Appropriate use of the Request for Additional Information (RAI) process

The RAI process should not be used to establish new or revised generic positions. Rather, the RAI process should be used to ensure that the application meets established and properly promulgated regulatory requirements.

The NRC in the past has indicated an expectation that applicants review RAIs on previously applications. However, it has recently become apparent, as illustrated by the secondary impact issue, that the NRC may have an expectation that applicants review previous RAIs with the purpose to discern new or revised generic agency positions. This would be inconsistent with the existing regulatory processes, the role of the RAI process, and with the NRC's Principles of Good Regulation, in that it would not promote clarity, efficiency or reliability.

It is difficult, and in some cases impossible, for an applicant to extrapolate an NRC generic position from an RAI, since the RAI typically does not articulate the technical basis for the NRC concern. The RAI is also written to be specific to the conditions of that application, for which the similarities or difference to other applications may not be discernible. While we agree that review of previous RAIs is a prudent course of action, we also believe that the purpose of reviewing previous RAIs should be strictly limited to enhancing the quality of the application, and it would be unreasonable for the NRC to expect an applicant to address new or revised positions established through RAIs.

Use of appropriate processes to establish NRC positions

When a new regulatory position emerges without any corresponding generic evaluation or communications, it is very difficult for applicants to become adequately informed of the NRC's position, and more importantly, understand its technical basis prior to submitting an application. In such cases, as illustrated by the secondary impact issue, applicants for new or amended Certificates of Compliance would neither be able to address the NRC's new position nor propose alternative methods to address NRC concerns in the application submittal. This may result in several issues, including drawn-out rounds of RAIs and reviews, and potential withdrawal or denial of the application because the NRC's concern, including the regulatory and technical bases, is not as clearly articulated in the RAIs as it would be in a more appropriate generic communication. It is also important to note that in the absence of a generic evaluation, it is not possible to determine whether the concern is applicable to other applications, or whether it is a safety concern for previously approved designs. This results in an overall reduction of regulatory clarity and stability.

We believe that as soon as issues with the potential for generic implications are identified by the NRC, they should be immediately addressed through an appropriate process. In this context, it should be recognized that a majority of the cases in which a new NRC concern is identified during a review will be generic in nature, since there are substantial similarities among the dry storage and transportation cask designs previously approved by the NRC.

We recommend the NRC consider the following as it proceeds with establishing a process to evaluate whether a question raised during an application review should be addressed generically.

- The NRC should first determine if the new or revised NRC concern, position or acceptable method is unique to the design being reviewed or could apply to other designs. RAIs which may be applicable to other designs should be screened as potentially generic in nature.
- For issues identified as potentially generic in nature, the NRC should next identify whether
 the concern, position or acceptable method is new or different than what is addressed in
 current regulatory requirements or guidance, represents an immediate safety concern that
 applies to previously approved and loaded designs, or whether it is a safety enhancement
 being proposed for future applications. The NRC should also determine whether the new or
 revised NRC concern, position or acceptable method is consistent with the regulations.
 - In the former, an immediate safety concern, the appropriate process may be a Generic Letter or some other equivalent. If the new position is inconsistent with the regulations, then the NRC should determine if a rulemaking may also be warranted.
 - o In the latter, a safety enhancement, the appropriate process may be to create or revise a Regulatory Guide, Standard Review Plan, or equivalent guidance. If the new position is inconsistent with the regulations, then the NRC should determine if the safety enhancement warrants a rulemaking, or whether a rulemaking is not warranted and the NRC should instead rely on the prior NRC established position.
- The third step would be for the NRC to determine how the new or revised NRC concern, position or acceptable method should be addressed for the application under review.
 - If the issue is an immediate safety concern, then the application review should ensure that the NRC and applicant address it in a manner consistent with the generic response, e.g. Generic Letter or equivalent.
 - o If the issue is a safety enhancement, the application should not be required to address it, since meeting existing regulations and prior NRC guidance would be ensuring adequate protection, and the applicant could not have been reasonably expected to have prior knowledge of the new NRC position. Furthermore, since the applicant could not have been reasonably expected to have prior knowledge of a new or changed NRC position for a safety enhancement, expecting an applicant to comply with the new or changed position would be inconsistent with NRC Principles of Good Regulation of reliability, clarity and efficiency.

It is noted that the above described process for addressing potentially generic issues during the RAI process is consistent with principles of 10 CFR 72.62 Backfitting.

Specific concerns about NRC's position

The NRC has not formally or generically communicated the technical and regulatory bases for its concerns on secondary impacts. We believe—based upon the NRC's limited communications of the concern and position through RAIs and SERs—that the NRC's emerging new position is as follows:

The initial conditions of the test configurations [hypothetical accident conditions] should include a gap between the fuel and canister, thus causing secondary impacts during the canister drop. The NRC's basis is that, if the loaded condition results in a gap between the fuel and cask lid, then not including this gap and considering secondary impacts would not represent realistic as-shipped conditions.¹

As explained below, the emerging new NRC position on secondary impacts appears to be inconsistent with 10 CFR 71.73 in that the new position seeks to establish a new hypothetical accident condition (HAC). We further believe that the existing regulations ensure safety and adequate protection, such that a new position on secondary impacts, which would require rulemaking, is not warranted. The emerging new NRC position also appears to be inconsistent with prior NRC positions on HACs established in Regulatory Guides 7.8 and 7.9, and through precedent established in previous Certificate of Compliance approvals, as well as the international standard IAEA TS-R-1.

The emerging new NRC position appears to be creating a new set of hypothetical accident conditions that combine the most limiting or extreme conservatisms from both hypothetical and realistic accidents, thus creating new super-hypothetical accident conditions. We believe this would be inconsistent with the regulations and the regulatory approach of 10 CFR 71.73, which establishes HAC that already include an extreme amount of conservatism.

The existing regulatory approach to establish HAC is based upon defining a set of accident conditions that are extremely conservative, standard, and can be consistently reproduced for the purposes of testing required by 10 CFR 71.41. Introduction of conservatisms from realistic accidents that are not physically possible for the hypothetical accident conditions would be a new regulatory position, and would be inconsistent with the current regulations. This new regulatory position would create unnecessary burdens without improvements to safety, and, to the contrary, might even be counter to safety as explained below.

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¹ ML081640185, ML082260289, ML082760021, ML091420472, ML101680558, ML110910458

Industry's detailed concerns of the NRC's emerging new position:

- We believe that the hypothetical accident conditions were not intended to include considerations of physical arrangements that are inconsistent with the physical realities of such hypothetical accident conditions. The new super-hypothetical accident conditions do not reflect the realistic test conditions, and therefore are not reproducible under test conditions.
- The NRC's position for secondary impacts appears to be imposing an initial condition that is inconsistent with the laws of nature. Specifically, in the context of the end, center-of-gravity over corner, and slap-down drop conditions of the HAC, the NRC position appears to apply gravity to be operative on the packaging but not on the used fuel contents at the initial condition. This would not be a credible initial condition, and, as it would be impossible to create the gap between the fuel and canister for a drop test. Thus, it would not be possible to meet the testing requirements under 10 CFR 71.41, in order to confirm the HAC in 10 CFR 71.73.
- We are concerned that the NRC's indicated resolution to secondary impacts, i.e. use of spacers inside the cask to minimize gaps to ~1/2", could actually increase overall risks. The use of spacers would result in additional worker dose due to the additional time it would require working near the cask. In addition, it is very difficult to have the best estimate 1/2" gap when you consider the fabrication tolerance of the cask, various fuel assembly lengths, burnup vs. radiation growth, and the thermal growth due to hot/cold and heat loads. Therefore, use of spacers may introduce a new potential accident, e.g. crushing assemblies when installing the lid, since the elongation of some assemblies may not be predictable. The spacer would be loaded into the cask and an unexpected elongated assembly could be crushed unknowingly when the lid is installed on top of the spacer.

A transportation accident is highly unlikely to occur, and it is even more unlikely, in fact highly improbable, that a realistic accident would be more severe than the HAC. It is also noted that the HAC are established as a set sequential conditions, that when combined include even more conservatism. While it may be possible to postulate an accident that is more severe than a HAC, we believe that the current regulations ensure safety and adequate protection due to the extreme conservatisms already included in the HAC. Furthermore, when we apply risk insights to the NRC's emerging new position on secondary impacts, we believe the increase in risk due to the proposed solution could outweigh the improvement to safety.