These are the questions and comments that were received electronically prior to the public workshop

DG-1145 Process Development Questions

- 1 10 CFR 52.77 requires combined license (COL) applications to contain the general information specified in 10 CFR 50.33. Will DG-1145 provide guidance on this information?
- Will Part I of DG-1145 specify which final safety analysis report (FSAR) Chapter(s) should include the information in items 23 and 31 of the COL Acceptance Review Checklist?
- Will DG-1145 include guidance on Tier 1 information?

DG-1145 Development Questions

- C.I.4 The guidance in this section appears to be a consolidation of Regulatory Guide 1.70 and the Draft SRPs for Chapter 4. It provides a comprehensive set of information requirements for this chapter. It would be more beneficial for prospective combined license (COL) applicants to have a listing of the difference (delta) between the comprehensive set and the information supplied in a referenced design control document (DCD) for safety analysis report (SAR) Chapter 4. This kind of information was provided for Chapter 12 in the March 15, 2006 workshop in a set of slides. It appears that section III.1 will address the deltas but it is not clear if it will be general in nature or provide the information for each SAR chapter. This would be a good discussion topic for the April 20th workshop to allow for industry input for this and future sections.
- C.II-1 The title of Section C, Part II should be changed to "Additional Technical Information." This would be consistent with the proposed 10 CFR 52.80.
- C.II.3-1

 Please explain why the NRC staff did not follow the outline of RG 4.2 or NUREG-1555 when issuing environmental impact statements (EISs) for the 3 lead early site permit (ESP) applications. Will this NRC staff practice continue for future ESP and combined license (COL) applications? Wouldn't stakeholders have a better understanding if the NRC's EISs followed the same outline that the NRC staff requires for ESP and COL environmental reports (Ers)?
- C.II.3-2 This section references Regulatory Guide 4.2 and recognizes it is outdated. What is the schedule for updating the Regulatory Guide?
- C.II.3-3 The section references NUREG-1555 which was a valuable resource in

preparing early site permit (ESP) applications. The NUREG should be updated to reflect changes associated with the non-regulated power markets of today, such as the need for power analyses. What is the schedule for updating the NUREG?

- C.II.3-4 The guidance should address the staff expectations for a supplemental environmental report (ER) for combined license (COL) applications referencing an ESP. In these cases, most of the ER information would have been submitted with ESP.
- C.II.3-5 Design certifications were issued with an environmental assessment concerning severe accident mitigation and design alternatives (SAMDA). Industry anticipates that the generic design control document (DCD) information on SAMDA would be referenced in the combined license (COL) environmental report (ER) and the staff's environmental assessment (EA) for the DCD would be referenced in the environmental impact statement (EIS) as the acceptance. Does the Staff agree that, using this approach, the DCD SAMDA information is resolved for the COL since it was incorporated by reference in the Design Certification rule?
- C.III.3-1 In section C.III.3, the first and second sentences of the fourth paragraph contradict each other. And the second sentence in the fourth paragraph does not agree with the wording in the second paragraph which states "...it should be noted that the EIS (and not the applicants ER) provides the basis for issuing the ESP." If the environmental impact statement (EIS) provides the basis for issuing the ESP, why is there a need to consider the ESP application to determine if there is "new" information? When addressing new and significant information, the ESP EIS should be the only document considered in the COL applicant's environmental report.
- C.III.3-2 Does the NRC agree that if "new" information concerning matters previously considered in the early site permit (ESP) environmental report (ER) or environmental impact statement (EIS) is determined via a "reasonable process" to be not-significant, that information and significance assessment need not be presented in the COLA ER but should be retained by the applicant in auditable form, available for NRC Staff review?
- C.III.3-3

 It appears that the Staff uses a format for its environmental impact statement (EIS) that is different from that used in Regulatory Guide 4.2 and NUREG-1555. Should the application's environmental report (ER) and the staff EIS observe the same format (table of contents). This is may be of particular value for COL applications referencing an ESP since the staff's EIS has been identified as the starting point for evaluation of new and significant information.
- C.III.3-4 Please respond to the seven points in NEI's letter dated September 27, 2005, including points regarding a focus on adverse environmental impacts and determining significance based on a change from small to moderate impact or moderate to large.

- C.III.3-5 If a combined license (COL) application cannot contain complete environmental information, what process, e.g., analogous to license conditions, will be used to facilitate issuance of the COL? For example, specific routes for new transmission lines, and thus assessment of associated environmental impacts, may not be identified until after the EIS and COL are issued.
- C.III.3-6 In paragraph 3, the phrase "reasonable process to ensure that it (applicant) becomes aware of 'new and significant' information" is used. Page C.III.3-2 provides guidance on the nature of the reasonable process. This guidance appears to be based on Regulatory Guide 4.2 Supp. 1. In the 3rd paragraph on page C.III.3-2, the reader is directed to Regulatory Guide 4.2 Supp 1 for additional information on the attributes of the process. Yet, the guidance now provided in C.III.3 appears to contain the essential material from Position B.5. This reference to Regulatory Guide 4.2 Supp. 1 appears unnecessary.
- C.III.3-7 Section C.III.3 describes the NRC's expectations of combined license (COL) applicants regarding processes for the awareness of new information and evaluating its significance. Please identify the process that the NRC staff will use in these two areas. Will NRC staff reviews be conducted during pre-application or only after COL application receipt? Will the results of the NRC's ongoing reviews, information exchanges, consultations, etc. be made available to stakeholders prior to COL EIS issuance?
- C.III.3-8 In section C.III.3, the second to last paragraph states, "...Toward that end, the COL EIS will provide a summary discussion of the NRC staff's conclusion from the ESP EIS or EA. This approach is to ensure that the EIS is complete..." Please confirm that this approach of providing a summary discussion is also acceptable for the applicant in the COL application environment report (ER).
- C.III.4-1 Section III.4.1 says that Sections III.1 and III.2 will provide COL applicants with a complete set of information that needs to be included in the COL application. Please elaborate on the nature and purpose of these sections of DG-1145, how they are being developed, and their relationship with Section IV.1, COL Checklist, and the SRP.
- C.III.4-2 In Section C.III.4.3, the staff says it intends to include license conditions for COL action or information items that a COL applicant "cannot address" before the license is issued. COL applications must, and therefore will, address all required COL items. For items that refer to actions that will take place after the license is issued, COL applications will contain commitments to complete those activities at the appropriate point in the construction or operation of the plant. These commitments are expected to be inspected as part of the NRC construction inspection program and typically do not rise to the level of significance that would call for creation of a license condition. Why does the staff intend to create a suite of license conditions, rather than rely on its CIP, for COL Items that refer to actions that will take place after the license is issued?

- C.III.4-3 It is anticipated that there will be COL action items included in ESPs. Since some of the information for these items may not be complete at the time the COL is issued, will these be treated the same as DCD information/action items?
- C.IV.4-1 A letter from NEI to the staff dated August 31, 2005, recommended that the scope of operational programs subject to license conditions on their implementation should be those programs explicitly required by regulation. SECY/SRM-05-0197 states that, in addition, if a COL applicant chooses to use an operational program to satisfy a regulation, a license condition would be established on the implementation of that program.

In a December 1, 2005, public meeting with the Staff, industry expressed concern that this part of the SECY could be misinterpreted to sweep in numerous operational programs that are not explicitly required by regulation but could be indirectly linked to a regulatory requirement. For example, Erosion Corrosion Programs are not explicitly required by regulation but could be linked to 10 CFR 50, Appendix A, Appendix B, or 50.65. In the meeting, we received assurance from the Staff that 1) it was not the Staff's intent for this part of the SECY to result in a substantial increase in the scope of license conditions established on operational program implementation; and 2) the Staff would clarify its intent in future guidance.

DG-1145 is the right place to clarify this point but Section C.IV.4 does not do so. Please reaffirm the Staff's intent and discuss how the DG-1145 will be revised to address this issue. It is important to document this clarification in guidance for future members of the industry and Staff.

Our recommendation remains as stated in the 8/31/05 letter, i.e., that the scope of operational programs subject to license conditions on their implementation should be focused on those programs explicitly required by current or future regulations. We understand the ongoing SRP update process may identify a small number of additional programs that meet this criterion.

- C.IV.4.1-1 Why is operational reliability assurance process (O-RAP) not listed in section C.IV.4.1?
- C.IV.4.1-2 In regard to the last paragraph of Section C.IV.4.1, it is surprising that assessments still continue considering that operational programs have been an issue for many years.
- C.IV.4.2-1 Please delete the phase, "Given that ...(SAR)," in the last paragraph of section C.IV.4.2. This phrase is misleading and does not add anything to the paragraph.
- C.IV.4.2-2 It is recommended that the following be added to Section C.IV.4.2:

"In its SRM regarding SECY-04-0032 entitled, "Programmatic Information Needed for Approval of a Combined License Without Inspections, Tests, Analyses and Acceptance Criteria", the Commission clarified the phrase "....the program and its implementation are fully described in the application... as used in the SRM on SECY-02-0067" The Commission SRM on SECY-04-0032 noted "In this context, "fully described" should be understood to mean that the program is clearly and sufficiently described in terms of the scope and level of detail to allow a reasonable assurance finding of acceptability. Required programs should always be described at a functional level and at an increased level where implementation choices could materially and negatively affect the program effectiveness and acceptability."

- C.IV.4.2-3 In the first paragraph of Section C.IV.4.2, the guidance states that the applicant "shall" describe ----. Since this is a guidance document, the verb "should" should be used.
- C.IV.4.2-4 At the top of page 2, item (1) states the operational program, consistent with the level of information provided in final safety analysis reports (FSARs). The last paragraph of Section C.IV.4.2 states that current FSARs do not consistently contain the level of detail that the Staff needs to review and approve an operational program. This inconsistency should be resolved.
- C.IV.4.4-1 Section C.IV.4.4 is duplicated.
- C.IV.4.4-2 The second paragraph of Section C.IV.4.4 should be modified as follows: "COL applicants may propose ITAAC for a particular operational program as an alternative to fully describing the implementation of the program in the COL application. In this case, the COL applicant must"
- C.IV.7-1 In regards to the last sentence in the second paragraph of Section C.IV.7, this sentence and the difference in subsections 7.1 and 7.2 are not clear. It suggests that environmental issues are not part of the combined license (COL) application.
- C.IV.7-2 The guidance does not discuss the potential beneficial pre-application reviews of technical subjects in topical reports or other submittals. The concept has been discussed with the Staff under the Design Centered Approach concept and would seem to fall into the category of a pre-application interaction.
- C.IV.7-3 Early NRC meetings with the public should be discussed with the prospective applicant to allow for applicant company and public coordination and awareness.
- C.IV.7-4 Both the DCD and Environmental reviews involve interactions with other Federal, State and local governments. Early discussion with the Staff would help coordinate these interactions and allow a common understanding of the required sequence of applications and approvals.
- C.IV.7-5 Experience with ESP applications indicates that there should be early interaction

and agreement between NRC and applicants on the sources of historical site information for meteorology, socio-economic data, geology, etc. These data apply to both the DCD and Environmental parts of a COL.

- C.IV.7.1-1 The guidance does not address pre-application reviews of COL sections for sufficiency. Applicants and NRC would benefit from developing a common, early understanding of what is acceptable for docketing.
- C.IV.7.1-2 This section doesn't mention the applicants QA program or design reliability assurance program (DRAP) in the list of early interactions. NEI 04-01 highlighted these as programs that are implemented early.
- C.IV.7.1-3 Should Section C.IV.7.1 be titled "Pre-Application Activities that Support the Plant Specific DCD"? Pre application activities that support the Environmental Review are addressed in C.IV.7.2.
- C.IV.7.1-4 The early site work done to support plant construction (site characterization, sub-surface evaluation, etc.) should be considered a subject for early interaction with the Staff so that any issues are identified early.
- C.IV.7.1-5 Prospective applicants have found that there is considerable lead time in reaching agreement with the regional transmission organization (RTO) or other transmission provider to support the offsite power analyses required to support a COL. This would be a good subject for early NRC/Applicant discussion.
- C.IV.7.1.1-1 The third bullet in section C.IV.7.1.1 discusses the need to address plans for addressing FSER Action Items but does not address COL Information items. The third bullet should reflect the discussion in Section C.III.4 of DCD items vs. FSER items.
- C.IV.7.1.3-1 Should Section C.IV.7.1.3 address pre-application interactions on the site subsurface investigation and the applicable NRC inspection guidance?
- C.IV.7.2-1 This sub-section is largely written as guidance for the Staff, much like an SRP. As a COL guidance document, it should be written as guidance for an applicant. For example, C.IV.7.2 could be written to address the actions NRC expects prospective applicants to take relative to monitoring plans prior to application submittal.
- C.IV.7.2.4.-1 There were many differences identified in data sources used by the applicant versus those used by the NRC and its contractors (e.g., different National Weather Stations) for the 3 leading ESP applications. In regards to the first bullet of Section C.IV.7.2.4, should this pre-application activity include discussing data sources with the applicant?
- C.IV.7.2.4-2 The last bullet of Section C.IV.7.2.4 identifies a pre-application environmental activity of reviewing the COL application sections as they become available. Why

is this activity not also included in section C.IV.7.1 for other parts of the COL application? (For example, FSAR, Tech Specs, etc)