

### 4.1.3 Contractor Review

Occasionally, technical staff will use contractors to assist in performing a review. Project Managers should treat the amendment the same as a technical staff review and communicate with the technical staff member designated as the contract's technical monitor. Project Managers should work with the technical monitor to establish the level of review, schedule, and the statement of work.

## 4.2 Use of Precedent Safety Evaluations

There are a number of considerations and cautions regarding the use of a precedent safety evaluation by NRR staff. These include, but are not limited to, the following:

- ▶ maximize the use of precedents to achieve efficiency and consistency
- ▶ ensure that the precedent is appropriate for use with the intended amendment
- ▶ ensure that the precedent meets current expectations for format, findings, internal NRR guidance for the item, NRR guidance to industry, and technical content
- ▶ ensure that previous plant-specific information is replaced with information relevant to the current plant
- ▶ obtain TB concurrence, unless formal guidance has been issued giving an alternative concurrence process

## 4.3 Requests for Additional Information

Requests for additional information (RAIs) serve the purpose of enabling the staff to obtain all relevant information needed to make a decision on a licensing action request that is fully informed, technically correct, and legally defensible. RAIs are necessary when the information was not included in the initial submittal, is not contained in any other docketed correspondence, or cannot reasonably be inferred from the information available to the staff. RAIs should be directly related to the applicable requirements related to the amendment application, and consistent with the applicable codes, standards, regulatory guides, and/or the applicable Standard Review Plan sections. RAIs should not be used as general information requests or as a means to encourage commitments from licensees. This guidance can be utilized for other licensing actions such as exemption and relief requests.

The staff is accountable for the appropriateness of RAIs and should ensure that each question in an RAI was developed with proper consideration of the following:

- ▶ regulatory basis of request
- ▶ technical complexity of request

- ▶ risk significance of issue in question
- ▶ existence of precedent amendments
- ▶ appropriate scope and depth of review
- ▶ resource implications for both the staff and the licensee
- ▶ information already on the docket

The following guidance is provided for common RAI concerns:

1. Questions included in the formal RAI should ask for information that is required to make the regulatory finding. Each question should have a clear nexus to the staff's regulatory finding. Including the regulatory basis in the question is a good practice.
2. The staff should not issue any RAIs if the staff has (or can infer with a reasonable degree of confidence) the necessary information to make the regulatory finding. When an RAI is necessary, the staff should make every effort to limit itself to one round of RAIs per TB for an amendment application. The established timeliness goals are likely to be exceeded if multiple RAIs are needed to complete the staff's review of a license amendment application.
3. Frequent and early communications between the PM, TB staff, and the licensee can avoid the need for many RAIs. To ensure an effective and efficient review, PMs are required to notify the licensee prior to issuing an RAI and document the conversation in the RAI cover letter. This notification should be a meeting or conference call attended by the PM, TB reviewer, and licensee. The proposed RAI questions should be discussed and a mutually agreed upon due date should be established. This due date should be reflected in the RAI cover letter. In order to facilitate resolution of the issues, questions may be faxed or e-mailed to the licensee prior to the meeting or conference call. Answers that are needed to make a regulatory finding (i.e., that are not merely clarifications of information already on the docket) should be placed on the docket. The staff's questions may be docketed by forwarding an official RAI to the licensee, generating a memo to file and placing it on the docket or by having the licensee refer to the teleconference/e-mail/fax in their docketed response. The specific method used is case-specific and depends on the needs of the licensee, the potential public interest, and the needs of the NRC staff.
4. Before developing an RAI, the staff should ensure that the information is not already available to the staff or that the answer could not reasonably be inferred from general knowledge, existing regulatory requirements, previously docketed correspondence, or generally accepted industry practice.
5. Questions should be specific rather than overly broad, and the response to the RAI should be of value to the staff's safety evaluation basis.
6. If an RAI is issued and the licensee's response does not fully address the RAI, the PM will set up a meeting or conference call attended by the PM, TB reviewer and licensee management to discuss the discrepancy and what needs to be provided to the staff on a timely basis in order to complete the amendment review. Failure of the licensee to provide

timely information may result in a denial or withdrawal of the amendment based on a deficiency in the submittal as opposed to a definitive, negative finding by the staff based on the technical merits of the proposed change. The licensee may submit a new application (with the identified discrepancies corrected) at any time in the future.

7. If a disagreement arises with the licensee regarding the appropriateness of an RAI or whether or not the information was provided, the issues should be raised immediately to management for proper resolution.
8. Consistent with Section 4.2, the staff should make use of previous reviews in order to avoid asking unnecessary questions.
9. The timely issuance of an RAI, if necessary, and the licensee's agreed upon time to respond should be factored into the schedule established to complete the review within the licensing action timeliness goals (e.g., FY00 and beyond goals of completing 95% of applications in less than 1 year).

The intent of this guidance is not to limit the staff from getting the information that is needed to perform a technical review; rather, this practice is needed to ensure that the information requests will be productive and focus staff and licensee resources on the pertinent issues necessary to make a regulatory decision.

#### **4.4 Regulatory Commitments**

During the review of license amendment applications, the staff will base its findings on a variety of information provided by the licensee. Some information considered important by the reviewer will not be addressed specifically in the affected technical specifications (which would require prior NRC approval of subsequent changes). Those matters considered important to the staff but not requiring the staff's prior approval of subsequent changes have been traditionally referred to as commitments. It is important to consider commitment management in its proper context as an integral part of licensees' and the NRC staff's control of each facility's licensing-basis information. A hierarchy of licensing-basis information relating to the change control and reporting processes is as follows:

1. Obligations - conditions or actions that are legally binding requirements imposed on licensees through applicable rules, regulations, orders, and licenses. The imposition of obligations (sometimes referred to as regulatory requirements) during routine interactions with licensees should be reserved for those matters warranting prior NRC approval of changes.
2. Mandated Licensing Basis Documents - documents, such as the UFSAR, the quality assurance program, the security plan, and the emergency plan, for which the NRC has established requirements for content, change control, and reporting.