



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

SFST Office Instruction Change Notice

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Revision:

1. Revised to remove auxiliary information and to incorporate lessons learned from previous use.
2. Added guidance on level of effort estimation during the acceptance review.

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U.S. Nuclear Regulatory Commission

SFST OFFICE INSTRUCTION

SFST OFFICE INSTRUCTION SFST-14

ACCEPTANCE REVIEW PROCESS

1.0 PURPOSE AND APPLICABILITY

The purpose of the U.S. Nuclear Regulatory Commission's (NRC's) Office of Nuclear Material Safety and Safeguards (NMSS), Division of Spent Fuel Storage and Transportation (SFST), Office Instruction No. 14, "Acceptance Review Process," is to provide guidance to SFST staff (staff) who conduct acceptance reviews for new applications and licensing amendments submitted under: Title 10, Part 71, "Packaging and Transportation of Radioactive Material," of the *Code of Federal Regulations* (10 CFR Part 71); requests from Department of Transportation for recommendations for revalidations under International Atomic Energy Agency TS-R-1; 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"; and other licensing actions such as exemption requests or responses to a Request for Additional Information. This Office Instruction provides staff a basic framework for performing an acceptance review upon receipt of a Requested Licensing Action (RLA). The objectives of this Office Instruction include:

- Promote consistency in the performance of acceptance reviews;
- Establish the priority of acceptance reviews and define time frames for completion to facilitate resource management; and
- Reduce unnecessary delays, and increase the efficiency in the review of RLAs.

The acceptance review process is designed to support both safety and timeliness objectives by helping to ensure that applicants provide adequate information to support a detailed staff review of applications falling within the scope of this Office Instruction. The quality of a RLA has a significant impact on the amount of staff resources expended in the review process. RLAs that include information of a sufficient scope and depth allow staff to focus its efforts on reviewing the technical and regulatory adequacy of the information put forth by the applicant. When a RLA lacks critical information necessary for the staff to complete its review (e.g., analyses/calculations or use of new or unconventional methodologies without proper justification), additional staff and applicant time and resources will be required to complete the review. Therefore, the acceptance review process, which provides for early identification of insufficient information, benefits both staff and the applicant.

This Office Instruction will not be applied to RLAs that are clearly acceptable for review as

determined by the Project Manager (PM). Examples of such RLAs include renewal requests or simpler requests, which may include one-time authorization requests.

2.0 GENERAL REQUIREMENTS AND DEFINITIONS

During the acceptance review, the staff conducts an administrative and technical sufficiency review. The staff's technical sufficiency review ensures that the application contains sufficient technical information, in scope and depth, for the staff to not only conduct a detailed technical review, but to complete it within a predictable time frame. Standard Review Plans (SRPs) and Interim Staff Guidance (ISG) documents provide guidance to the staff on performing their reviews of RLAs. These documents may be used, in part, to evaluate and determine completeness. The acceptance review process does not determine the technical correctness of the applied methodologies or the accuracy of the results; rather, the acceptance review process increases the likelihood that SFST will expend resources on applications that will ultimately be successful. This approach supports both efficient and timely review of the application. The acceptance review process is intended to ensure SFST only reviews high quality applications. Incomplete or poor quality applications will normally be rejected.

The acceptance review should be completed as soon as practical, but should not take longer than 60 days. For simple and routine amendment requests, 30 days or less is the goal. Unless otherwise noted, all time frames are defined as calendar days. Staff may, depending on workload, case familiarity, and priority, begin the RLA acceptance review in parallel with docketing the RLA into the Agencywide Documents Access and Management System (ADAMS) (if the applicant sends a copy of the application to the PM at the time it also submits the application to NRC's Document Control Desk).

Requests for Supplemental Information (RSIs): RSIs are information requests needed to support beginning a detailed technical review and are requested during the acceptance review. RSIs are distinguished from Requests for Additional Information (RAIs), as RAIs are needed to determine whether a regulatory requirement is met and are typically requested after the detailed technical review has begun. Appendix C of this Office Instruction (OI), "Examples of Requests for Supplemental Information," contains examples of RSIs that may occur and a discussion of each as to whether it would cause an RLA to not be acceptable for review. The examples are provided as only a guide.

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

SFST Operating Plan Metrics: "SFST Operation Plan Casework Performance Measures" (reference SFST Office Instruction No. 10, Section 2.5) start when SFST receives an acceptable application. Therefore, the metric start date depends on whether staff requests supplemental information. If the application is determined to be acceptable for a technical review without the

need for RSIs, the metric start date is the same date as the NRC receipt date of the RLA (i.e., the date the RLA is added to ADAMS and distributed to SFST staff via E-RIDS distribution). If staff generates RSIs, then the metric start date will be when the applicant provides an adequate response to the RSIs (i.e., the date the applicant's RSI letter is received, if the response is adequate). SFST's operating plan metrics are to: (1) complete 80% of transportation cases within 225 days and 100% of the cases within 2 years (excluding RAI response time); and (2) complete 80% of the storage cases within 383 days and 100% of the cases within 2 years (excluding RAI response time).

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

Acceptable for Review: A staff conclusion that the application appears to contain sufficient technical information, both in scope and depth, to complete the detailed technical review in a predictable time frame. This time frame typically includes one round of RAIs.

3.0 PROCESS OVERVIEW

A high level breakdown of acceptance review procedure follows:

- PM distributes RLA to technical branches within 7 days after the NRC receipt date (i.e., the date the RLA is added to ADAMS and distributed to SFST staff via E-RIDS distribution), or earlier if possible.
- PM sends an acknowledgement e-mail to the applicant within 7 days of the NRC receipt date, acknowledging receipt of the application in ADAMS and commencement of the acceptance review.
- PM and Technical Review Directorate (TRD) communicate any RSI(s) to each other within 35 days of NRC receipt of the RLA, or earlier if possible or if an earlier schedule was established.
- PM issues RSI(s) within 60 days of NRC receipt of the RLA, or earlier if possible or if an earlier schedule was established.
- Applicant responds to RSI(s) within 15 days of the applicant receiving the RSI(s), or earlier if possible.
- TRD reviews the applicant's RSI response for adequacy and responds to the PM within 15 days of TRD receiving the RSI responses, or earlier if possible.
- SFST accepts or rejects the RLA, informs the applicant, and documents results. If the RLA is acceptable, the PM emails the applicant within 5 days and sends the acceptance letter within 21 days of SFST accepting the application. If the RLA is unacceptable due

to unresponsive RSIs, the PM informs the applicant within 14 days. After informing the applicant, the PM issues the non-acceptance letter within 3 working days.

The level of effort expended in the acceptance review of RLAs is based on many factors and may vary significantly. Therefore, in performing the acceptance review, the expectation is that an individual staff member, typically, should be able to complete the acceptance review in a relatively short period of time. Experience has shown that most acceptance reviews can be completed within about 24 review hours per staff reviewer. However, due to the complexity and uniqueness of the review, a reviewer may need more time. Should the reviewer determine that the acceptance review will exceed 24 staff review hours, the reviewer should identify the need for additional review time and discuss the reasons with the TRD Branch Chief (BC) and the PM. The TRD BC will determine the appropriateness of the request for additional review time.

4.0 ACCEPTANCE REVIEW GUIDANCE

4.1 Distribution and Involvement

When SFST receives an application, the Licensing Branch (LB) BC will assign a PM for the RLA. Once the RLA has been entered into ADAMS, or earlier if possible, the assigned PM will request a Technical Assignment Control (TAC) number to be opened, create a schedule, and obtain the names of the assigned technical reviewers (to perform the acceptance review) from the TRD BCs. The PM will also send an acknowledgement e-mail to the applicant within 7 days of the NRC receipt date, acknowledging receipt of the application in ADAMS and commencement of the acceptance review (see Appendix B of this OI for an example of an acknowledgement e-mail).

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

4.2 Acceptance Review Criteria

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

4.2.1 Project Manager Criteria

- **Administrative Criteria:** Determine whether the RLA includes information described in appropriate Regulatory Guides, such as Regulatory Guides 3.48, 3.61, and 7.9, and other administrative criteria, including:
 - Identify actions where applicants have requested an expedited review, and provided a basis for the expedited review;

- Determine whether the applicant appropriately identifies deviations from the SRP or ISG, concerning application sections that the PM is cognizant (e.g. Sections 1, 7 and 8 for transportation PMs);
 - Verify the applicant properly identifies proprietary information, justifies, and includes the affidavit (addressed to the Document Control Desk, submitted under Oath and Affirmation) in accordance with 10 CFR 2.390 (technical aspects of the proposed proprietary information may require review by technical groups). To expedite the review, the applicant should consider providing both a proprietary version and a non-proprietary/non-sensitive unclassified non-safeguards information (SUNSI) version. In this way, a public version of the application will be available in ADAMS sooner;
 - Verify attachments are included and that significant references are available;
 - Ensure contents of the application are legible and coherent (contents may include evaluations, drawings, and data tables);
 - Ensure that the format and content of the application sections is consistent with established criteria, and that deviations are explained and applicable references are provided;
 - Confirm that the applicant provided instructions on updating NRC's copy of the Safety Analysis Report (SAR). While providing SAR updates is not required to begin a detailed technical review, providing SAR updates up front may significantly reduce review time as often SAR updates are needed in order for staff to determine regulatory compliance;
 - Specific to Part 72 amendments, the applicant should provide proposed Final Safety Analysis Report (FSAR) update pages that are based upon the current design and contents that are proposed for use in the amendment request, including any changes that were made beforehand in accordance with 10 CFR 72.48. The applicant should demarcate, or otherwise indicate, portions of the FSAR and design that were changed in accordance with 10 CFR 72.48, separate from changes requested in the amendment. FSAR update pages are required prior to approval.
- **Use of Guidance:** Determine whether the RLA cites guidance not yet adopted by the NRC. Examples include draft American Society of Mechanical Engineers (ASME) Code cases or Code cases approved by external codes and standards organization as an exception to current code or standard practices. Guidance not yet adopted or incorporated by NRC may be used as the basis for a new application or a proposed change. However, the applicant should supply justification and technical basis to support the change or departure from current adopted or internal guidance. Simply citing guidance is not acceptable. Perform a review that is sufficient to determine if any reference guidance or documents have been misapplied and ensure that the SAR for the RLA is clear. Staff should also ensure that internal draft guidance or unadopted external guidance, whether in draft or final form, is not used as a basis for determining whether an application is acceptable for review, unless proper justification is provided.
 - **Additional Criteria:** For certain RLAs, ensure that the applicant addresses any specific criteria associated with a particular action. These criteria are typically identified either in the regulations (10 CFR Part 71 or 10 CFR Part 72), or in associated guidance. An example is when the applicant uses an alternative to NRC guidance, where the applicant

should justify the acceptability of the proposed alternative. Reviewing an alternative may require additional review time and resources. Another example would be failure of the applicant to have applied for an NRC approved quality assurance program either prior to the RLA or along with the RLA.

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

4.2.2 Technical Staff Criteria

- **Completeness of Scope:** Determine if there are significant analyses/evaluations or detailed summaries of the analytical calculations¹ missing from the RLA, as provided for in the applicable SRP or ISG. Ensure representative input/output files for any relevant calculation packages are included and/or thoroughly documented.

Often, the appropriate analysis scope and depth are designated in industry codes and standards such as Regulatory Guides. An RLA lacking a relevant analysis, or a required evaluation, necessary for the staff review, should not be considered acceptable for review. Determine that the applicant fully identifies SRP/ISG deviations or necessary exemptions. The reviewer should cite the basis for the needed analysis (regulation, SRP, ISG, Regulatory Guide, industry standard, etc.).

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

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 time frame. 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 not be considered acceptable for review.

¹ Detailed summaries should include: a) all files and/or calculation packages in list form including final revision number and detailed description of the calculation; and b) the documented calculations are complete and immediately available to staff upon request during the detailed technical review

- **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 significant justification and basis should not be considered acceptable for review.
- **Regulatory Basis:** Determine whether the applicable regulations and criteria are properly identified. The applicant should identify the criteria used to determine that the RLA meets regulatory requirements. The staff may use guidance documents such as the SRPs or ISGs for review of RLAs. Meeting guidance criteria is not a regulatory requirement; however, this may facilitate a timely review. Staff should be cognizant that the applicant may have evaluated a proposed change contained in the RLA in a different manner. Regardless, the staff should be able to identify the applicable criteria and licensing bases by which to evaluate the proposed action based on the information contained in the application. When alternatives are provided, the staff should spend extra time verifying the completeness of the scope and bases of the alternate methodology.
- **Use of Issued Guidance:** Determine whether industry codes, ASME code cases, Regulatory Guides, NRC Technical Reports (NUREGs), or ISGs cited in the application are used in accordance with the limitations and conditions imposed by staff on their use or imposed by the document itself.

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

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

Previous staff approval of a cited precedent does not automatically approve the acceptance of the precedent's method or results for the RLA (staff's determination for the use or applicability of a precedent to the RLA may be influenced by new safety-significant knowledge and information that was not available in the past). Because certain past staff approvals may be based on unique or specific provisions contained in

the previous evaluations, or unique or specific circumstances, its use in another evaluation may not be appropriate unless the applicant addresses all of the provisions which the staff considered when approving the precedent. 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 an exhaustive search, but instead promote awareness of any readily available information or knowledge pertinent to the RLA.

When precedents are cited, or documents identified as having been previously submitted to the NRC are cited, either an ADAMS Accession Number or a copy of appropriate pages of these documents should be provided. If a large document (over 20 pages) is cited, the page or section numbers of the citation should be identified to best facilitate location of the information. In addition, the applicant should provide information that indicates the basis for a precedent used by one Vendor is applicable for another Vendor's design. In all cases, the application should contain sufficient information for staff to make a safety finding consistent with the regulations.

Note: The TRD staff should review the PM Criteria in Section 4.2.1 of this OI, and apply the criteria as necessary during their acceptance review activities.

4.2.3 Quality Issues in the Application

Quality issues in a RLA could include:

- Inconsistencies between values referenced in the application and parameters used in the models;
- Missing information as required by 10 CFR Part 71 or 10 CFR Part 72;
- Use of new or unconventional methodology or deviation from regulatory guidance, without proper technical justification ; or
- More than 5% of references in error.

The above list of quality issues is not necessarily all inclusive. Quality issues may impact the ability to complete the detailed technical review in a timely manner and may result in an unacceptable application or a longer review schedule.

4.3 Acceptance Review Results

Upon completion of the acceptance review, staff will determine that the application is either:

- Acceptable (refer to Section 4.3.1 of this OI);
- Acceptable Once Supplemented (Request for Supplemental Information) (refer to Section 4.3.2 of this OI); or
- Unacceptable (refer to Section 4.3.3 of this OI).

4.3.1 Acceptable

SFST will consider a RLA to be acceptable for a detailed technical review upon the staff's conclusion that the application appears to contain sufficient technical information, both in scope and depth, to complete the detailed technical review in a predictable time frame. The RLA may also be considered acceptable 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).

Upon determination that an RLA is acceptable for review, the PM should notify the applicant, via e-mail to the PM's licensing contact, within 5 days of accepting the RLA. Following the transmission of this e-mail, the PM should document in a letter to the applicant the schedule for the detailed technical review within 21 days of accepting the RLA. In the case where an RLA is determined to be acceptable for review (without the need for supplemental information), the acceptance letter should be issued within 60 days of NRC receipt of the RLA. An example acceptance letter is provided in Appendix B of this OI.

Note: It is important that the PM ensures that e-mail documentation of the acceptance for review is documented in ADAMS as an Official Agency Record (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 Office Instruction No. 4). The technical staff performing the detailed technical review may not be the same staff that performed the acceptance review.

4.3.2 Acceptable Once Supplemented (Request for Supplemental Information)

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 to ensure that all parties understand the information insufficiencies and agree that the insufficiencies are within the scope of the review. 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, the staff should initiate the following RSI process.

The PM (with support of the technical staff) should compile a list of the RSIs and observations² and inform the associated BCs via e-mail. For complex or problematic issues, and if consistent with the acceptance review schedule, the TRD BCs should consider a peer review to confirm the need for the RSIs prior to contacting the applicant. The performance of a peer review, or a

² "Observations" include questions (identified by staff during the acceptance review), which do not rise to the level of a RSI that needs to be resolved before the RLA could be accepted for review, but may require staff to issue a RAI during the detailed technical review. The observations may be provided in the RSI to the applicant, and if the applicant wishes, it may respond to the observation in its response to the RSI to avoid the need for an RAI on the question during the staff's detailed technical review.

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 complex or problematic issues are agreed upon, the PM should notify the associated division management (BCs, Deputy Division Directors (DDD) and Division Director (DD)) via e mail, briefly summarizing the issues.

4.3.2.1 Communication of Request for Supplemental Information to the Applicant

The PM should inform the applicant that the staff determined that supplemental information is needed before the RLA can be accepted for a detailed technical review, and the PM should arrange a conference call with the applicant to discuss the RSIs. The PM may either provide the identified insufficiencies on the phone to the applicant (so that the applicant can arrange for the necessary technical staff to participate in the conference call), or provide the identified insufficiencies to the applicant, via an e-mail, prior to the call. For problematic or complex issues, the PM should consult the BCs prior to identifying the insufficiencies to the applicant via e-mail. Regardless of the method used to transmit the identified RSIs to the applicant, the PM should ensure documents and telephone conversations are properly captured as OARs. The conference call should occur as soon as possible, but no later than one week after providing the applicant the information insufficiencies.

During the call to discuss the RSIs, staff should identify the omitted or insufficient information to the applicant, discuss the appropriate course of action, and establish a time frame for when the information will be submitted. This time frame (typically 15 days from the date of the RSI letter) should be established as one that is supportive of staff's timely review, not simply when the information will be available. 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 the time frame established during the call.

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 whether the information is still needed to perform the detailed technical review. If the staff determines that the insufficiency is still valid, the staff will include the insufficiency in an RSI letter to the applicant.

After discussing the RSIs with the applicant, a letter requesting supplemental information should be sent by the PM (with LB Branch Chief, and if applicable, TRD Branch Chief concurrence) to the applicant that clearly identifies:

- The information needed for the NRC staff to begin its detailed technical review;
- The time frame for the submission of the information; and
- A statement identifying that failure to submit the information within the time frame will result in non-acceptance of the application and cessation of staff review activities.

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

The PM and the applicant may arrange an open meeting to discuss the insufficient information. Since an open meeting requires 10 days advance public notification, the meeting may impact the applicant's ability to respond to the RSIs within the typical 15-day response time frame, which may be justified.

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.

4.3.2.2 Applicant Supplements to Requested Licensing Action

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 staff's concerns. The same criteria used in the initial acceptance review should be applied, although the review should be focused on the areas previously identified as not acceptable for review. The PM is responsible for tracking the submission of the information by the applicant and distribution of the submitted information to the technical staff. The technical staff is responsible for identifying any issues (e.g., staff reassignments or other high priority work) that may impact the acceptance review schedule to the PM and his or her BC.

If the information provided is both timely and responsive, notify the applicant in accordance with Section 4.3.1, "Acceptable," and transition into a detailed technical review. The applicant may provide supplemental information during and after the acceptance review period, provided the information is either requested by the NRC staff or it corrects an error identified by the applicant. Acceptance of the supplemental information will be evaluated on a case by case basis.

If it appears that the applicant is not able to submit the information in the established time frame, the information to be submitted is unlikely to be responsive to the NRC staff's concerns, or the supplemental information submitted continues to be insufficient, 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. The staff should proceed with non-acceptance of the application and follow the guidance in Section 4.3.3, "Unacceptable."

4.3.3 Unacceptable

If, during the acceptance review of the RLA, the NRC staff finds deficiencies so significant that they impede completion of the acceptance review, the RLA should be returned to the applicant as unacceptable for review, pursuant to 10 CFR 71.7 or 10 CFR 72.11.

The staff may determine that a RLA is unacceptable if:

- at the completion of the acceptance review, the staff has identified major deficiencies that would be better addressed by discontinuing the staff's review and returning the RLA to the applicant for resolution;

- the supplement to the RLA (response to RSI) has been determined to be unresponsive or inadequate to address staff concerns; or
- the applicant does not provide the supplementary information within the agreed-upon time frame.

It is noted that once the staff has started the acceptance review process, staff should complete their acceptance review and document their findings, as discussed below. All copies of the application should either be discarded or returned to the applicant, except for the ADAMS version.

4.3.3.1 Communication of Non-Acceptance of the Requested Licensing Action (Unacceptable)

Upon staff's determination to discontinue the review due to unresponsive RSIs, the PM should communicate the staff's decision to discontinue the review to the applicant within 14 days. During this time period, the PM should proceed with preparing the non-acceptance letter and obtain SFST BCs, DDDs, and DD concurrence. While not required, OGC 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 unacceptable for staff review, the NRC staff should communicate this decision to the Director, NMSS, and the Executive Director for Operation's (EDO's) office (via an EDO daily note) prior to contacting the applicant.

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

Upon notification of the NRC staff's decision to not accept the RLA, the applicant should also be made aware that it may withdraw the application, pursuant to 10 CFR 2.107. The applicant should be informed that the NRC intends to issue the letter of non-acceptance within 3 working days, and if the applicant chooses to withdraw its application, it should do so prior to that date. 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.

For applications where the applicant fails to supplement the RLA within the agreed-upon time frame, the letter of non-acceptance should be issued within 14 days of the time frame established for supplementing the RLA. For applications with significant deficiencies, the letter of non-acceptance should be issued within 60 days of SFST receiving the RLA.

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

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

5.0 LEVEL OF EFFORT ESTIMATING

During the acceptance review process, the PM, with input from TRD staff, produces an estimate of the staff review hours needed to complete the detailed technical review and generate a final safety evaluation report, given one round of RAIs. The level of effort will be commensurate with the complexity of the RLA. PMs should refer to the PM Handbook (the most recent version is on the Licensing Branch page in Sharepoint) for guidance on level of effort estimating.

6.0 RESPONSIBILITIES AND AUTHORITIES

The sections that follow describe specific responsibilities and authorities for PMs, TRD staff, and BCs during various portions of the acceptance review process.

6.1 Project Manager Responsibilities

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
- With assistance from TRD, determine the scope and depth of the detailed technical review (including need for contractor support or development of independent models)
- Ensure the application is entered into ADAMS in a timely manner. Although the applicant is required to ensure the application is adequate for entering into ADAMS and should notify SFST that the application has been submitted, the PM should monitor this process. If the document is not entered into ADAMS in a timely manner, the PM should contact the ADAMS administrator and the applicant to facilitate entering the application into ADAMS
- With the coordination of BCs, establish a schedule and identify the appropriate technical branches needed to support the acceptance and detailed technical reviews
- Document a level of effort estimate for the detailed technical review, prior to acceptance of the RLA.
- Promptly distribute copies of the RLA and associated documents or make them electronically available to the appropriate technical branches to begin the acceptance review process (within 7 days after the NRC receipt date, or earlier if possible)
- Send an acknowledgement e-mail to the applicant within 7 days after the NRC receipt date, acknowledging receipt of the application in ADAMS and commencement of the acceptance review (see Appendix B of this OI for an example of an acknowledgement e-mail).

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

- Review the RLA for administrative sufficiency in accordance with Section 4.2.1, “Project Manager Criteria,” of this OI
- Collect and review the input provided by the technical branches
- Determine the significance of any administrative RSIs, assist in determining the significance of technical RSIs (identified by TRD staff), and make recommendations to management, as appropriate
- Notify management and the associated technical branches of the results of the acceptance review
- Ensure implementation or revision of the schedule in a timely manner
- Communicate any PM-related RSIs to the LB BC and technical staff as soon as possible, with a goal of 35 days from the receipt of the RLA by the NRC
- Notify management, as early as possible, of potential delays in meeting an acceptance review schedule

PMs are responsible for the following activities regarding the resolution of RSIs:

- Ensure the criteria described in Section 4.2, “Acceptance Review Criteria,” 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 should submit the information (typically 15 days after the applicant receives the RSI letter)
- If required, contact the applicant and communicate the information needed and the deadline for submitting the information, in order to clearly obtain an understanding of the required course of action
- Notify management and technical branches of whether the applicant intends to supplement its RLA within the established time frame (typically 15 days from the date of the RSI letter).
- Draft a letter to the applicant identifying the information needed and the deadline for submitting the information
- Coordinate any necessary interfaces with other offices (e.g., OGC, Office of Federal and State Materials and Environmental Management Programs, Office of Nuclear Security and Incident Response, etc.)

- Notify management and technical branches of any significant change in the schedule

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

- Document the decision regarding the administrative and technical sufficiency of the RLA in a letter to the applicant or in an e-mail as discussed in Section 4.3, "Acceptance Review Results," of this OI
- Notify the applicant of the results of the acceptance review activities
- Assemble level of effort estimates to support BC scheduling

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

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

6.2 Technical Review Directorate Staff Responsibilities

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

- Review the RLA for technical sufficiency in accordance with Section 4.2.2, "Technical Staff Criteria," of this OI
- Communicate any TRD-related RSIs to TRD BCs and the PM as soon as possible, with a goal of 35 days from the date of receipt of the RLA by the NRC. Provide a recommendation to TRD management and the PM regarding the significance of any technical RSIs
- Notify TRD BCs (as soon as conflicts are identified) of workload conflicts associated with performing an acceptance review. BCs are responsible for resolution of workload conflicts
- Document a level of effort estimate for the detailed technical review, via e-mail to the PM and respective BC.

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

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

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

- Communicate the adequacy (to begin a full detailed technical review – not whether the design meets the regulation) of the RLA to management and the PM
- Support the PM in documenting the results of the acceptance review, including the level of effort estimate

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

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

6.3 Branch Chief Responsibilities

TRD Branch Chiefs are responsible for the following activities regarding the establishment of scheduling and resources for the acceptance review:

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

- Notify division-level management (DDD and DD), in coordination with the PM, of potential delays in meeting an acceptance review schedule

The LB and TRD BCs are responsible for the following activities regarding the resolution of RSIs:

- Support and guide the staff in determining the appropriate course of resolution regarding RSIs
- Maintain an awareness of SFST priorities and how these may affect the RLA acceptance review schedule
- Provide oversight of acceptance review activities and direct the implementation
- Support the PM and technical staff by informing management of any scheduling conflicts or acceptance review activities, as appropriate
- Ensure consistency in the conduct of acceptance reviews
- Facilitate peer reviews, when appropriate, to confirm the RSI prior to contacting the applicant
- Ensure timely communication of the status of these reviews and any adverse impacts on office resources to SFST management
- Advise PM of supplying RSIs to applicant for problematic or complex issues per Section 4.3.2.1, "Communication of Request for Supplemental Information to the Applicant," of this OI.

7.0 ACCEPTANCE REVIEW PERFORMANCE MEASUREMENT

The Acceptance Review Performance Measurement will be developed as part of ongoing process improvements.

8.0 PRIMARY CONTACTS

SFST/LB
301-492-3268
Jennivine.Rankin@nrc.gov

SFST/TRD
301-492-3286
Jason.Piotter@nrc.gov

9.0 RESPONSIBLE ORGANIZATION

SFST/LB

SFST/TRD

10.0 EFFECTIVE DATE

February 2011 - SFST staff involved in performing acceptance reviews should submit suggestions for improvement to this guidance to their management or the contacts listed for this Office Instruction (SFST-14).

11.0 REFERENCES

- 11.1 10 CFR Part 71, 10 CFR Part 72
- 11.2 Regulatory Guide 3.48, "Standard Format and Content for the Safety Analysis Report for an Independent Spent Fuel Storage Installation."
- 11.3 Regulatory Guide 3.61, "Standard Format and Content for a Topical Safety Analysis Report for a Spent Fuel Dry Storage Cask."
- 11.4 Regulatory Guide 7.9, "Standard Format and content for Part 71 Applications for Approval of Packaging for Radioactive Materials."
- 11.5 Regulatory Issue Summary 2004-20, "Lessons Learned from Review of 10 CFR Parts 71 and 72 Applications."
- 11.6 Regulatory Issue Summary 2005-27, Rev. 1, "NRC Timeliness Goals, Prioritization of Incoming License Applications and Voluntary Submittal of Schedule for Future Actions for NRC Review."
- 11.7 Regulatory Issue Summary 2007-09, "Examples of Recurring Requests for Additional Information (RAIs) for 10 CFR Part 71 and 72 Applications."

12.0 ENCLOSURES

- Appendix A: Change History
- Appendix B: Example Letters & E-Mails
- Appendix C: Examples of Requests for Supplemental Information
- Appendix D: Acceptance Review Process Flowchart

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

SFST No 14 - Change History - Page 1			
Revision Date	Description of Changes	Method Used to Announce & Distribute	Training
April 30, 2010	Replaced Acknowledgement Reviews with Acceptance Review Process	E-mail to staff	Training Sessions
February 3, 2011	Replaced Acceptance Review Process, Revision 0 with Revision 1	E-mail to staff	Training Sessions

**United States
Nuclear Regulatory Commission**

SFST-14 Appendix B

Example Letters & E-Mails

Division of Spent Fuel Storage and Transportation

ACCEPTANCE

[DATE]

[ADDRESSEE]

SUBJECT: APPLICATION FOR [DESCRIPTION] – ACCEPTED FOR REVIEW

Dear [ADDRESSEE]:

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

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

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

Sincerely,

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

Docket No. [DOCKET NO.]

TAC No. [TAC NO.]

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

NON-ACCEPTANCE

[DATE]

[ADDRESSEE]

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

Dear [ADDRESSEE]:

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

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

LIST INFORMATION NEEDED

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

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

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

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

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

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

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

Sincerely,

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

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

Enclosure: As stated

Distribution: Tech Reviewers
Concurrence: PM, LA, BCs, DDDs, DD

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 TRD Branch Chiefs, TA, Deputy Directors
Concurrence: PM, LA, Licensing Branch Chief

**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 of 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 C

Examples of Requests for Supplemental Information

Division of Spent Fuel Storage and Transportation

Examples of Requests for Supplemental Information (RSIs)

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

ADMINISTRATIVE RSI Example

Criteria: Affidavit required for proprietary information (Section 4.2.1, Administrative Criteria)

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

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

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

MATERIALS RSI Example

Criteria: Section 4.2.2, Alternatives or Missing Information

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

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

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

CRITICALITY RSI Example

Criteria: Section 4.2.2, Sufficiency of Information

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

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

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

SHIELDING RSI Example

Criteria: Section 4.2.2, Completeness of Scope

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

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

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

CONTAINMENT RSI Example

Criteria: Section 4.2.2, 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 [i.e., the earlier revision of the package was approved with no hydrogen generation in the package and an activity inventory assumption (e.g., 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: The applicant can provide a solid basis and provide adequate justification for its revised basis and assumptions in the amendment request, within the typical 15-day time frame for responding to RSIs.

STRUCTURAL RSI Example

Criteria: Section 4.2.2, Completeness of Scope

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

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

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

May be Acceptable for Review if: The applicant provides these LS-DYNA output files, within the typical 15-day time frame for responding to RSIs.

THERMAL RSI Example

Criteria: Section 4.2.2, Sufficiency of Information

Situation: The applicant submits a thermal-hydraulic analysis of a transfer cask design that includes a liquid neutron shield. The transfer cask is transported horizontally which may limit convection heat transfer in the liquid neutron shield region. In order to take credit for

convection, the applicant uses a “general” correlation claiming to be applicable for this case without providing any justification or explanation.

Acceptable for Review? - No, because in order to use a correlation for an internal cavity, the correlation should have been obtained for similar geometry and boundary conditions. Also, in order to use the correlation, the applicant should perform an adequate validation applying Computational Fluid Dynamics (CFD) best-practice guidelines.

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

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SFST-14 Appendix D

Acceptance Review Process Flowchart

Division of Spent Fuel Storage and Transportation

**Timeframes
(Reference)**

Acceptance Review Process Flowchart

