailed interviews were conducted at selected sites with both field office and contractor personnel.

Site / Facility: _____				
Please populate the table with information on safety basis submittals and resubmittals (if rejected or withdrawn) since January 1, 2018 (up to five annual updates). For safety basis changes requiring DOE approval, include no more than ten. Quality of submittal is a subjective determination (high, medium, and low) based on the effort needed to revise the submitted documentation to achieve an approvable version.				
Submittal date	Type of submittal (AU, AUC, or C)	Approval or rejection / withdrawal date (formal or informal)	Quality of submittal (H, M, L) based on generated comments and their resolution	Additional Information, such as: -Reason for rejection or withdrawal -Reason for review and approval taking longer than expected -Safety basis includes multiple documents other than a single DSA and SER -Any other relevant comments

Figure 4-1. Query Sheet Example

Appendix A lists the EA management and the review team members responsible for this review.

4.0 RESULTS

4.1 Consolidated Results

Query responses were received for 18 DSAs. The level of detail in the query responses, such as those related to discussion of iterations during the review and approval process, scope issues, and bases for quality determination, varied across field offices. Data from 164 safety basis change submittals were provided in the query responses and are summarized in Table 4-1. Of the 164 submittals, 126 were approved, 33 did not require approval, and 5 were still under review when the query responses were received.

Table 4-1. Summary of Query Data (2017-2022)

Site	DSA	Number of Submittals	Document Type			Document Quality*		
			Annual Updates (AUs)	AUs with Changes	Changes Only	H	M	L
Hanford	WESF**	9	5	0	4	1	2	1
	SWOC**	10	3	0	7	2	1	3
	CSB**	5	3	1	1	2	0	0
	ISA**	7	5	0	2	0	0	2
	Tank Farms	10	4	0	6	4	5	1
	Total	41	20	1	20	9	8	7
Pantex	Mass Properties	8	4	0	4	4	0	0
	Sitewide	8	4	0	4	2	1	0
	Staging	10	5	0	5	6	2	0
	W88	12	4	0	8	5	4	0
	Total	38	17	0	21	17	7	0
SRS	DWPF**	12	1	4	7	9	2	0
	H-Canyon	16	2	3	11	15	1	0
	K-Area Complex	12	5	0	7	10	2	0
	Total	40	8	7	25	34	5	0
LANL	RANT**	9	3	1	5	0	0	0
	TA-55	10	3	4	3	0	0	0
	TA-16	10	1	3	6	0	0	0
	Total	29	7	8	14	0	0	0
LLNL	Building 332	5	3	0	2	1	3	1
	Building 334	3	3	0	0	1	2	0
	Total	8	6	0	2	2	5	1
PNNL	325 Building	8	0	6	2	5	2	0
	Total	8	0	6	2	5	2	0
Total for All 6 Sites / 18 DSAs Reviewed		164	58	22	84	67	27	8

* Document quality (High [H], Medium [M], and Low [L]) was a judgement made by the field office. This information was not provided in all cases.

** Names of the facilities associated with the DSAs: Waste Encapsulation and Storage Facility (WESF), Solid Waste Operations Complex (SWOC), Canister Storage Building (CSB), Interim Storage Area (ISA), Defense Waste Processing Facility (DWPF), and Radioactive Assay Non-destructive Testing Facility (RANT).

The review and approval duration for each of the submittals was determined based on the time from either the formal submittal or draft submittal for in-process review until approval. In-process reviews of safety basis changes are used at some sites to minimize the time spent generating formal transmittals for draft documents and early comments. For the documents that were still under review when the query sheet was submitted, the duration reflects the end of the data collection period (June 30, 2023) for purposes of depicting review durations. Figure 4-2 provides a distribution for the review and approval duration for the 131 documents that have been approved or were still under review.

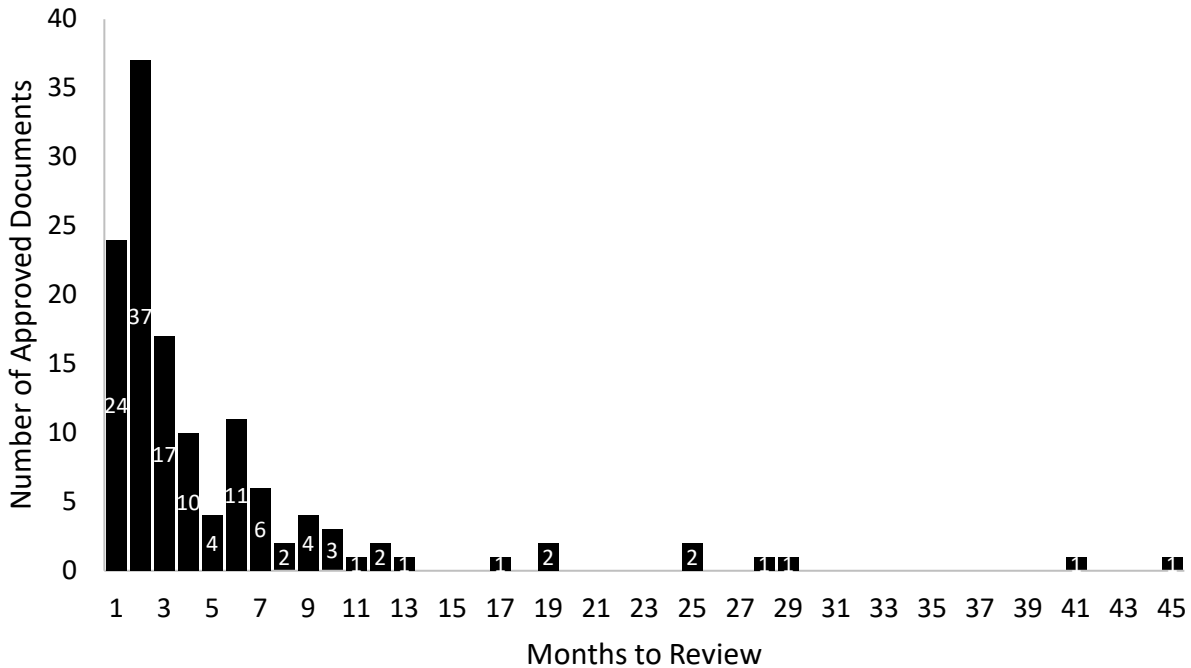


Figure 4-2. Distribution of Duration for Document Review and Approval (Consolidated)

A total of 88 submittals (67% of the documents) were approved within four months. The review and approval duration follows a log-normal distribution with the following attributes:

- Mean: 143 days
- Median: 68 days
- Standard Deviation (an indicator of the variability of the data relative to the mean): 211 days.

The relatively large standard deviation is primarily due to 10 outliers across 3 sites. The review and approval duration for these outliers exceeded a year, ranging from 378 to 1,327 days. Eliminating these outliers from the distribution would significantly lower the mean to 92 days (with a standard deviation of 81 days), which is well within the expectation for a timely review (within 90 to 120 days of submission) stated in section 7.1.2 of DOE-STD-1104-2016, *Review and Approval of Nuclear Facility Safety Basis and Safety Design Basis Documents*. Additionally, the lower standard deviation of 81 days indicates less variability across the sites.

The reasons for the outliers were investigated to determine whether common causes existed that could be addressed by global process improvements. The EA team determined that the outliers are due to unique situations. PNNL had two instances where two consecutive annual update submittals were approved together. In one case, approval of the first submittal was delayed by reviews of a substantive and higher-priority safety basis addendum and a proposal to change the functional classification of a safety system that was ultimately not pursued. The subsequent year’s annual update submittal included the proposed changes for both annual updates, and approving both submittals simultaneously was considered an efficient use of limited resources. Additional delays resulted from an extended review (more than three years) of a change due to the addition of a new capability within the facility required to support the facility’s mission. Personnel shortages contributed to the inability to support all changes simultaneously. At Pantex, numerous changes are processed across 17 separate safety basis documents. Delays are due primarily to mission priority changes and design changes necessary for mission accomplishment. LLNL’s practice is to include all changes needed to support the laboratory mission in the annual update

submittal each year. This practice has resulted in long review durations based on the extent and complexity of the changes. In summary, these outliers appear to result from unrelated causes that could not be easily addressed through universal recommendations.

The data were further analyzed to determine the potential for correlations between review and approval duration and document type, document quality, or site-specific considerations. Figures depicting site-specific distributions are included in appendix B and illustrate that the reviewed sites for which the data are statistically sufficient follow the consolidated distribution shown in Figure 4-2, leading to the conclusion that unreviewed sites likely follow a similar distribution. Potential correlations related to document type or document quality are discussed below.

4.2 Document Type

Distributions for review and approval durations for the three document types (annual updates, annual updates with changes, and changes only) are shown in Figures 4-3, 4-4, and 4-5, respectively. The figures illustrate that document type does not significantly influence review and approval duration. The distributions show groupings of documents that were approved promptly (within a month), while others took well over a year. Discussions with field office and contractor personnel indicated that project objectives and mission needs tend to be the primary drivers for the review and approval duration; submittals that are reviewed promptly tend to be priority driven.

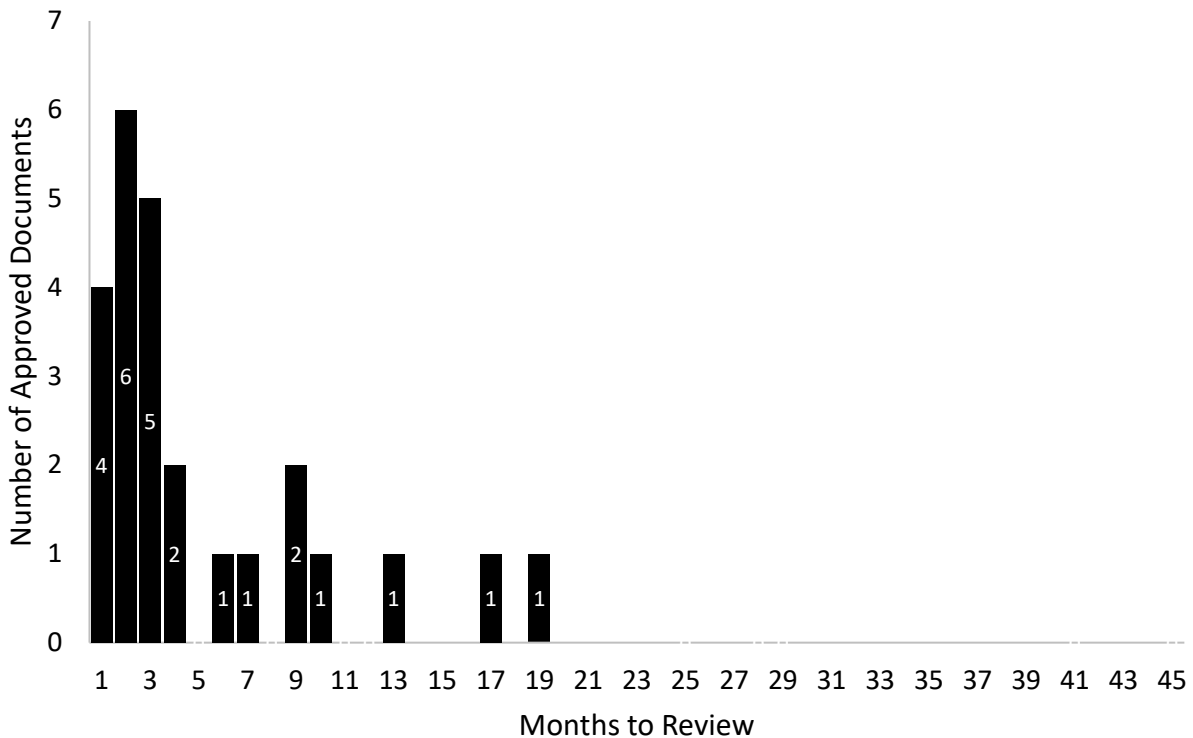


Figure 4-3. Distribution of Duration for Review and Approval of Annual Updates

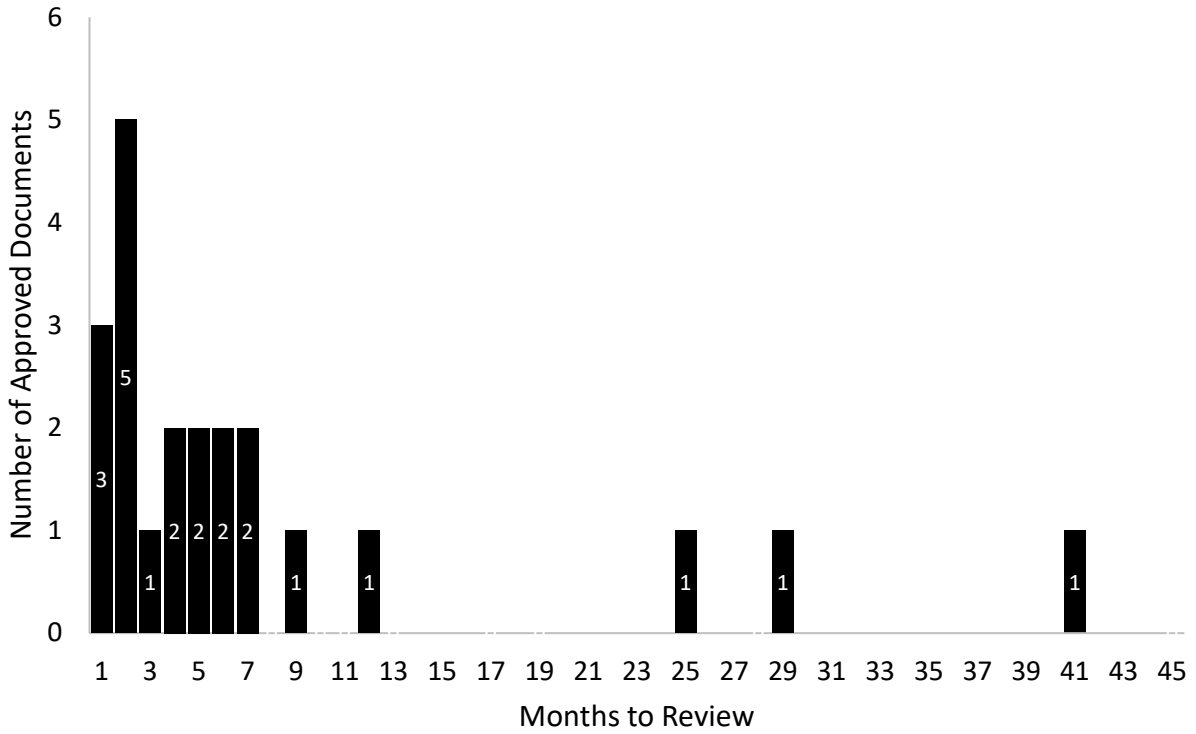


Figure 4-4. Distribution of Duration for Review and Approval of Annual Updates with Changes

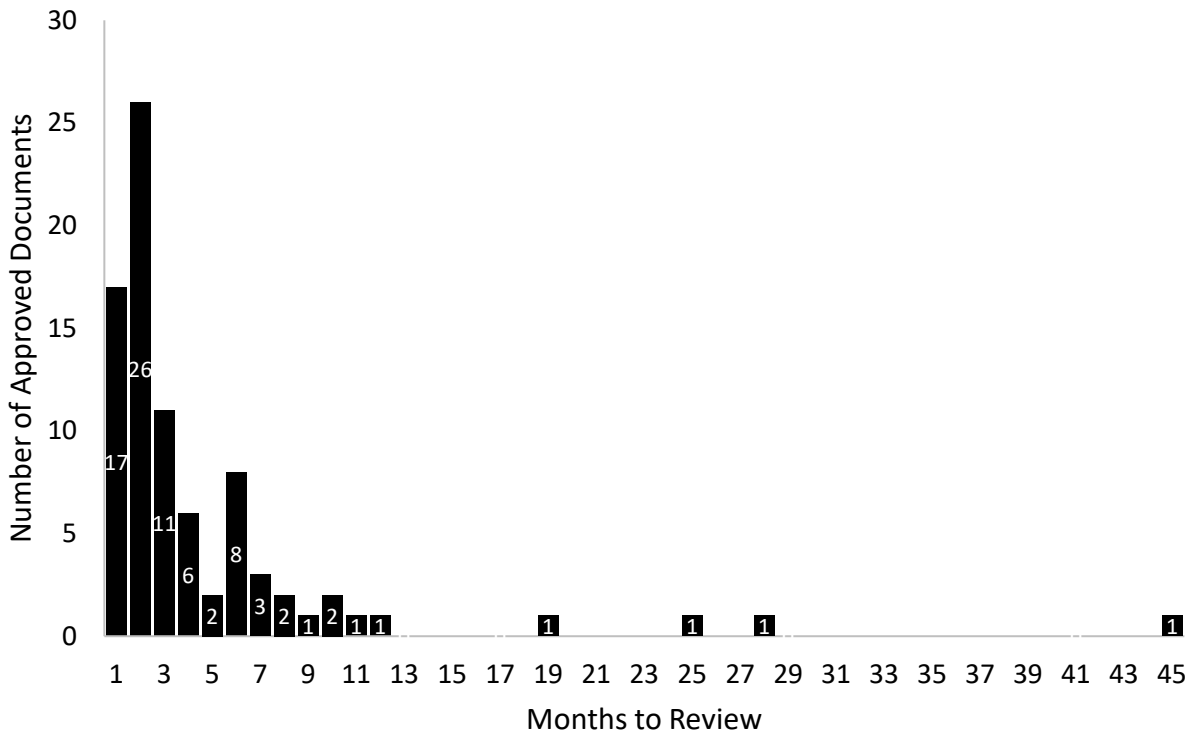


Figure 4-5. Distribution of Duration for Review and Approval of Submittals with Changes Only

In 2020, DOE revised its nuclear safety management rule (10 CFR 830, *Nuclear Safety Management*), eliminating the requirement for DOE approval of annual update submittals. Despite this rule change, some sites continue to use these submittals to process multiple changes, including some requiring DOE approval (i.e., mission changes or facility modifications resulting in a positive unreviewed safety question [USQ] determination). For example, at LLNL, annual update changes are combined with other, more significant changes required for the year. Consequently, the annual update submittal often includes changes to the technical safety requirements, which always require DOE approval. This practice results in extended review and approval time frames and additional time to implement the changes. In contrast, for the Hanford Tank Farms, only changes that resulted in negative USQ determinations are included in annual update submittals, and, thus, these changes can be implemented immediately.

Another observed variation pertains to the durations between annual submittals. The rule requires the current DSA to be provided annually to DOE but does not specify how “annually” is determined, and there is no corresponding guidance given in current directives or standards. Therefore, contractors for some site facilities (e.g., Hanford Tank Farms) submit their annual updates on the same date each year. In contrast, contractors at other sites (e.g., LLNL) submit their annual updates a year after approval of the previous update, a practice that is recognized in NNSA Technical Bulletin 2017-2 as meeting regulatory expectations. In some cases, this practice has resulted in two or more years between annual update submittals, meaning some document updates may go unreviewed for well over a year. In one case, at PNNL, two annual updates were approved with one SER more than three years after the submittal of the first annual update.

At most sites, the DOE field office no longer requires approval of annual update submittals because they are based solely on negative USQ determinations; however, most field offices that EA interviewed perform and document some form of review of the annual update submittal. These field offices are incorporating reviews into their operational awareness activities and documenting the review in local systems within 90 days of submittal. At Pantex, the field office works to incorporate reviews in a timely manner (e.g., within a month of receipt) into their operational awareness activities as described in their safety basis program procedure.

4.3 Quality

Overall, field office and contractor personnel are satisfied with the quality of change submittal documents and feedback. Field office personnel stated that, with a few exceptions, the received documents are approvable with only minor changes. Contractors also stated that the feedback received from the field offices, either in the form of comments that are resolved prior to final document approval or in the form of conditions of approval or directed actions in the SER, is valid and adds value to the document. Not all field offices use conditions of approval or directed actions; rather, some field offices ensure that comments are resolved prior to final submittal and approval of the change.

Multiple methods are used to ensure that change and approval documents are developed to high standards of quality. Several layers of review and concurrence/approval are built into contractor procedures for safety basis document submittals. An example in which a review and approval process incorporates additional review is found at both Hanford field offices, which use a Senior Review Board for complex changes to ensure that the SER is ready for approval by the safety basis approval authority. Additionally, some sites use metrics to track key parameters associated with safety basis submittals and approvals (e.g., days required for processing or approval, numbers of comments received). These metrics can be valuable tools for identifying problem areas. For example, the safety basis for the SRS Defense Waste Processing Facility has undergone many changes recently. The facility contractor established performance metrics to track document quality, which are analyzed and reported on a quarterly basis. A reviewed quarterly report provided a sound explanation of observed trends and the basis for some enhancements being

evaluated by the nuclear safety organization. In the query response for this facility, submittals were reported to have been predominantly high quality and approved promptly.

Determination of document quality is highly subjective and most likely reflects the amount of rework required to address review comments. In the absence of specific, objective measures of quality, EA relied on the opinions expressed in the query responses to evaluate whether document quality potentially affects the duration of the review. The review and approval duration distributions based on the perceived quality of the change submittals, as subjectively determined by the DOE field offices, are shown in Figures 4-6, 4-7, and 4-8 for High-, Medium-, and Low-quality submittals. These distributions indicate that: (1) there is no correlation between review and approval durations and document quality for the High- and Medium-quality datasets (i.e., they follow similar log-normal distributions) and (2) there is insufficient data to support a trend for the Low-quality dataset. This observation further emphasizes the conclusion that review and approval durations are largely driven by project and mission needs.

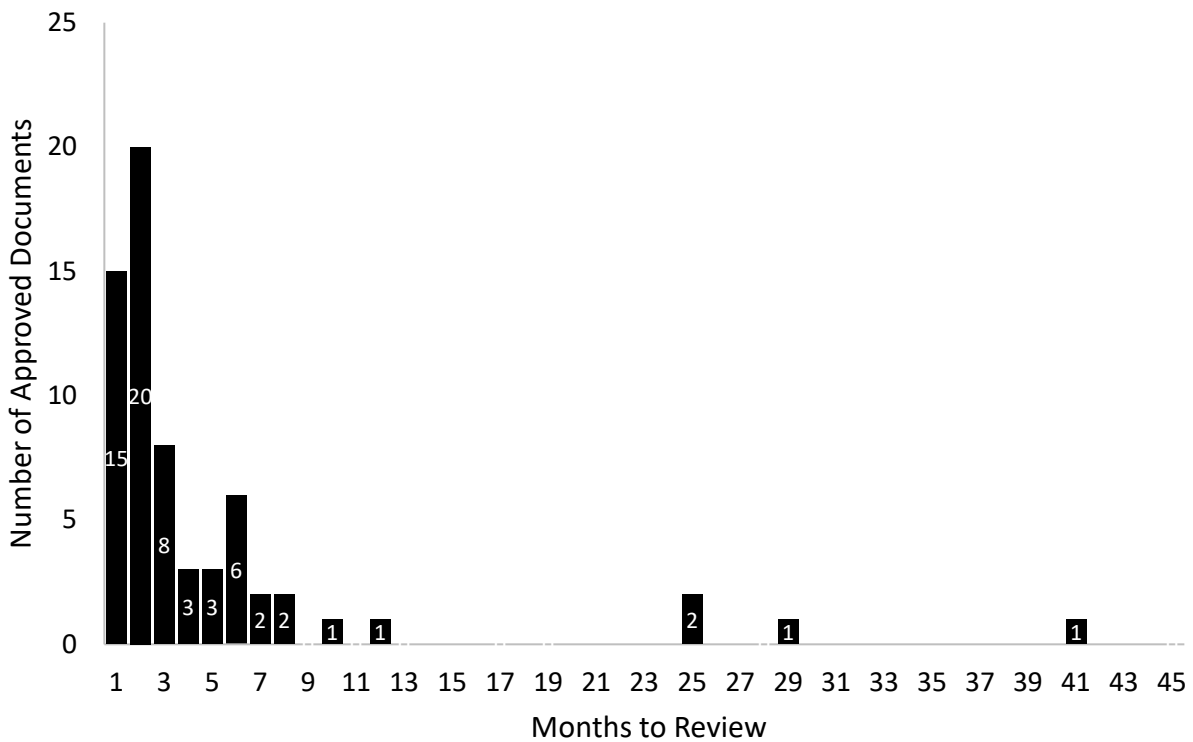


Figure 4-6. Distribution of Duration for Review and Approval of High-quality Submittals

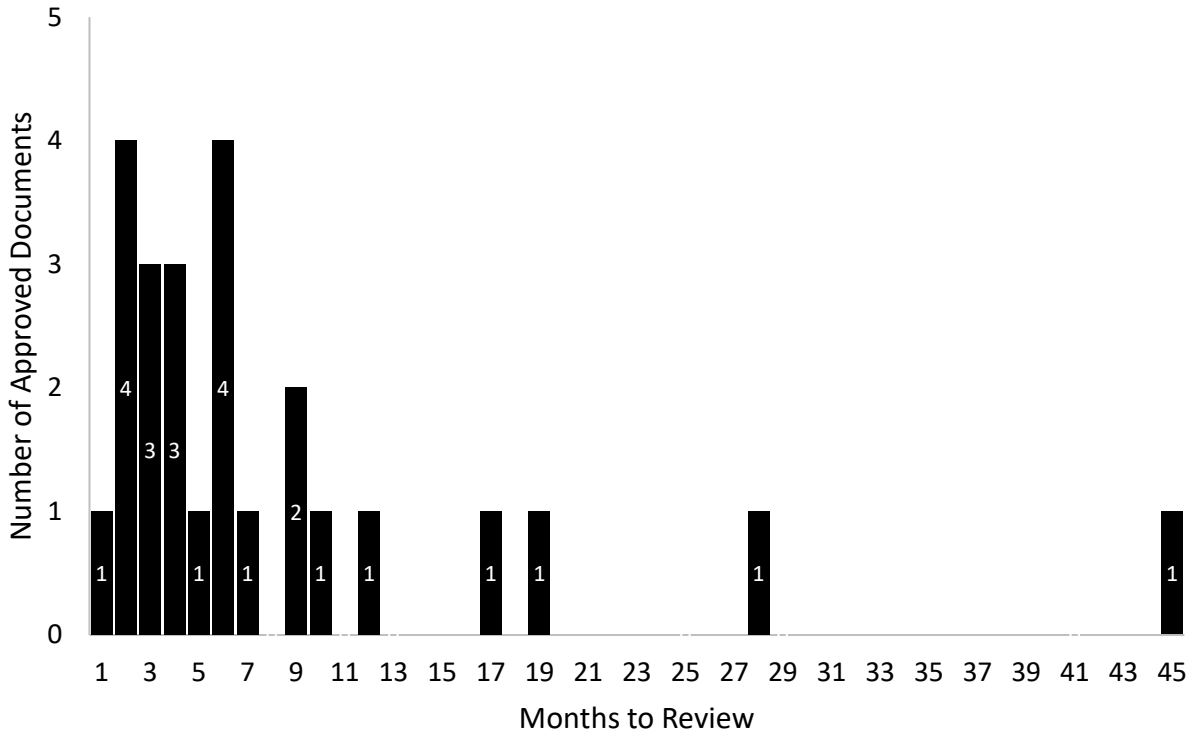


Figure 4-7. Distribution of Duration for Review and Approval of Medium-quality Submittals

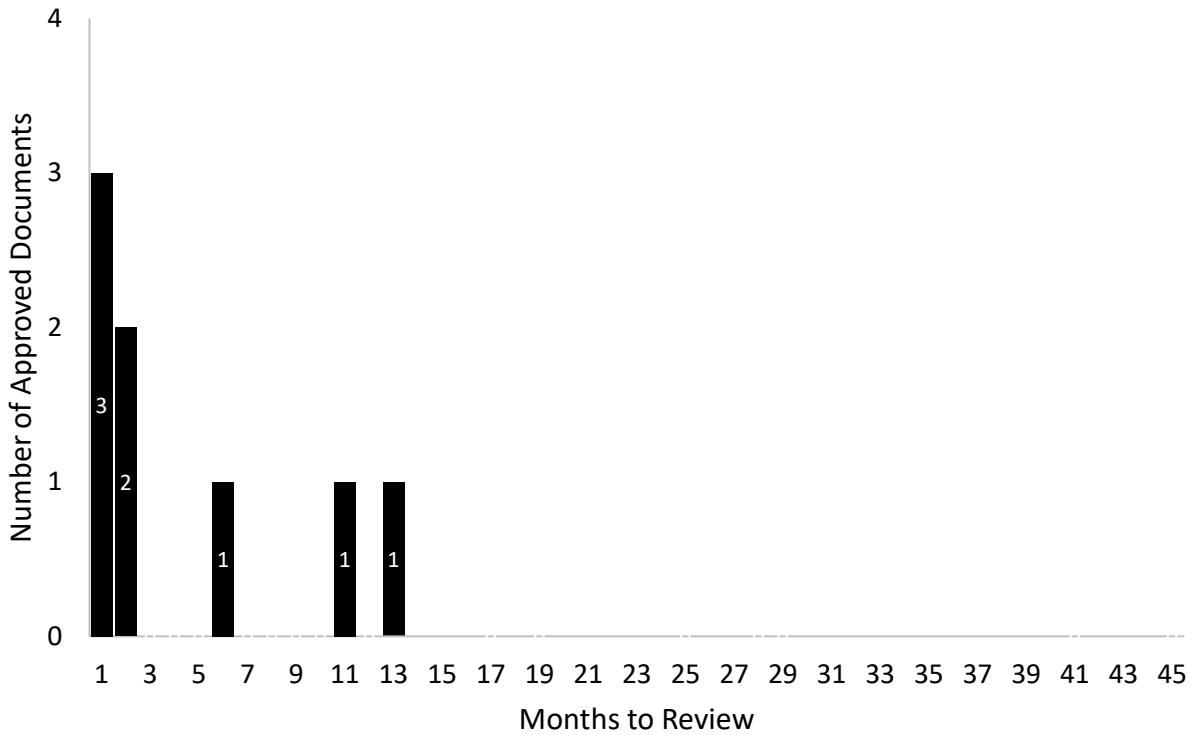


Figure 4-8. Distribution of Duration for Review and Approval of Low-quality Submittals

4.4 Staffing

During discussions regarding the sufficiency of resources for safety basis management, most field offices noted that they are understaffed, often with vacancies that they are struggling to fill. Completing qualification as a nuclear safety specialist takes approximately 18 months, further exacerbating the issue. Despite these challenges, DOE personnel at the reviewed sites are managing to keep up with approving required safety basis changes through careful prioritization and planning. Some field offices use contractors to fill gaps, but others, such as Pantex, find this more difficult due to security requirements (e.g., remote work is not an option).

One reviewed site contractor is understaffed to the extent that some annual updates (for facilities with few changes and USQ determinations) are not being performed. Although remote work is allowed, and most employees believe it is effective, subcontractors are not being used at this particular site in a manner that would allow completion of all required safety basis activities. In this case, field office personnel have agreed that delaying specific annual updates is appropriate so that limited resources can be applied to higher priority activities.

4.5 DSA Upgrades to DOE-STD-3009-2014

In several cases, sites have upgraded, or are in the process of upgrading, specific DSAs to meet the requirements of DOE-STD-3009-2014. Of the 18 DSAs included in this review, one was written to the new standard and several others were in the process of being upgraded. As allowed by DOE-STD-3009-2014, some sites do not intend to upgrade their DSAs to the new standard. For example, Pantex field office personnel do not believe that DSAs that comply with DOE-STD-3009-2014 can easily be developed based on the site's unique hazard analysis and design requirements. Other site contractors indicated that the upgrade process is difficult and takes a significant amount of time to prepare, review, and approve (from one year to more than five years). However, a contractor that has completed a DSA upgrade noted that since the process was completed, the DSA has been easier to maintain (e.g., USQ determinations are more straightforward due to clear and well-understood hazard and accident analyses) and the association of hazard analysis and related controls is clearer.

4.6 Notable Practices

During discussions with field office and contractor personnel, EA identified the following practices that work well and facilitate the preparation, review, and approval processes:

- Early planning of safety basis work, including developing a schedule of all major deliverables for the contractor and DOE personnel, ensures agreement by all parties on the technical bases and mission requirements for changes early in the process. Regular meetings (as often as weekly) between DOE and contractor counterparts are conducted to discuss upcoming safety basis changes and issues associated with current changes.
- Keeping the scope of changes small (e.g., one distinct process or design change) facilitates timely review and approval. This practice also reduces the time and effort for the resultant implementation activities.
- Limiting the annual update to changes resulting from negative USQ determinations (i.e., changes not requiring DOE approval) ensures that approval organizations do not have to differentiate which changes in their submittal require their approval.
- Some contracts stipulate an allowable time period for review and approval of safety basis changes. Even when not contractual, most DOE and contractor personnel have an understanding that this process should take approximately 90 days. In order to meet mission priorities, contractors must be

aware of the expected time for DOE review and approval. Additionally, completing a timely review minimizes configuration management challenges and the possibility that the personnel who prepared the change package will be unavailable for consultation.

- At one site, a Senior Review Board is used to facilitate field office SER approvals. This practice helps managers responsible for operations understand the safety basis change.
- DOE and contractor personnel use metrics to understand the effectiveness of and bottlenecks in the DSA preparation, review, and approval processes. The use of metrics associated with, for example, development time, review time, numbers of comments received, and conditions of approval could aid in identifying process improvements to address areas where quality objectives are not being met.

4.7 Conclusions

Review of information provided in the dataset of representative safety basis submittals indicates that the number of months it takes to review and approve submittals follows a log-normal distribution, with most submittals being approved within the four months expected by current DOE guidance. Examples of submittals that took relatively long periods to review (more than a year) can be found at several sites, for reasons that are unique to each DSA and that could not be attributed to a common cause based on the collected data. The similarity of duration distributions among the sites covered under this review suggests that sites not included in the review likely follow a similar pattern.

Among the factors considered to possibly influence review duration was the type of change covered in the submittal (e.g., an update to reflect USQ determinations rather than an amendment to reflect facility or operational changes). No discernible differences in review duration among the types of submittals were observed. Discussions with personnel responsible for preparing and reviewing submittals indicate that project objectives and mission needs tend to be the primary drivers for how quickly change submittals undergo preparation and review. Further, a correlation between the perceived quality of the change submittal, as subjectively determined by the DOE field office, and the time for its review and approval was not supported by the collected data. Field office personnel are generally satisfied with the level of quality provided in submittals, and contractor personnel are generally satisfied with the level of feedback they receive.

Annual updates were found to be handled in different ways among the reviewed sites. Although annual updates no longer require DOE approval, some sites continue to use annual updates to include changes that do require approval. Also, annual updates are prepared and submitted from different reference points; some are submitted on the same date each year, and some are submitted a year after approval of the previous update, when that update required approval. Simplifying the way annual updates are handled may benefit some sites. Most field offices have instituted practices to document their review of annual update submittals not requiring approval. The entire DOE complex would benefit from having clearly defined DOE expectations and guidance on conducting such reviews now that approval is no longer required.

Although DOE contractor and field office organizations face challenges in recruiting, training, and retaining personnel capable of preparing and reviewing safety basis documents, organizations are managing safety basis changes through planning and prioritization. The elimination of the requirement to approve annual updates appears to have resulted in some resource savings, but there has not been enough time since the rule change became effective to determine the extent of the savings. Some sentiment has been expressed that upgrading DOE-STD-3009-94, *Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Documented Safety Analyses*, DSAs to the 2014 version of the standard relieves some burden in document maintenance, but the small population of DSAs having undergone this conversion is insufficient to make a definitive conclusion.

Several notable practices were observed that contribute to timely development of safety basis changes: early planning and appropriate scoping, agreed-upon schedules, regular communication, additional levels of review, and effective use of metrics. All the safety basis change submittals reviewed by EA were approved in time to support mission activities, demonstrating that contractors and DOE field offices have effectively worked in partnership.

5.0 RECOMMENDATIONS

Recommendations that may enhance efficiency and effectiveness of the preparation, review, and approval of safety basis change documents are based on the analysis of data and interviews described in section 4 of this report. These recommendations are provided for consideration by the relevant DOE program offices; field offices; and the Office of Environment, Health, Safety and Security, as appropriate:

Recommendation for DOE program offices and field offices: Ensure that protocols to formally manage the safety basis change process are established and followed. To improve effectiveness, the protocols should include these common project management practices:

- Establish and document agreement between DOE and the contractor on the scope and schedule of anticipated submittals as soon as the need for changes is identified.
- Ensure that the scope of the change is aligned with the operational need.
- Identify key milestones for both the preparation and review processes, with interim review points as appropriate for the level of complexity of the planned changes.
- For submittals requiring DOE approval, establish the anticipated review period and incorporate it into the schedule.
- Conduct regular meetings (such as weekly) to discuss progress and identify paths of resolution for technical and logistical issues.
- Develop and monitor metrics to understand the effectiveness of and bottlenecks in the processes for preparing, reviewing, and approving DSAs, including metrics that would demonstrate that quality objectives are being met.
- Document lessons learned from submittals considered to be either extremely successful or extremely unsuccessful and evaluate them on a periodic basis as part of the organization's feedback and improvement process. Determinants of success should include timeliness, quality, and mission enablement.

Recommendation for the DOE Office of Environment, Health, Safety and Security: Include guidance in DOE-STD-1104-2016, or other documentation as appropriate, on how to handle annual update submittals that do not include changes requiring DOE approval. This guidance should include the following:

- Recommended practices for documenting receipt and review of annual update submittals. The practice of treating the review as operational awareness is used by several field offices.
- A recommendation to limit annual update submittals to changes resulting from negative USQ determinations, such that DOE approval is not required.
- An explicit method for establishing the due date for an annual update submittal, based on the last approved version of the DSA.

Appendix A Supplemental Information

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Appendix B
Site-specific Distributions of Review and Approval Durations

