

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 1 of 35
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Entire document revised

1. PURPOSE

This procedure describes the process for screening activities at an Independent Spent Fuel Storage Installation (ISFSI) that could be changes to facility procedures, hardware, and design documents; and evaluating changes to ISFSI programs; changes to the facility and its design; changes to facility procedures; facility tests and experiments; and maintenance activities. The screen of activities will determine if they meet the criteria for changes and, thus, require evaluation. The evaluation of the changes will determine if they require Nuclear Regulatory Commission (NRC) approval.

2. SCOPE

This procedure applies to Department of Energy (DOE)-owned spent fuel storage facilities that are licensed by the NRC under 10 CFR Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste” and reflects implementation guidance recommended by the Nuclear Energy Institute (NEI) and endorsed by the NRC.

3. RESPONSIBILITIES

Performer	Responsibilities
Requester	Assuring the change package is complete and accurate before presenting the information to the screener. Ensuring the completed change package is submitted to records.
Screener	Perform the screen as described in this procedure only if the training required by the ISFSI Management department is satisfied.
Evaluator	Perform the evaluation as described in this procedure only if the training required by the ISFSI Management department is satisfied and you have been designated as an evaluator by the ISFSI Management department manager.
ISFSI Manager	Approve evaluations after ensuring the appropriate technical reviews have been performed. Ensure changes requiring evaluation or license amendment are not implemented until DOE or NRC approval is obtained.
Regulatory Compliance	Prepare the reports of changes made pursuant to evaluations and without NRC approval.

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 2 of 35
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4. INSTRUCTIONS

4.1 Screening Changes

NOTE: *Screens may be requested before the completion of a document change, but the screen should not be provided on a screen form until all changes are documented. Changes made to a document after the screen is completed may invalidate the screen.*

4.1.1 Change Requester (Requester): Submit a Document Revision Form (DRF) for a procedure change, a Facility Design Change (FDC) for a design change, a Facility Change Form (FCF) for a facility change, an Engineering Design File (EDF) for a design analysis or calculation, or a Work Order for a maintenance activity per the applicable procedure.

NOTE 1: *The Requester may be the change requester, DCC Administrator, document owner, project manager, engineer, or other person needing a regulatory compliance review.*

NOTE 2: *Screens are not required for administrative procedures.*

NOTE 3: *Screens are not required for revision number changes to the SARs when no other changes are being made.*

4.1.2 Requester: After resolving comments, provide all relevant information for the change request for the following activities as they relate to an ISFSI to a trained screener:

- A. Proposed new operating, maintenance, or test procedures and procedure revisions used for an ISFSI or for the *licensed transport (see def.)* of NRC-licensed material
- B. Proposed licensed cask or facility modifications, including changes to procurement specifications, calculations, analyses, design inputs, design methods, or drawings
- C. Proposed tests or experiments at an ISFSI.

NOTE: *Screens need not be documented if it is acknowledged that evaluation(s) per Section 4.2 or a license amendment is required.*

4.1.3 Requester: Identify other issues for screening by preparing the following document package:

- A. Description of the issue, concern, or question
- B. A list of the relevant license basis document sections.

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 3 of 35
------------------------------------	--

- 4.1.4 Screener: Screen activities in accordance with Appendix A, “10 CFR Part 72 Screen Guidance.”
- 4.1.4.1 Document the screen result on Form 431.48, "10 CFR Part 72 Screen."
- 4.1.4.2 Describe the activity being screened in sufficient detail to permit an independent reviewer to reach the same conclusion.
- NOTE:** *The activity description should include the DRF, FDC, FCF, or EDF number, as appropriate, associated with the activity. The screener should wait until the activity has been reviewed to ensure the screen considers all the changes. Preliminary screens may be provided informally, but avoid using Form 431.48 for this purpose.*
- 4.1.4.3 List the documents reviewed or considered.
- 4.1.4.4 Answer the questions on the screen form and describe the basis for obtaining these answers. Provide sufficient explanation for each answer to permit an independent reviewer to reach the same conclusions.
- 4.1.4.5 Obtain an independent review of the screen by a qualified screener.
- 4.1.5 Requester: If the answers to all the screen questions are negative, then proceed with the proposed activity.
- 4.1.6 If the results of the screen indicate that the proposed facility or procedure change, test, or experiment requires a 72.48 or 72.44 evaluation, then ensure the evaluation is performed prior to proceeding with the proposed activity.
- 4.1.7 Obtain approval from the NRC before performing the activity if it is associated with a change in the license conditions, a change in a commitment made to the NRC, or requires an exemption to NRC's regulations.
- 4.1.8 Ensure the approved screen, evaluation, or NRC approval is attached to the completed change package (documentation described in Step 4.1.1) or, for other issues (described in Step 4.1.3), is transmitted to records.

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 4 of 35
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4.2 Performing 72.48 Evaluations

- 4.2.1 Evaluator: If the screen conclusion requires a 72.48 evaluation or if any change is being made to the Technical Specification Bases, then perform the evaluation in accordance with Appendix B.
- 4.2.1.1 Answer the questions in Appendix B, 72.48 Evaluation Guidance, and describe the basis for obtaining those answers.
- 4.2.1.2 Ensure the evaluation is complete enough to allow an independent reviewer of the report to reach the same conclusions.
- 4.2.1.3 Include a conclusion as to whether the proposed cask or facility or procedure change, test, or experiment requires a license amendment.
- 4.2.2 Obtain staff reviews of the evaluation as directed by the ISFSI Manager.
- 4.2.3 Obtain the approval from the ISFSI Manager.
- 4.2.4 Obtain the review and concurrence from the review committee or board designated by the ISFSI Management department manager.
- 4.2.5 Obtain approval from the DOE-ID ISFSI Facility Director.
- 4.2.6 ISFSI Manager: If the activity results in any of the 72.48 evaluation questions being “Yes,” NRC approval via a license amendment in accordance with 10 CFR 72.56 is required before proceeding with the activity. Other possible options include cancelling the planned activity, or redesigning the proposed activity so that it may proceed without prior NRC approval.
- NOTE:** *If the activity results in all questions being “No,” NRC approval is not required and the activity may proceed.*
- 4.2.7 Provide a copy of the completed evaluation to the ISFSI Safety Review Committee Chair.

4.3 Performing 72.44 Evaluations

- 4.3.1 Evaluator: If there is a change to an essential program, physical security plan (physical protection plan), or emergency plan, then perform a 72.44 evaluation in accordance with Appendix C.

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 5 of 35
------------------------------------	--

- 4.3.1.1 Answer the questions in Appendix C, Program Change Evaluation Guidance, and describe the basis for obtaining those answers.
- 4.3.1.2 Ensure the evaluation is complete enough to allow an independent reviewer of the report to reach the same conclusions.
- 4.3.1.3 Include a conclusion as to whether the proposed program change requires a license amendment.
- 4.3.1.4 Include a conclusion as to whether the resulting program would continue to comply with the applicable regulations.
- 4.3.2 Obtain staff reviews of the evaluation as directed by the ISFSI Manager.
- 4.3.3 Obtain the approval from the ISFSI Manager.
- 4.3.4 Obtain the review and concurrence from the review committee or board designated by the ISFSI Management department manager.
- 4.3.5 Obtain approval from the DOE-ID ISFSI Facility Director.
- 4.3.6 ISFSI Manager: If the 72.44 evaluation identifies a reduction in program effectiveness or the need for a license amendment, then NRC approval is required before proceeding with the change.

NOTE: *If the evaluation results in a determination that there is no decrease in effectiveness, then NRC approval is not required and the change may proceed.*

- 4.3.7 Provide a copy of the completed evaluation to the ISFSI Safety Review Committee Chair.

4.4 Application of 72.48 to Compensatory Actions to Address Nonconforming or Degraded Conditions

NOTE: *Several general courses of action may be available to address nonconforming and degraded conditions. Whether or not 10 CFR 72.48 must be applied, and the focus of a 72.48 evaluation if one is required, depends on the corrective action plan chosen. In resolving degraded or nonconforming conditions, the need to obtain NRC approval for a proposed activity does not affect the licensee's authority to operate the ISFSI, provided that necessary SSCs are operable and the degraded condition is not in conflict with technical specifications or the license.*

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 6 of 35
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- 4.4.1 If the intent is to restore an SSC back to its as-designed condition, then this corrective action should be performed in accordance with 10 CFR 72, Subpart G (i.e. in a timely manner commensurate with safety). This activity is not subject to 10 CFR 72.48.
- 4.4.2 If an interim compensatory action is taken to address the condition and involves a temporary procedure or facility change, then 10 CFR 72.48 should be applied to the temporary change to determine whether the temporary change or compensatory action itself (not the degraded condition) impacts other aspects of the facility or procedures described in the SAR.
- 4.4.3 In considering whether a temporary change impacts other aspects of the facility or procedures described in the SAR, pay particular attention to ancillary aspects of the temporary change that result from actions taken to directly compensate for the degraded condition.
- 4.4.4 If the corrective action is either to accept the condition “as-is” resulting in something different than its as-designed condition, or to change the facility or procedures, then 10 CFR 72.48 should be applied to the corrective action, unless another regulation applies. In such cases, the final corrective action becomes the proposed change that would be subject to 72.48.

4.5 Preparing 72.48 Reports

NOTE: *Reports associated with changes made to SAR updates and changes to DOE's essential programs are described in MCP-3177.*

- 4.5.1 Regulatory Compliance: Prepare periodic report containing a brief description of changes, tests, and experiments that required a 72.48 evaluation, including a brief summary of each safety evaluation.
- 4.5.2 ISFSI Manager: Approve report and provide to DOE-ID Facility Director for approval and transmittal to NRC.

5. RECORDS

NOTE: *The records generated by this procedure are non-quality.*

Screens for procedures and implementing documents

Screens for equipment, including design changes

Screens for other issues

72.48 Evaluations

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 7 of 35
------------------------------------	--

72.44 Evaluations

72.48 Reports

NOTE: [MCP-557, "Records Management,"](#) the [INL Records Schedule Matrix](#), and associated [record types list\(s\)](#) provide current information on the storage, turnover, and retention requirements for these records.

6. DEFINITIONS

Accident previously evaluated in the SAR means a design basis accident or event described in the SAR including accidents (such as those specifically analyzed in the accident section of the SAR) and events the ISFSI is required to withstand (such as floods, fires, earthquakes, and other essential hazards).

Change, in 72.48 reviews, means a modification or addition to, or removal from, the ISFSI structures, equipment, design, or procedures that affects: (1) a design function, (2) a method of performing or controlling the design function, or (3) an evaluation that demonstrates that intended design functions will be accomplished.

Design functions are SAR-described design basis functions and other structural and equipment functions described in the SAR that support or impact design basis functions. Implicitly included within the meaning of design function are the conditions under which intended functions are required to be performed, such as equipment response times, process conditions, structural and equipment qualification, and failure mode.

Design basis functions are functions performed by structures and equipment that are (1) required by or otherwise necessary to comply with regulations, license conditions, or technical specifications or (2) credited in licensee safety analyses to meet NRC requirements.

SAR description of design functions may identify what equipment and structures are intended to do, when and how design functions are to be performed, and under what conditions. Design functions may be performed by important-to-safety equipment and structures or non-important-to-safety equipment and structures and include functions that, if not performed, would initiate an accident that the facility or design is required to withstand.

Departure from a method of evaluation described in the SAR used in establishing the design bases or in the safety analyses means (i) changing any of the elements of the method described in the SAR unless the results of the analysis are conservative or essentially the same; or (ii) changing from a method described in the SAR to another method unless that method has been approved by the NRC for the intended application. The 10 CFR 72.48 definition of *departure from a method of evaluation described in the SAR* provides licensees with flexibility to make changes in methods of evaluation that are conservative or that are not important with respect to demonstrating that structures and equipment can perform their intended functions.

SCREEN AND EVALUATE CHANGES

Identifier: MCP-2925

Revision*: 18

Page: 8 of 35

Design bases means that information that identifies the specific functions to be performed by a structure or equipment of an ISFSI and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be restraints derived from generally accepted state-of-the-art practices for achieving functional goals or requirements derived from analysis (based on calculation or experiment) of the effects of a postulated event under which a structure or equipment must meet its functional goals. The values for controlling parameters for external events include:

- Estimates of severe natural events (10 CFR 72.92) to be used for deriving design bases that will be based on consideration of historical data on the associated parameters, physical data, or analysis of upper limits of the physical processes involved.
- Estimates of severe external man-induced events (10 CFR 72.94) to be used for deriving design bases that will be used on analysis of human activity in the region, taking into account the site characteristics and the risks associated with the event.

Essential Program is a program approved by the NRC and subject to program change controls contained in ISFSI TS 5.5.2 (Training, Radiological Environmental Monitoring, Quality Assurance), 72.44(e) (Security), or 72.44(f) (Emergency).

Facility means an independent spent fuel storage installation (ISFSI). A *Facility as described in the SAR* means: (1) the structures and equipment that are described in the SAR; (2) the design and performance requirements for such structures and equipment; and (3) the evaluations or methods of evaluation included in the SAR for such structures and equipment which demonstrate that their intended function(s) will be accomplished.

Independent Review is a review of a prepared Screen performed by a qualified screener. The standard of independence is met by the need for minimal input from the reviewer during the development of the screen or by the need for minimal corrections resulting from the review.

Licensed Transport is transport of licensed material performed under the regulations of Part 71 (generally, shipments over public conveyances) or Part 72 (on-Site shipments).

Maintenance Activities (as defined in NEI 96-07) are activities that restore SSCs to their as-designed condition, including activities that implement approved design changes. Maintenance activities are subject to 10 CFR 72.48 and may include troubleshooting, calibration, refurbishment, maintenance-related testing, identical replacements, housekeeping and similar activities that do not permanently alter the design, performance requirements, operation, or control of SSCs. Maintenance activities also include temporary alterations to the facility or procedures that directly relate to and are necessary to support the maintenance.

SCREEN AND EVALUATE CHANGES

Identifier: MCP-2925

Revision*: 18

Page: 9 of 35

Methods of evaluation are the calculational framework used for evaluating behavior or response of the ISFSI (a structural or equipment item). Examples of methods of evaluation are presented in the table below. Changes to such methods of evaluation require evaluation under 10 CFR 72.48(c)(2)(viii) only for evaluations used either in SAR safety analyses or in establishing the design bases, and only if the methods are described, outlined, or summarized in the SAR. Methodology changes that are subject to 10 CFR 72.48 include changes to elements of existing methods described in the SAR and to changes that involve replacement of existing methods of evaluation with alternative methodologies.

Methods of evaluation described in the SAR subject to Question 8 are:

- Methods of evaluation used in analyses that demonstrate the design basis limits of fission product barriers are met (i.e., for the parameters subject to Question 7).
- Methods of evaluation used in SAR safety analyses including accident analyses (of Chapter 8), to demonstrate that consequences of accidents do not exceed 10 CFR 72.106 dose limits.
- Methods of evaluation used in supporting SAR analyses that demonstrate intended design functions will be accomplished under design basis conditions that the ISFSI is required to withstand, including natural phenomena, environmental conditions, and dynamic effects.
- Methods of evaluation used in the SAR analyses that demonstrate that radioactive doses from normal operations and anticipated occurrences will be within the limits of 10 CFR 72.104.

Procedures as described in the SAR are those procedures that contain information described in the SAR such as how equipment is operated and controlled including any assumed operator actions and response times, if any.

The *Safety Analysis Report (SAR)* for an ISFSI is the document prepared in accordance with 10 CFR 72.24, submitted in accordance with 10 CFR 72.16, and updated in accordance with 10 CFR 72.70. Various documents, including the regulations, refer to the “FSAR (as updated)”; however, there is no intent to use a SAR that is not adequately maintained. Therefore, the additional adjectives are not needed and the term *SAR* shall suffice in all implementing documents.

Safety analyses are analyses that demonstrate the design and performance of structures and equipment important to safety with the objective of assessing the impact on public health and safety resulting from ISFSI operation. Safety analyses can include determination of margins of safety during normal operations and expected operational occurrences during the life of the ISFSI and the adequacy of structures and equipment provided for the prevention of accidents and the mitigation of consequences of accidents.

SCREEN AND EVALUATE CHANGES

Identifier: MCP-2925

Revision*: 18

Page: **10** of 35

Tests or experiments not described in the SAR are any activity where structures or equipment is operated or controlled in a manner that is outside the reference bounds of the design bases or inconsistent with the analyses or description in the SAR.

7. REFERENCES

10 CFR Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste”

NEI 96-07, Appendix B, “Guidelines for 10 CFR 72.48 Implementation,” May 5, 2001

8. APPENDIXES

Appendix A, 10 CFR Part 72 Screen Guidance

Appendix B, 72.48 Evaluation Guidance

Appendix C, 72.44 Evaluation Guidance

Appendix D, Procedure Basis

SCREEN AND EVALUATE CHANGES

Identifier: MCP-2925

Revision*: 18

Page: 11 of 35

Appendix A**10 CFR Part 72 Screen Guidance****Introduction**

Proposed activities are reviewed to determine whether the scope statements of 10 CFR 72.48(c)(1) apply. The scope statements are combined with the definitions of change, facility, and procedure into a screen process. If the scope statements are determined to apply to the proposed activity, then the activity is determined to require a 72.48 evaluation. If the scope statements are determined not to apply, then the proposed activity may be described as having been “screened out”.

There are three parts of the 10 CFR 72 screen. These three parts are used to ensure: (1) no change is made to the license conditions and no exemption to regulations is taken without NRC approval, (2) changes to a licensed cask or facility (including the design) are evaluated, and (3) changes to operating, maintenance, and test procedures for a licensed cask or facility are evaluated. If the answers to all three conditions are negative, then the change has been "screened" and the activity may proceed. If the first condition is not satisfied, then a change to the license or an exemption to the regulations and NRC approval must precede the activity. If the second or third condition is not satisfied, then a "72.44" or "72.48" evaluation is required to determine whether NRC approval is required.

Review of the Activity

To determine whether or not a proposed activity affects a design function, method of performing or controlling a design function, or an evaluation that demonstrates that design functions will be accomplished, a thorough understanding of the proposed activity is essential. A given activity may have both direct and indirect effects that the screening review must consider. The following questions illustrate a range of effects that may stem from a proposed activity:

- Does the activity decrease the reliability of the structure or equipment design function, including functions that are relied upon for prevention of a radioactivity release?
- Does the activity reduce existing redundancy, diversity, or defense-in-depth?
- Does the activity add or delete an automatic or manual design function or passive design characteristic of the ISFSI?
- Does the activity convert a feature that was automatic to manual or vice versa?
- Does the activity introduce an unwanted or previously unreviewed system interaction?

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 12 of 35
------------------------------------	---

- Does the activity adversely affect the ability or response time to perform required actions; e.g., alter equipment access or add steps necessary for performing tasks?
- Does the activity degrade the seismic, structural, heat removal, shielding, or criticality control capability of the structure or equipment?
- Does the activity adversely affect other casks that are in use at the ISFSI?
- Does the activity affect a method of evaluation used in establishing the design bases or in the safety analyses?
- For activities affecting structures or equipment, procedures, or methods of evaluation that are not described in the SAR, does the activity have an indirect affect on structural integrity, environmental conditions, or other SAR-described design functions?

1. Change in License Conditions or Exemption to Regulations

License conditions incorporated into the ISFSI license (the Material License and the Technical Specifications) may be derived from the analyses and evaluations included in the SAR and amendments thereto. License conditions pertain to design, construction, and operation. The NRC may also include additional license conditions as it finds appropriate. Any activity that requires a change in the ISFSI license conditions must have prior NRC approval and cannot be performed under 10 CFR 72.48, 10 CFR 72.44, TS 5.5.1, or TS 5.5.2.

Any activity which would not meet any applicable regulation requires an exemption to be issued by the NRC pursuant to 10 CFR 72.7.

2. Facility Change

An evaluation is required for changes that adversely affect design functions, methods used to perform or control design functions, or evaluations that demonstrate that intended design functions will be accomplished. Changes that have no adverse effects or have positive effects may be screened out because only adverse changes have the potential to increase any of the risk factors (probability or likelihood, consequences, or new accidents or malfunctions). (Note that any change that alters a design basis limit for a fission product barrier—positively or negatively—is considered adverse and must be evaluated.)

If a change has both positive and adverse effects regardless of the magnitude of the adverse effects, then the change should be screened in and the 72.48 evaluation should focus on the adverse effects. The 72.48 evaluation will address the magnitude of the adverse effect. In other words, the screening process determines whether any adverse effect exists pertaining to design functions and the evaluation process looks at the effects of the changes in design function on risk and other licensing criteria.

SCREEN AND EVALUATE CHANGES

Identifier: MCP-2925

Revision*: 18

Page: 13 of 35

If the effect of the change is such that a safety analysis is no longer bounding, then the change must be screened in, the safety analysis must be re-run to demonstrate that all safety functions and design requirements are met, and the revised safety analysis used in support of the 72.48 evaluation. Changes that entail update of the safety analyses to reflect improved performance or capacity resulting from a change (beneficial effects on design functions) are not considered adverse and need not be screened in even though the change calls for safety analyses to be updated.

Methods of evaluation included in the SAR to demonstrate that intended structure or equipment design functions will be accomplished are considered part of the facility. Thus, use of new or revised methods of evaluation is considered to be a change as part of this screening step. Adverse changes to elements of a method of evaluation require a 72.48 evaluation. Changes to methods of evaluation may not require evaluation against the first seven Questions.

Changes to methods of evaluation not included in the SAR or to methodologies included in the SAR that are not used in the safety analyses or to establish design bases would screen out at this step.

Methods of evaluation that may be identified in references listed at the end of SAR sections or chapters are not subject to control under 10 CFR 72.48 unless the SAR states that they were used for specific analyses within the scope of Question 8.

Changes to methods of evaluation are considered adverse if the changes are outside the constraints and limitations associated with use of the method (e.g., identified in a topical report, SER, or consensus standard). Proposed use of an alternate method is considered an adverse change.

Tests and experiments that are described in the SAR may be screened out at this step. Tests and experiments that are not described in the SAR may be screened out provided that the test or experiment is bounded by tests and experiments that are described in the SAR. Similarly, tests and experiments not described in the SAR may be screened out provided that affected items will be appropriately isolated from the ISFSI.

An important consideration is the necessity to distinguish changes from maintenance activities. Purely maintenance activities are not required to be evaluated under 10 CFR 72.48. Maintenance includes calibration, refurbishment, replacement with an equivalent component (an identical component, or one meeting all design and seismic specifications and quality level, or one demonstrated and documented to be equivalent), and housekeeping. However, if components described in the SAR are permanently removed, or their function is altered, or if changes remain following completion of a maintenance activity, the activity is no longer considered to be maintenance and would be subject to a 72.48 evaluation. A maintenance package involving any temporary or permanent change to the facility should have an engineering package included in, or as the basis for, the maintenance package.

SCREEN AND EVALUATE CHANGES

Identifier: MCP-2925

Revision*: 18

Page: 14 of 35

Temporary changes should be screened to determine if the temporary condition needs to be evaluated. Changing facility configurations while work is in progress may need to be evaluated as a configuration different than the completed modification.

In the case of a nonconforming or degraded condition, there are three potential outcomes:

- If the condition is accepted "as-is" or is "repaired" resulting in something different than the original design, then new or proposed condition should be screened or evaluated.
- If the SSC will be restored to its designed or specified condition, then this corrective action should be performed in accordance with the appropriate corrective action administrative controls and an evaluation is not required. (If the SSC can't be corrected in a timely manner, then the current configuration should be screened or evaluated.)
- If an interim compensatory action is taken to address the condition and involves a procedure or facility change, then the interim action should be screened or evaluated. The intent is to determine whether the compensatory action itself (in this case, not the current nonconforming or degraded condition) impacts other aspects of the facility.

Changes to equipment or other resources claimed or affecting one of the essential programs (QA, training, radiological environmental monitoring, emergency response, or security) also need to be considered. If a change to an essential program would be required by a facility change, then a 72.44 evaluation is required.

3. Procedure Change

Changes to procedures are *screened in* (i.e., require a 72.48 evaluation) if they adversely affect how design functions are performed or controlled (including changes to SAR-described procedures, assumed operator actions, and response times). Changes to a procedure that do not affect (or have positive effects) how equipment design functions described in the SAR are performed or controlled would screen out.

For purposes of 10 CFR 72.48 screening, changes that fundamentally alter (replace) the existing means of performing or controlling design functions should be conservatively treated as adverse and screened in. Such changes include replacement of automatic action by manual action (or vice versa), changes to the man-machine interface, changing a valve from "locked closed" to "administratively closed", and similar changes.

It is important to note that the scope of "procedures described in the SAR" is defined in the FSV ISFSI SAR, the TMI-2 ISFSI SAR, and the ISFF ISFSI SAR in SAR Section 9.4. All procedure changes falling within this scope definition must be screened.

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 15 of 35
------------------------------------	---

Procedures at other facilities affecting the preparation, conditioning, or packaging of fuel or other SSCs can be reviewed within the scope of this procedure. However, the screen of such procedures does not fall within the scope of changes to ISFSI procedures. Instead, such procedure changes need to consider whether a change to the facility could result from the procedure change. For example, if a procedure change could affect the condition of the fuel or fuel package fabrication (such as lid closure), then such a procedure change should point to the need for a 72.48 evaluation on the basis that it is a facility change. In this respect, procedures at other facilities should be considered in the same respect as procedures at vendor facilities.

The question is intended to identify an activity that would cause the facility to operate in an unanalyzed mode or would cause design parameters and assumptions in the SAR to be exceeded. In this case, the Technical Specifications and their Bases provide additional guidance regarding compensatory actions for abnormal modes of operation. Since these modes of operation are described in the Technical Specifications, they are considered to be "described in the SAR." Thus, if the activity is to be performed outside the modes of operation described in the Technical Specifications (or any other SAR document), the answer to this question would be "YES."

4. SAR Method of Evaluation Change

Methods of evaluation included in the SAR to demonstrate that intended SSC design functions will be accomplished are considered part of the "facility as described in the SAR." The use of new or derived methods of evaluation is considered to be a change that is controlled by 10 CFR 72.48 and needs to be considered as part of the screening. Adverse changes to elements of a method of evaluation included in the SAR, or use of an alternative method, must be evaluated to determine if prior NRC approval is required. Changes to methods of evaluation (only) do not require evaluation against the first seven criteria.

Screening Documentation

Recordkeeping requirements of 10 CFR 72.48 apply to 72.48 evaluations. However, documentation should be maintained in accordance with procedures of screening that conclude a proposed activity screened out. The basis for the conclusion should be documented to a degree commensurate with the safety significance of the change and, of course, should conclude that there would be no adverse effect on design functions. Typically, the screening documentation is retained as part of the change package. This documentation does not constitute the record of changes required by 10 CFR 72.48 and thus is not subject to the associated reporting requirements. Screening records are not necessary for activities for which a 72.48 evaluation or a license amendment was required.

SCREEN AND EVALUATE CHANGES

Identifier: MCP-2925

Revision*: 18

Page: 16 of 35

Appendix B**72.48 Evaluation Guidance**

Once it has been determined that an activity has an adverse effect on a design function and requires a 72.48 evaluation, the written evaluation must address the applicable Questions from 10 CFR 72.48(c)(2). If any of the Questions are answered affirmatively, a specific licensee must apply for and obtain a license amendment before implementing the activity. Each element of a proposed activity must undergo a 72.48 evaluation, except in instances where linking elements is appropriate. The test for whether elements can be linked is interdependence. It is appropriate for discrete elements of a proposed activity to be evaluated together if (1) they are interdependent as in the case where a modification to a system or component necessitates additional changes to other systems or procedures; or (2) they are performed collectively to address a design or operational issue.

Although the conclusion in any of the eight questions may simply be “yes”, “no”, or “not applicable”, there must be an accompanying explanation providing adequate basis for the conclusion. These explanations should be complete in the sense that another knowledgeable reviewer could draw the same conclusion. Restatement of the question in a negative sense or making simple statements of conclusion is not sufficient and should be avoided. The experience and engineering knowledge of the evaluator are often relied upon in determining whether evaluation criteria are met and the questions effectively answered. The basis for the engineering judgment and the logic used in the determination should be documented to the extent practical and to a degree commensurate with the safety significance and complexity of the activity, especially where no established consensus methods are available.

1. Does the Activity Result in More than a Minimal Increase in the Frequency of Occurrence of an Accident Previously Evaluated in the SAR?

In answering this question, the first step is to identify the accidents that have been evaluated in the SAR that are affected by the proposed activity. A determination should then be made as to whether the frequency of these accidents occurring would be more than minimally increased.

ISFSI design events have been divided into categories based upon a qualitative assessment of frequency, as discussed in NUREG-1567 and ANSI/ANS-57.9:

- Normal Operations—Events that are expected to occur regularly or frequently in the course of normal operations of the ISFSI.
- Anticipated Occurrences (Off-Normal Events)—Events that can be expected to occur with moderate frequency or on the order of once per calendar year of ISFSI operation.
- Accident Events—Events considered to occur infrequently, if ever, during the lifetime of the ISFSI.

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 17 of 35
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During initial ISFSI licensing, design events were assessed in relative frequencies, as described above. Minimal increases in the frequency of occurrence of an accident resulting from subsequent activities do not significantly change the licensing basis of the ISFSI and do not impact the original conclusions reached about the acceptability of the ISFSI design. Since accident frequencies were considered in a broad sense as described above, a change from one frequency category to a more frequent category is clearly an example of a change that results in *more than a minimal increase* in the frequency of occurrence of an accident.

Changes within a frequency category could also result in more than a minimal increase in the frequency of occurrence of an accident. Normally, the determination of a frequency increase is based upon a qualitative assessment using engineering evaluation consistent with the SAR analysis assumptions. Reasonable engineering practices, engineering judgment, and probabilistic risk assessment (PRA) techniques, as appropriate, should be used in determining whether the frequency of occurrence of an accident would more than minimally increase as a result of implementing a proposed activity. The effect of a proposed activity on the frequency of an accident must be discernable and attributable to the proposed activity in order to exceed the *more than minimal increase* standard.

Although this Question allows minimal increases, licensees must still meet applicable regulatory requirements and other acceptance criteria to which they are committed (such as contained in Regulatory Guides, codes, and standards). Further, departures from the design, fabrication, construction, testing, and performance standards as outlined in the General Design Criteria (Subpart f to Part 72) are not compatible with a *no more than minimal increase* standard.

Because frequencies of occurrence of natural phenomena were established as part of initial licensing and are not expected to change, changes in design requirements for earthquakes, tornadoes, and other natural phenomena should be treated as potentially affecting the likelihood of a malfunction rather than the frequency of occurrence of an accident.

2. Does the Activity Result in More than a Minimal Increase in the Likelihood of Occurrence of a Malfunction of an Item Important to Safety Previously Evaluated in the SAR?

The term *malfunction of an item important to safety* refers to the failure of structures and equipment to perform their intended design functions—including both ITS items and NITS items when the failure of NITS items to perform their design functions could affect the ability of ITS items to perform their design functions. The cause and mode of a malfunction should be considered in determining whether there is a change in the likelihood of a malfunction. The effect or result of a malfunction should be considered in determining whether a malfunction with a different result is involved.

In determining whether there is more than a minimal increase in the likelihood of occurrence, the first step is to determine what items are affected by the proposed activity. Next, the effects of the proposed activity on the affected items should be determined. This evaluation should include both direct and indirect effects.

SCREEN AND EVALUATE CHANGES

Identifier: MCP-2925

Revision*: 18

Page: 18 of 35

Direct effects are those where the proposed activity affects the items. Indirect effects are those where the proposed activity affects one item and that item affects the capability of another item to perform its SAR-described design function. Indirect effects also include the effects of proposed activities on the design functions of items credited in the safety analyses. The safety analysis assumes certain design functions of items in demonstrating the adequacy of design. Thus, certain design functions, while not specifically identified in the safety analysis, are credited in an indirect sense.

After determining the effect of the proposed activity on the ITS items, a determination is made of whether the likelihood of a malfunction of the ITS items has increased more than minimally. Qualitative engineering judgment or industry precedent [or a calculation, if available and practical] is typically used to determine if there is more than a minimal increase in likelihood of malfunction. The effect of a proposed activity on the likelihood of malfunction must be discernable and attributable to the proposed activity in order to exceed the more than minimal increase standard.

Evaluations of a proposed activity for its effect on likelihood of a malfunction would be performed at the level of detail that is described in the SAR. The determination of whether the likelihood of malfunction is more than minimally increased is made at a level consistent with the existing SAR-described failure modes and effects analyses. While the evaluation should take into account the level that was previously evaluated, it also needs to consider the nature of the proposed activity.

Changes in design requirements for natural phenomena should be treated as potentially affecting the likelihood of malfunction.

Although this Question allows minimal increases, licensees must still meet applicable regulatory requirements (Subpart F) and other acceptance criteria (Section 4 of the Technical Specifications and criteria in the SER). Such departures are not compatible with a *no more than minimal increase* standard.

3. Does the Activity Result in More than a Minimal Increase in the Consequences of an Accident Previously Evaluated in the SAR?

The SAR, based on logic similar to ANSI standards, relates (explicitly or implicitly) acceptance criteria and frequency for *conditions of design*. When determining which activities represent more than a minimal increase in consequences, it must be recognized that *consequences* means dose. Therefore, an increase in consequences must involve an increase in radiological doses to the public. Changes in barrier performance or other outcomes of the proposed activity that do not result in increased radiological dose to the public are addressed under Question 7 concerning integrity of fission product barriers.

Activities affecting onsite dose consequences that may require prior NRC approval are those that impede required action to mitigate the consequences of accidents. The consequences governed by 10 CFR 72.48 do not apply to occupational exposures resulting from routine operations, maintenance, testing, etc. Occupational doses are controlled and maintained ALARA.

SCREEN AND EVALUATE CHANGES

Identifier: MCP-2925

Revision*: 18

Page: 19 of 35

The consequences covered include dose resulting from any accident evaluated in the SAR (typically covered in the accident analysis section). The dose consequences referred to in 10 CFR 72.48 are those calculated by licensees; not the results of independent, confirmatory dose analyses by the NRC (documented in SERs).

The evaluation should determine the dose that would likely result from accidents associated with the proposed activity. When a change in consequences is so small or the uncertainties in determining whether a change in consequences has occurred are such that it cannot be reasonably concluded that the consequences have actually changed, the change need not be considered an increase in consequences.

10 CFR 72.106 establishes dose limits for ISFSI design basis accidents. The calculated doses, if any, for a given accident would be identified in the SAR. An increase in accident consequences is defined to be no more than minimal if the increase is less than or equal to 10% of the difference between the current bounding calculated dose and the regulatory limit.

10 CFR 72.104 establishes the annual dose limits for ISFSI anticipated occurrences (off-normal events) combined with normal operations and other site operations. For anticipated occurrences, a *minimal increase* would include any increase up to the 10 CFR 72.104 limits.

In determining if there is more than a minimal increase in consequences, the first step is to determine which accidents evaluated in the SAR may have their radiological consequences affected as a direct result of the activity. Questions that assist in this determination are:

- Will the proposed activity change, prevent, or degrade the effectiveness of actions described or assumed in an accident discussed in the SAR?
- Will the proposed activity alter assumptions previously made in evaluating the radiological consequences of an accident described in the SAR?
- Will the proposed activity play a direct role in mitigating the radiological consequences of an accident described in the SAR?

The next step is to determine if the proposed activity does, in fact, increase the radiological consequences of any of the accidents evaluated in the SAR. If it is determined that the proposed activity does have such an effect, then either:

- Demonstrate and document that the radiological consequences of the accident described in the SAR are bounding for the proposed activity, or
- Revise and document the analysis taking into account the proposed activity and determine if more than a minimal increase has occurred as described above.

4. Does the Activity Result in More than a Minimal Increase in the Consequences of a Malfunction of an Item Important to Safety Previously Evaluated in the SAR?

In determining if there is more than a minimal increase in consequences, the first step is to determine which malfunctions evaluated in the SAR have their radiological consequences

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 20 of 35
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affected as a result of the proposed activity. The next step is to determine if the proposed activity does increase the radiological consequences and, if so, are they more than minimally increased. The guidance for this section is essentially the same as the guidance for the consequence of an accident.

5. Does the Activity Create a Possibility for an Accident of a Different Type Than Any Previously Evaluated in the SAR?

The set of accidents that an ISFSI must postulate for purposes of safety analyses are often referred to as *design basis accidents*. The terms *accident* and *off-normal event* are used in the Standard Review Plan, where off-normal events are viewed as the more likely, low consequence events and where accidents are less likely and more serious. This Question deals with creating the possibility for accidents of similar frequency and significance to those already included in the SAR. Thus, accidents that would require multiple independent failures or other circumstances in order to be created would not invoke an affirmative answer from this Question.

Certain accidents are not discussed in the SAR because their effects are bounded by other related events that are analyzed. For example, a postulated cask drop of a certain distance may not be specifically evaluated in the SAR because it is less than the evaluated cask drop. For activities that would introduce a cask drop of a distance less than the evaluated drop, the new drop need not be considered an accident of a different type.

The possible accidents of a difference type are limited to those that are as likely to happen as those previously evaluated in the SAR. The accident must be credible in the sense of having been created within the range of assumptions previously considered in the licensing basis. A new initiator of an accident previously evaluated in the SAR is not an accident of a different type (but could affect the frequency of that accident) unless the accident was previously thought to be incredible becomes as credible.

6. Does the Activity Create a Possibility for a Malfunction of an Item Important to Safety with a Different Result Than Any Previously Evaluated in the SAR?

Malfunctions of items are generally postulated as potential single failures to evaluate ISFSI performance with the focus being on the result of malfunction rather than the cause or type of malfunction. A malfunction that involves an initiator or failure whose effects are not bounded by those explicitly described in the SAR is a malfunction with a different result. A new failure mechanism is not a malfunction with a different result if the result or mechanism is not a malfunction with a different result if the result or effect is the same as, or bounded by, that previously evaluated in the SAR.

Certain malfunctions are not explicitly described in the SAR because their effects are bounded by other malfunctions that are described. For example, failure of an air pad carrying a loaded cask and subsequent drop of the pad may not be explicitly described in the SAR because the drop would be bounded by the cask drop analysis.

SCREEN AND EVALUATE CHANGES

Identifier: MCP-2925

Revision*: 18

Page: 21 of 35

The possible malfunctions with a different result are limited to those that are as likely to happen as those described in the SAR. For example, a seismic induced failure of a component that has been designed to the appropriate seismic criteria will not cause a malfunction with a different result. However, a proposed change that increases the likelihood of a malfunction previously thought to be incredible to the point where it becomes as likely as the malfunctions assumed in the SAR could create a possible malfunction with a different result.

In evaluating a proposed activity against this Question, the types and results of failure modes of items that have previously been evaluated in the SAR and that are affected by the proposed activity should be identified. Attention must be given to whether the malfunction was evaluated in the accident analyses at the component level or a higher level. While the evaluation should take into account the level that was previously evaluated in terms of malfunctions and mitigation impacts, it also needs to consider the nature of the proposed activity. Thus if a single failure proof lifting device were to be replaced with a non-single failure proof lifting device, but the lift height is within the cask drop analysis, the consequences should still be evaluated to determine if any new outcomes are introduced.

Once the malfunctions previously evaluated in the SAR and the results of these malfunctions have been determined, then the types and results of failure modes that the proposed activity could create are identified. Comparing the two lists can provide the answer to the Question.

7. Does the Activity Result in a Design Basis Limit for a Fission Product Barrier as Described in the SAR Being Exceeded or Altered?

Fission product barriers are the fuel cladding and the confinement boundary for the storage system. Dry spent fuel storage systems are designed in accordance with NRC requirements to preserve both fuel cladding integrity and confinement capability during all credible normal, off-normal, and accident events. Integrity of the fuel cladding is required to maintain retrievability and subcriticality of the stored spent fuel. Even if the cladding is not explicitly credited in the SAR as a fission product boundary, such as when damaged fuel is stored in a cask, effects of a proposed activity on cladding should still be considered when answering Question 7 if the cladding would continue to maintain retrievability and subcriticality.

Preservation of the confinement boundary is required to ensure against the uncontrolled release of radioactive materials. The makeup of the confinement boundary depends on the storage system design as described in the SAR.

Evaluation under Question 7 focuses on the fission product barriers and on the critical design information that supports their continued integrity. Guidance for applying this Question is structured on a two-step approach: (1) Identification of affected design basis limits for a fission product barrier; (2) Determination of when those limits are exceeded or altered.

Identification of affected design basis limits for a fission product barrier. Design basis limits for a fission product barrier are the numerical values established during the licensing review as presented in the SAR for any parameter(s) used to determine the integrity of the fission product barrier. These limits have three key attributes:

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 22 of 35
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- The parameter is fundamental to the barrier's integrity. They are the limiting values for parameters that directly determine the performance of a fission product barrier. That is, design basis limits are fundamental to barrier integrity and may be thought of as the point at which confidence in the barrier begins to decrease.
- The limit is expressed numerically. Design basis limits are numerical values used in the overall design process, not descriptions of functional requirements. Design basis limits are typically the numerical event acceptance criteria used in the accident analysis methodology.
- The limit is identified in the SAR. They may be located in a vendor topical report that is incorporated by reference in the SAR. Any design basis limit for a fission product barrier that is controlled by another, more specific regulation or Technical Specification would not require evaluation under Question 7.

8. Does the Activity Result in a Departure from a Method of Evaluation Described in the SAR Used in Establishing the Design Bases or in the Safety Analyses?

The SAR contains design and licensing basis information for an ISFSI, including description on how regulatory requirements for design are met and the adequacy of structures and equipment provided for the prevention of accidents and the mitigation of consequences of accidents. Analytical methods are a fundamental part of demonstrating how the design meets regulatory requirements and why the ISFSI's response to accidents and events is acceptable. As such, in cases where the analytical methodology was considered to be an important part of the conclusion that the ISFSI met the required design bases, these analytical methods were described in the SAR and received varying levels of NRC review and approval during licensing. Changes to the methodologies described in the SAR are evaluated under Question 8.

In general, licensees may make changes to elements of a methodology without first obtaining a license amendment if the results are essentially the same as, or more conservative than, previous results. Licensees may also use different methods without first obtaining a license amendment if those methods have been approved by the NRC for the intended application. If the proposed activity does not involve a change to a method of evaluation, then the 72.48 evaluation should reflect that Question 8 is not applicable. If the proposed activity involves only a change to a method of evaluation, then the 72.48 evaluation should indicate that Questions 1 through 7 are not applicable.

The first step in applying Question 8 is to identify the affected methods of evaluation. This step is accomplished during the application of the screening criteria. Next, the licensee determines whether the change requires NRC approval because it is a:

- Change to any element of analysis methodology that yields results that are non-conservative or not essentially the same as the results from the analysis of record.

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 23 of 35
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- Use of new or different methods of evaluation that are not approved by NRC for the intended application.

By way of contrast, the following changes do not require NRC approval:

- Departures from methods of evaluation that are not described, outlined, or summarized in the SAR.
- Use of new NRC-approved methodology (e.g., new or upgraded computer code) to reduce uncertainty, provide more precise results, or other reason, provided such use is (a) based on sound engineering practice, (b) appropriate for the intended application, and (c) within the limitations of the applicable SER. The basis for this determination should be documented in the 72.48 evaluation.
- Use of a methodology revision that is documented as providing results that are essentially the same as or more conservative than either the previous revision of the same methodology or with another methodology previously accepted by the NRC through issuance of an SER.
- Use of a methodology which is described in the SAR but which has not been specifically approved by the NRC wither through a Topical Report review or through endorsement in the ISFSI SER.

SCREEN AND EVALUATE CHANGES

Identifier: MCP-2925

Revision*: 18

Page: 24 of 35

Appendix C

72.44 Evaluation Guidance

Evaluations of essential programs are termed “72.44 evaluations” even though only the security and emergency program change evaluations are described in 10 CFR 72.44 (e) and (f). (The other three essential programs, quality assurance, training, and radiological environmental monitoring, have the same change evaluation standard provided through Technical Specification 5.5.2 for the FSV, TMI-2, and ISFF ISFSIs.) The standard for 72.44 evaluations is the full description of program changes to determine whether there is a decrease in effectiveness. If a decrease in effectiveness is determined, then NRC approval of the change is required.

The following definition for *decrease in effectiveness* is the most conservative standard for reviewing changes. Changes meeting this standard are the most easily approved.

- The term for *decrease in effectiveness* from 10 CFR 72.44 is most conservatively interpreted as a reduction in any commitment. If a program document states that a certain quantity or quality of a resource (personnel, procedure, equipment, facilities, or administrative control) exists and this resource is reduced in quality (frequency is reduced, for example) or quality (relocated farther away, for example), then the effectiveness has been reduced even if the reduction is accompanied by an increase in a compensating resource.
- There may be cases where linking elements of a change may be appropriate for determining that a decrease in one resource doesn't result in a decrease in effectiveness because of an increase in another resource. The test for acceptable linking of changes for a 72.44 evaluation is *interdependence*. If a proposed change to a resource requires a subsequent change in another resource, then the changes are linked. *Required* should be interpreted with respect to function or performance of the resource, not that the first change, absent the subsequent change, would result in a decrease in effectiveness. However, if a change to a resource can be made without affecting other resources, then the proposed changes are separate changes under this definition.

Changes not meeting the above standard may be approved based upon the following standards. Such changes must be adequately described to demonstrate that they meet the appropriate standard.

More Recently Approved Standard

Changes to an NRC-approved program may adopt a program standard (such as NQA-1 for the quality assurance program) approved by the NRC but only if it is more recent than the standard used as the basis for the current program being evaluated. The use of a more recent standard must account for any conditions of the NRC endorsement of the standard or site-specific situations.

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 25 of 35
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NRC-Approved Exception

If a program standard alternative or exception has been approved by the NRC in a safety evaluation, use of this alternative or exception does not constitute a decrease in effectiveness provided that the bases of the NRC approval are applicable to the licensed facility. The 72.44 evaluation must demonstrate, however, that the conditions under which the previously endorsed alternative or exception was granted apply to DOE's licensed facility as well. That is to say that the NRC safety evaluation performed to grant the previous alternative or exception is relevant to the DOE's facility and that any program elements credited by the original licensee or the NRC staff are applied as part of the implementation of the position.

Organizational Titles

Replacement of specific organizational and position titles with generic titles that clearly denote the position function, supplemented as necessary by descriptive text, may be made without prior NRC approval provided that the functional description and organizational relationship of the position remain unchanged, or satisfy any commitments for authority and organization freedom as described below.

Changes in organization may be made without NRC approval that ensure that persons and organizations performing QA functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations. This guidance applies to other programs where comparable organizational authority and freedom have been made. Changes in organization, however, must continue to assure the proper authority and organizational freedom of the QA program functions (i.e., to identify problems, to promote solutions, and to verify implementation of activities) from cost and schedule pressures by maintaining independence and an adequate level of management reporting. Of particular importance to an effective QA program is the independence between the performing and verifying activities in the areas of auditing, inspection, and procurement.

Organizational Charts

NRC-approved program documents may make use of generic organization charts to indicate functional relationships, authorities, and responsibilities, or alternatively descriptive text, as opposed to specific ones. Functional relationships and responsibilities, and lines of authority may be described generically by charts or descriptive text provided that the flow of organizational authority and responsibility is clearly presented. Changes to adopt such generic charts do not require NRC approval.

Duplicated Program Commitments

Program information may be eliminated that duplicates language in regulatory guides and standards to which the program is committed.

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 26 of 35
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For example, QA programs typically present information in descriptive text that discusses how each of the eighteen program criteria are met. In addition, typical QA programs describe the level of commitment to QA regulatory guides and QA standards. Changes are allowed that eliminate information that duplicates the commitments.

Additions, Clarifications, and Exceptions

Occasionally, the scope of activities at a facility will change. Consider, as examples, facility loading is completed, the facility responds to changes in a national security threat, or handling of individual fuel elements is anticipated. Adapting essential programs may be appropriate.

Adding requirements is usually no problem with respect to a 72.44 evaluation; however, adding scope without addressing additional program requirements could be a problem. An example of a potential problem would be the addition of equipment and procedures for handling fuel which would be described in the facility and operational sections of the SAR. This type of change could also include changes to address additional training and emergency planning requirements, and these programs could be considered less effective if the associated program changes were not incorporated.

Removing requirements in response to decreased scope could appear to be a decrease in effectiveness upon cursory examination. However, if program requirements were intended to address facility activities (scope) that are no longer intended or credible, then removal of the requirements from the program document may not decrease the effectiveness of the program. Arguments justifying the removal of program requirements should be fully developed to permit subsequent reviewers to fully understand the justification for removal.

Other Changes

If a proposed change does not meet the above criteria then the proposed change needs to be evaluated against the following definition.

- Proposed changes will not decrease program effectiveness if the program will continue to satisfy the requirements to at least the standards of the current licensee commitments.

NRC guidance (e.g., Regulatory Guide or Standard Review Plan) may provide the standard upon which the program was developed by DOE and approved by NRC. The program is comprised of licensee commitments, statements that meet or exceed requirements used to demonstrate how the licensee will meet the applicable requirements, and descriptive information not intended to be commitments.

The licensee's authority to interpret commitments may be exercised but should be adequately explained. Applicable NRC guidance should be used to demonstrate in the evaluation that the restated commitment continues to satisfy the standard upon which the program was developed and approved and is therefore not a decrease in effectiveness.

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 27 of 35
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Appendix D

Procedure Basis

Step	Basis	Source	Citation
Entire procedure	Written procedures shall be established, implemented, and maintained for the following: administrative controls.	FSV/TMI/ISFF TS	5.4.1.a
Entire procedure	Written procedures shall be established, implemented, and maintained for the following: facility changes, test, and experiments.	FSV/TMI/ISFF TS	5.4.1.e
Entire procedure	Written procedures shall be established, implemented, and maintained for the following: all programs specified in Section 5.5.	FSV TS	5.4.1.o
		TMI TS	5.4.1.p
		ISFF TS	5.4.1.o
	FSV/TMI/ISFF 5.5.1 Technical Specification (TS) Bases Control Program		
	FSV/TMI 5.5.2 Essential Program Control (QA, REMP, Training)		
	TMI 5.5.3 Radioactive Effluent Control Program		
		5.5.4 Physical Protection Program	
	FSV 5.5.3 Natural Gas and Oil Monitoring Program		
		5.5.4 Radioactive Effluent Control Program	
	ISFF 5.5.2 Radioactive Effluent Control Program		
	5.5.3 Fuel Handling Program		
	5.5.4 Fire Protection Program		
	5.5.5 Radiation Protection Program		

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 28 of 35
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Step	Basis	Source	Citation
Entire procedure	<p>Essential Program Control shall be established, implemented, and maintained.</p> <p>A. This program provides a means for processing changes to the following essential programs.</p> <ol style="list-style-type: none"> 1. Quality Assurance Program 2. Radiological Environmental Monitoring Program 3. Training Program. <p>B. Changes to essential programs shall be made under appropriate administrative controls and reviews.</p> <p>C. Changes may be made to essential programs without prior NRC approval provided the changes do not involve either of the following:</p> <ol style="list-style-type: none"> 1. A change in the TS incorporated in the license 2. A decrease in effectiveness. <p>D. The Essential Programs Control program shall contain provisions to ensure essential programs are maintained consistent with the regulations.</p> <p>E. Proposed changes (to essential programs) which don't meet the criteria of 5.5.2.3 above shall be reviewed and approved by the NRC before implementation.</p> <p>F. Changes to essential programs implemented without prior NRC approval shall be provided to the NRC on a frequency consistent with 10 CFR 72.70(b).</p> <p>G. DOE-ID shall review and approve all submittals to the NRC pursuant to TS 5.5.2.5 and TS 5.5.2.6.</p>	FSV/TMI TS	5.5.2

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 29 of 35
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Step	Basis	Source	Citation
Entire procedure	All reports required by 10 CFR Part 72 for the TMI-2 and FSV ISFSIs and all reports required by the TMI-2 and FSV ISFSI licenses and TS, shall be submitted by the Manager of DOE-ID or the DOE-ID Facility Director.	FSV/TMI TS	5.6.1
Entire procedure	<p>The DOE-ID FSV/TMI Facility Director or alternate shall review and concur with, All, the following:</p> <ul style="list-style-type: none"> A. All 72.48 evaluations for the FSV ISFSI B. 10 CFR 72.44(e)—Physical Protection Plan evaluations and 10 CFR 72.44(f)—Emergency Plan evaluations C. Changes to the TS Bases D. All changes to the SAR E. Annual SAR update F. Nuclear Material Status Reports G. Annual Environmental Report. <p>Other reports which may be submitted to NRC in response to conditions or events which are not submitted by the Manager of DOE-ID.</p>	FSV/TMI/ISFF SAR	9.1.2.2.1

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 30 of 35
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Step	Basis	Source	Citation
Entire procedure	<p>FSV: Detailed written procedures will be developed and maintained for the ISFSI operations, maintenance, surveillance, and testing described in Section 5.1.1. These procedures shall constitute the “procedures described in the SAR” associated with the requirements of 10 CFR 72.48.</p> <p>TMI: Detailed written procedures will be developed and maintained for the ISFSI operations, maintenance, surveillance, and testing described in Section 5.1.1 and 5.1.2. Procedure changes in 5.1.1 are subject to DOE Unreviewed Safety Question analysis as they are conducted under the parameters and cognizance of the TAN SAR under DOE regulation. However, any procedure changes that could have an impact or bearing on the design basis or safety basis of TMI ISFSI components, performance specifications or requirements in the TMI SAR or Tech Specs shall also be subject to 10 CFR 72.48. Such applicable activities will be clearly denoted in Section 5.1.1 procedures. All TMI ISFSI procedures will be developed, reviewed, revised, approved, and controlled by the ICP contractor in accordance with approved administrative procedures.</p> <p>ISFF: Procedures are used to document the performance of ITS activities and compliance with regulatory requirements. The format and content of written procedures include:</p> <ul style="list-style-type: none"> - Introduction (includes purpose and scope) - precautions and limitations - prerequisites - instructions (sequence, forms to be completed, acceptable conditions, actions if conditions aren't acceptable, approvals) - records 	FSV/TMI/ISFF SAR	9.4.1.1 st

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 31 of 35
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Step	Basis	Source	Citation
Entire procedure	<p>Detailed written procedures will be developed and maintained for the ISFSI activities described in Section 5.1.</p> <p>To include: purpose, scope, and applicability; limitations and precautions; prerequisites; personnel and equipment required; detailed instruction (sequence, forms, acceptable conditions, actions if conditions aren't acceptable, records generated, approvals).</p>	FSV/TMI/ISFF SAR	9.4.1
4.1 Appendix A	<p>A licensee may make changes in the facility or spent fuel storage cask design as described in the SAR, make changes in the procedures as described in the SAR, and conduct tests or experiments not described in the SAR, without obtaining a license amendment pursuant to Sec. 72.56 if (A) A change to the technical specifications incorporated in the specific license is not required; or (C) The change, test, or experiment does not meet any of the criteria in paragraph (c)(2) of this section.</p>	10 CFR 72.48 (c) (1)	

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 32 of 35
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Step	Basis	Source	Citation
4.2	A licensee shall obtain a license amendment pursuant to Sec. 72.56 prior to implementing a proposed change, test, or experiment if it would: (i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the SAR; (ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a system, structure, or component (SSC) important to safety previously evaluated in the SAR; (iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the SAR; (iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the SAR; (v) Create a possibility for an accident of a different type than any previously evaluated in the SAR; (vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the SAR; (vii) Result in a design basis limit for a fission product barrier being exceeded or altered as described in the SAR; or (viii) Result in a departure from a method of evaluation described in the SAR used in establishing the design bases or in the safety analyses.	10 CFR 72.48 (c) (2) TS 5.5.1	

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 33 of 35
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Step	Basis	Source	Citation
4.2.5, 4.3.5	<p>The Manager, DOE-ID is responsible for the operation of the FSV ISFSI and for compliance with all applicable regulatory requirements and license conditions.</p> <p>The Facility Director is responsible for overall ISFSI operation. The Facility Director and any alternates shall be designated in writing.</p> <p>Although not in residence at the FSV ISFSI, the Facility Director shall maintain routine electronic and verbal communication with the facility staff.</p> <p>The Facility Director shall be present during significant operational or maintenance evolutions, emergency exercises, and announced NRC inspections. During prolonged evolutions, the Facility Director shall be present during initial activities and at least monthly thereafter.</p> <p>The Facility Director shall visit the FSV ISFSI at least twice a year for the purpose of verification or audit of FSV ISFSI compliance with regulatory requirements and license basis commitments, to communicate in person with facility staff, and to apprise DOE-ID management of FSV ISFSI status based on observations.</p> <p>The Facility Director shall review and concur with all FSV ISFSI evaluations prepared pursuant to 10 CFR 72.44(e), 10 CFR 72.44(f), 10 CFR 72.48, ITS 5.5.1.b, ITS 5.5.2.3, and ITS 5.5.3.2.</p>	FSV TS	5.1 5.1.1 5.1.2 5.1.3 5.1.4 5.1.5 5.1.6

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 34 of 35
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Step	Basis	Source	Citation
4.2.5, 4.3.5	<p>The Manager, DOE-ID, is responsible for the operation of the TMI-2 ISFSI and for compliance with all applicable regulatory requirements and license conditions.</p> <p>The TMI-2 Facility Director is responsible for overall ISFSI operation. The TMI-2 Facility Director and any alternates shall be designated in writing.</p> <p>The TMI-2 Facility Director shall maintain routine electronic and verbal communication with the facility staff.</p> <p>The TMI-2 Facility Director is stationed near the TMI-2 ISFSI at the INL site or in Idaho Falls, Idaho.</p> <p>The TMI-2 Facility Director shall review and concur with all TMI-2 ISFSI evaluations prepared pursuant to 10 CFR 72.44(e), 10 CFR 72.44(f), 10 CFR 72.48, TS 5.5.1.b, and TS 5.5.2.3.</p>	TMI TS	5.1 5.1.1 5.1.2 5.1.3 5.1.4 5.1.5
4.2.5, 4.3.5	<p>The ISF Facility Director shall be responsible for overall facility operation and shall delegate in writing the succession to this responsibility during his absence.</p> <p>The ISF Facility Director or his designee shall approve, prior to implementation, each proposed change, test, or experiment to structures, systems, or components that are important to safety as defined in 10 CFR 72.3.</p>	ISFF TS	5.1 5.1.1 5.1.2
4.3	[Proposed program changes may be made without prior NRC approval provided the changes do not involve either a change in the Technical Specification incorporated in the license or a decrease in effectiveness.]	10 CFR 72.44(e) 10 CFR 72.44(f) TS 5.5.2 ISFF TS 5.5.1	

SCREEN AND EVALUATE CHANGES	Identifier: MCP-2925 Revision*: 18 Page: 35 of 35
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Step	Basis	Source	Citation
4.3.7	[Update reports required for changes made pursuant to 10 CFR 72.48, 10 CFR 72.44(e) and (f), TS 5.5.1, and TS 5.5.2.]	10 CFR 72.48 (d) (2) 10 CFR 72.44 (e) and (f) TS 5.5.1 and TS 5.5.2	
5	[The licensee shall maintain records of changes in the ISFSI, design, and procedures.]	10 CFR 72.48 (d)	