

**The following questions and comments were submitted by the public in the DG-1145 public workshop held on April 20-21, 2006**

**Bin 1: DG-1145 Process Development Questions**

The following comments and questions are related to the process being used to develop DG-1145. These comments and questions will be discussed at a future workshop.

- 1-1 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?
- 1-2 Will DG-1145 include guidance on Tier 1 information?
- 1-3 The title of Section C, Part I should be revised. This section is not the entire combined license (COL) application, it is just the final safety analysis report (FSAR).
- 1-4 After reviewing the list of questions that were submitted during the March 15<sup>th</sup> public workshop, it was determined that comments 1-9, 1-10, 2-1, 2-3 and 6-6 addresses sections C.IV.1 and C.IV.2. It is suggest that these comments be placed in Bin 5.

**Bin 5: DG-1145 Development Questions**

The following questions are directly related to the development of DG-1145. These questions will be addressed on the NRC website and included in DG-1145, Section C.IV.11, when it is issued for public comment.

- C.I.4-1 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 between the comprehensive set and the information supplied in a referenced design control document (DCD) for chapter four of the safety analysis report (SAR). This kind of information was provided for Chapter 12 during the March 15, 2006 workshop in a set of slides. It appears that section C.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.I.4-2 One of the "to do list" items for Chapter 4 is the program to manage aging of reactor internal components. Is the level of detail that has typically been submitted for license renewal applications considered sufficient for a combined license (COL) application?
- C.I.4-3 The third item in the "to do list" for Chapter 4 asked for a description of the

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materials and processes of construction which will be used for the reactor vessel internals to demonstrate that the facility will be consistent with technical information reviewed in the design control document (DCD). If the COL application does not depart from the generic DCD information, what additional information would the staff expect to see in this chapter? And what is the basis for this expectation?

- C.I.4-4 Do the four items on the slides entitled "DG-1145, Section C.I.4: Reactor", as well as reference to the generic design control document (DCD), identify all the information the staff would expect to see in Chapter 4 of a combined license (COL) application?
- C.I.4-5 The fourth bullet in the slides regarding Section C.I.4, requests a description of an aging management program for reactor internals materials. The draft Section C.I.4 does not appear to explicitly discuss the need for a program related to aging management over the life of the licensed facility. Further, there is no explicit discussion, information item or commitment in the AP1000 or ESBWR design control documents (DCDs) addressing such an aging management program. Since the aging management program is not discussed in the draft guidance, the AP1000 and ESBWR DCDs, or the AP1000 final safety evaluation report (FSER), what is the basis for requiring this information in a combined license (COL) application referencing a generic DCD?
- C.I.4-6 The first bullet in the first slide identified the combined license (COL) information item that any changes to the referenced design be identified to the staff. As discussed in the workshop, the final fuel design and loading pattern may not be available until after the application and possibly after the COL is issued. In this case, the final design would be submitted as a license amendment request under the Tier 2\* change process after the COL is issued. Does the staff agree that the design in the generic design control document (DCD) is the required design until the license amendment request is approved, and the COL may be issued based on the approved fuel design described in the generic DCD?
- C.I.4-7 DG 1145 should be modified to make clear that details of the fuel design and the core design such as those identified on page C.I.4-3 can be provided by referencing an approved design control document (DCD) and/or by the use of NRC approved methods and fuel reference topical reports. Chapter 4 should provide a summary description of the mechanical, nuclear and T&H designs of the various reactor components including fuel.
- C.I.4-8 The NRC made the comment that reload licensing for licenses referencing a certified design would continue to be governed by the applicable Design Certification rule. What does the staff see as the difference in how reloads would be implemented under Part 52 (for a license that references a design control document) versus the current Part 50 process?
- C.II-1 The title of Section C, Part II should be changed to "Additional Technical

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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 Regulatory Guide 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. NUREG-1555 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-1555?
- 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. 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 by using this approach, the DCD SAMDA information is resolved for the COL since it was incorporated by reference in the Design Certification rule?
- C.II.3-6 The schedules for revising Regulatory Guide 4.2 and NUREG 1555 to address combined license (COL) reviews are well beyond the time frame needed for the first set of COL applications being developed. Has the Staff considered other mechanisms for updating specific portions of those documents such as the Interim staff guidance previously utilized to update portions of the Review Standards such as RS-002 for Early Site Permits?
- C.III.1-1 It is recommended that additional guidance be provided to the staff to clearly identifying the regulatory basis for any guidance provided in DG-1145, section C.I and "to do list" items in C.III. And the language that is used in the "to do list" items for Section C.III.1 should be consistent with Section C.I. One staff member suggested that it would be helpful if DG-1145 content were identified as applicable regardless of departures from the certified design (i.e., information required beyond the design control document) or applicable only when departures from the generic design control document (DCD) are proposed. This

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same information should be incorporated in the standard review plan (SRP) for the benefit of future reviewers.

- 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 combined license (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 by a "reasonable process" to be insignificant, that information and significance assessment does not need to be presented in the combined license (COL) ER but should be retained by the applicant and made 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 combined license (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 environmental impact statement (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.

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- 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 and significance information. Please identify the process that the NRC staff will use in this area. 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 environmental impact statement (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.3-9 Staff members indicated during the workshop that they will need sufficient information presented in the combined license (COL) application to determine that each bounding analysis in the early site permit (ESP) is bounding for the selected plant design. 52.79(a)(1) requires that the application "demonstrate that the design of the facility falls within the parameters specified in the early site permit...". To date, the parameters to be specified in the early site permit have not been identified. DG-1145 should identify how the specific parameters can be identified if the ESP has not been issued at the time of COL application.
- C.III.3-10 During the workshop, the staff indicated that not all information provided in early site permit (ESP) environmental reports (ERs) is utilized and that the information does not need to be provided in the combined license (COL) application ER. Can the staff provide a listing of information that has been provided in ESP ERs and not utilized? This information could be eliminated from the ESP ERs and result in better utilization of both Staff and applicant resources.
- C.III.3-11 The staff indicated during the workshop, that any new environmental information since the ESP must be submitted with the combined license (COL) environmental report (ER) so that the staff can determine its significance. 52.79(a)(1) states that "----the application need not contain information or analyses submitted to the Commission in connection with the early site permit, but must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the parameters specified in the early site permit, and to resolve any other significant environmental issue not considered in any previous proceeding ----" (emphasis added). The intent is that only the new and significant information needs to be provided. This is consistent with the practice under License Renewal. Please explain the basis for the staff's view that COL applications must identify all new environmental information.
- C.III.3-12 During the workshop, the staff stated that the information in a July 6, 2005 letter is the staff's position on combined license (COL) environmental report (ER) content and that the September 27, 2005 NEI letter appeared to interpret the

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staff's position. Industry stated that the September 27, 2005 letter was intended to explain the industry's understanding of the staff's position. This subject should be discussed further at a later meeting.

- C.III.3-13 Transmission line routings for a proposed facility will likely not be finalized when a combined license (COL) application is filed or even when the license is issued. The COL environmental impact statement (EIS) should address the impacts of transmission line routes. Guidance should be provided on what should be included in the application and whether or not a license condition may be used for this and other unresolved environmental issues.
- C.III.3-14 The staff indicated during the workshop that the combined license (COL) environmental report (ER) must contain environmental information that was not submitted previously for an early site permit (ESP), including specific design information in areas, such as the cooling water intake structure, where environmental impacts were addressed for ESP based on more general or typical design information and enveloping design parameters. A central principal of the plant parameter envelope approach for ESP is that environmental impacts thus concluded for ESP envelope those for a specific plant design whose characteristics fall within the site characteristics and design parameters on which the ESP is based. COL applications must demonstrate that the actual proposed facility falls within the ESP site characteristics and design parameters. Please explain why and the regulatory basis for the staff view that COL applications must contain specific design information in areas where environmental impacts were concluded for ESP on the basis of enveloping design information.
- C.III.4-1 Section III.4.1 says that Sections III.1 and III.2 will provide combined license (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 standard review plan (SRP).
- C.III.4-2 In Section C.III.4.3, the staff says it intends to include license conditions for combined license (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 (CIP) 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 combined license (COL) action items included in early site permits (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

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design control document (DCD) information/action items?

- C.III.4-4 DG-1145 should recognize that combined license (COL) information items may have multiple parts. Some parts can be closed in the COL application and other parts may need to await plant construction for closure.
- C.III.4-5 The first two workshops resulted in some confusion over the "to do list" items that will be published as sections C.III.1 and C.III.2 of the guide. Discussion with the staff helped clarify the issue, in some cases, of which information was expected to be included in the application and which should be made available for inspection during construction or operation of the plant. It would be helpful to organize sections C.III.1 and C.III.2 into sub-sections separating the application information from design verification/inspection items. A third possible group could be the inspection, test, analyses, and acceptance criteria (ITAAC) items associated with a chapter. The categorization of combined license (COL) information items in future workshops for the individual chapter technical information discussion would be beneficial.
- C.III.4-5 The regulatory basis for each "to do list" item is necessary. For example, the items required by combined license (COL) Information items are required to be addressed by DCR IV.A.2.e. The regulatory basis would be especially important for information that supplements the generic design control document (DCD) scope design information and that is not required by a COL information or action item.
- C.III.5-1 In the workshop, the staff recognized that some combined license (COL) applicants would like to close design acceptance criteria (DAC) and inspection, test, analyses, and acceptance criteria (ITAACs) before the COL is issued. Please provide guidance on where and how these closures should be identified in the application.
- C.IV.1-1 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?
- 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. In the meeting, we received assurance from the staff that it was not the staff's intent for this part of

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the SECY to result in a substantial increase in the scope of license conditions established on operational program implementation. And 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.

- 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 phrase, "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 Item one, at the top of page two states "the operational program, consistent with the level of information provided in FSARs". The last paragraph of Section C.IV.4.2 states that current FSARs does 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

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application. In this case, the COL applicant must ...."

- C.IV.4.4-3 Section C.IV.4.4 needs to clarify that a reference to an applicant choosing to use a program to satisfy a regulation even though the regulation does not require a program is applicable to future regulations and, the fact that a program is discussed or identified in a referenced generic design control document (DCD) does not necessarily make that program one that is required by regulation.
- C.IV.7-1 In regards to the last sentence in the second paragraph of Section C.IV.7, this sentence and the differences 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 design control document (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 early site permit (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 design control document (DCD) and Environmental parts of a COL.
- C.IV.7.1-1 The guidance does not address pre-application reviews of combined licenses (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.

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- 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 combined license (COL). This would be a good subject for early NRC and 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 final safety evaluation report (FSER) action items but does not address COL information items. The third bullet should reflect the discussion in Section C.III.4 of design control document (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 combined license (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 combined license (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)