



# U.S. Nuclear Regulatory Commission Office of Nuclear Material Safety and Safeguards

## SFST Office Instruction Change Notice

Office Instruction No.: **SFST - 14, Rev. 0**  
 Office Instruction Title: **Acceptance Review Process**  
 Effective Date: **April 30, 2010**  
 Primary Contacts: **Chris Staab and Jason Piotter**

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Revision:

1. Original Issue

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# U.S. Nuclear Regulatory Commission

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## SFST OFFICE INSTRUCTION

### SFST OFFICE INSTRUCTION SFST-14

#### ACCEPTANCE REVIEW PROCESS

##### 1. PURPOSE

The purpose of the U.S. Nuclear Regulatory Commission's (NRC's) Office of Nuclear Material Safety and Safeguards (NMSS), Division of Spent Fuel Storage and Transportation (SFST), Office Instruction No. 14, "Acceptance Review Process," is to provide guidance to SFST staff (staff) who conduct acceptance reviews for new applications and licensing amendments submitted under Title 10, Part 71, "Packaging and Transportation of Radioactive Material," of the *Code of Federal Regulations* (10 CFR Part 71), and 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste."

The acceptance review process is designed to support both safety and timeliness objectives by helping to ensure that applicants provide adequate information to support a detailed staff review of applications falling within the scope of this office instruction.

##### 2. APPLICABILITY

This SFST Office Instruction is applicable to new applications, amendment requests, and Request for Additional Information (RAI) responses as necessary. Simple, routine amendment requests and RAI responses may undergo a brief acceptance review by the receiving NRC project manager under a shorter acceptance review schedule. Typically, this shorter acceptance review will not exceed 30 calendar days from the receipt date. The shorter acceptance review is not a technical review. The review is an administrative evaluation for completeness of the application and for general omission of information. For complex or first-of-a-kind applications, the shorter review may not be appropriate. The project manager should consult management to identify and characterize the need for longer acceptance reviews which require Technical Review Directorate (TRD) resources. Typically, the longer acceptance review will not exceed 60 calendar days from the receipt date. Guidance for both long and shorter acceptance reviews is provided in Appendix B section 3.1.

##### 3. GENERAL REQUIREMENTS

The NRC may evaluate an application requesting approval of a proposed 10 CFR Part 71 or 10 CFR Part 72 action for completeness as discussed in Sections 71.7 and 72.11. The staff conducts a completeness review to ensure that the applicant has submitted the information required by applicable regulations in Part 71 and Part 72 such that staff can conduct a detailed technical review. Any application for a requested action under Part 71 or Part 72 shall be referred to in this office instruction as a Requested Licensing Action (RLA).

During the acceptance review, the staff conducts an administrative and technical sufficiency review. The staff's technical sufficiency review ensures that the application contains sufficient technical information in scope and depth for the staff to not only to conduct a detailed technical review, but to complete it within a predictable timeframe. Regulatory Guides and interim staff guidance (ISG) documents provide guidance to the staff on performing their reviews of RLAs. These documents may be used, in part, to evaluate and determine completeness. Meeting guidance is not a regulatory requirement. However meeting guidance will facilitate a timely review. The staff should not perform its detailed technical review during the acceptance review process. The acceptance review should be completed as soon as practical, however, should not take longer than 60 days. For simple and routine amendment requests, 30 days or less is the goal.

Requests for Supplemental Information (RSIs): RSIs are information requests needed to support beginning a detailed technical review and are requested during the acceptance review. RSIs are distinguished from RAIs as RAIs are needed to determine whether a regulatory requirement is met and are typically requested after the detailed technical review has begun. Some examples of RSIs may be found in Appendix D.

Requests for Additional Information (RAIs): Performance of an adequate acceptance review, using the Division's technical assets, may reduce RAIs by identifying missing information or other elements of an incomplete application. The Division's goal is zero RAIs during the overall review of the application. SFST recognizes one round of RAIs will often be needed. Minimizing the number of RAIs requires the applicant to provide a complete safety case in its initial submittal, and the staff to do a sufficient acceptance review, as well as a complete detailed review before any RAIs are sent. There should rarely be second round RAIs based on new areas of review.

SFST Metrics: SFST's internal metric clock starts when SFST receives an acceptable application. Therefore, the receipt date may shift depending on whether staff requests supplemental information. If staff generates RSIs, then the receipt date will be when the applicant provides an adequate response to the RSIs.

#### **4. OBJECTIVES**

This Office Instruction, along with the attached Appendix B, "Guide for Performing Acceptance Reviews," provides staff a basic framework for performing an acceptance review upon receipt of an RLA. For the purpose of this procedure, a RLA is defined as a licensing action requiring NRC approval prior to implementation.

This Office Instruction should enhance SFST's efficiency in responding to the needs of both the applicants and the public. Specific objectives include the following:

- Promote the submission of acceptable RLAs by applicants;
- Provide general guidance to NRC staff, applicants, and the public defining acceptable RLAs;
- Facilitate the effective application of NRC resources in reviewing RLAs;

- Promote consistency in the performance of acceptance reviews;
- Establish the acceptance review process as an integral part of an effective licensing review;
- Establish the priority of acceptance reviews and define time frames for completion;
- Reduce unnecessary delays, and increase the efficiency in the review of RLAs; and
- Promote effective internal and external communications.

## **5.0 BACKGROUND AND GENERAL GUIDANCE**

### **5.1 Benefits of the Acceptance Review**

The quality of a RLA has a significant impact on the amount of staff resources expended in the review process. RLAs that include information of a sufficient scope and depth allow staff to focus its efforts on reviewing the technical and regulatory adequacy of the information put forth by the applicant. When a RLA lacks critical information necessary for the staff to complete its review (e.g., analyses/calculations or unjustified use of unapproved methodologies), an inordinate amount of staff time may be required to obtain this information. Staff requires analyses and calculations to make safety findings. To aid in a timely review, the applicant should at a minimum provide a summary overview of the calculations and analyses performed, up front. Note that a list may not be enough for staff to make a safety finding.

A thorough acceptance review is integral to the efficient review of a RLA. The early identification of insufficient information benefits both staff and the applicant. The staff benefits by limiting resource expenditures on less than quality applications. The applicant benefits by identification of RLA information “gaps” sooner in the review process.

### **5.2 Guidance Provided in Appendix B**

The attached guidance provides a procedure for performing acceptance reviews of RLAs. The process includes the following subprocesses:

- Establishment of schedules and resources for the acceptance review;
- Review of the RLA for administrative and technical sufficiency;
- Identification or resolution of any informational insufficiencies; and
- Documentation of results.

Activities covered by this Office Instruction are those that require NRC approval prior to implementation (e.g., new storage and transportation applications and amendments to existing licenses or CoCs). Selective portions of this Office Instruction may be applied to acceptance reviews involving submittals from the Department of Transportation (DOT) and Department of Energy (DOE), such as DOT revalidations and DOE transportation packages. The Project

Manager (PM) may recommend that a detailed acceptance review, in accordance with this office instruction, is not required. The Branch Chiefs (BCs) will jointly decide whether an acceptance review is required. This Office Instruction will not be applied to RLAs that are clearly acceptable for review as determined by the PM. An example includes renewal requests or simpler requests, which may include one-time authorization requests.

SFST will consider a RLA to be acceptable for a detailed technical review upon the staff's conclusion that the application appears to contain sufficient technical information, both in scope and depth, to complete the detailed technical review in an appropriate time frame. In rare cases, staff may determine an application is of poor quality and lacks sufficient information during the detailed technical review, after the acceptance review has been completed. In these cases, staff may still request supplemental information or reject the application, depending on the quantity of missing information.

While the goal of the acceptance review process is to facilitate submittal of acceptable RLAs, the acceptance of an RLA should not be interpreted to imply that additional questions may not be raised during the actual technical review process. Serious insufficiencies in the application (possibility resulting in denial of the RLA), may be identified during the detailed technical review. The acceptance review process does not determine the technical correctness of the applied methodologies or the accuracy of the results. Rather, the acceptance review is a tool used by the staff to identify unacceptable RLAs early in the review process so that they can be returned to the applicant, and the applicant then given an opportunity to supplement the RLA. The acceptance review process is intended to ensure SFST only reviews high quality applications. Incomplete or poor quality applications will be rejected under the acceptance review process.

## **6.0 RESPONSIBILITIES AND AUTHORITIES**

All SFST staff and management are responsible, as assigned, for reading, understanding, and applying the guidance contained in the attached "Guide for Performing Acceptance Reviews." They are also responsible for identifying possible improvements to the guidance and submitting suggestions for such improvements to their management and to the assigned contacts for this Office Instruction.

Throughout the process, SFST management and staff are responsible for ensuring the consistent application of the process, communication of the process objectives, and status to internal and external stakeholders. They are also responsible for tracking and reporting statistics for implementation of this procedure and establishing criteria for identifying overall progress and success of the acceptance review process. Unless otherwise noted, all time frames are defined as calendar days.

For purposes of setting the review schedule to be provided to the applicant, the RLA will be considered received by the NRC the day staff receives an acceptable application. It is the responsibility of the applicant to ensure documents are submitted properly and comply with NRC guidance for electronic and hardcopy submittals. The NRC public web site provides guidance on how to submit documents electronically and 10 CFR 71.1 and 72.4 provide guidance on how to submit documents by hardcopy. In order to support SFST's overall philosophy and expectation in Section 1, staff may, depending on workload, case familiarity, and priority, begin the RLA review in parallel with docketing the RLA into ADAMS.

## **7.0 ACCEPTANCE REVIEW PROCESS PROCEDURE**

The sections that follow describe specific responsibilities and authorities for each sub-process in performing an acceptance review. Additional information on the responsibilities and timing of the various steps in the acceptance review process is provided in Appendix B. The following sections represent expectations of SFST that primary technical reviews are the responsibility of technical staff and primary project management reviews are the responsibility of project managers.

### **7.1 Establishment of Schedules and Resources for Acceptance Review**

Project Managers (PMs) are responsible for the following activities regarding the establishment of schedules and resources for the acceptance review:

- General oversight and coordination of SFST acceptance review activities
- Ensure the application is entered into ADAMS in a timely manner. Although the applicant is required to ensure the application is adequate for entering into ADAMS and notifying SFST that the application has been filed, the PM should monitor this process. If the document is not entered into ADAMS in a timely manner, the PM should contact the ADAMS administrator and the applicant to facilitate entering the application into ADAMS
- With the coordination of Branch Chiefs (BCs), establish a schedule and identify the appropriate technical branches needed to support the acceptance and detailed technical reviews
- Promptly distribute copies of the RLA and associated documents or make them electronically available to the appropriate technical branches to begin the acceptance review process (within 5 working days after being entered into ADAMS or earlier if possible)

Technical Review Directorate (TRD) Branch Chiefs are responsible for the following activities regarding the establishment of scheduling and resources for the acceptance review:

- Promptly assign technical reviewers
- Promptly perform an acceptance review of the RLA in accordance with the associated acceptance review schedule
- Identify the technical disciplines required to perform the ensuing detailed technical review (w/ PM assistance)

The Licensing Branch Chief is responsible for providing oversight of PM responsibilities.

## 7.2 Review of the Application for Administrative and Technical Sufficiency

PMs are responsible for the following activities regarding the acceptance review of the RLA for administrative and technical sufficiency:

- Review the RLA for administrative sufficiency in accordance with Appendix B, “Guide for Performing Acceptance Reviews,” of this Office Instruction
- Collect and review the input provided by the technical branches
- Determine the significance of any administrative RSIs, assist in determining the significance of technical RSIs (identified by TRD staff), and make recommendations to management, as appropriate
- Notify management and the associated technical branches of the results of the acceptance review
- Ensure implementation or revision of the schedule in a timely manner
- Communicate any PM-related RSIs to the Licensing Branch (LB) BC and technical staff as soon as possible, with a goal of 5 weeks from the receipt of the RLA by the NRC
- Notify management, as early as possible, of potential delays in meeting an acceptance review schedule

TRD staff is responsible for the following activities regarding the acceptance review of the RLA for technical sufficiency:

- Review the RLA for technical sufficiency in accordance with Appendix B, “Guide for Performing Acceptance Reviews,” of this Office Instruction
- Communicate any TRD-related RSIs to TRD BCs and the PM as soon as possible, with a goal of 5 weeks from the date of receipt of the RLA by the NRC. Provide a recommendation to TRD management and the PM regarding the significance of any technical RSIs
- Notify TRD BCs (as soon as conflicts are identified) of workload conflicts associated with performing an acceptance review. Branch Chiefs are responsible for resolution of workload conflicts
- TRD Branch Chief, in coordination with the PM, will notify division-level management of potential delays in meeting an acceptance review schedule

### 7.3 Resolution of RSIs

PMs are responsible for the following activities regarding the resolution of RSIs (see Appendix B, Section 1.3.4 for the definition of a RSI):

- Ensure the criteria described in Appendix B are being applied consistently in accordance with regulatory requirements, policies, and guidance
- Establish, in conjunction with TRD staff, the date-specific deadline by which the applicant must submit the information - 15 calendar days after the applicant receives the RSI letter
- If required, contact the applicant and communicate the information needed and the deadline for submitting the information, in order to clearly obtain an understanding of the required course of action
- Notify management and technical branches of whether the applicant intends to supplement its RLA within 15 days
- Draft a letter to the applicant identifying the information needed and the deadline for receiving the information
- Coordinate any necessary interfaces with other offices (e.g., Office of General Counsel (OGC), Office of Federal and State Materials and Environmental Management Programs (FSME), Office of Nuclear Security and Incident Response (NSIR), etc.)
- Notify management and technical branches of any significant change in the schedule

TRD staff is responsible for the following activities regarding the resolution of RSIs:

- Prompt verbal and written notification of the RSI to their BCs and the PM (RSI will be written up in the RAI format, as specified in SFST Office Instruction No. 3)
- Provide written input to the PM documenting the RSIs (an e-mail from the Branch Chief to document concurrence with the RSIs is acceptable)
- Support the PM in discussions with the applicant to explain RSIs
- Review the supplemental information to ensure the supplemental information requested has been provided within 15 days of distribution by the PM
- Inform the PM and BCs of any conflicting responsibilities that may adversely impact the schedule
- Support the PM in briefing management, as appropriate

The Branch Chiefs are responsible for the following activities regarding the resolution of RSIs:

- Support and guide the staff in determining the appropriate course of resolution regarding RSIs
- Maintain an awareness of SFST priorities and how these may affect the RLA acceptance review schedule
- Provide oversight of acceptance review activities and direct the implementation
- Support the PM and technical staff by informing management of any scheduling conflicts or acceptance review activities, as appropriate
- Ensure consistency in the conduct of acceptance reviews
- Facilitate peer reviews, when appropriate, to confirm the RSI prior to contacting the applicant
- Ensure timely communication of the status of these reviews and any adverse impacts on office resources to SFST management

The SFST Deputy Division Directors (DDD) are responsible for the following activities regarding the resolution of RSIs:

- Provide oversight to all Branch Chief responsibilities

The SFST Division Director is responsible for the following activities regarding the implementation and documentation of the results of the acceptance review:

- Provide oversight to the DDD responsibilities

#### 7.4 Documentation of Results

PMs are responsible for the following activities regarding the documentation of the acceptance review results:

- Document the decision regarding the administrative and technical sufficiency of the RLA in a letter to the applicant or in an e-mail as permitted by Section 6.0 in Appendix B of this Office Instruction
- Notify the applicant of the results of the acceptance review activities

The TRD staff is responsible for the following activities regarding the implementation and documentation of the acceptance review results:

- Communicate the adequacy (to begin a full detailed technical review – not whether the design meets the regulation) of the RLA to management and the PM

- Support the PM in documenting the results of the acceptance review

#### 7.5 Review of the Supplemental Information (If Required)

PMs are responsible for the following activities regarding the review of the supplemental information for the acceptance review results:

- Coordinate the dissemination of the RLA supplement to technical branches
- Review the supplemental information within 15 days of distribution
- Communicate the adequacy of the supplemental information to management and the TRD reviewers
- Document the results of the review of the supplemental information
- Notify the applicant of the results of the supplemental information reviews

Technical staff is responsible for the following activities regarding the implementation and documentation of the acceptance review results:

- Review the supplemental information within 15 days of distribution by the PM
- Communicate the adequacy of the supplemental information to management and the PM
- Support the PM in documenting the results of the review of the supplemental information (if required)

#### 8.0 PRIMARY CONTACT

SFST/LB  
301-492-3321  
[Christopher.Staab@nrc.gov](mailto:Christopher.Staab@nrc.gov)

SFST/TRD  
301-492-3286  
[Jason.Piotter@nrc.gov](mailto:Jason.Piotter@nrc.gov)

#### 9.0 RESPONSIBLE ORGANIZATION

SFST/LB

SFST/TRD

#### 10.0 EFFECTIVE DATE

April 2010 - SFST staff involved in performing acceptance reviews should submit suggestions for improvement to this guidance to their management or the contacts listed for this Office Instruction (SFST-14).

#### 11.0 REFERENCES

11.1 10 CFR Part 71, 10 CFR Part 72

- 11.2 NMSS Policy and Procedures Letter (P&PL) 1-51, dated April 10, 1997, revised September 1999
- 11.3 Regulatory Guide 3.48, "Standard Format and Content for the Safety Analysis Report for an Independent Spent Fuel Storage Installation."
- 11.4 Regulatory Guide 3.61, "Standard Format and Content for a Topical Safety Analysis Report for a Spent Fuel Dry Storage Cask."
- 11.5 Regulatory Guide 7.9, "Standard Format and content for Part 71 Applications for Approval of Packaging for Radioactive Materials."
- 11.6 Regulatory Information Summary 2004-20, "Lessons Learned from review of 10 CFR Parts 71 and 72 Applications."
- 11.7 Regulatory Information Summary 2005-27, "NRC Timeliness Goals, Prioritization of Incoming License Applications and Voluntary Submittal of Schedule for Future Actions for NRC Review."
- 11.8 Regulatory Information Summary 2007-09, "Examples of Recurring Requests for Additional Information for 10 CFR Part 71 and 72 Applications."

## **12.0 ENCLOSURES**

1. Appendix A: Change History
2. Appendix B: Guide for Performing Acceptance Reviews
3. Appendix C: Guide for Performing Acceptance Reviews, Example Letters and E-Mails
4. Appendix D: Information Insufficiency Examples
5. Appendix E: Summary of Public Comments Not Incorporated
6. Appendix F: Public Comments and NRC Responses
7. Appendix G: Acceptance Review Process Flowchart

**Appendix A - Change History****Office Instruction SFST-14  
"Acceptance Review Process"**

| <b>SFST No 14 - Change History - Page 1</b> |   |   |                   |
|---|---|---|-------------------|
| <b>Revision Date</b>                        | <b>Description of Changes</b>                                   | <b>Method Used to Announce &amp; Distribute</b> | <b>Training</b>   |
| April 30, 2010                              | Replaced Acknowledgement Reviews with Acceptance Review Process | E-mail to staff                                 | Training Sessions |
|   |   |   |                   |

**United States  
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## **SFST-14 Appendix B**

# **Guide for Performing Acceptance Reviews**

**Division of Spent Fuel Storage and Transportation**

## Appendix B

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### Abbreviations

|       |   |
|-------|---|
| ADAMS | Agencywide Documents Access and Management System |
| ASME  | American Society of Mechanical Engineers          |
| BC    | Branch Chief                                      |
| DDD   | SFST Deputy Division Director                     |
| DOE   | U. S. Department of Energy                        |
| DOT   | U. S. Department of Transportation                |
| EDO   | Executive Director for Operations                 |
| FR    | Federal Register                                  |
| ISG   | Interim Staff Guidance                            |
| LB    | Licensing Branch                                  |
| LID   | Licensing and Inspection Directorate              |
| NMSS  | Office of Nuclear Material Safety and Safeguards  |
| NRC   | Nuclear Regulatory Commission                     |
| OAR   | Official Agency Record                            |
| OGC   | Office of the General Counsel                     |
| PM    | Project Manager                                   |
| RAI   | Request for Additional Information                |
| RLA   | Requested Licensing Action                        |
| SAR   | Safety Analysis Report                            |
| SFST  | Division of Spent Fuel Storage and Transportation |
| SRP   | Standard Review Plan                              |
| STS   | Standard Technical Specifications                 |
| TAC   | Technical Assignment Control                      |

|     |                              |
|-----|------------------------------|
| TAR | Technical Assistance Request |
| TRD | Technical Review Directorate |
| TS  | Technical Specifications     |

## 1.0 INTRODUCTION

The goal of the acceptance review process is to facilitate submittal of acceptable RLAs, the acceptance of an RLA should not be interpreted to imply that additional questions may not be raised during the actual technical review process. Serious insufficiencies in the application (possibility resulting in denial of the RLA), may be identified during the detailed technical review. The acceptance review process does not determine the technical correctness of the applied methodologies or the accuracy of the results. Rather, the acceptance review is a tool used by the staff to identify unacceptable RLAs early in the review process so that they can be returned to or supplemented by the applicant. The acceptance review process is intended to ensure SFST only reviews high quality applications. Incomplete or poor quality applications will be rejected under the acceptance review process.

### 1.1 Objectives

The objective of this guide is to help SFST enhance its efficiency in responding to the needs of the applicants. Specific objectives include the following:

- Promote the submittal of acceptable, high-quality, RLAs;
- Provide general guidance to staff on defining acceptable RLAs;
- Facilitate an effective use of staff resources in reviewing RLAs;
- Promote consistency in the performance of acceptance reviews;
- Establish the acceptance review process as an integral part of an effective licensing review;
- Establish the priority of acceptance reviews and define time frames for completion;
- Reduce unnecessary delays in the detailed technical review of RLAs; and
- Ensure effective internal and external communications.

### 1.2 Process Overview

High level breakdown of acceptance review procedure:

- PM distributes RLA to technical branches within 5 working days after the RLA is entered into ADAMS, or earlier if possible.
- PM and TRD communicate any RSI(s) to each other within 5 weeks of NRC receipt of the RLA, or earlier if possible or if an earlier schedule was established.
- PM issues RSI(s) within 60 calendar days of NRC receipt of the RLA, or earlier if possible or if an earlier schedule was established.
- Applicant responds to RSI(s) within 15 calendar days of the applicant receiving the RSI(s), or earlier if possible.

- TRD reviews RSI(s) for adequacy and responds to the PM within 15 calendar days of TRD receiving the RSI responses, or earlier if possible.

The level of effort expended in the acceptance review of RLAs is based on many factors and varies significantly. Therefore, in performing the acceptance review, the expectation is that an individual staff member, typically, should be able to complete the acceptance review expending no more than 24 staff hours. However, due to the complexity and uniqueness of the review, a reviewer may need more time. Should the reviewer determine that the acceptance review will exceed 24 staff hours; the reviewer must identify the need for additional review time and discuss the reasons with the TRD BC and the PM. The TRD BC will determine the appropriateness of the request for additional review time.

If a more significant effort is needed to complete the acceptance review, this may indicate that too detailed an acceptance review is being performed, that the RLA is more complex than expected, that the RLA is poorly written, or that the RLA is not sufficient to be accepted for review. Prior to expending this significant effort, staff should consult with their BC and PM.

The PM's role in the acceptance review process for RLAs is to manage the staff's review of the RLA, by performing part of the review and by coordinating the review performed by other staff. The technical branch supports the PM by reviewing aspects of the RLA requested by the PM. The initial step in the overall review process is to perform the acceptance review. Subsequently, the PM ensures that reviews are performed in accordance with the associated Office Instruction and other procedural guidance, as appropriate. The acceptance review consists of the following high-level processes:

- Establishment of schedules and resources (e.g., technical review disciplines needed) for the acceptance review;
- Review of the application for administrative and overall technical sufficiency;
- Resolution of RSIs; and
- Documentation of results.

### 1.3 Definitions

#### 1.3.1 Acceptable for Review

A staff conclusion that the application appears to contain sufficient technical information, both in scope and depth, to complete the detailed technical review in an appropriate time frame for determining whether the associated action meets applicable regulatory requirements for ensuring protection of public health, safety, and security. This time frame is typically, no more than one round of RAIs.

#### 1.3.2 Receipt by the NRC

Receipt by the NRC will be considered for timeliness metrics purposes, as the date staff receives an acceptable application. It is the responsibility of the applicant to ensure that

documents are complete, submitted properly, and comply with NRC guidance for Electronic Submittals, if applicable. The NRC public web site provides guidance on how to submit documents both electronically and by hard copy to the NRC. However, in order to support SFST's overall philosophy and expectation, staff will on a case by case basis, depending on workload, case familiarity, and priority, begin RLA review in parallel with docketing the RLA into ADAMS. In this way, staff may begin case reviews earlier, if possible.

### 1.3.3 Readily Available Information

Readily Available Information is information that can be provided by the applicant within 15 calendar days such that the staff's review resources and schedules will not be adversely affected and the detailed technical review can proceed. Considerations that could adversely affect resources and schedules include availability and complexity of the outstanding items, work priorities, PM and technical staff availability, and other casework.

### 1.3.4 RSI (information insufficiency)

Failure of an RLA to meet one or more of the acceptance review criteria in Section 3.1 is indicative of an unacceptable application. The criteria are not all inclusive. Staff discretion and engineering judgment will be used as part of the determination of whether or not an application is acceptable for review.

## **2.0 DISTRIBUTION AND INVOLVEMENT**

When the applicant submits the RLA, the applicant should inform the Licensing Branch (LB) BC by e-mail or by telephone. The LB BC will assign a PM for the RLA. Once the RLA has been entered into ADAMS, or earlier if possible, the assigned PM will request a technical assignment control (TAC) number to be opened, create a schedule, and obtain the names of the assigned technical reviewers (to perform the acceptance review) from the TRD BCs.

The technical staff is responsible to inform the PM of information needs, including access to the initial submittal.

The applicant should ensure documents are submitted properly and comply with NRC guidance for Electronic Submittals, if applicable. The NRC public web site provides guidance on how to submit documents both electronically and by hard copy to the NRC.

Time spent performing the acceptance review should be charged to the same TAC number associated with the detailed technical review.

## **3.0 REVIEW OF APPLICATION FOR COMPLETENESS AND ACCEPTABILITY**

This SFST Office Instruction is applicable to new applications, amendment requests, and Request for Additional Information (RAI) responses as necessary. Simple, routine amendment requests and RAI responses may undergo a brief acceptance review by the receiving NRC project manager under a shorter acceptance review schedule. Typically, this shorter acceptance review will not exceed 30 calendar days from the receipt date.

### 3.1 Acceptance Review Criteria

The shorter acceptance review is not a technical review. The review is an administrative evaluation for completeness of the application and for general omission of information. For complex or first-of-a-kind applications, the shorter review may not be appropriate. For applications which appear to contain all required sections by “quick” glance, a shorter acceptance review will be proposed.

The longer acceptance review is not a technical review. The review is an administrative evaluation for completeness of the application and for general omission of information. The longer acceptance review is more appropriate for complex, first-of-a-kind applications, or applications which do not closely follow the Standard Review Plan.

The following guidance highlights key elements that should be contained in an RLA and potential questions that the staff should address during the acceptance review. The PM and technical staff should make the following determinations with regard to the RLA. Application of the criteria should not replace sound technical and regulatory judgment. In certain circumstances, there may be situations where, although evaluation of an RLA against the criteria would suggest one action, another may be more appropriate, based on engineering judgment and staff recommendations to SFST management. In the instances where such circumstances occur, the basis for decisions different from the criteria should be well understood and clearly documented.

Appendix D, “RSI Examples,” contains examples of RSIs that may occur and a discussion of each as to whether it would cause an RLA to be unacceptable for review. The examples are provided as only a guide. Alternatively, the staff may develop discipline specific acceptance review checklists (an example of this type of checklist is provided in Appendix D). The following sections represent expectations of SFST that technical reviews are the responsibility of technical staff and project management reviews are the responsibility of project managers and they may overlap in areas. For example, transportation project managers and technical staff are responsible for sections 1, 7, and 8 and technical staff is responsible for sections 2 – 7 of the SAR as contained in the NUREG-1609 “Standard Review Plan for Transportation Packages for Radioactive Material.” Responsibility will overlap in areas; however, to ensure responsibilities are clear, project managers and technical staff are responsible for the following criteria as they apply to their respective reviews.

#### 3.1.1 PM Criteria

- **Administrative Criteria:** Determine whether the RLA addresses criteria in appropriate Regulatory Guides, such as Regulatory Guides 3.48, 3.61, and 7.9, and other administrative criteria, including:
  - Identify actions where applicants have requested an expedited review, and provided a basis for the expedited review;
  - Determine whether the applicant appropriately identifies deviations from the Standard Review Plan (SRP) or Interim Staff Guidance (ISG), concerning application sections that the project manager is cognizant;

- Verify the applicant properly identifies proprietary information, justifies, and includes the affidavit (addressed to the Document Control Desk, submitted under Oath and Affirmation) in accordance with 10 CFR 2.390 (technical aspects of the proposed proprietary information may require review by technical groups). To expedite the review, the applicant should consider providing both a proprietary version and a non-proprietary version. In this way, a public version of the application will be available in ADAMS sooner;
  - Verify attachments are included and that significant references are available;
  - Ensure contents of the application are legible and coherent (contents may include evaluations, drawings, and data tables);
  - Ensure that the format and content of the application sections is consistent with established criteria, and that deviations are explained and applicable references are provided; and
  - Confirm that the applicant provided instructions on updating NRC's copy of the Safety Analysis Report (SAR). While providing SAR updates is not required to begin a detailed technical review, providing SAR updates up front may significantly reduce review time as often SAR updates are needed in order for staff to determine regulatory compliance. Therefore, staff recommends the applicant provide SAR updates up front rather than later during the review process as part of a RAI.
  - Specific to Part 72 amendments, the applicant should provide proposed FSAR update pages that are based upon the current design and contents that are proposed for use in the amendment request, including any changes that were made beforehand in accordance with 10 CFR 72.48. The applicant should demarcate, or otherwise indicate, portions of the FSAR and design that were changed in accordance with 10 CFR 72.48, separate from changes requested in the amendment. FSAR update pages are required prior to approval.
- **Use of Guidance:** Determine whether the RLA cites guidance not yet adopted by the NRC. Examples include draft American Society of Mechanical Engineers (ASME) Code cases or Code cases approved by external codes and standards organization as an exception to current code or standard practices. Guidance not yet adopted or incorporated by NRC may be used as the basis for a new application or a proposed change. However, the applicant must supply justification and technical basis to support the change or departure from current adopted or internal guidance. Simply citing guidance is not acceptable. Perform a cursory review to determine if any reference guidance or documents have been misapplied and ensure that the SAR for the RLA is clear. Staff should also ensure that internal draft guidance or unadopted external guidance, whether in draft or final form, is not used as a basis for determining whether an application is acceptable for review, unless proper justification is provided.
  - **Additional Criteria:** For certain RLAs, ensure that the applicant addresses any specific criteria associated with a particular action. These criteria are typically identified either in the regulations (10 CFR Part 71 or 10 CFR Part 72), or in associated guidance. An example can be found in alternatives to NRC guidance, where the applicant must justify the acceptability of the proposed alternative. Another example would be failure of the applicant to have applied for an NRC approved quality assurance program either prior to

the RLA or along with the RLA. Reviewing an alternative may require additional review time and resources.

- **Dependent/Linked RLAs:** Determine whether the approval of the RLA is contingent upon the approval of other RLAs currently under review. An RLA should not be accepted for NRC review and approval until all prerequisite RLAs have been reviewed and approved by the NRC. SAR change pages submitted with linked RLAs shall include changes for both RLAs. It is important to note that if multiple RLAs that affect the same storage cask design or transportation package or Technical Specifications (TSs) are unrelated and not linked, it may be possible to issue these RLAs in any order and without regard to the results of the review of the others. Close engagement between the applicant and Project Manager concerning any queries on dependency is encouraged.

### 3.1.2 Technical Staff Criteria

- **Completeness of Scope:** Determine if there are significant analyses/evaluations or detailed summaries\* missing from the RLA, as provided for in the applicable SRP or ISG. Ensure representative input/output files for any relevant calculation packages are included and/or thoroughly documented.

Often, the appropriate analysis scope and depth are designated in industry codes and standards such as Regulatory Guides. An RLA lacking a relevant analysis, or a required evaluation, necessary for the staff review, should be considered unacceptable. Determine that the applicant fully identifies SRP/ISG deviations or necessary exemptions. The reviewer should cite the basis for the needed analysis (regulation, SRP, ISG, Regulatory Guide, industry standard, etc.).

\*includes a) all files and/or calculation packages in list form including final revision number and detailed description of the calculation and b) the documented calculations are complete and immediately available to staff upon request during the detailed technical review.

- **Sufficiency of Information:** Determine if the RLA provides the expected content identified in the related SRP sections including applicable ISGs. Determine if the RLA contains sufficient technical information in scope and depth to begin and complete the detailed technical review within a predictable timeframe (no more than one round of RAIs).

Reviewing for technical sufficiency enables the staff to identify significant deficiencies in the RLA which would preclude the staff from starting its technical review; or that would potentially require significant time and resources to resolve, and could challenge the ability for staff to reach a finding of reasonable assurance in a predictable timeframe. Technical staff may use various measures for such criteria, such as the volume and magnitude of questions that could be generated based simply on the initial reading of the application. If significant problems or deficiencies are identified, the RLA should be considered unacceptable.

- **Alternatives or Missing Information:** Determine if the RLA identifies alternatives to or does not address the provisions contained in the applicable SRP or ISG. Determine if a technical justification and a basis for the alternative or omission have been provided. An RLA lacking justification and basis should be considered unacceptable.
- **Regulatory Basis:** Determine whether the applicable regulations and criteria are properly identified. The applicant should identify the criteria used to determine that the RLA meets regulatory requirements. The staff may use guidance documents such as the SRPs or ISGs for RLAs. However, meeting guidance criteria is not a regulatory requirement. Staff should be cognizant that the applicant may have evaluated a proposed change contained in the RLA in a different manner. Regardless, the staff should be able to identify the applicable criteria and licensing bases by which to evaluate the proposed action based on the information contained in the application. When alternatives are provided, the staff should spend extra time verifying the completeness of the scope and bases of the alternate methodology.
- **Use of Issued Guidance:** Determine whether industry codes, code cases, regulatory guides, NRC Technical Reports (NUREGs), or ISGs cited in the application are used in accordance with the limitations and conditions imposed by staff on their use or imposed by the document itself.

Appropriate guidance constitutes any of the documents listed that have been published and in effect for a minimum of 6 months prior to submittal of a RLA for an amendment or 1 year prior to submittal of an RLA for a new application. An exception to this standard would be in those cases where deviation from recently approved guidance documents would create a safety concern. Using different standards, or codes (or the use of codes outside the limitations adopted by the NRC staff) may be acceptable when the applicant has provided a full analysis to justify why the proposed use is appropriate. However, simply referencing standards, code or code cases is unacceptable. Additionally, deviations from guidance should not be considered acceptable unless fully justified. If reports are cited in the RLA, sufficient information should be submitted along with the reports for the staff to judge the quality and applicability of the information.

- **Use of Precedent:** A previous precedent of approval, of and by itself, is not a justification for a proposed change. Determine whether cited precedents are justified and used appropriately and whether any deviations from the precedent appear to be justified.

The use of precedents may be acceptable if it provides a resource savings by allowing the technical staff to make use of information from previous reviews of sufficiently similar RLAs. The technical staff should be aware that, in addition to inappropriate use of a cited precedent, there may also be applicable precedent that was not cited. Evaluation against such criteria is not meant to initiate exhaustive search, but instead promote awareness of any readily available information or knowledge pertinent to the RLA. However, previous staff approval of a cited precedent does not automatically approve the acceptance of a method or results in the RLA (staff determination for the use of a precedent may be influenced by new safety-significant knowledge and information that was not available in the past). In all cases, the application should contain sufficient

information for staff to make a safety finding consistent with the regulations. When precedents are cited, or documents identified as having been previously submitted to the NRC are cited, either an ADAMS accession number or a copy of appropriate pages of these documents should be provided. If a large document (over 20 pages) is cited, the page or section numbers of the citation should be identified to best facilitate location of the information. Because certain past staff approvals may be based on unique or specific provisions contained in the previous evaluations, or unique or specific circumstances, its use in another evaluation may not be appropriate unless the applicant addresses all of the provisions which the staff considered when approving the precedent. In addition, the applicant should provide information that indicates the basis for a precedent used by one Vendor is applicable for another Vendor's design.

Note: The TRD staff should review the PM Criteria in Section 3.1.1 of this Office Instruction, and apply the criteria as necessary during their acceptance review activities.

### 3.1.3 Quality Issues in the Application

Quality issues are those issues in the RLA that may significantly impact the ability to complete the detailed technical review in a timely manner. Quality issues in the RLA may be found acceptable for review during the acceptance review process, however staff may determine that because of quality issues in the application, an additional amount of review time will be required. Quality issues may significantly impact the detailed technical review schedule. In certain instances, quality issues may be justification for staff not to accept a RLA. The following should be considered when determining how quality issues will impact the acceptability or review schedule of an RLA.

**Will the detailed technical review be able to be completed in a timely manner?**

**Have proposed alternatives to SRP and ISG acceptance review criteria and regulatory guides been identified and a sound technical basis provided?** Are the bases and justifications for proposed alternatives or omissions to SRP provisions sufficient?

**Identification of Dependencies among Concurrent Reviews:** The technical staff and applicant should identify any known dependencies among concurrent reviews. An example of a dependency is as follows. If the staff has identified an issue with a cask basket's structural integrity, the resolution of that issue could affect the criticality analysis. These dependencies should be communicated by the technical staff to the PM to assist the integrated management of the concurrent reviews, such that a slippage in the RLA technical review schedule will be evaluated for possible impacts to the overall schedule. Further, are cross-references within the application correct? If the SAR has several volumes, does it appear that the requested change has been appropriately addressed in all volumes of the SAR. Although not directly applicable, consideration should be given to any dependencies to linked RLAs (see Section 3.1.1 of this office instruction). The applicant, for example, should identify any known dependencies among concurrent submittals in the context of assumptions made pertaining to the successful approval of an in-process amendment request. Therefore, if quality issues are present on one linked submittal, the other linked submittal may be adversely affected.

**Identification of quality issues in an acceptable RLA that will impact the technical review schedule.** An RLA may be considered minimally acceptable for staff to begin the detailed technical review with a small number of quality issues present in the application. However, based on the quality issues, staff may not be able to determine a predictable timeframe to complete the review. Therefore, staff may not be able to develop a schedule for reviewing the application. In such cases the technical review may be started, but staff may not issue the associated review schedule. A letter will be sent to the applicant identifying the quality issues and a meeting with the applicant may ensue. The applicant may decide to supplement the RLA, in order to achieve the appropriate review schedule. Following receipt of an acceptable modified RLA, staff would establish the review schedule.

The following definition of quality issues in a RLA is not necessarily all inclusive. However, quality issues in a RLA could be:

- More than 5% of references in error,
- Missing information as required by 10 CFR Part 71 or 10 CFR Part 72,
- Use of non-NRC endorsed methodology, deviation from regulatory guidance, or use of improper technical justification, or
- Inclusion of issues which render the RLA not in compliance with regulations.

### 3.2 Acceptance Review Results

#### 3.2.1 Unacceptable

If, during the acceptance review of the RLA, the NRC staff finds deficiencies so significant that they impede completion of the acceptance review, the RLA should be returned to the applicant as unacceptable for review, pursuant to 10 CFR 71.7 or 10 CFR 72.11. Further, at the completion of the acceptance review, the staff may have identified major deficiencies that would be better addressed by discontinuing the staff's review, and returning the RLA to the applicant for resolution. It is noted that once the staff has started the acceptance review process, staff shall complete their acceptance review and document their findings. The PM, with input from the technical staff, will send a letter to the applicant that identifies the deficiencies and states that the review has been discontinued. This letter will identify all deficiencies found during the acceptance review. Additionally, the letter will identify that other aspects of the RLA may be insufficient but were not reviewed due to the significance of the aforementioned information insufficiency. SFST management need to concur with this action and the letter's content. If it is determined that the information insufficiencies are too significant for staff to continue its review, Section 5.0, "Non-Acceptance of the RLA," should be utilized. The PM should then close the TAC and cease review activities. All copies of the application should either be discarded or returned to the applicant, except for the ADAMS version. An example of a non-acceptance letter for an RLA is provided in Appendix C.

#### 3.2.2 Acceptable Once Supplemented

After the completion of the acceptance review of the RLA, if either the PM or the technical staff feels that the submittal does not meet the definition of acceptable for review, they should promptly contact the other SFST staff involved in the review to discuss the impact of the information insufficiencies. The PM, technical staff, and the BCs should discuss the information

insufficiencies. This discussion should focus on ensuring that all parties understand the information insufficiencies, and agree that the insufficiencies are within the scope of the review of the proposed action.

If it is determined that the information insufficiencies are too significant for the RAI process, but not significant enough to result in staff discontinuing its review, Section 4.0, "Resolution of Information Insufficiencies," should be utilized, and a request to provide supplemental information should be considered. Observations may be provided in the request for supplemental information.

Both the PM and technical staff should consider the generic implications of information insufficiencies. If the potential exists for an issue to be generically applicable, the involved parties should decide on the appropriate way to resolve the issue.

The RLA is considered received by SFST the day staff receives an acceptable application.

### 3.2.3 Acceptable

If the RLA is found to be acceptable for review, or if it is determined that the informational needs identified during the acceptance review are not significant enough to fail the acceptance review and can be addressed in the technical review process (i.e., via RAIs), the acceptance of the RLA for review should be communicated to the applicant per Section 6.0, "Documentation of an Application Found Acceptable for NRC Staff Review."

## 4.0 **RESOLUTION OF A RSI**

Upon determination that a RLA contains insufficient information to be considered acceptable for review, the PM (with support of the technical staff) should compile a list of the RSIs and observations and inform the associated BCs. For complex or high visibility issues, and if consistent with the acceptance review schedule, the TRD BCs should consider a peer review to confirm the RSIs prior to contacting the applicant. The performance of a peer review, or a review of an issue by the discipline technical specialty group, is optional, at the discretion of the appropriate BC. The peer review is not intended to be another full acceptance review, but rather an independent assessment of the issues identified. If the issues are agreed upon, the PM shall notify the associated division management via e-mail, briefly summarizing the issues.

### 4.1 **Discussion of RSIs with the Applicants**

The PM should inform the applicant that the RLA has been found unacceptable for review and set up a conference call to discuss the RSIs. This call should occur as soon as possible, but no later than one week after providing the applicant the information insufficiencies. The PM should avoid lengthy, detailed, discussions with the applicant in setting up the call. Instead, the PM should simply provide enough information such that the applicant can have the necessary technical staff participate in the call. The PM may, as agreed to by the BCs, provide the identified insufficiencies to the applicant, via an e-mail, prior to the call. Regardless of the method used to transmit the identified RSIs to the applicant, the PM should ensure documents and telephone conversations are properly captured as Official Agency Records (OARs).

During the call to discuss the RSIs, staff should identify the omitted or insufficient information to the applicant, discuss the appropriate course of action, and establish a tentative date the information will be submitted. It is important that the call result in a clear communication, to the applicant, of the information needed and that staff gain an understanding of whether the applicant plans to submit the information within staff's deadline established during the call (i.e., less than 15 days). The 15 days begin when the applicant receives the RSIs from staff.

Note: During the call, the applicant should be provided the opportunity to justify the apparent omission of sufficient information by identifying to the NRC staff where the responsive information is contained in the RLA. The staff will evaluate this justification to determine whether the staff's insufficient information determination is still valid, and is still needed to perform the detailed technical review. If the staff determines that the insufficiency is still valid, and the justification to address the information insufficiencies (provided to staff during the call) appears to be acceptable, the applicant needs to supplement the SAR with this justification.

The RLA will be considered received by SFST the day staff receives an acceptable application. SFST's internal metric clock starts when SFST receives an acceptable application.

Following the call to discuss the information insufficiencies with the applicant, the PM should confer with the technical staff on the results to determine if the information is likely to be submitted within 15 days of the call. If it is unlikely, in staff's judgment, that the information is readily available, the PM should generate a letter documenting the non-acceptance of the RLA and process it through concurrence. This action will facilitate a timely issuance of the letter at a later date, if necessary.

The PM and the applicant may arrange a meeting to discuss the insufficient information. A public meeting will be held to discuss the RSIs and will require 10 days advance notification; the meeting therefore may impact the applicant's ability to respond to the RSIs within the required 15 days.

If the staff determines that the insufficiency is still valid, and the justification to address the information insufficiencies (provided to staff during the call) appears to be acceptable, the applicant needs to supplement the SAR with this justification.

Regardless of whether the applicant indicates a desire to withdraw the RLA, the PM should prepare a letter requesting the information in accordance with Section 4.2, "Applicant Supplements to RLA." The associated TRD Branch Chiefs need to concur with the letter or the technical input to the letter.

If a hearing has been granted regarding an RLA, the PM should be aware that additional rules and guidance govern the NRC staff's actions. In this case, SFST staff should interface closely with the Office of the General Counsel (OGC) to determine the proper course of action.

#### 4.2 Applicant Supplements to RLA

Regardless of whether the staff believes that the RLA can be supplemented with readily available information, or if the applicant indicated a preference to withdraw the application, a letter requesting supplemental information should be sent to the applicant that clearly identifies:

- The information needed for the NRC staff to begin its detailed technical review;
- The time frame for the submission of the information. This time (typically 15 days from the date of the call) should be established as one that is supportive of staff's timely review, not simply when the information will be available; and
- A statement identifying that failure to submit the information within the time frame will result in non-acceptance of the application and cessation of staff review activities.

This letter should be sent to the applicant as soon as practical, however, should not take longer than 60 days from the date of the receipt of the RLA by the NRC.

If the requested supplemental information is provided within the agreed-upon time frame, the PM should ensure that the supplement is provided to all technical staff assigned to the RLA acceptance review. Within 15 days of receipt of the supplement from the PM, the technical staff should review the supplementary information to ensure that it is responsive to the original staff's concerns. The same criteria used in the initial acceptance review shall be applied, although the review should be focused on the areas previously identified as non-acceptable.

The PM is responsible for tracking the submission of the information by the applicant and distribution of the submitted information to the technical staff. The technical staff is responsible for identifying any issues (e.g., staff reassignments or other high priority work) that may impact the acceptance review schedule to the PM and his or her BC. If it appears that the applicant is not able to submit the information in the established time frame (or the information to be submitted is unlikely to be responsive to the NRC staff's concerns), the associated division management (BCs, DDDs, and the DD) should be informed of the NRC staff's intent to not accept the application and cease review activities.

If the applicant does not provide the requested information within the time frame specified in the staff's correspondence, or if the provided information is not responsive to the NRC staff's concerns, Section 5.0, "Non-Acceptance of the RLA," should be used to proceed with non-acceptance of the application. This course of action should also be considered in the event that the staff determines the information provided by the applicant continues to be insufficient.

If the information provided is both timely and responsive, notify the applicant in accordance with Section 6.0 and transition into a detailed technical review. The applicant may provide supplemental information during and after the acceptance review period provided the information is either requested by the NRC staff or it corrects an error identified by the applicant. Acceptance of the supplemental information will be evaluated on a case by case basis.

## **5.0 NON-ACCEPTANCE OF THE RLA**

If the RLA is initially determined to be non-acceptable, and if the supplement to the RLA has been determined to be unresponsive or inadequate to address staff concerns or the applicant does not provide the supplementary information within the agreed upon time frame, or if the applicant chooses not to provide the supplement, staff should proceed with actions to not accept the application and discontinue the review. Upon identification of the determination to discontinue the review and concurrence with the action by the associated SFST BCs, DDDs,

and DD, the PM may involve OGC depending on the significance of the case. Additionally, while not required, the staff counsel should be afforded the opportunity to determine whether there is no legal objection to the staff's proposed action. Upon the determination that a more significant or controversial RLA is not acceptable for staff review, the NRC staff should communicate this decision to the Director, NMSS, and the Executive Director for Operation's (EDO's) office (via an EDO daily note) prior to contacting the applicant.

Following the completion of the above actions, the PM should then communicate the staff's decision to discontinue the review to the applicant.

**Note: When communicating the non-acceptance of an RLA to the applicant, the NRC staff should avoid debating the issue with the applicant. Instead, the NRC staff should ensure that the reasons for the NRC staff's actions are clearly communicated.**

Upon notification of the NRC staff's decision to not accept the RLA, the applicant should also be made aware that it may withdraw the application pursuant to 10 CFR 2.107. The applicant should be encouraged to fully document the reasons for withdrawal in its letter and understand that the NRC staff will, likewise, document the information insufficiencies in the letter of non-acceptance of the RLA or the withdrawal acknowledgement letter.

Regardless of whether the applicant intends to withdraw the RLA, PM activities associated with processing of the non-acceptance of the RLA should continue. If determination that the RLA is not acceptable for staff review is a result of insufficiencies identified by the technical staff, written input should be provided to the PM clearly documenting the issues.

If the applicant fails to supplement the RLA within the agreed upon time frame or the supplement is found to be unresponsive staff's concerns, the letter of non-acceptance should be issued within 15 days of the deadline established for supplementing the RLA.

If the applicant, prior to issuance of the non-acceptance letter, submits a written request to withdraw the RLA, the NRC staff should modify the letter to accept the withdrawal and terminate the review. The documentation of the insufficiencies that led to the withdrawal should be maintained in the letter. This action is both supportive of a clear public record and informative to other applicants that may be preparing similar RLAs. Examples of both non-acceptance of an RLA and withdrawal acknowledgement letters are provided in Appendix C.

Upon issuance of the letter of non-acceptance of the RLA, or the withdrawal acceptance letter, the PM should close the associated TAC number.

## **6.0 DOCUMENTATION OF AN APPLICATION FOUND ACCEPTABLE FOR NRC STAFF REVIEW**

Upon determination that an RLA is acceptable for review, this result should be communicated to the applicant. This notification may be made by e-mail.

If the RLA was supplemented, the acceptance for review shall be documented in a letter to the applicant. An example letter is provided in Appendix C.

Typically, if the applicant's submittal was found to be acceptable without any supplements, an e-mail to the PM's licensing contact would be sufficient to document the completion of review. Following the transmission of this e-mail, the PM shall email a schedule or prepare a letter to the applicant in accordance with SFST Office Instruction No. 4, identifying the schedule for completing the detailed technical review for the RLA. The RLA will be considered received by SFST the day staff receives an acceptable application. SFST's internal metric clock starts when SFST receives an acceptable application.

**Note: It is important that the PM ensures that e-mail documentation of the acceptance for review is documented in ADAMS as an OAR. This can be accomplished by the electronic addition of the e-mail or manual scanning.**

At the conclusion of the acceptance review, the PM and technical staff will begin the detailed technical review in accordance with the appropriate process (e.g., SFST-4). The technical staff performing the detailed technical review may not be the same staff that performed the acceptance review.

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## **SFST-14 Appendix C**

# **Guide for Performing Acceptance Reviews, Example Letters & E-Mails**

**Division of Spent Fuel Storage and Transportation**

**ACCEPTANCE**

[DATE]

[ADDRESSEE]

SUBJECT: APPLICATION FOR [DESCRIPTION] – ACCEPTED FOR REVIEW

Dear [ADDRESSEE]:

By letter dated [DATE], you submitted an application for [AMENDMENT/APPROVAL] of [PACKAGE/CASK/FACILITY]. You requested [BRIEF DESCRIPTION OF REQUEST]. Staff performed an acceptance review of your application to determine if the application contains sufficient technical information in scope and depth to allow the staff to complete the detailed technical review.

This letter acknowledges acceptance of your application. The application appears to contain the information needed for our technical review. We have established a schedule for the review. The schedule allows for staff to issue a Request for Additional Information (RAI) in [MONTH YEAR] and a CoC/SER in [MONTH YEAR], based on the applicant responding to RAIs in [MONTH YEAR]. If no RAI is needed, and based on the staff's evaluation, the approval may be issued at approximately that time. In general, no additional changes to the application should be submitted except for changes resulting from your response to an RAI.

If you have any questions regarding this matter, please contact me at [PM PHONE NUMBER].

Sincerely,

[PM NAME]  
Division of Spent Fuel Storage and Transportation  
Office of Nuclear Material  
Safety and Safeguards

Docket No. [DOCKET NO.]

TAC No. [TAC NO.]

Distribution: Tech Reviewers and Tech Review Branch Chiefs

Concurrence: PM LA Licensing Branch Chief

**SUPPLEMENTAL INFORMATION NEEDED**

[DATE]

[ADDRESSEE]

SUBJECT: APPLICATION FOR [DESCRIPTION] – SUPPLEMENTAL INFORMATION NEEDED

Dear [ADDRESSEE]:

By letter dated [DATE], you submitted an application for [AMENDMENT/APPROVAL] of [PACKAGE/CASK/FACILITY]. You requested [BRIEF DESCRIPTION OF REQUEST]. Staff performed an acceptance review of your application to determine if the application contains sufficient technical information in scope and depth to allow the staff to complete the detailed technical review.

This letter is to advise you that based on our acceptance review, the application does not contain sufficient technical information. The information needed to continue our review is described in the enclosure to this letter. In order to schedule our technical review, this information should be provided by [DATE]. If the information described is not received by this date, the application will not be accepted for review. This letter confirms our [E-MAIL or PHONE CALL] on [DATE] with respect to the supplemental information needed and the date for your submittal.

If you have any questions regarding this matter, please contact me at [PM PHONE].

Sincerely,

[PM NAME]  
Division of Spent Fuel Storage and Transportation  
Office of Nuclear Material  
Safety and Safeguards

Docket No. [DOCKET NO.]  
TAC No. [TAC NO.]

Enclosure: As stated

Distribution: Tech Reviewers and Tech Review Branch Chiefs  
Concurrence: PM LA Licensing Branch Chief

**NON-ACCEPTANCE**

[DATE]

[ADDRESSEE]

SUBJECT: APPLICATION FOR [DESCRIPTION] – NOT ACCEPTED FOR REVIEW

Dear [Addressee]:

By letter dated [DATE], you submitted an application for [AMENDMENT/APPROVAL] of [PACKAGE/CASK/FACILITY]. You requested [BRIEF DESCRIPTION OF REQUEST]. Staff performed an acceptance review of your application to determine if the application contains sufficient technical information in scope and depth to allow the staff to complete the detailed technical review.

This letter is to advise you that the application does not contain sufficient technical information to allow the staff to complete its detailed technical review and to determine that the [PACKAGE/CASK/FACILITY] meets the requirements of 10 CFR Part [71/72]. In a previous NRC letter, staff identified the following information was needed to begin its technical review:

**LIST INFORMATION NEEDED**

[IF THE APPLICANT IS NOT BEING ALLOWED TO SUPPLEMENT THEIR REQUEST, USE THIS PARAGRAPH

Because of the extensive nature of the information needed, the NRC staff finds the request for approval of the proposed action to be unacceptable for NRC review pursuant to [10 CFR 71.31/33, 72.11]. NRC staff activities on the review have ceased and the associated Technical Assignment Control number has been closed.]

[IF THE APPLICANT WAS REQUESTED TO SUPPLEMENT THEIR REQUEST AND DID NOT PROVIDE A SUPPLEMENT, USE THIS PARAGRAPH

The NRC staff has not received communications from you regarding the supplementary informational need. Therefore, the NRC staff does not accept the application for review. NRC staff activities on the review have ceased and the associated Technical Assignment Control number has been closed.]

[IF THE APPLICANT PROVIDED AN INADEQUATE SUPPLEMENT, USE THIS PARAGRAPH

By letter dated [DATE], you provided a supplement to this submittal. The NRC staff has found the supplement unresponsive to the cited informational needs. Therefore, the NRC staff finds the request for approval of the proposed action to be unacceptable for NRC review. NRC staff activities on the review have ceased and the associated Technical Assignment Control number has been closed.]

If you have any questions regarding this matter, please contact me at [PM PHONE].

Sincerely,

[PM NAME]  
Division of Spent Fuel Storage and Transportation  
Office of Nuclear Material  
Safety and Safeguards

Docket No. [DOCKET NO.]

TAC No. [TAC NO.]

Enclosure: As stated

Distribution: Tech Reviewers and Tech Review Branch Chiefs

Concurrence: PM LA Licensing Branch Chief

**ACKNOWLEDGEMENT OF WITHDRAWAL**

[DATE]

[ADDRESSEE]

SUBJECT: APPLICATION FOR [DESCRIPTION] – ACKNOWLEDGEMENT OF WITHDRAWAL

Dear [Addressee]:

By letter dated [DATE], you submitted an application for [AMENDMENT/APPROVAL] of [PACKAGE/CASK/FACILITY]. You requested [BRIEF DESCRIPTION OF REQUEST]. Staff performed an acceptance review of your application to determine if the application contains sufficient technical information in scope and depth to allow the staff to complete the detailed technical review.

By letter dated [DATE], you requested to withdraw the application from NRC review. The NRC acknowledges your request to withdraw the application. NRC staff activities on the review have ceased and the associated Technical Assignment Control number has been closed.

The NRC staff notes that its review to date has identified that your application did not provide the following technical information in sufficient detail to enable the staff to complete its detailed review. Therefore, if you decide to re-submit the request, it must include the following information:

## LIST INFORMATION NEEDED

If you have any questions regarding this matter, please contact me at [PM PHONE NUMBER].

Sincerely,

[PM NAME]  
Division of Spent Fuel Storage and Transportation  
Office of Nuclear Material  
Safety and Safeguards

Docket No. [DOCKET NO.]

TAC No. [TAC NO.]

Distribution: Tech Reviewers and Tech Review Branch Chiefs TA Deputies Director  
Concurrence: PM LA Licensing Branch

**EXAMPLE OF E-MAIL NOTIFYING THAT REQUEST HAS BEEN ENTERED INTO ADAMS AND STAFF HAS STARTED ACCEPTANCE REVIEW**

SUBJECT: RECEIPT OF APPLICATION - ACKNOWLEDGMENT LETTER

Dear [Applicant]:

By letter dated [ENTER DATE], [Applicant] submitted an application for [Requested Licensing Action]. The application proposes [Describe Action]. This e-mail acknowledges receipt of your application in ADAMS [enter date when entered into ADAMS] and informs you that our Acceptance Review has started. Within 60 days, we will notify you the results of our acceptance review.

If you have any questions regarding this matter, please contact me at [PM PHONE NUMBER].

Sincerely,

[PM NAME]  
Division of Spent Fuel Storage and Transportation  
Office of Nuclear Material  
Safety and Safeguards

Docket No. [DOCKET NO.]

TAC No. [TAC NO.]

**United States  
Nuclear Regulatory Commission**

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## **SFST-14 Appendix D**

# **Guide for Performing Acceptance Reviews, Examples of Requests for Supplemental Information (RSIs)**

**Division of Spent Fuel Storage and Transportation**

## **Examples of Requests for Supplemental Information (RSIs)**

The purpose of the examples included in this Appendix is to better delineate where an informational insufficiency or Request for Supplemental Information (RSI) would result in a requested licensing action (RLA) being unacceptable for review versus where it would be more appropriately dealt with via the request for additional information (RAI) process. In each example, criteria are provided that can be used to determine whether an identified insufficiency would cause the RLA to be found unacceptable for detailed technical review and whether any changes to the situation exist that may change this finding.

### **ADMINISTRATIVE RSI Examples**

#### **Administrative Example No. 1**

**Criteria:** Affidavit required for proprietary information (Appendix B, Section 3.1.1 Administrative Criteria)

**Situation:** An application for a transportation package is submitted with some information marked as proprietary, but without an affidavit.

**Acceptable for Review? - No.** The basis for proprietary withholding must be identified and documented in a properly executed affidavit in accordance with 10 CFR 2.390.

**May be Acceptable for Review If:** The information requested to be withheld is clearly identified, is consistent with standard withholding practice, is limited in scope (e.g., packaging drawings), and the applicant agrees by telephone to submit an affidavit within 15 days. Note: Staff will still prepare a letter requesting supplemental information.

#### **Administrative Example No. 2**

**Criteria:** Use of Approved Guidance (Appendix B, Section 3.1.1, Use of Approved Guidance).

**Situation:** An application for a transportation package does not include complete Operating Procedures.

**Acceptable for Review? - No.** The Standard Review Plan specifies the content of Section 7 of the application.

**May be Acceptable for Review If:** The applicant agrees to submit a complete set of Operating Procedures within 15 days.

#### **Administrative Example No. 3**

**Criteria:** Failure to have an NRC-Approved Quality Assurance (QA) Program (Appendix B, Section 3.1.1, Additional Criteria)

**Situation:** An application for a transportation package is submitted, but the applicant does not hold an NRC-approved QA program.

**Acceptable for Review?** - No. Holders of Certificate of Compliance must have an NRC-approved QA program.

**May be Acceptable for Review If:** The applicant applies for a QA program approval prior to the RLA or along with the RLA, or there is evidence that the package development has been performed in accordance with a QA program that meets the requirements of Subpart H of 10 CFR Part 71, or if the applicant is the DOE, and QA requirements have been addressed in Chapter 9 of the application.

### **MATERIALS RSI Examples**

#### **Materials Example No. 1**

**Criteria:** Appendix B, Section 3.1.2, Alternatives or Missing Information

**Situation:** The applicant requests that both stainless steel and zircaloy clad fuel rods be acceptable contents for storage. The application uses the temperature limits recommended in ISG-11, Revision 3, to support that none of the rods will develop gross breaches.

**Acceptable for review?** - No. ISG-11, Revision 3, states that it is only applicable to zirconium based cladding. The temperature limits set in ISG were based on the degradation mechanisms applicable to Zircaloy. The staff should not accept the RLA until the potential mechanisms for degradation of the stainless steel cladding, as a function of storage temperature, are evaluated.

**May be Acceptable for Review If:** The potential mechanisms for degradation of stainless steel cladding, as a function of storage temperature, are evaluated by the applicant, and adequate justification is provided, including supplemental technical data and analyses.

### **CRITICALITY RSI Examples**

#### **Criticality Example No. 1**

**Criteria:** Appendix B, Section 3.1.2, Completeness of Scope

**Situation:** An applicant with an approved Part 71 transportation package wishes to add other fissile contents. Although the applicant performs "bounding" criticality analyses, the applicant does not provide a description of the contents that will be allowed to be shipped.

**Acceptable for Review?** - - No, because the applicant failed to provide information that is required in 10 CFR 71.33 and critical to staff's review (Completeness of Scope) by not providing any information about the contents that will be shipped. Therefore the staff cannot make an appropriate determination that analyses are truly "bounding."

**May be Acceptable for Review if:** The applicant supplements the application with additional details on the contents within the allowed time frame.

**Criticality Example No. 2**

**Criteria:** Appendix B, Section 3.1.2, Sufficiency of Information

**Situation:** An applicant submits a new application for a Part 71 transportation package. The staff notices a fundamental error, in the calculations that encompasses all contents that would be allowed to be transported as well as sensitivity studies performed on the package.

**Acceptable for Review?** - No, because the applicant's supporting analyses are erroneous and the staff cannot rely on any of the conclusions made by the applicant using the erroneous analyses.

**May be Acceptable for Review if:** The error is small enough that the staff can be relatively certain that correcting the error would not invalidate the applicant's conclusions for the package. The applicant corrects the error and supplements the application with corrected analyses within the allowed 15-day timeframe.

**SHIELDING RSI Examples****Shielding Example No. 1**

**Criteria:** Appendix B, Section 3.1.2, Completeness of Scope.

**Situation:** The applicant's shielding evaluation relies upon computer modeling to demonstrate shielding performance, with a non-standard code, without providing a detailed description of the model, including a sample input file(s), or the code used for the analyses.

**Acceptable for Review?** – No. The applicant needs to provide a description of the model and the non-standard code that enables a reviewer to independently confirm that the model and the code are appropriate for evaluating the proposed shielding design and contents.

**May be Acceptable for Review:** The application may be acceptable if detailed descriptions of the shielding model and the non-standard code are provided. The application should include a description of the underlying analytical method and its limitations, cross-section libraries if used with the code, and a justification of the code's applicability to the shielding design evaluation. The application should have a description of the model that includes the configuration of the shielding (material specifications and dimensions), the source term specification and configuration, other key inputs, and the modeling assumptions, and the basis for modeling assumptions and differences between the model and the actual design (as described in the application). Sample input files should be provided to allow for verification that the shielding model is properly input into the code.

**Shielding Example No. 2**

**Criteria:** Appendix B, Section 3.1.2, Completeness of Scope/Sufficiency of Information.

**Situation:** The applicant performed source term calculations for proposed spent fuel contents having burnup values that are outside the range of burnup values for which the code is validated. The basis for this usage of the code was not provided.

**Acceptable for Review? – No.** The applicant needs to justify the acceptability of the use of the specific computer code outside its validation range, describing the considerations that support that conclusion.

**May be Acceptable for Review:** The application may be acceptable if a basis, or justification, is provided. The applicant should justify using the code and show that the code will accurately predict the source term. The applicant should define the code limitations, if any, of the method(s) used to address these concerns.

### **CONTAINMENT RSI Examples**

#### **Containment Example No. 1**

**Criteria:** Appendix B, Section 3.1.2, Completeness of Scope

**Situation:** The applicant requested approval of a newly designed transportation package. In the safety analysis report, a containment release analysis is not clearly performed, and ANSI N14.5 leak tightness is not cited, nor met. The staff has difficulty to evaluating the integrity of containment system.

**Acceptable for Review? - No,** because applicant is responsible for demonstrating the integrity of containment system, and allowable leak rates, as necessary.

**May be Acceptable for Review If:** If the analysis is readily available within the allowable 15 days time limit, the applicant may be able to supplement the application for staff review.

#### **Containment Example No. 2**

**Criteria:** Appendix B, Section 3.1.2, Use of Precedent

**Situation:** The applicant requested an amendment to the Certificate of Compliance of a previously approved transportation package. In the safety analysis report, the applicant used data and claimed credit which were approved by staff in earlier revisions, but staff determined that this information was no longer valid (e.g., the earlier revision of the package was approved with no hydrogen generation in the package and an activity inventory assumption (i.e., 3000 A2), but the applicant requests new contents in the waste package with no analysis of hydrogen generation and revised source terms). The staff is not able to continue the review because of the lack of a technical basis.

**Acceptable for Review? - No,** because applicant needs to justify its revised basis and assumptions in an amendment request when they are altered by the design change.

**May be Acceptable for Review if:** Perhaps, if within 15 days, the applicant can provide a solid basis, and provide adequate justification for its revised basis and assumptions in the amendment request.

### **Containment Example No. 3**

**Criteria:** Appendix B, Section 3.1.2, Sufficiency of Information

**Situation:** An applicant submits an application for storage/transportation without details of acceptance criteria and test sensitivity for required leakage rate tests during design, fabrication, maintenance, periodic, and pre-shipment stages per ANSI N14.5-1997 standards.

Design leakage test, if applicable, is performed during design evaluation for all containment components. Fabrication leakage test is performed prior to first use of each packaging for the entire containment boundary including welds, seals, closures, valves, and rupture disks. Maintenance leakage tests are required after each maintenance repair. Periodic leakage rate tests are required to confirm that the containment capabilities are not deteriorated over an extended period of use, say, every 12 months. Preshipment leakage tests are required to confirm that the containment system is properly assembled for shipment and the test is to be performed prior to each shipment on seals and valves that have been opened.

**Acceptability for Review?** - No, because the applicant failed to provide complete information as to the procedure, numerical acceptance criteria, and sensitivity of leakage rate test for all the required leakage tests for the particular storage/transportation system.

**May be Acceptable for Review if:** Reviewer identifies which leakage rate tests are applicable for the package. If the applicant provides all the necessary details such as the procedure, equipment, acceptance criteria and sensitivity of the required leakage rate tests, within the specified period, the application is ready for regulatory review.

### **STRUCTURAL RSI Examples**

#### **Structural Example No. 1**

**Criteria:** Appendix B, Section 3.1.2, Completeness of Scope

**Situation:** An applicant has resubmitted a transportation application including a new structural impact limiter analyses. The applicant stated that a revised structural analysis using LS-DYNA was performed for the 30 ft side drop considering a maximum gap between the fuel assembly and support surface as well as the fuel basket and the containment boundary. The applicant also stated that those files do exist, however, those files were not present in the information submitted for review. The applicant did not provide the LS-DYNA output files which would allow the staff to perform an evaluation of the drop.

Previously, staff had suspended review of the application because of significant issues identified with the justification and benchmarking the LS-DYNA model.

**Acceptable for Review?** - No, because the applicant stated that a revised structural analysis using LS-DYNA was performed for the 30 ft side drop considering a maximum gap between the fuel assembly and support surface as well as the fuel basket and the containment boundary. The applicant did not provide the LS-DYNA output files which would allow the staff to perform an evaluation of the drop. The applicant also stated that those files do exist, however, those files were not present in the information submitted for review.

**May be Acceptable for Review if:** If the applicant provides these LS-DYNA output files in a timely manner, then the review can proceed.

### **Structural Example No. 2**

**Criteria:** Appendix B, Section 3.1.2, Regulatory Basis

**Situation:** An applicant has requested an amendment to an existing spent fuel storage certificate of compliance seeking authorization to store certain high burn-up (up to 60 Giga watt-days/metric ton uranium) spent Pressurized Water Reactor fuel assemblies and to include several other changes to enhance the loading and storage operation of the system. The applicant's basis for approval is predicated on both the cladding and the fuel pellet flexural rigidity contributing to the bending strength of individual fuel rods.

**Acceptable for Review? - No,** because the structural evaluations in the RLA compute the flexural rigidity (EI) of the fuel rod as the sum of the flexural rigidity of the cladding and 50 percent of the flexural rigidity of the fuel pellets. The fuel in high burn-up fuel rods is highly fractured and granular, and the rim region between the cladding and the granular fuel is comprised of even finer particles. In addition, during the cooling of the rods after their removal from the reactor the fuel tends to shrink more than the cladding, widening the interface between the granular particles and between the fuel and cladding. Under these conditions it is not physically possible for the fuel to possess bending stiffness, and the NRC Staff knows of no basis for making such an assumption.

**May be Acceptable for Review if:** If the applicant provides revised calculations for the structural evaluation of high burn-up fuel cladding for all evaluations in which the flexural rigidity (EI) of the fuel pellet has been used in the computation of the flexural rigidity of the fuel rod. The revised calculations must only take credit for the flexural rigidity of the fuel cladding in the computation of fuel rod bending stiffness.

### **THERMAL RSI Examples**

#### **Thermal Example No. 1**

**Criteria:** Section 3.1.2, Sufficiency of Information

**Situation:** The applicant submits a thermal-hydraulic analysis of a transfer cask design that includes a liquid neutron shield. The transfer cask is transported horizontally which may limit convection heat transfer in the liquid neutron shield region. In order to take credit for convection the applicant uses a "general" correlation claiming to be applicable for this case without providing any justification or explanation.

**Acceptable for Review? - No,** because in order to use a correlation for an internal cavity, the correlation should have been obtained for similar geometry and boundary conditions. Also, in

order to use the correlation, the applicant should perform an adequate validation applying Computational Fluid Dynamics (CFD) best-practice guidelines.

**May be Acceptable for Review if:** The applicant can demonstrate the correlation is applicable for the considered geometry and the analysis results are either realistic or conservative. Also, proper validation will be necessary so the applicant can use the correlation for similar situations.

**Thermal Example No. 2**

**Criteria:** Section 3.1.2, Sufficiency of Information

**Situation:** The applicant submits a thermal analysis of a vertical, ventilated storage cask design that uses a turbulence model which is applicable only to high Reynolds numbers. It is well known that the flow through the annular gap between the canister and the storage cask is best characterized as transitional.

**Acceptable for Review? - No,** because in order to properly model the transitional air flow through the annular gap, the applicant should use a model that includes transitional effects. Use of a turbulence model only applicable to high Reynolds numbers will overestimate the convection heat transfer in the annular gap.

**May be Acceptable for Review if:** The applicant uses an applicable turbulence model for this type of flow (i.e., a model which includes transitional effects) along with use of CFD best-practice guidelines.

### **Thermal Example No. 3**

**Criteria:** Section 3.1.2, Sufficiency of Information

**Situation:** The applicant submits a two-dimensional (2-D) thermal analysis of a transfer cask claiming this model is conservative as compared to a more detailed three-dimensional analysis model. Axial conduction for this design seems important due to the relatively high thermal conductivity of the basket material and canister. Also, the stored fuel assemblies have an axially varying decay heat profile.

**Acceptable for Review? - A 2D model may be acceptable in some cases if it conservatively estimates heat transfer phenomena for the system, and is validated per the guidance of the SRP.**

**May be Acceptable for Review if:** A 2D model may be acceptable in some cases if it conservatively estimates heat transfer phenomena for the system, and is validated per the guidance of the SRP.

**EXAMPLE OF AN ACCEPTANCE REVIEW CHECKLIST**

TRD Staff may develop specific discipline review checklist to assist in their acceptance review. The following is an example.

**EXAMPLE ACCEPTANCE REVIEW CHECKLIST  
CONTAINMENT****Are the proposed contents clearly described and consistent (Chapters 1 & 4)?**

- General physical forms?
- Chemical forms?
- Radionuclide activities?
- SNF types

ITC: Are the contents described in enough detail (or reasonably limited by acceptable administrative controls), to make a clear determination on the releasable material concentrations and/or hydrogen generation rates?

**For multiple types of SNF contents, is the design basis fuel(s) type for containment specified with a specified bases?****Does the application address hydrogen generation and other chemical/galvanic reactions?**

- Is a calculation of maximum hydrogen concentration and/or user methodology provided for any hydrogen generating materials?

**Is the containment boundary and containment system clearly defined (Drawings & Chapter 4)?**

- Is the proposed configuration of primary containment boundary, secondary containers/lids, inner containers/lids, baskets, bottles, source tubes, etc, and associated leak testing requirements, clearly distinguished?
- Is the containment seal size and material(s) specified?
- Are groove dimensions and parameters specified on drawings?
- Are the leak test /paths ports shown?
- Are the lid bolt torques specified?
- Are containment weldments shown on drawings?

**Are the performance limits for the seals provided?**

- Is a justification provided that demonstrates the containment seal remains intact after the structural and thermal HAC (either by prototype test or analyses)?
- Is justification provided for any drop test results that indicated possible failure of the containment boundary?

ITC: Do the seal temperature limits appear to be consistent with other similar seal materials for other approved packages?

**Are the major elements of the ANSI-N14.5 allowable leakage rate calculations provided in the application ?**

- Internal Volume calculation?
- Effective A2 calculation?
- Release Fraction values?
- Leak Path calculation?
- Allowable leak rate?
- Equivalent leak rates for various test gases?

ITC: Do the A2 values appear generally consistent with the proposed contents?

ITC: Is justification provided for release fractions that are not consistent with ISG-5 Rev. 1??

ITC: Do the ANIS N14.5 calculations appear to be correctly stated and applied as intended?

**Are specific numerical values for proposed leak test rate sensitivities for the ANSI N14.5 tests specified (Chapter 4, 7, & 8)?**

- Design leak test?
- Fabrication leak test?
- Maintenance leak test?
- Periodic leak test?
- Pre-shipment?

ITC: Do the stated allowable leak rates appear to be generally consistent with allowable leak rates for other package and contents of this type?

**Is the testing leak testing method specified (Chapter 7 & 8)?**

ITC: Do they appear to be appropriate for the proposed sensitivities?

ITC: Does the application appear to consider and address relevant containment acceptance criteria (or provide alternate justification) in ISG-5 or ISG-18?

**United States  
Nuclear Regulatory Commission**

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**SFST-14 Appendix E**

# **Summary of Public Comments Not Incorporated**

**Division of Spent Fuel Storage and Transportation**

### **Summary of Five Public Comments Not Incorporated**

**NEI 4, 8, 18a, 29, 31b and NAC 4, 5** – Clarify to what extent industry should provide calculations and analyses to support a Requested Licensing Action (RLA). Industry does not believe regulations require calculations or analyses to be submitted to support RLAs.

Response: Staff requires analyses and calculations to make safety findings. To facilitate a timely review, the applicant should at a minimum provide a summary overview of the calculations and analyses performed. Note that a list may not be enough for staff to make a safety finding.

**NEI 1a and NAC 3** – Industry recommends that the technical acceptance review be performed by or reviewed by experienced SFST technical reviewers.

Response: Staff with appropriate experience and qualifications is assigned to carry out licensing actions. The length of time and effort in performing acceptance reviews is often influenced by resource availability and the initial quality of the application.

**NEI 11 and AREVA** – The type and amount of supplemental information required can vary widely. Industry suggests not including a specific time frame of 15 days for this supplemental information to be provided. The time frame should be agreed upon between the applicant and the SFST PM on a case-specific basis.

Response: If the applicant requires longer than 15 days to provide the supplemental information required for a complete application, then the applicant can resubmit the application on a schedule that works for the applicant, once the TAC is closed and the schedule reset.

**NEI 7, 18b** – Regulatory Guides 3.48, 3.61, and 7.9 are significantly out of date and generally not used by applicants. For example, the SAR chapter numbers and content in RG 3.61 do not align with NUREG-1536. Instead, applicants use the SFST SRPs in developing their SARs. Industry suggests replacing these RGs with NUREGs 1536, 1567, and 1617. There is vagueness in stating what documents the reviewer is using to determine whether the application is complete. Perhaps a listing of possible documents would be appropriate (i.e., SRP, ISG, regulation, Reg. Guide, etc.)

Response: Standard Review Plans are guidance to staff and Regulatory Guides are guidance to applicants. The technical relevance of each type of document is therefore independent in terms of how the documents are used. However, staff intends on updating Regulatory Guides. Reviewers use the regulations, SRPs, ISGs, and Regulatory Guides to make safety findings.

**NEI 1b** – Industry recommends adding a glossary, to include definitions of the following: Acceptance Review, Readily Available Information, and Information Sufficiency (or Insufficiency).

Response. Not Incorporated. Definitions are provided in the procedure for the three examples above. A consolidated glossary of definitions for three items is not provided.

**United States  
Nuclear Regulatory Commission**

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**SFST-14 Appendix F**

# **Public Comments and NRC Responses**

**Division of Spent Fuel Storage and Transportation**

## **Public Comments and NRC Responses**

### **Editorial**

#### **NEI1c**

Industry recommends adding instructions to clearly establish a distinction between reviewer requests for supplemental information to make the application complete and requests that more appropriately should be part of an RAI. (*General*)

Resolution: Incorporated.

#### **NEI6**

Add “if applicable” at the end of the 2nd sentence. (*Section 5, 3<sup>rd</sup> para.*)

Resolution: Incorporated.

#### **NEI9**

Should SFST have as a stated goal of the acceptance review process “zero RAIs” or should it be “an application that is complete and acceptable for review without supplementation”? (*App. B, 1.0, 5th para.*)

Resolution: Incorporated. The stated goal of zero RAIs concerns the overall review process, not the acceptance review. Clarification was provided in the General Requirements Section and Appendix D. Goals for the acceptance review process are adequately described under the Purpose section.

#### **NEI10**

The guidance on electronic submittals is easily found, but not for hard copy submittals. Can a link be included in this section for that guidance? (*App. B, 1.3.2*)

Resolution: Incorporated. Guidance is clear in 10 CFR Part 71.1 for transportation submittals and 10 CFR Part 72.4 for storage submittals. Clarification provided.

#### **NEI13**

The 2nd and 3rd paragraphs appear to be better suited for Section 2.0. Consider relocating them there. (*App. B, 3.0*)

Resolution: Partially incorporated. Clarified text and consolidated paragraphs into one paragraph for Section 3.0.

#### **NEI26**

The first sentence of this paragraph is not clear and appears to have a grammatical error after “RLAs.” Can you clarify? (*App. B, 5.0, last para.*)

Resolution: Incorporated.

**NEI33**

- a) p. 16, 2nd paragraph: Add “Additional” after “for.”
- b) p. 17, 3rd full paragraph: Change “a acceptance review” to “an acceptance review.”
- c) p.21, “Dependent/Linked RLAs”: Add “be” between “may” and “possible.”
- d) p. 22, 5th line from bottom: Delete “to.”
- e) p. 38, Example 2: Change “s” to “is.”
- f) p. 38, Example 3: Delete “have”
- g) p. 39, 2nd paragraph: Change “CFT” to “CFR.”
- h) p. 41, 1st paragraph: Change “has” to “have.”
- i) p. 44, Example 2, ‘Situation’: 2nd sentence should begin “It is well known...”
- j) p. 46, Second ITC question: Change “Does” to “Do”
- k) p. 46, last sentence: Change “other consider” to “consider other.”

Resolution: Incorporated.

**Non-Editorial****NEI1a**

Industry recommends that the technical acceptance review be performed by or reviewed by experienced SFST technical reviewers. (*General*)

Resolution: Not incorporated. Staff with appropriate experience and qualifications is assigned to carry out licensing actions. The length of time and effort in performing acceptance reviews is often influenced by resource availability and the initial quality of the application.

**NEI1b**

Industry recommends adding a glossary, to include definitions of the following: Acceptance Review, Readily Available Information, and Information Sufficiency (or Insufficiency). (*General*)

Resolution. Not Incorporated. Definitions are provided in the procedure for the three examples above. A consolidated glossary of definitions for three items is not provided.

**NEI2**

The 60-day limit for acceptance reviews is appropriate for the more complex applications. Thirty days or less should be suggested as a goal for non-complex applications. (*Section 2, 2<sup>nd</sup> para.*)

Resolution: Incorporated.

**NEI3**

The first sentence states that an acceptance review can obviate the need for a second round of RAIs. We believe that the acceptance review is unrelated to whether a second round of RAIs is needed. The acceptance review can obviate certain first round RAIs that identify missing information or other elements of an incomplete application. The need for second round RAIs should be solely based on the adequacy of the response by the applicant to first round RAIs. There should be no second round RAIs that are based on new areas of review. For example, if a first round RAI response included a new analysis, then a second round RAI may be required pertaining to that analysis, but no RAIs related to new issues should be required at that point

because a complete review of the application should have been performed in creating the first round of RAIs. (*Section 2, 3<sup>rd</sup> para*)

Resolution: Partially incorporated. Any follow up questions or queries to first round RAIs by staff which relate to an incomplete response provided by the applicant are still related to the regulatory issue, basis, and question provided in the first round RAI. Therefore, if the applicant provided an incomplete response, or if subsequent queries arise which deal with analyses provided in the applicant's response, then the follow up queries are still associated with the first round RAI, not a new or second round RAI.

Staff agrees with NEI's assertion that "the acceptance review can obviate certain first round RAIs that identify missing information...." The acceptance review therefore may eliminate the need for second round RAIs on this basis. Staff also agrees "there should rarely be second round RAIs based on new areas of review, however staff may, for varying reasons, identify additional information that is needed to verify a proposed design is safe and compliant with regulations."

#### **NEI4**

The third sentence implies that an application not containing "entire analyses/calculations or unjustified use of unapproved methodologies" may be considered unacceptable. The regulations do not require analyses/calculations to be submitted and the appropriateness of the use of previously unapproved methodologies can only be determined through the detailed staff technical review, not the acceptance review. This statement should be deleted or clarified. (*Section 4.1, 1<sup>st</sup> para.*)

Resolution: Partially Incorporated. Staff partially agrees with this comment. As an example, regulations requiring tests, but subsequently satisfied with analytical calculations that the Commission deems acceptable, are within the purview of the regulatory requirements. Details beyond summary information have been consistently shown to be necessary to make a safety finding. Staff will accept a summary overview of the analytical calculations provided that a) all files and/or calculation packages are thoroughly documented in list form including final revision number and detailed description of the calculation and b) the documented calculations are complete and immediately available to staff upon request during the detailed technical review. Applicants should be aware that by selecting this approach, there is a high likelihood of a longer total review based on past experience of SFST staff. This position is reflected in the OI language and staff does not believe this language needs to be revised at this location in the document. The language is present to emphasize that incomplete or missing calculation packages or missing or incomplete justifications have the potential to extend review times significantly. This language is not implying that the staff cannot make a finding as to whether an application is sufficiently acceptable.

#### **NEI5a**

Clarification is required in these sections as to when the application is considered received by the staff. Is it when SFST receives it (typically via electronic means), when it is entered into the internal NRC ADAMS system, when it is available in the public ADAMS system, or some other milestone? Section 2.0 in particular states that the acceptance review may not begin until an ADAMS accession number is received. These milestones and their definitions should be included in the flow chart in Appendix E. (*App. B: 1.3.2, 2.0, 3<sup>rd</sup> para., and 3.0*)

Resolution: Partially incorporated. Regardless of when the acceptance review is initiated by staff, the applicant should still work to provide an application which follows NRC guidance for ADAMS acceptability of documents. Staff and the Project Manager will work with the applicant regarding receipt of an electronic submission of the application in order to begin the review earlier, if possible, depending on workload and priority. Clarification provided.

**NEI5b**

It should also be made clear that if requests for supplemental information (RSIs) are generated by staff and responded to by the applicant, the application-receipt-date is not affected by these events. (*Appendix C*)

Resolution: Partially incorporated. The receipt date is when staff receives an acceptable application. Therefore, if staff generates RSIs, then the receipt date will be when the applicant responds to the RSIs, if staff determines the RSI responses are sufficient and acceptable. Clarification provided.

**NEI7**

a) Regulatory Guides 3.48, 3.61, and 7.9 are significantly out of date and generally not used by applicants. For example, the SAR chapter numbers and content in RG 3.61 do not align with NUREG-1536. Instead, applicants use the SFST SRPs in developing their SARs. We suggest replacing these RGs with NUREGs 1536, 1567, and 1617. b) The following generic communications may be appropriate to add to the reference section: RIS 2004-11; RIS 2004-20; RIS 2005-27, Rev. 1; RIS 2005-31; and RIS 2007-09. (*Section 10*)

Resolution: Not incorporated. Standard Review Plans are guidance to staff and Regulatory Guides are guidance to applicants. The technical relevance of each type of document is therefore independent in terms of how the documents are used. However, staff intends on updating Regulatory Guides. Staff included RIS 2004-20, RIS 2005-27, and RIS 2007-09 as references.

**NEI8**

The third sentence implies that an application not containing analyses and/or calculations may be considered unacceptable. The regulations do not require analyses/calculations to be submitted. Please clarify this statement to reflect the need to submit adequate summaries of analyses and calculations important to the safety basis of the application in the SAR. (*App. B, 1.0, 3<sup>rd</sup> para.*)

Same response as to NEI4.

**NEI11**

The type and amount of supplemental information required can vary widely. We suggest not including a specific time frame of 15 days for this supplemental information to be provided. The time frame should be agreed upon between the applicant and the SFST PM on a case-specific basis. (*App. B, 1.3.3*)

Resolution: Not incorporated. If the applicant requires longer than 15 days to provide the supplemental information required for a complete application, then the applicant can resubmit

the application on a schedule that works for the applicant, once the TAC is closed and the schedule reset.

**NEI12**

a) Please clarify whether this means an electronic submittal or an electronic copy of a hard-copy submittal. b) Should the electronic copy be provided to both the Document Control Desk and the SFST PM? (*App. B, 2.0, 4th para.*)

Resolution: Incorporated. The applicant should provide an electronic copy of a signed hardcopy submittal whenever possible to potentially expedite the review process. Hardcopies should be provided to the Document Control Desk in accordance with 10 CFR 71.1 and 72.4 and the Project Manager to expedite the start of the acceptance review.

**NEI14**

Administrative Criteria:

a) It would be a clearer presentation of the information to list items 'a' through 'g' in a list format rather than embedded in the paragraph.

Resolution: Incorporated.

b) In item 'g', please clarify the intent of requesting SAR update instructions, the extent to which SAR pages must be provided, and the baseline FSAR to which they apply. Is it the latest revision submitted under 10 CFR 72.248 or may another version be submitted that may include additional changes such as those made under 10 CFR 72.48? See also Comment 'c' below.

Resolution: Incorporated. Clarification was provided. While providing SAR updates may not be required to begin a detailed technical review, providing SAR updates up front may significantly reduce review time as often SAR updates are needed in order for staff to determine regulatory compliance. Therefore, during the acceptance review, staff recommends the applicant provide SAR updates up front rather than later during the review process as part of a RAI.

Specific to Part 72 amendments, the applicant should provide proposed FSAR update pages that are based upon the current design and contents that are proposed for use in the amendment request, including any changes that were made beforehand in accordance with 10 CFR 72.48. The applicant should demarcate, or otherwise indicate, portions of the FSAR and design that were changed in accordance with 10 CFR 72.48, separate from changes requested in the amendment.

c) NRC staff may wish to reconsider having applicants submit SAR pages with the application on a mandatory basis. This could streamline their review. Some site specific license holders do not currently submit FSAR change pages with their Part 72 amendment applications. Under the NRR LAR process suggested in NEI 06-02, applicants describe and justify the proposed changes uniquely in the application without introducing the formality of fitting the information into the FSAR format or submitting SAR change pages. After the Part 50 amendment is approved, the licensee updates the FSAR appropriately to include changes resulting from the amendment. SFST may want to consider adopting this same approach to better focus the technical staff review on the content of the information rather than the format.

Resolution: Incorporated. Clarification provided. While providing SAR updates is not required to begin a detailed technical review, providing SAR updates up front may significantly reduce review time as often SAR updates are needed in order for staff to determine regulatory compliance. Therefore, staff recommends the applicant provide SAR updates up front rather than later during the review process as part of a RAI. If the applicant can, in a clear way describe the SAR change in the application, rather than provide the SAR change outright, then the description may be sufficient for staff to determine regulatory compliance. However, it may behoove the applicant to provide the outright SAR change in order to ensure a timely review by staff.

Specific to Part 72 amendments, the applicant should provide proposed FSAR update pages that are based upon the current design and contents that are proposed for use in the amendment request, including any changes that were made beforehand in accordance with 10 CFR 72.48. The applicant should demarcate, or otherwise indicate, portions of the FSAR and design that were changed in accordance with 10 CFR 72.48, separate from changes requested in the amendment. FSAR update pages are required prior to approval.

d) Please provide instructions clarifying NRC's expectations on the timing for applicants to provide non-proprietary versions of proprietary documents submitted with the application and how that would factor into the acceptance review. (*App. B, 3.1.1*)

Resolution: Incorporated.

#### **NEI15**

Use of Approved Guidance:

- a) Please clarify the meaning of the statement "unapproved guidance not yet approved by the NRC." Do you mean codes and standards approved by the authoring body but not endorsed by the NRC? Because SFST does not formally approve ASME Code Cases as in Part 50, it is unclear how applicants can, or should use approved ASME Code Cases, interpretations, etc.
- b) The instructions should include clear guidance for the staff that new or revised review guidance, such as ISGs, that are still unapproved not be used as a basis for the acceptance review. (*App. B, 3.1.1*)

Resolution: Incorporated.

- a) Text clarified
- b) Text clarified

#### **NEI16**

Additional Criteria:

- a) The instructions state that the applicant "must demonstrate that there are special circumstances present that justify the use of the alternative." This is an inappropriate criterion for use of an alternative to guidance and should be deleted. Applicants are free to offer proposed alternatives to guidance for any reason and justify them appropriately.

Resolution: Incorporated. Reviewing an alternative may require additional review time and resources.

- b) The instructions refer to the applicant not having an NRC-approved QA program. New

applicants may not have an NRC-approved QA program. A request for that approval may be part of the application, which should not render the application unacceptable for review. (Also applies to Administrative Example No. 3) (*App. B, 3.1.1*)

Resolution: Incorporated. Clarification was provided to state a QA program must be approved prior to or a along with a requested licensing action.

#### **NEI17**

Dependent/Linked RLAs:

Please clarify “approval of other RLAs currently under review.” Does “approval” mean issuance of the draft CoC and preliminary SER by SFST or the completion of rulemaking? (*App. B, 3.1.1*)

Resolution: Incorporated. Clarification provided. Typically, approval does mean issuance of the draft CoC and preliminary SER by SFST, unless SFST receives a comment in rulemaking, then SFST must re-evaluate.

#### **NEI18**

Completeness of Scope:

a) The instructions imply computer code input and output files are required to be submitted. This is not consistent with the NRC’s review being an audit review. The regulations require adequate, summary-level information to be submitted to permit NRC to make a safety judgment. Submittal of input/output files should be discretionary and not submitting them with the application should not be a criterion for the staff reviewer to decide whether the applicant is complete.

Resolution: Partially Incorporated. See response to NEI 4.

b) There is vagueness in stating what documents the reviewer is using to determine whether the application is complete. Perhaps a listing of possible documents would be appropriate (i.e., SRP, ISG, regulation, Reg. Guide, etc.) (*App. B, 3.1.2*)

Resolution: Not Incorporated. Required documents are already listed in the OI. Reviewers use the regulations, SRP, ISGs, and Regulatory Guides to make safety findings.

#### **NEI19**

Regulatory Basis:

a) The instructions state that the reviewer determine whether the “applicable regulations and criteria are properly applied.” Application of the regulations and criteria would be the object of the technical review, not the acceptance review. We suggest changing “properly applied” to “properly identified.”

Resolution: Incorporated.

b) The instructions state that meeting guidance criteria is not a regulatory requirement. We believe this should also be clearly stated in Section 2, “General Requirements” as a fundamental principal the reviewers must adhere to, to avoid RAIs where guidance is presented as requirements.

Resolution: Incorporated. Meeting guidance is not a regulatory requirement. However meeting guidance will facilitate a timely review.

c) Please provide an example or two of “specific review standards for RLAs.” (*App. B, 3.1.2*)

Resolution: Partially incorporated. Wording removed.

#### **NEI20**

Use of Issued Guidance:

This section is included in both Section 3.1.1 (for PMs) and 3.1.2 (for technical staff). Please clarify the respective scopes of review in this common area between the two groups. (***App. B, 3.1.2***)

Resolution: Partially incorporated. Project managers and TRD staff work together to determine whether regulatory requirements have been met. Meeting guidance is not a regulatory requirement. However meeting guidance will facilitate a timely review.

#### **NEI21**

Use of Precedent:

a) The instructions state that “staff determination for the use of a precedent may be influenced by new knowledge and information that were not available in the past.” This statement must be presented in the context of safety significance for two reasons: 1) New or different information may or may not be relevant or required to be considered in the review unless a safety nexus is identified. An example would be the use of the latest computer code. Unless a safety-significant error is discovered in a previous code version, applicants are not required to update to the latest code version. 2) NRC could bring into question the validity of their own past SERs approving previous licensing actions.

Resolution: Incorporated. Text modified to clarify the intent and scope of the statement called out above.

b) In the 9th sentence, we suggest the following clarifications: Add “or section” after “page” and add “whichever best helps the Staff to locate the information” at the end of the sentence. (*App. B, 3.1.2*)

Resolution: Incorporated.

#### **NEI22**

“Have proposed alternatives...”: It is implied in this paragraph that a complex alternative could be a reason for calling the application unacceptable. Complexity can affect the review duration, but not acceptability of the application. This should be clarified. (*App. B, 3.1.3*)

Resolution: Incorporated. Text modified for clarity.

**NEI23**

“Identification of Dependencies...”: The applicant should also be responsible for identifying any known dependencies among concurrent submittals in the context of assumptions made pertaining to the successful approval of an in-process amendment request. (*App. B, 3.*)

Resolution: Incorporated.

**NEI24**

The term “poor quality RLA” should be defined to some extent to assure a mutual understanding of what is truly a poor quality application and what is simply a difference in expectations between NRC and the applicant in the content and level of detail contained in an application. As it stands this term is highly subjective. (*App. B, 3.1.3*)

Resolution: Incorporated.

**NEI25**

In the 3rd sentence the guidance states “...(or the information to be submitted is unlikely to be responsive to the NRC staff’s concerns)...” This statement implies that the staff is pre-judging the merits of information not yet submitted. This parenthetical statement should be deleted. (*App. B, 4.2, 4th para.*)

Resolution: Incorporated.

**NEI27**

The sample letter provides for establishing a date for issuing the first RAI. It should also include estimated dates for the vendor RAI response, draft SER/CoC, second RAI and response (if necessary) and rulemaking. We understand that the latter dates would be speculative. (*Sample Acceptance Letter*)

Resolution: Partially incorporated. Second round RAIs are not initially scheduled.

**NEI28**

a) In general, there are several examples of vague wording (e.g., “relatively straightforward”) and unclear applicability in the examples (i.e., does it apply to a storage or transport application?) that could be improved.

Resolution: Incorporated.

**NEI29**

Again, the instruction implies the application must submit detailed computer input files. This extends the NRC review from an audit review to a detailed calculation validation and confirmation that the applicant is using the computer code appropriately. These are activities adequately governed by the applicant’s QA program. NRC can always perform their own independent calculations as part of the review or conduct an inspection of the applicant’s QA program implementation. Applicants are only required to summarize the key inputs, modeling assumptions, and results in the SAR. (*Shielding Example 1*)

Resolution: Staff has reviewed NEI's comment and, in response to that comment, has revised the following example. Staff notes that the current standard review plans for both storage and transportation direct staff to, as part of its review, examine the applicant's computer code input to verify that information from the shielding model (e.g., dimensions, material properties, appropriate cross-section libraries, etc.) is properly included. Staff finds errors in applying computer codes in sufficient quantity to warrant a review of the applicant's input.

### NEI30

The specific example used is not appropriate because a) it gives the reviewer technical review guidance rather than acceptance review guidance and b) the example contradicts previous NRC-approved RLAs that have successfully extrapolated computer codes beyond their formal validation range. This example would be more appropriate if it were modified by removing all references to specific burnup values and additional safety margin. In addition, it is suggested that the criteria be slightly modified to read as follows: "Discussion of computer code validation for the specified range of fuel burnup not provided." This change is proposed because the acceptance review should only be used to determine if the appropriate information is provided, not if that information is technically acceptable. (*Shielding Example 2*)

Resolution: Incorporated. Staff has reviewed NEI's comment and has revised the following example to be more generic and applicable to the scope of an acceptance review.

### NEI31

a) The "Situation" simply states that the applicant has applied for approval to store high burnup fuel and it is considered unacceptable for review. This is incorrect as applicants are permitted to request approval for storage of high burnup fuel. Please delete this example or revise the "Situation" to clearly describe the problem causing the application to be unacceptable. b) The "May be Acceptable" section of this example states that calculations must be submitted. The regulations do not require the submittal of calculations. Calculations only need to be appropriately summarized in the SAR. (*Structural Example No. 2*)

a) Resolution: Incorporated. Text revised.

b) Resolution: Not Incorporated.

Staff disagrees with this comment. For this particular example as a resubmittal that is explicitly evaluating a calculation for adequacy, not including the calculation would prevent the staff from making a safety finding.

Details beyond summary information have been consistently shown to be necessary to make a safety finding. Staff will, in general, accept a summary overview for cases that do not specifically require those files or calculations at the outset of the review provided that a) all files and/or calculation packages are thoroughly documented in list form including final revision number and detailed description of the calculation and b) the documented calculations are complete and immediately available to staff upon request during the detailed technical review. Applicants should be aware that by selecting this approach, there is a high likelihood of a longer total review based on past experience of SFST staff.

### NEI32

This example seems to imply that 2-D modeling could not be used in certain circumstances, notwithstanding the level of conservatism imparted in the model. In certain cases (e.g., low heat

load cases) it is possible to create a 2-D model with sufficiently conservative inputs and assumptions to allow use of less precise, less time-intensive 2-D modeling techniques and still create a bounding model.  
(*Thermal Example No. 3*)

Resolution: Incorporated. Staff agrees that a 2D model may be acceptable in some cases if it conservatively estimates heat transfer phenomena for the system, and is validated per the guidance of the SRP. We have found instances, however, where a 2D model was used non-conservatively.

### **NAC2**

#### 2. Add new Section 2. APPLICABILITY

**“This SFST Office Instruction is applicable to new applications and complex amendment requests. Simple, routine, “straightforward” amendment requests shall undergo a brief acceptance review by the receiving NRC Project Manager (PM) under an appropriately shortened acceptance review schedule not to exceed 30 calendar days from receipt.”**

Renumber subsequent sections.

Resolution: Incorporated.

### **NAC3**

#### 3. Section 2, GENERAL REQUIREMENTS,

Insert after first paragraph:

**“Whenever possible, acceptance review should be performed by experienced staff members familiar with the affected storage or transport system in order to minimize effort and the length of time required to complete the acceptance review.”**

Resolution: Not incorporated. Staff with appropriate experience and qualifications is assigned to carry out licensing actions. The length of time and effort in performing acceptance reviews is often influenced by resource availability and the initial quality of the application.

**NAC4**

4. Section 4.1, Benefits of the Acceptance Review, first paragraph, third sentence states: “When an application lacks critical information necessary for the staff to complete its review (e.g., entire analyses/calculations ...)” implies that analyses and calculations would need to be submitted as part of the applications. Recommend replacing the sentence with **“Identification of critical information (e.g., entire analyses/calculations or justification of unapproved methodologies) necessary for the staff to complete its review during the acceptance review may minimize the amount of staff time required to obtain such information during the technical review.”**

NOTE: The acceptance review should identify the calculations/analyses required by the staff to complete its review. These calculations/analyses will then be provided separately by the applicant. This will minimize submittal and subsequent handling of proprietary calculation packages by the PM. This note also applies to the third paragraph, third sentence of Appendix B, Section 1.0, INTRODUCTION.

Resolution: Not Incorporated. See response to NEI 4.

**NAC5**

5. Section 6.1, Establishment of Schedules and Resources for Acceptance Review, under Technical Review Directorate staff responsibilities, a fourth bullet should be added:

“• **Identification of calculations/analyses required from the applicant to complete the technical review.**”

Resolution: Not Incorporated. See response to NEI 4.

**NAC6**

6. Appendix B, Section 3.1.2, Technical Staff Criteria, fifth bullet, **Use of Approved Guidance** Approved guidance should be defined as follows:

Insert after first sentence:

**“Approved guidance constitutes any of the documents listed that have been published and in effect for a minimum of six months prior to submittal of a Request for License Amendment (RLA) or one year prior to submittal of a new application, except for cases where deviation from approved guidance would result in safety implication.”**

Resolution: Incorporated.

**NAC7**

7. Section 3.1.3, Quality of the Application. The term “poor quality RLA” should be defined in order to communicate NRC expectations more clearly to staff members and applicants. Insert after first paragraph:

**“The application should be written to a standard intended to a reasonably competent professional engineer as the reader. An application is considered of poor quality if any of the following criteria apply:**

- **More than 0.5 typos or formatting (pagination, missing revision bars, etc.) errors per page,**
- **More than 5 % of references in error (no safety significance),**
- **Missing information required by 10 CFR 71 or 72,**
- **Use of non-NRC endorsed methodology without justification,**
- **Deviation from regulatory guidance (Reg. Guide/ISG/NUREG/etc.) without justification,**
- **Any issue with safety significance”**

NOTE Not describing generally accepted engineering principles and assumptions that apply to the discipline being addressed should not result in a “poor quality” determination.

Resolution: Incorporated. Quality issues in a RLA could be:

- More than 5% of references in error,
- Missing information as required by 10 CFR 71 or 10 CFR 72,
- Use of non-NRC endorsed methodology, deviation from regulatory guidance, or use of improper technical justification, or
- Inclusion of issues which render the RLA not in compliance with regulations.

**NAC8**

8. Appendix B, Section 4.2, Licensee or Applicant Supplements to RLA, add new paragraph to the end of the section:

**“The Licensee/Applicant may provide supplemental information during and after the acceptance review period provided the information is either requested by the NRC staff or it corrects an error identified by the Licensee/Applicant and it does not have an adverse impact on the overall schedule and use of NRC resources. In some cases, supplemental information may aid the reviewer and shorten the review time. Acceptance of a Licensee/Applicant initiated supplement will be evaluated on a case-by-case basis to ensure minimal or no impact on the requested or established schedule.”**

Resolution: Partially incorporated. The following was added: “The applicant may provide

supplemental information during and after the acceptance review period provided the information is either requested by the NRC staff or it corrects an error identified by the applicant. Acceptance of the supplemental information will be evaluated on a case by case basis." It is unlikely this supplemental information would shorten the review time. It would more likely prevent the review time from being lengthened.

## **AREVA**

Comment:

I believe it is important to keep a clear line between submittal deficiencies which justify rejection of the submittal, and deficiencies which qualify for a RAI (Request for Additional Information). There is the potential for the acceptance review itself to become the first round of RAIs, sort of like "RAI zero". That would be the case if the staff identifies a list of missing information which must be supplied within 15 days or the application is rejected. I think the key is to clearly state the KIND of missing information that qualifies for rejection of the submittal.

I think the distinctive difference is this: missing information which is of such a fundamental nature that it either prevents detailed review, or makes such further review non-meaningful or ambiguous, is the kind which justifies rejection of the submittal. Missing information that should be noted in an RAI is information that is necessary in its own right, but does not significantly affect review of other parts of the submittal. Here are some examples:

Causes for rejection of the submittal:

1. The applicant uses a computer code that is clearly obsolete to do shielding or criticality analyses. The shielding or criticality results cannot be reviewed.
2. The applicant fails to specify the governing temperature for the NCT structural analyses, making all further determination of allowable stresses ambiguous.
3. Materials are not sufficiently identified on the General Arrangement drawings to allow meaningful review of the thermal analysis - heat paths cannot be defined, materials conducting heat cannot be identified. The thermal review cannot be performed.

Deficiencies that should be handled by RAIs:

1. The applicant fails to adequately discuss corrosion of the structural materials. The rest of the structural review is unimpeded.
2. The applicant completely omits any discussion of how the relevant properties of the redwood in the impact limiter will be controlled. The rest of the structural review is unimpeded.
3. The applicant uses unapproved guidance for a buckling analysis in an appendix. The rest of the structural review is unimpeded.
4. The physical configuration of the package going into the fire is not clearly stated. The rest of the thermal review is unimpeded.

I think also that the rejection of a submittal is something that should be avoided if possible - the "bias" should be against it, unless the deficiencies are egregious. It should be an action that BOTH the applicant AND the NRC dread taking.

If the applicant has met with the NRC once or twice during the development phase of the application, and if the staff concerns are properly heeded, there should be no reason to reject the application. There will be RAIs, but no cause to reject.

Note also that in cases of significant missing information, 15 days may be insufficient to supply the lack. If, as I fear, this process morphs into "RAI zero", it will be a negative development, since standard RAIs have at least one month for responses, the application is safely placed in the queue, and the response time is negotiable. In the case of the acceptance review, the response time is shorter and not negotiable, and the review schedule is indeterminate.

In summary, I believe strongly that rejection of submittals for RLAs should be limited to cases where major portions of the detailed technical review would be significantly hampered or rendered futile by the deficiencies. For deficiencies of a more "stand alone" nature (even if significant in themselves), the standard RAI is the appropriate action.

Resolution: Clarification was provided in the General Requirements section to establish a distinction between reviewer requests for supplemental information and requests that more appropriately should be part of an RAI. The 15 days for responding to RSIs remains unchanged. If the applicant requires longer than 15 days to provide supplemental information required for a complete application, then the applicant can resubmit the application on a schedule that works for the applicant, once the TAC is closed and the schedule reset.

**United States  
Nuclear Regulatory Commission**

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## **SFST-14 Appendix G**

# **Acceptance Review Process Flowchart**

**Division of Spent Fuel Storage and Transportation**