### U.S. Nuclear Regulatory Commission

### DRAFT 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 the 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."

Overall SFST Philosophy and Expectation: Licensing casework is of very high priority in SFST as documented in SFST Office Instruction - 10. Case reviews must focus on both safety and timeliness, as both are essential to the Office's mission. Safety will not be compromised for any reason. The acceptance review process supports both safety and timeliness by helping ensure that applicants provide adequate information to support detailed staff review of applications falling within the scope of this office instruction. The staff's objective is to complete its reviews on the original schedule provided to the applicant. Achieving this objective requires the applicant to submit a complete application and the staff to do an efficient and timely review.

#### 2. <u>GENERAL REQUIREMENTS</u>

The regulations in 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceeding and Issuance of Orders," prescribe the requirements for determining the acceptability of an application for an amendment of a license or a new license. In accordance with 10 CFR Part 2.101(a), 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. Although Part 71 and Part 72 refer to specific licensing actions submitted by a licensee, certificate holder, or an applicant for a license or Certificate of Compliance (CoC), all such actions are identified as Requested Licensing Actions (RLAs) in this office instruction.

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 not only to conduct a detailed technical review, but to complete it within a predictable timeframe. The Standard Review Plans (SRPs), listed in Reference Section 10 of this instruction, along with applicable 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. However, 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.

Requests for Information (RAIs): Performance of an adequate acceptance review, using the Division's technical assets, should in many cases obviate the need for a second round of Requests for Additional Information (RAIs). The Division's goal, along with the applicant's goal, is zero RAIs, SFST recognizes one round of RAIs will often be needed. By helping ensure "up front" that an application contains sufficient information for the staff's review, the need for a second round of RAIs should be reduced or eliminated. 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 to do a complete detailed review before any RAIs are sent.

SFST Metrics: SFST's internal metric clock starts when SFST receives an acceptable application.

#### 3. 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, an 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 licensees or applicants and the public. Specific objectives include the following:

- Promote the submission of acceptable RLAs by licensees and applicants;
- Provide general guidance to NRC staff, licensees and applicants, and the public defining acceptable RLAs;
- Allow 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

• Ensure effective internal and external communications.

#### 4. BACKGROUND AND GENERAL GUIDANCE

#### 4.1 <u>Benefits of the Acceptance Review</u>

The quality of an 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 licensee or applicant. When an application lacks critical information necessary for the staff to complete its review (e.g., entire analyses/calculations or unjustified use of unapproved methodologies), an inordinate amount of staff time may be required to obtain this information. Additionally, time spent on reviewing RLAs that are unacceptable for review results in longer review periods for the RLA and adversely impacts the resources and schedules for the review of other, acceptable, RLAs.

A thorough acceptance review is integral to the efficient review of an RLA. The early identification of insufficient information benefits both staff and the applicant. The staff benefits by identifying informational needs earlier and expending fewer resources completing its overall review. The applicant benefits by understanding potential NRC staff concerns and needs earlier, in addition to getting faster decisions on RLAs.

#### 4.2 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 application 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). This Office Instruction does not apply to exemption requests. 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 determine that a detailed acceptance review, in accordance with this office instruction, is not required. The Branch Chiefs (BCs) will jointly decide whether or not an acceptance review is required. This Office Instruction should not be applied to RLAs that require a regulatory decision in such a limited time that performance of an acceptance review would not be practicable.

SFST will consider an RLA to be acceptable for a detailed technical review upon staff's conclusion that the application appears to contain sufficient technical information, both in scope

and depth, to complete the detailed technical review and render, in an appropriate time frame for the associated action, an independent assessment of the proposed action with regard to applicable regulatory requirements and the protection of public health, safety, and security.

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 or supplemented by the applicant.

#### 5. <u>RESPONSIBILITIES AND AUTHORITIES</u>

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 contact 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 program. 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 that documents are submitted properly and comply with NRC guidance for electronic submittals. The NRC public web site provides guidance on how to submit documents electronically to the NRC. However, in order to support SFST's overall philosophy and expectation in section 1, staff will on a case by case basis, depending on workload, case familiarity, and priority, begin RLA review in parallel with inputting the RLA into ADAMS. In this way, staff may begin case reviews earlier, if possible.

#### 6. ACCEPTANCE REVIEW PROCESS

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.

#### 6.1 <u>Establishment of Schedules and Resources for Acceptance Review</u>

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;
- Ensuring 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 (i.e., one week), the PM should contact the ADAMS administrator and the applicant and coordinate accordingly.
- With the coordination of Branch Chiefs, establishment of a schedule and identification of appropriate technical branches needed to support these reviews for both the acceptance review and detailed technical review;
- Promptly distributing copies of the RLA and associated documents or making 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); and
- Dissemination of RLA documents and revisions, following the acceptance review process, to support the schedule for the detailed technical review process.

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

- Prompt assignment of technical reviewers by the TRD BCs.
- Prompt acceptance review of the RLA in accordance with associated acceptance review schedule by the TRD staff.
- As part of the acceptance review, identification of technical disciplines required to perform the ensuing detailed technical review.

#### 6.2 <u>Review of the Application for Administrative and Technical Sufficiency</u>

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

- Review the submittal 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 information insufficiencies, assist in determining the significance of technical insufficiencies (identified by TRD staff), and make recommendations to SFST management;

- Notify SFST 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 information insufficiencies found to the Licensing BC and technical staff as soon as possible, but no later than 5 weeks from the receipt of the RLA by the NRC; and
- Notify management, as early as possible, of potential failures to meet an acceptance review schedule.

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

- Review the RLA for technical sufficiency in accordance with Appendix B, "Guide for Performing Acceptance Reviews," of this Office Instruction;
- Communicate results of the acceptance review to technical BCs and the PM as soon as possible, but no later than 5 weeks from the date of receipt of the RLA by the NRC. Provide a recommendation to TRD management and the PM, in parallel, regarding the significance of any technical information insufficiencies;
- Notify TRD BCs (as soon as conflicts are identified) of workload conflicts associated with performing an acceptance review. The Branch Chief is responsible for resolution of workload conflicts; and
- TRD Branch Chief, in coordination with the PM, will notify division-level management of potential failures to meet an acceptance review schedule.

#### 6.3 <u>Resolution of Information Insufficiencies</u>

PMs are responsible for the following activities regarding the resolution of any information insufficiencies (see Appendix B, Section 1.3.4 for the definition of an information insufficiency):

- 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 (normally 15 days after receipt of insufficiency letter);
- If required, contact the licensee or 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 division-level management and technical branches of whether the licensee or applicant intends to supplement its RLA within 15 days;

- Generate a letter to the licensee or applicant identifying the information needed and the verbally-established deadline;
- Coordinate any necessary interfaces with other offices (e.g., Office of General Council (OGC), Office of Federal and State Materials and Environmental Management Programs (FSME), Office of Nuclear Security and Incident Response (NSIR), etc.); and
- Notify management and technical branches of any significant change in the schedule.

TRD staff are responsible for the following activities regarding the resolution of any information insufficiencies:

- Prompt verbal and written notification of the information insufficiency to their BCs, the PM (sufficiency will be written up in the RAI format, as specified in SFST Office Instruction No. 3);
- Provide written input to the PM documenting information insufficiencies (an e-mail with Branch Chief concurrence is acceptable);
- Support the PM in discussions with the licensee or applicant to explain the requested supplemental information;
- Review the supplemental information for responsiveness to the NRC staff's concerns within 15 working days of distribution by the PM;
- Inform the PM of any conflicting responsibilities that may adversely impact the schedule; and
- Support the PM in briefing SFST management.

The Branch Chiefs are responsible for the following activities regarding the resolution of any information insufficiencies:

- Support and guide the staff in determining the appropriate course of resolution for the information insufficiencies;
- 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, when appropriate, by informing SFST management;
- Ensure consistency in the conduct of acceptance reviews;

- Facilitate peer reviews, when appropriate, to confirm the information insufficiency prior to contacting the licensee or applicant; and
- Ensure timely communication of the status of these reviews and any adverse impacts on office resources to SFST management.

The SFST Deputy Division Directors (DDDs) are responsible for the following activities regarding the resolution of any information insufficiencies:

- Maintain an awareness of other SFST activities and how these may affect the RLA review schedule and other resources;
- Work collaboratively to revise schedules and resources, as appropriate, to effectively support office priorities; and
- Ensure consistency in the administration of acceptance reviews.

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

- Ensure all applicable regulatory requirements, guidance, and policy are accurately and consistently presented;
- Ensure consistency in the administration of acceptance reviews; and
- Monitor the effectiveness of this process.

#### 6.4 Implementation and Documentation of Results

PMs are responsible for the following activities regarding the implementation and 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;
- Coordinate the dissemination of any RLA supplement to the technical branches; and
- Notify the applicant of the results of the acceptance review activities.

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

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

• Support the PM in documenting the results of the acceptance review.

#### 6.5 <u>Review of the Supplemental Information (If Required)</u>

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

- Review the supplemental information within 15 working 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; and
- Notify the applicant of the results of the supplemental information reviews.

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

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

#### 7. PERFORMANCE MEASURES (Performed by the Licensing Branch (LB) BC)

Appropriate metrics to support the acceptance review procedure will be provided in the SFST Division operating plan. Because it is the intent of this office instruction to identify all "show-stopper" or "fatal flaw" deficiencies during the acceptance review, the percentage of applications denied after the full technical review is an important metric to determine the effectiveness of the acceptance review process. SFST Management will establish criteria to evaluate the overall progress and success of the acceptance review program. These criteria will be used to review the initial implementation of the program. For timeliness metrics purposes, the RLA will be considered received by the NRC the day NRC receives an acceptable application.

#### 7.0 PRIMARY CONTACT

SFST/Licensing Branch 301-492-3321 Christopher.Staab@nrc.gov SFST/TRD 301-492-3286 Jason.Piotter@nrc.gov

#### 8.0 **RESPONSIBLE ORGANIZATION**

SFST/Licensing Branch

SFST/TRD

#### 9.0 EFFECTIVE DATE

February 2009

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).

#### 10.0 <u>REFERENCES</u>

- 10.1 10 CFR 2.101
- 10.2 10 CFR Part 71, 10 CFR Part 72

10.3 NMSS Policy and Procedures Letter (P&PL) 1-51, dated April 10, 1997, revised September 1999

10.4 Regulatory Guide 3.48, "Standard Format and Content for the Safety Analysis Report for an Independent Spent Fuel Storage Installation."

10.5 Regulatory Guide 3.61, "Standard Format and Content for a Topical Safety Analysis Report for a Spent Fuel Dry Storage Cask."

10.6 Regulatory Guide 7.9, "Standard Format and content for Part 71 Applications for Approval of Packaging for Radioactive Materials."

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: Flow Chart (Under Development)

#### Appendix A - Change History

#### Office Instruction SFST-14 "Acceptance Review Procedure"

| SFST No 14 - Change History - Page 1 |  |  |                   |  |
|--------------------------------------|--|--|-------------------|--|
| Revision<br>Date                     | Description of Changes   | Method<br>Used to<br>Announce<br>&<br>Distribute | Training          |  |
| March<br>2009                        | Replaced Acknowledgement Reviews with<br>Acceptance Review Procedure | E-mail to staff                                  | Training Sessions |  |
|                                      |  |  |                   |  |

United States Nuclear Regulatory Commission

SFST-14 Appendix B

# Guide for Performing Acceptance Reviews

**Division of Spent Fuel Storage and Transportation** 

### Appendix B

### 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   | Internal 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

Overall SFST Philosophy and Expectation: Licensing casework is of very high priority in SFST as documented in SFST Office Instruction - 10. Case reviews must focus on both safety and timeliness, as both are essential to the Office's mission. Safety will not be compromised for any reason. The acceptance review process supports both safety and timeliness by helping ensure that applicants provide adequate information to support detailed staff review of applications falling within the scope of this office instruction. The staff's objective is to complete its reviews on the original schedule provided to the applicant. Achieving this objective requires the applicant to submit a complete application and the staff to do an efficient and timely review.

This Office Instruction intends to meet SFST's overall philosophy and expectations and provide staff in 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), with a basic framework for performing an acceptance review of a requested licensing action (RLA). The Office Instruction is for use by Project Managers (PMs), technical staff, and their respective management. Additionally, this Office Instruction is for use by NRC staff in other organizations/offices when they are performing an acceptance review of an RLA at the request of SFST. The PM shall follow the appropriate procedure for requesting work from another office (e.g., the Technical Assistance Request process). This Office Instruction provides a general description of the acceptance review procedure to be followed. However, it is recognized that RLAs are reviewed under various conditions that may require flexibility in the planning and execution of application reviews. This Office Instruction is intended to allow that necessary measure of flexibility. This Office Instruction does not apply to exemptions or requested licensing actions that require a regulatory decision in such a limited time that performance of an acceptance review would not be practicable. Selected 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 PM may determine that a detailed acceptance review, in accordance with this Office Instruction, is not required, and may meet with the Branch Chiefs (BCs) to discuss this detailed acceptance review. The BCs will jointly decide whether or not an acceptance review is required. The acceptance review only accepts the RLA for further review, and no safety or regulatory determinations are made regarding the contents of the application.

The quality of an RLA has a significant impact on the amount of NRC staff resources expended in the technical review process. RLAs that include information of sufficient scope and depth allow staff to focus its efforts on reviewing the technical and regulatory merits of the information provided in the application. When an application lacks critical information necessary for staff to complete its review (e.g., sections, analyses, calculations, justifications for departure from published guidance), an inordinate amount of staff time is spent gathering this information. Additionally, time spent on RLAs that are unacceptable for review results in longer review periods for the RLA and adversely impacts the resources and schedules for review of other, acceptable, RLAs.

A thorough acceptance review is integral to the efficient review of an RLA. The early identification of insufficient information benefits both staff and the licensee or applicant. The NRC staff benefits by identifying informational needs earlier and expending less resources in

completing its detailed technical review. The applicant benefits by understanding potential NRC staff concerns and needs earlier, in addition to getting faster decisions on RLAs.

Requests for Information (RAIs): Performance of an adequate acceptance review, using the Division's technical assets, should in many cases obviate the need for a second round of Requests for Additional Information (RAIs). The Division's goal, along with the applicant's goal, is zero RAIs, SFST recognizes one round of RAIs will often be needed. By helping ensure "up front" that an application contains sufficient information for the staff's review, the need for a second round of RAIs should be reduced or eliminated. 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 to do a complete detailed review before any RAIs are sent.

SFST Metrics: SFST's internal metric clock starts when SFST receives an acceptable application.

#### 1.1 <u>Objectives</u>

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 <u>Process Overview</u>

The staff's overall review process for RLAs begins with the acceptance review as described in this Office Instruction. The performance of an acceptance review is an important part of the overall review of RLAs. When properly implemented, acceptance reviews will allow for a more effective and efficient use of staff resources and promotes the submittal of RLAs that are acceptable for staff review. PMs, technical staff, and applicants should be in regular contact to discuss NRC's ongoing reviews. Frequent and early communications between the staff and the applicant can help avoid unnecessary delays in processing submittals. Pre-application meetings or conference calls (discussions regarding future RLAs prior to the request being

submitted) between the applicants and staff members can be beneficial and are encouraged. Unless otherwise noted, all time frames discussed in this guide are defined as calendar days.

The Technical Review Directorate (TRD), Licensing and Inspection Directorate (LID), and Branch Chiefs (BCs) will evaluate the complexity and uniqueness of the RLA and determine how the acceptance review shall be accomplished to achieve maximum review efficiency and effectiveness. The TRD staff selected for performing the acceptance reviews should be experienced reviewers, knowledgeable in their areas of review. Typically, technical staff performing the acceptance review will be assigned to perform the detailed technical review. However, at the discretion of the BC, during the initial implementation of this office instruction, core discipline acceptance review teams may be formed for performing the initial acceptance review activities; thus, a reviewer may be assigned to do the acceptance review and a different reviewer be assigned to do the detailed technical review.

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 40 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 a 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 any information insufficiencies; and
- Documentation of results.
- 1.3 <u>Definitions</u>
- 1.3.1 Acceptable for Review

A determination made by the NRC staff that the application appears to contain reasonably sufficient technical information, both in scope and depth, for staff to complete a detailed technical review, and render, in a predictable timeframe (no more than one round of Requests for Additional Information (RAIs)) for the associated action, an independent assessment of the RLA with regard to meeting applicable regulatory requirements and the protection of public health, safety, and security.

#### 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 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 in section 1, staff will on a case by case basis, depending on workload, case familiarity, and priority, begin RLA review in parallel with inputting 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 licensee or applicant within a reasonable time frame such that the staff's review resources and schedules will not be adversely affected and the review, in its entirety, 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 office metrics for timeliness goals. Information that is readily available should not take longer than 15 days to be submitted to the NRC staff.

#### 1.3.4 Information Sufficiency

Failure of an RLA to meet one or more of the Section 3.1 acceptance review criteria is indicative of an unacceptable application. However, these criteria are neither all inclusive nor absolute and staff discretion and judgment should be a part of the process.

#### 2.0 DISTRIBUTION AND INVOLVEMENT

When the applicant or licensee submits the RLA, they 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 PMs will inform their branch chief, open a technical assignment control (TAC) number, 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 for informing the PM of any information needs (including access to the initial submittal).

The formal scheduling and performance of the acceptance review may not begin until an ADAMS Accession number is received. This is why 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.

To facilitate the review process and decrease the overall NRC review time as seen by the applicant, applicants or licensees should submit an electronic copy of the submittal whenever possible.

The PM is responsible for notifying the applicant that the acceptance review has begun. This notification may be by e-mail (See example e-mail in Appendix C of this office instruction). This notification should be made within 5 working days after the RLA has been successfully entered into ADAMS, or earlier if possible. The PM should ensure that these notifications are properly captured as Official Agency Records (OARs).

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

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

The PM and technical staff should complete the administrative and technical acceptance review process as soon as practical, however, should not take longer than 60 days of receipt of the RLA by the NRC. Staff may complete the acceptance review earlier depending on need, complexity, and/or workload. The technical staff should identify, to the PM, any information insufficiencies within 5 weeks of the date of receipt of the RLA by the NRC (within 4 weeks of the date TRD staff receives the RLA from the PM). Likewise, the PM should identify, to the technical staff, any information insufficiencies within 5 weeks of the date of receipt of the date of receipt of the RLA by the NRC. If the RLA is determined to be acceptable, the PM will send an e-mail to the applicant informing that the RLA has been found to be acceptable and that a letter will be prepared and sent (in accordance with SFST Office Instruction No. 4) identifying the schedule for completing the detailed technical review.

If there are factors that would justify a longer acceptance review period for the acceptance review, or a delayed start due to unavailability of staff, the PM and technical staff must obtain approval of the SFST Management (both TRD and LID Deputy Directors).

Due to the limited time available to perform the review, the staff should recognize that other, inprogress, reviews may be impacted by performance of the acceptance review. If other work efforts have the potential to be impacted by the performance of the acceptance review, the appropriate branch chief shall assign priority, reassign, or reschedule work as appropriate.

#### 3.1 Acceptance Review Criteria

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 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, "Information Insufficiency Examples," contains examples of information insufficiencies that may occur and a discussion of each as to whether it would or would not 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. For example, transportation project managers are responsible for sections 1, 7, and 8 and the technical staff is responsible for sections 2 – 7 of the SAR as contained in the Standard Review Plan for Transportation Packages for Radioactive Material. Responsibility may overlap in areas; however, to ensure responsibilities are as clear as possible in order to ensure the Division's timeliness goals are observed, project managers and technical staff are responsible for the following criteria as they apply to the application sections that each reviewer is cognizant.

#### 3.1.1 PM Criteria

- Administrative Criteria: Determine whether the RLA addresses appropriate regulatory and administrative criteria, including: a) Identify actions where applicants have requested an expedited review, and have a basis for the expedited review; b) Determine whether the applicant identifies deviations from the Standard Review Plan (SRP) or Internal Staff Guidance (ISG), concerning application sections that the project manager is cognizant; c) Verify the applicant identifies proprietary information, that it is properly identified, justified, and provides the proper 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; d) Verify attachments are included and that significant references are available; e) Ensure contents of the application that the project manager is cognizant are legible and coherent (contents may include evaluations, drawings, and data tables); f) Ensure that the format and content of the application sections that the project manager is cognizant is consistent with established criteria, and that deviations are explained and applicable references are provided; and g) Confirm that the applicant provided instructions on updating NRC's copy of the Safety Analysis Report (SAR) (a current, complete application – amendment or otherwise- is needed prior to beginning the ensuing detailed technical review). Administrative criteria, though often easily corrected, should be met prior to acceptance for the ensuing detailed technical review.
- Use of Approved Guidance: Determine whether the RLA cites any unapproved guidance not yet approved by the NRC, or draft American Society of Mechanical Engineers (ASME) Code cases. Unapproved guidance 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 guidance. Simply citing unapproved guidance is not acceptable. Perform a cursory review to determine if any reference guidance or documents have been mis-applied and ensure that the safety analyses report for the RLA is clear.

- 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 not only justify the acceptability of the proposed alternative, but must demonstrate that there are special circumstances present that justify the use of the alternative. Another example would be failure of the applicant to have an NRC approved quality assurance program.
- **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. Recognizing that the NRC previously accepted linked RLAs, linked RLAs will be allowable for a period of 6 months from the date of issuance of this procedure. Linked RLAs allowed during this period need to have been discussed prior to submittal of the RLA and agreed upon by the NRC staff. 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 cask design or transportation package or Technical Specifications (TSs) are unrelated and not necessarily linked, it may possible to issue these RLAs in any order and without regard to the results of the review of the others.

#### 3.1.2 Technical Staff Criteria

- **Completeness of Scope:** Determine if there are significant analyses or evaluations missing from the RLA in their entirety, as provided for in the applicable SRP or ISG. Ensure representative input/output files for any relevant calculation packages are included. Often, the appropriate analysis scope and depth are designated in industry codes and standards, NRC Regulatory Guides, Regulatory Issue Summaries, etc. 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 site the basis for the needed analysis (SRP, ISG, regulation, industry standard, etc.).
- Sufficiency of Information: Determine if the RLA provides the expected content identified in the related SRP sections or ISG. Determine if the RLA contains sufficient technical information in scope and depth to begin and complete the detailed technical review within a predicable 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 applied. The applicant should identify the criteria used to determine that the RLA meets regulatory requirements. The staff may use guidance documents such as the SRP, ISG, or specific review standards 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 Approved Guidance: Determine whether any approved 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 are imposed by the document itself. Using unapproved standards, or codes (or the use of codes outside the limitations endorsed by the NRC staff) may be acceptable when the licensee or applicant has provided a full analysis to justify why the proposed use is appropriate. However, simply referencing an unapproved standard, code or code case is unacceptable. Additionally, deviations from guidance should not be considered acceptable unless fully justified. If reports are cited in the RLA, sufficient information shall 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 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 knowledge and information that were not available in the past). Regardless, the application, alone, must contain sufficient information for staff to make its regulatory decision. 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 to be provided. If a large document over 20 pages is cited, the page numbers of the citation should be identified. Because certain past staff approvals may be based on unique or specific provisions contained in the SARs, its use in another SAR may not be appropriate unless the applicant addresses all of the provisions which the staff

considered when approving the precedent. In all instances, the applicant needs to provide information that indicates the basis for the 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 of the Application

The overall quality of the RLA may significantly impact staff's ability to complete the ensuing detailed technical review in a timely manner and predictable timeframe. A poor quality RLA may be found acceptable for review during the acceptance review process, however staff may determine that because of the poor quality of the application, an additional-abnormal amount of review time will be required. Poor quality may significantly impact the detailed technical review schedule. In certain instances, poor overall quality may be justification for staff not to accept an application. The following should be considered when determining how poor quality 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? How complex are the proposed alternatives? Is the basis and justification for proposed alternatives or omissions to SRP provisions sufficient or very weak?

**Identification of Dependencies among Concurrent Reviews:** The technical staff 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 identified by the technical staff 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).

Identification of quality concerns in an acceptable RLA that will impact (cause significant longer than normal review time) the technical review schedule: The RLA is of marginal quality. The application is considered minimally acceptable for staff to begin the detailed technical review. Because of the quality concerns, staff has determined that the RLA can not be completed within a predictable timeframe because it may lack certain information which would prevent the staff from being able to develop a specific review schedule. In such cases the technical review can be started, but the staff would not issue an associated review schedule. A letter should be sent to the applicant identifying the quality related shortcomings. However, the staff has the option to not accept the RLA and not issue a schedule based on the poor quality of an application. A meeting with the applicant may be required to convey this information. The applicant may decide to voluntarily supplement the RLA. Following receipt of an acceptable modified RLA, the staff would then establish the review schedule.

#### 3.2 <u>Acceptance Review Results</u>

#### 3.2.1 Unacceptable With No Opportunity to Supplement

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 licensee or applicant as unacceptable for review, pursuant to 10 CFR 2.101. 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 licensee or 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 licensee or 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. An example of a non-acceptance letter for an RLA is provided in Appendix C.

#### 3.2.2 Unacceptable With Opportunity To Supplement

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.

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.

If an applicant submits supplemental information, the review schedule for that RLA is reset and if the supplemental information is considered acceptable for the staff to conduct a detailed technical review, a new review schedule is established "the review clock starts over."

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

#### 3.2.3 Acceptable for Review

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 licensee or applicant per Section 6.0, "Documentation of an Application Found Acceptable for NRC Staff Review."

#### 4.0 **RESOLUTION OF INFORMATION INSUFFICIENCIES**

Upon determination that an RLA contains insufficient information to be considered acceptable for review, the PM (with support of the technical staff) should compile a list of the insufficiencies and ensure that the associated BCs are informed of the insufficiencies. 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 information insufficiencies prior to contacting the licensee or 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 <u>Discussion of Information Insufficiencies with the Applicants</u>

The PM should inform the applicant that the RLA has been found unacceptable for review and set up a conference call to discuss the information deficiencies. This call should occur as soon as possible, but no longer than one week from notifying the applicant of 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 in draft form, via an e-mail, prior to the call. Regardless of the method used to transmit the identified insufficiencies 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 information insufficiencies, 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).

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. In other words, SFST's internal metric clock starts when SFST receives an acceptable application.

Following the call, 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, as approved by the LID DDD, and if requested by the applicant, may arrange a meeting with the applicant to discuss the insufficient information. A public meeting will be held to discuss the insufficient information and will require 10 days advance notification. Again, in accordance with SFST's Rules of Engagement (see SFST Office Instruction No. 15), should the applicant request this type of meeting, the "clock" starts over with respect to the number of days to review the RLA.

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, "Licensee or 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 Licensee or Applicant Supplements to RLA

Regardless of whether the staff believes that the RLA can be supplemented with readily available information, or if the licensee or applicant indicated a preference to withdraw the application, a letter requesting supplemental information should be sent to the licensee or 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 pursuant to 10 CFR 2.101.

This letter should be sent to the licensee or 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. Staff may complete the acceptance review earlier depending on need, complexity, and/or workload.

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 licensee or 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 licensee or 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 pursuant to 10 CFR 2.101.

If the licensee or 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 pursuant to 10 CFR 2.101. This course of action should also be considered in the event that the staff determines the information provided by the licensee or applicant continues to be insufficient.

If the information provided is both timely and responsive, notify the licensee in accordance with Section 6.0 and transition into a detailed technical review.

#### 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 licensee or 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. OGC may be informed of the situation and the proposed action. 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 licensee.

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

# Note: When communicating the non-acceptance of an RLA to the licensee or 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, pursuant to 10 CFR 2.101, the licensee or 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 licensee or 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, the letter of nonacceptance of the RLA should be issued within 15 days of the deadline established for supplementing the RLA, depending on OGC interactions. If the supplement is found to be unresponsive to the NRC staff's concerns, the letter of non-acceptance of the RLA should be issued within 15 days of this determination, depending on OGC interactions (which is 15 days following receipt of the supplement, per Section 4.2 of this Office Instruction).

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 licensees or 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.

Requests to discuss a non-accepted RLA with staff should be treated as pre-application meetings and will be entertained only if they do not adversely impact the staff's review of the RLAs must have been accepted for review. The NRC staff should treat these discussions as they would a pre-application discussion for the re-submission of any RLA.

#### 6.0 <u>DOCUMENTATION OF AN APPLICATION FOUND ACCEPTABLE FOR NRC STAFF</u> <u>REVIEW</u>

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 licensee or applicant. An example letter is provided in Appendix C.

Typically, if the licensee's submittal was found to be acceptable without any supplements, an email 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 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. In other words, 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.

United States Nuclear Regulatory Commission

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]. 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 LICENSEE 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, 72.11,10 CFR 2.101]. NRC staff activities on the review have ceased and the associated Technical Assignment Control number has been closed.]

[IF THE LICENSEE 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 pursuant to 10 CFR 2.101. 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 pursuant to 10 CFR 2.101. 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

SFST-14 Appendix D

# Guide for Performing Acceptance Reviews, Information Insufficiency Examples

**Division of Spent Fuel Storage and Transportation** 

#### **Examples of Informational Insufficiencies**

The purpose of the examples included in this Appendix is to better delineate where an informational insufficiency 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**

#### 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 agees 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 s submitted and does not include a complete Package Operations in Section 7 of the of the Safety Analysis Report (SAR).

**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 the omitted sections of Package Operations section within 15 days.

#### Administrative Example No. 3

**Criteria:** Failure to have hold 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, and 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 CFT Part 71, or if the applicant is the DOE, and QA requirements have been addressed in Chapter 9 of the application.

#### **MATERIALS**

#### Materials Example No. 1

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

**Situation:** The licensee 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 technical data, analyses, etc.

#### **CRITICALITY**

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

Criteria: Appendix B, Section 3.1.2, Completeness of Scope

**Situation:** An applicant with an approved Part 71 transportation cask 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 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 contents are relatively straightforward and documented in open literature or literature readily available to the staff. 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 cask. The staff notices a fundamental error, such as in the calculations that encompasses all types of materials that would be allowed to be transported as well as sensitivity studies performed on the cask.

**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 on the cask. The applicant corrects the error and supplements the application with corrected analyses within the allowed 15 days time frame.

#### SHIELDING

#### Shielding Example No. 1

**Criteria:** Applicant fails to provide sufficient shielding computer modeling information.(Appendix B, Section 3.1.2, Completeness of Scope)

**Situation:** An applicant submits an application that required substantial computer modeling to demonstrate shielding performance, but does not include any representative s**a**mple input files. The applicant used a non-standard code, and does not provide adequate justification for the cited neutron spectrum used.

Acceptable for Review? - No, because the applicant failed to include analyses that are critical to the staff's review. Sample input files of SAS2H, MCNP, MCBEND, etc., are necessary to assist in confirming the applicant's modeling methodology and configuration. Non-standard codes need to be justified as to their use as well as any modifications to the code. The neutron spectrum must be provided and if the spectrum was rebinned, the applicant must justify the methodology.

**May be Acceptable for Review If:** Since most applications rely on computer modeling, sample input files are likely available, and if the applicant is able to be provide them to the NRC staff within 15 days, then the application may be acceptable for review. For non-standard codes, it may take longer than 15 days to adequately justify their use. Since computer modeling is typically performed, then the neutron spectrum should be available, and if provided to staff within 15 days, then the application may be acceptable for review.

#### Shielding Example No. 2

Criteria: Use of computer code that is not validated for the specified range of fuel burnup.

**Situation:** Applicant performed a source term calculation using a computer code (such as SAS2H/ ORIGEN) that is not validated for high burnup fuel of burnup beyond 47 GWd/MTU. These source terms were used in the shielding calculation to obtain dose rates at various locations around the transportation cask package.

Acceptable for Review:? - No. Point depletion codes such as SAS2H/ORIGEN-S combination has only been validated for PWR fuel assemblies for up to about 47 GWD/MTU burnup, and for BWR assemblies for up to 57 GWd/MTU burnup. For high burnup fuel, the errors in the calculated isotopic concentrations of actinides and fission products from SAS2H/ORIGEN-S system of codes will be higher than accepted levels. This will result in cumulative errors in calculated source terms and eventually in the dose rates.

**May be acceptable for Review:** The application may be acceptable if the applicant imposes an additional safety margin to account for the unknown uncertainties in the calculations. The extra safety margin may be determined based on modeling analyses, loading curves and published sensitivity analyses.

#### **CONTAINMENT**

#### **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, 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:** Applicant fails to provide complete information on numerical acceptance criteria and test sensitivity for the package for various required leakage tests. (Appendix B, Section 3.1.2, Sufficiency of Information)

**Situation:** An applicant submits an application for storage/transportation without details of 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**

#### **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 benhmarking 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 PWR fuel assemblies and to include several other changes to enhance the loading and storage operation of the system.

**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 <u>all evaluations</u> 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.

The regulation 10 CFR Part 72.122(b) requires all structures, systems, and components (SSCs) important.

#### **THERMAL**

#### Thermal Example No. 1

Criteria: Technical Staff, Use of Adequate Modeling Guidance

**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: Technical Staff, Use of Adequate Modeling Guidance

**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. Tit 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 needs to 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 flows (i.e., a model which includes transitional effects) along with use of CFD best-practice guidelines.

#### Thermal Example No. 3

Criteria: Technical Staff, Use of Proper Analysis Methods

**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 to be important due to the relatively high thermal conductivity of the basket material and canister internals. Also, the stored fuel assemblies have an axially varying decay heat profile.

**Acceptable for Review? -** No, because for this case 2-D analysis does not justify how to properly capture the canister heat transfer characteristics.

**May be Acceptable for Review if:** The applicant uses a detailed 3-D analysis to properly capture the heat transfer characteristics of the transfer cask.

#### 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: Does 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, ISG-18, and other consider associated request for additional information items in the RIS for RAIs?

United States Nuclear Regulatory Commission

### SFST-14 Appendix E

## Guide for Performing Acceptance Reviews, Flow Chart

A flow chart is currently under development for inclusion in a subsequent revision to this office instruction

**Division of Spent Fuel Storage and Transportation**