

The following questions and comments were submitted by the public during the DG-1145 Workshop held on June 13-14 2006

DG-1145 Development Questions

C.I.1-1 There are several places where the applicability of this guidance for different combined license (COL) application scenarios is stated. The applicability is stated differently in different subsections. For example, the first paragraph states "The guidance provided in DG-1145, Section C.1, is applicable to a combined license applicant that references neither a certified design nor an early site permit. Additional guidance for COL applicants referencing a certified design and/or early site permit is provided in Section C.III of this document." Section 1.4 states that "The division of responsibility between the reactor designer or certified plant designed (sic), architect-engineer, constructor, ----". Section 1.8 states "The guidance provided in this regulatory guide is for a COL applicant that does not reference a certified design as part of the application". Section 1.8 goes on to say that there would be no interfaces for an application that includes all design and site information without reference to a design control document (DCD) or early site permit (ESP).

Our understanding was that DG-1145 is intended to cover all scenarios, i.e., COL applications referencing a Certified Design and/or ESP as well as a COL application referencing either a DCD or ESP or neither. The wording in this section implies that all the information requirements for COL applications referencing a DCD and/or an ESP will be in Section C.III of the guidance. The intent of the approach for all of DG-1145 should be clarified since this is a critical aspect of the use of the guidance.

C.I.1.1.6.2-1 Section 1.1.6.2 addresses compliance with the standard review plan (NUREG-0800) for technical guidance and acceptance criteria. (emphasis added). However, 10 CFR 50.34 (g)(2) requires an evaluation of the differences in the design features, analytical techniques and procedural measures proposed for a facility and those corresponding features, techniques and measures given in the SRP acceptance criteria. 10 CFR 52.79(b) incorporates 50.34(g)(2) by reference. Is it the intent of the staff to expand the information required beyond that required in the rules?

C.I.1.1.6.6-1 In section C.I.1.1.6.6, Is the list of acronyms for the safety analysis report (SAR) or the entire application?

C.I.1.6-1 The guidance calls for summaries to be provided in the combined license (COL) application for information incorporated by reference. In general, if some sort of descriptive or summary information is required to fully understand the reference and the context in which it is being used, this information would typically be provided on a case-by-case basis in the COL application. The NRC agreed at the June 14th public workshop that these summaries are not required in all

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cases. Section C.I.1.6 should be revised to indicate that summaries of information incorporated by reference may be provided as appropriate.

- C.I.1.6-2 In section C.I.1.6, the last two sentences in the first paragraph requires a summary of information submitted to the Commission in other applications and incorporated by reference in the combined license (COL). Industry did not plan to summarize information in Topical Reports and other documents referenced in a generic design control document (DCD). We believe this requirement is carried over from the Part 50 licensing processes. Incorporation of the DCD by reference is permitted by 10 CFR 52 and that rule does not require the COL application to include a summary of the DCD. What is the intent of this requirement?
- C.I.1.9-1 Sections C.I.1.9.1, C.I.1.9.2, and C.I.1.9.3 requires a combined license (COL) applicant to provide an evaluation of compliance with regulatory guides, Standard Review Plans (SRPs), and generic issues in effect 6 months prior to the date of application. Industry understands that the effective date for such an evaluation for issues resolved in a referenced generic design control document (DCD) or early site permit (ESP) is tied to the application date for those documents. Therefore, the only evaluation required for a COL application referencing a certified design and/or ESP would be for those Reg. Guides, SRPs and generic issues that are beyond the scope of the referenced DCD and/or ESP. Please confirm this understanding.
- C.I.1.9-2 Section C.I.1.9 quotes the requirement in proposed 10 CFR 52.79(a)(37) for a combined license (CO)L applicant to include information in the application to demonstrate how operating experience insights from generic letters and bulletins up to 6 months before the docket date of the application have been incorporated into the plant design. Since NRC is in the process of updating the standard review plans (SRPs), and the updated SRPs should include the latest NRC positions relative to operating experience, this requirement should use the date of the latest SRP revision date as the beginning date for this information review. This would avoid the duplication required in reviewing all bulletins and generic letters and also addressing the latest SRPs.
- C.I.1.9-3 It is recognized that Section C.I.1 is not intended to address combined license (COL) applications referencing a certified design (or early site permit). However, since the review guides and standard review plans (SRPs) are periodically revised, the industry requests that Section C.III.1 and C.III.2 present an appropriate discussion as to which guides and SRPs should be evaluated to the scope of information provided in the COL applicaton.

The COL application must address COL action items (including those pertaining to design) and any other information requirements that pertain to operational, administrative, procedural matters (not covered within the scope of the certified design proceeding. The COL application must also address COL actions items identified in the ESP. Therefore,

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a. Relative to the certified design and ESP scope, Sections C.III.1 and C.III.2 should make clear that the COL application need only provide conformance evaluations for the guidance and standards listed in C.I.1.9.1 through C.I.1.9.4 with respect to matters covered by COL action items and/or issues explicitly identified in the generic design control document (DCD) or early site permit (ESP) as applicable to the COL applicant scope.

b. The guidance and standards listed in C.I.1.9.1 through C.I.1.9.4 may be revised (or superseded) after the licensing basis of the referenced certified design (or the ESP) is established. Sections C.III.1 and C.III.2 should make clear that no re-evaluation of conformance is required for COL application for the design certification or ESP scope of information. The COL application need only address the revised guidance as it pertains to COL action items and/or operational, administrative, procedural matters beyond the scope of the design certification or ESP.

C.I.1.9-4 The second Section C.I.1.9.4 should be C.I.1.9.5.

C.I.1.9.2-1 in Section C.I.1.9.2. the last word in the last sentence should be requirement vs. requirements.

C.I.1.9.4-1 Section C.I.1.9.4 addresses the requirements for including information in an application that demonstrates how operating experience insights from generic letters and bulletins, or comparable international operating experience, have been incorporated into the plant design. The last sentence in paragraph 3 of Section C.I.1.9.4 states "- generic communications that remain open and which are technically relevant to the combined license (COL) applicant's facility design, including operational aspects of the facility, should be addressed in the application." (emphasis added) Please clarify if the operating experience review for insights is only applicable to facility design.

C.I.1.9.5 Section C.I.1.9.5 (second section numbered 1.9.4) requires combined license (COL) applicants to address the Commission licensing and policy issues for advanced and evolutionary light water reactors (LWRs). The guidance provides a list of SECY documents that address these issues but states it is not a comprehensive listing. The review of this list of SECYs (and others) to develop a list of issues to be addressed would be a subjective process and may not result in the list of issues the NRC wants to be addressed. Clearer direction should be provided with the actual list of issues as determined by the NRC and reviewed by stakeholders

C.I.2-1 Please confirm that a combined license application does not need to update siting information in an early site permit (ESP) to account for changes in NRC guidance issue after the ESP.

C.I.2-2 In general, the industry expects that the finality provisions of 10 CFR

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52.39 would serve as a fundamental basis for combined license (COL) application content when referencing an early site permit (ESP). For those matters addressed in the ESP application and resolved in the ESP proceeding, the industry would expect that no additional information need be provided in the COL application final safety analysis report (FSAR) 2, except as required by:

- (a) Site related COL action (or information) items as described in the referenced design control document (DCD) (if applicable)
- (b) COL action items established in the ESP
- (c) Information to show compliance with design certification (site related) interface requirements and site parameters (Design Certification Rule IV.A.2.d)
- (d) Terms and conditions of the ESP
- (e) Lastly, the COL applicant may become aware of information regarding site characteristics that represents significant impact to the conclusions reached in the ESP application or the NRC's ESP final safety evaluation report (FSER), such as the construction of new off-site industrial facilities not previously considered in the ESP external hazards analyses. In such cases, that information would be described and addressed in the COL application FSAR Chapter 2.

For matters addressed and resolved at ESP, not impacted by any of the above exceptions, the COL application FSAR Chapter 2 would provide a simple statement that the subject information was provided and resolved in the ESP proceeding.

Most plainly, the COL applicant would not be expected to broadly revisit, re-collect, re-analyze data, and then describe that information in COL application FSAR Chapter 2 to confirm that site characteristics established in the ESP remain valid.

The industry requests NRC staff perspectives on the above outlined understanding of ESP finality in the safety area.

- C.I.2.1.1.1-1 Section C.I.2.1.1.1 requires the location of each reactor at a site to be specified by latitude and longitude to the nearest second. Has the Commission determined that this information is not sensitive?
- C.I.2.1.2.1-1 Section C.I.2.1.2.1 refers to 10 CFR 100.3(a) as requiring an exclusion area boundary (EAB). There is no subsection (a) in 100.3 and 100.11 is the location of the requirement for an EAB.
- C.I.2.2.3.1-1 Section C.I.2.2.3.1 (5) discusses collisions with the intake structure. Since some new plant designs do not rely on an intake structure for safe shutdown, would a simple statement that the loss of intake structure has no safety impact be sufficient?
- C.I.2.3-1 Section C.I.2.3: During the workshop, the NRC noted that regulatory Guide 1.23 will be revised. The industry advised that it would not be possible for the group

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of prospective combined license (COL) applicants to meet revised requirements for met tower design since the data collection would have begun in 2005 and 2006.

- C.I.2.3.3-1 Section C.I.2.3.3 requires the applicant to provide at least two consecutive annual cycles of meteorological data collected on site with the application. Our understanding from statements at the workshop was that it will be acceptable for applicants to provide available data covering less than two years with the application and provide a commitment to submit the balance of the data during the COL application review.
- C.I.2.3.4.1-1 Section 2.3.4.1 indicates that the combined license (COL) application should provide both conservative and realistic estimates of atmospheric dispersion factors. What is the purpose for providing realistic estimates?
- C.I.2.4-1 Section C.I.2.4: Please clarify that if the selected reactor design technology in a combined license (COL) application precludes release of liquids containing radioactive materials, the COL application does not need to analyze transport of radioactive materials through soil and groundwater.
- C.I.2.4.3-1 Section C.I.2.4.3 of Regulatory Guide 1.70 references Regulatory Guide 1.59. Is this still an appropriate reference or has it been superseded?
- C.I.2.4.5.1-1 Section C.I.2.4.5.1 states "Present the determination of probable maximum meteorological winds in detail." How are the probable maximum meteorological winds different from the design basis maximum winds requested in section 2.3?
- C.I.2.4.9-1 Section C.I.2.4.9 refers to "thermal evidence" in the region in discussing upstream diversion or rerouting. What guidance is available for addressing thermal evidence?
- C.I.2.4.11-1 Please confirm that the reference to a "100-year drought" in Sections C.I.2.4.11.1 and C.I.2.4.11.5 refers to a drought with 100-year recurrence.
- C.I.2.5.2.1-1 It is Recommended that Section C.I.2.5.2.1 of the guidance explicitly state that the results of the EPRI-SOG PSHA (including in the context of this section, the use of the EPRI-SOG seismicity catalog) is acceptable for use.
- C.I.2.5.2.4-1 Section C.I.2.5.2.4 requests "Compare the controlling earthquake magnitudes and distances for the site with the controlling earthquakes and ground motions used in licensing (1) other facilities at the site, (2) nearby plants, or (3) plants licensed in similar seismogenic regions." For new plants, this would result in a comparison of different methodologies since most currently licensed plants were based on 10 CFR 100, Subpart A historical evaluations. What is the regulatory basis for these comparisons?

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- C.I.2.5.2.4-2 As the industry has discussed with the NRC staff, section C.I.2.5.2.4 should also describe a SCDF performance-based approach that would be acceptable for use on a case-by-case basis as an alternative to ASCE 43-05 (FOSID).
- C.I.2.5.2.5-1 Recommend that this section C.I.2.5.2.5 include a definition of "rock" (as opposed to "hard rock") in relation to the requirement to "provide the rationale for any assumed nonlinear rock behavior".
- C.I.2.5.3-1 Sections C.I.2.5.3.7 and C.I.2.5.3.8 refer to a zone requiring "detailed faulting investigation." Such investigations are only discussed in Appendix A to Part 100 which is not applicable to new plants. For the pre-1997 plants, these investigations were required by 10CFR 100.10(c). At least one of these sections should identify the regulatory basis (under Subpart B of part 100) for requiring this detailed faulting investigation for the new plants.
- C.I.2.5.4.6-1 Please provide guidance on the intent of the phrase "potential piping conditions during construction" as used in Section C.I.2.5.4.6.
- C.I.2.5.6.1-1 Is the Regulatory Guide 1.70 section 2.5.6 on embankments and dams no longer required or will it be included elsewhere in DG-1145?
- C.I.3.1.4.1-1 Section C.I.3.1.4.1(3) requires a discussion of the protection provided to cope with in-leakage from such phenomena as cracks in structure walls. This appears to be a new requirement. What is the regulatory basis for requiring this information?
- C.I.3.2.1-1 Section C.I.3.2.1 states that "Plant features, including foundations and supports, that are designed to remain functional in the event of a safe shutdown earthquake (SSE, see Section 2.5) or surface deformation should be designated Seismic Category I." What is the definition of "surface deformation" and the regulatory basis for this addition to the requirements in Regulatory Guide 1.70?
- C.I.3.2.1-2 Section C.I.3.2.1, last paragraph requires a list of structures, systems, and components (SSCs) designed for an operating-basis earthquake (OBE). Designing equipment for an OBE is no longer a requirement. What is the basis for this information requirement?
- C.I.3.2.1-1 Industry understands from the workshop discussion that, based on 10 CFR 50, Appendix S, an Operating Basis Earthquake (OBE) must be defined in the application. The last sentence in Section C.I.3.2.1 requires a listing of all structures, systems, and components (SSCs) or portions of SSCs that are intended to be designed for an OBE. The Staff stated that there may not be any SSCs in this category.
- C.I.3.3.1-1 Section C.I.3.3.1 requires the application to provide "current" references for the basis, including assumptions. What is intended by the use of the word current? Some references may not be the latest version of a document but may be

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adequate. Please clarify.

- C.I.3.3.2-1 Modify Item (3) in Section C.I.3.3.2 to clarify that if missile spectrum II of Revision 2 of SRP 3.5.1.4 is used for design of safety structures and if the nuclear plant site does not include special missile creating sources beyond those now present in non-safety buildings such as turbine building, office buildings, conventional laydown areas and warehouses of current nuclear plants; only effects of structural collapse of non-safety buildings on safety buildings need to be addressed.
- C.I.3.4.1-1 Section C.I.3.4.1(1) requires identification of safety- and non-safety-related structures, systems, and components (SSCs) that should be protected against external flooding resulting from natural phenomena and internal flooding resulting from failures of non-seismic tanks, etc. The requirement to address protection of non-safety related SSCs is new. Does the staff expect a statement in this section that non-safety SSCs are not credited in the design and therefore not included in the analysis?
- C.I.3.5-1 During the workshop the NRC indicated that the "to-do list" for C.III.1.3.5.3 would include "For each structures, systems, and components (SSC) that needs to be re-analyzed for a tornado, extreme wind, or site proximity missile impact or for aircraft impact, demonstrate the ability of each structure or barrier to resist missile hazards." The applicability of such an analysis for aircraft impact is not understood since the missile character does not change.
- C.I.3.5.1.3-1 Please modify Item (1)(f) in Section C.I.3.5.1.3 to clarify that if the missile generation probability of (2) is acceptably small and if the in service inspection and testing program of item (3) is acceptable, then the information for types of generated missiles is not necessary.
- C.I.3.5.1.6-1 In Section C.I.3.5.1.6, it is understood that the probability of occurrence of $>10^{-7}$ is intended to be more restrictive than the E-6 used in DOE Standard 3014-96. Do the DOE standard and its technical support documents provide an acceptable means of providing the parameters requested in the last paragraph of this section?
- C.I.3.5.1.6-2 The third paragraph in Section C.I.3.5.1.6 refers to radiological consequences in excess of the exposure guidelines of 10 CFR 100. The correct reference for exposure guidelines should be 10 CFR 50.34(a)(1).
- C.I.3.6-1 During the discussion of Section C.I.3.6, the NRC recognized that certain information required by the guidance would not be available at the time a combined license (COL) application is submitted, e.g., Section C.I.3.6.2.5 - final configurations of special features. There were comments made that any information not available in the application would be covered by inspection, test, analyses, and acceptance criteria (ITAAC). This general comment implies the extension of ITAAC beyond that contemplated in the generic design control

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documents (DCDs) and by prospective COL applicants. Section C.I.14.3 of the current approved generic DCDs provides criteria for ITAAC that have been assumed in the preparation of COL applications and site-specific ITAAC. These criteria should be used to determine when ITAAC are required

- C.I.3.6.2.1-1 Section C.I.3.6.2.1 requires that the combined license (COL) applicant, "Provide the resulting number and location of design basis breaks and cracks. Also provide the postulated rupture orientation ... for each postulated design basis break location." Given that the number and location of breaks and splits is typically dictated by detailed stress and fatigue analysis and that this detailed analysis will not be completed for all high and moderate energy piping until the detailed design phase (i.e. post COL application submittal), it is impractical for the COL applicant to provide this information in the COL application. This requirement essentially forces the applicant to guess where the breaks and splits will be in his high and moderate energy piping or to guess which break and split locations and orientations will be bounding. In either case, if the initial guesses do not prove to be accurate, there would be implications relative to licensing the plant. We recommend that this requirement be removed from DG-1145.
- C.I.3.6.3-1 Section C.I.3.6.3(1)(a) requires types of materials and material specifications (including heat numbers) used for base metal, weldments, nozzles and safe ends. This information will not be available at the time a combined license (COL) application is submitted and should be in the category of information to be verified by inspection during plant construction.
- C.I.3.6.3-2 Section C.I.3.6.3(1)(a) requires that the combined license (COL) applicant to "Identify the types of materials and material specifications (including heat numbers) used for the base metal, weldments, nozzles, and safe ends." [for LBB piping]. For the near term COL submittals that DG-1145 is provided for, the new plant designs LBB candidate piping components would not have been ordered so it is impractical (if not impossible) to provide heat numbers on these components. We recommend that this requirement be removed from DG-1145.
- C.I.3.6.3-3 Section 3.6.3(1)(b) requires that the application include material properties including toughness (J-R curves) and tensile (stress-strain curves) data at temperatures near the upper range of normal plant operation. As built properties will not be available at the time the application is submitted. The combined license (COL) application can include representative properties that would be updated to as-built conditions during construction.
- C.I.3.6.3-4 Section C.I.3.6.3(1)(b) requires that the COL applicant: "Provide the material properties, including the following: toughness (J-R curves) and tensile (stress-strain curves) data at temperatures near the upper range of normal plant operation; long-term effects attributable to thermal aging; yield strength and ultimate strength." [for LBB piping]. The material properties for the base metal, weldments and safe ends can only be provided for those materials and material specifications planned for use (detailed nozzle properties should not be required

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since they are not considered in an LBB analysis). That is to say, the material properties of the as-built materials will not be available until the construction phase . Material properties that will be very consistent with the actual materials that will be used and fabricated for the new plant design can be provided. We recommend that this requirement be reworded to allow the applicant to submit representative material properties.

- C.I.3.6.3-5 Section C.I.3.6.3(2)(a) requires that the application include as-built drawings of pipe geometry, etc. Obviously, these will not be available for the application but should be available for inspection during construction.
- C.I.3.6.3-6 Section C.I.3.6.3(2)(a) requires that the combined license (COL) applicant: "Provide as-built drawing(s) of pipe geometry (e.g., piping isometric drawings)." The as-built drawings would not be available until the construction phase . Design isometrics can be provided. We recommend deleting the word "as-built" from item 2(a).
- C.I.3.6.3-7 Section C.I.3.6.3(2)(c) requires a discussion of snubber reliability including any technical specification requirements. Typically, snubbers are no longer addressed in the tech specs.
- C.I.13.5-1 Section C.I.13.5 includes procedure requirements from ANSI N 18.7-1976/ANS-3.2. These procedure requirements have traditionally been required to be addressed in an applicant's Quality Assurance (QA) program. Section C.I.17.5 does not require the application to address these requirements. Is it the Staff's expectation that all this information would be provided in Section 13.5 of the combined license (COL) safety analysis report (SAR)?
- C.I.14-1 Does the NRC expect to update Regulatory Guides 1.16 and 1.68 in the near term?
- C.I.14.2.2-1 In the first sentence of section C.I.14.2.2, the term "organizational units" is used here and elsewhere in the guidance. Is that term defined elsewhere in regulatory guidance applicable to a combined license COL application? What is the definition?
- C.I.14.2.2-2 Section C.I.14.2.2 states that the applicant should develop a training program for each fundamental group in the organization relative to the schedule for pre-op and startup testing. This type of information was not developed in the past per Regulatory Guide 1.70. Is there guidance elsewhere for this training?
- C.I.14.2.2-3 The third sentence in section C.I.14.2.2 states that the safety analysis report (SAR) should describe how and to what extent the applicant's plant operating and technical staff will participate in each major test phase. Applicants can describe in general terms the degree of involvement of the plant staff in testing but the details will not be known at the time the combined license (COL) application is submitted.

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- C.I.14.2.4-1 The wording in section C.I.14.2.1 implies that the details of the administrative control procedures will be known and described in the combined license (COL) application. A general description can be provided in the COL application. The staff and Industry need to discuss the expectations for this section.
- C.I.14.2.4-2 Section C.I.14.2.4 states that the methods to be used to ensure retesting required for modifications or maintenance remains in compliance with inspection, test, analyses and acceptance criteria (ITAAC) requirements should be described. We expect that final safety analysis reports (FSARs) will describe that:
- The licensee is responsible for evaluating any work performed after an ITAAC determination has been made to ensure that the acceptance criteria continue to be met,
- This evaluation may be based on post-work testing, engineering analysis, or a combination of both testing and analysis, and available for NRC inspection, and
- Like non-ITAAC related work, this work will be performed under approved maintenance and/or plant change processes and procedures.
- The specific methods to be used (i.e., post-work testing and/or analysis) may be as varied as the ITAAC themselves and are thus not practical to describe the FSAR. Rather, does the staff agree that a more general description similar to the bullets identified above would be appropriate in this regard for Section C.I.14.2.4 of the FSAR?
- C.I.14.2.5-1 The last two sentences in section C.I.14.2.5 appear to be more appropriate for Section C.I.14.2.6.
- C.I.14.2.8-1 Section C.I.14.2.8 describes the review of operating and testing experience in the past tense, i.e., performed prior to combined license (COL) application submittal. It is more likely that operating experience closer to the time that the test procedures are written will be reviewed and experience applied to procedures as they are developed and as appropriate.
- C.I.14.2.8-2 The second paragraph in section C.I.14.2.8 requests a "summary description" of pre-op and startup testing for unique or first-of-a-kind design features. Does the NRC staff agree that the level of detail typically provided in safety analysis report (SAR) test abstracts is appropriate for this section?
- C.I.14.2.10-1 Section C.I.14.2.10 states that the applicant should "describe the procedures" that will guide initial fuel loading and initial criticality. The AP1000 and ESBWR provide criteria that must be met for procedures for initial fuel loading and criticality. Does the NRC staff agree that the information provided in these

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documents is the expected level of detail for a COL application?

- C.I.14.2.11-1 The fifth sentence in section C.I.14.2.11 states that each test required to be completed before initial fuel load or designed to satisfy the requirements for completing inspection, test, analyses, and acceptance criteria (ITAAC) should be identified, cross-referenced and provided with the combined license (COL) application or be made available for audit during NRC COL application review. These procedures will be prepared during construction and will, therefore, not be available prior to issuance of the COL.
- C.I.14.2.11-2 Section C.I.14.2.11.e requires approved test procedures be made available 60 days prior to use. This commitment can be made, but experience indicates that it is not unusual for procedures to be revised during this 60-day window due to testing experience and a number of other reasons. Providing an approved procedure 60 days prior to the scheduled testing should not be construed as a commitment to "freeze" the procedure during that window.
- C.I.14.2.11-3 The third sentence in the first paragraph of section C.I.14.2.11 states that the sequential test schedule for testing individual structures, systems, and components (SSCs) should be provided. The detailed testing schedule will not be available at the time the application is submitted but will be available later during construction. This section should indicate that a high level schedule be provided with the application.
- C.I.14.3-1 Section C.I.14.3, 4th paragraph, The third sentence in the fourth paragraph in Section C.I.14.3 references Section 13.6 for Security ITAAC, and Section C.I.13.6 references Section C.I.14.3.
- C.I.14.3-2 Section C.1.14.3 states that combined license (COL) inspection, tests, analyses, and acceptance criteria (ITAAC) should not be included as part of the final safety analysis report (FSAR) because ITAAC cease to exist after the Commission's Section 52.103(g) finding. ITAAC would not be unlike other FSAR info that has a limited FSAR lifetime, such as the Start-up Test Program, Technical Specifications and Construction QAP. Are there other reasons why ITAAC should be submitted separately from the FSAR?
- C.I.14.3-4 Section C.1.14.3 states that combined license (COL) applicants should describe their methods and criteria for establishing inspection, test, analyses, and acceptance criteria (ITAAC). Substantial guidance in this regard is provided in draft SRP 14.3 (1996) and in Section C.I.14.3 of the AP1000 DCD. As the industry has discussed with the NRC, COL applicants will use the same methods and criteria for defining site-specific ITAAC as were used for design certification ITAAC. Why has the staff not provided that type of guidance here, or will this type of guidance be provided in Section C.II.2? What is the relationship between the guidance in C.I.14.3, C.II.2, and C.III.7? Does the NRC agree that Section 14.3 for a COL applicatoin that references a design certification may consist largely of a reference to design control document (DCD) Section 14.3?

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- C.I.15.0-1 The first paragraph in section 15.0 refers to policies and procedures that may not be available at the time the combined license (COL) application is submitted. The balance of the Chapter 15 guidance does not refer to any policies or procedures. What policies and procedures are these?
- C.I.15.0-2 The fourth paragraph in Section C.I.15.0 lists a number of TMI Action Plan items that must be addressed. Some of these were not addressed in generic design control documents (DCDs) even though the subject matter is in the generic DCD scope. We understand that a combined license (COL) application referencing a certified design would not be required to address the generic design issues in this list since the DCD information was determined to be adequate for that scope during the design certification process. This comment also applies to the information on Generic Safety Issues and operating experience insights.
- C.I.15.0-3 Section C.I.15.0 includes a number of lists of Three Mile Island (TMI) items, USI/GSIs, and Bulletins and Generic Letters. Section C.I.1.9 requires that the application address similar documents. Section C.IV.8 also addresses generic regulatory guidance. These sections should be consistent and applicants should be allowed to provide the information in one place and reference it in the others.
- C.I.15.0-4 Section C.I.15.0, first paragraph reads "As with other chapters of this Regulatory Guide (RG), some policies and procedures will not be available at the time the combined operating license (COL) application will be submitted. In those cases, make a commitment in the application with a summary description of the procedures to be available by fuel load. Include a discussion of how the design meets the applicable regulatory requirements and regulatory guidance available." Is this generic to all sections or just to C.I.15?
- C.I.15.6.2-1 Item f in section 15.6.2 requests a discussion of the basis in the emergency operating procedures (EOPs) for operator response, available instrumentation and timing. Typical safety analysis report (SAR) Chapter 15 analyses include any credited operator actions in the sequence of events following an accident or transient. The basis for assumed action times and available instrumentation were described in the basis documentation for the EOPs. It is not clear what level of detail is requested here for inclusion in Chapter 15.
- C.I.15.6.2-2 What is the intent of the requirement to evaluate the effect of operator errors?
- C.I.15.6.2-3 What is a "plant operational analysis"?
- C.I.15.6.2-4 Section C.I.15.6.2 indicates that the combined license (COL) application should "Discuss the basis in the Emergency Operating Procedures (EOP) for operator response, available instrumentation, and timing." This guidance is not clear. For instance, it implies that a basis for operator response, available instrumentation, and timing should be included in each EOP that could be extracted and included in this section. Is this really asking for the basis for "available instrumentation"? To what "timing" is it referring, e.g., operator response or instrumentation?

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Please provide, or provide reference to additional guidance available to clarify this requested information.

- C.I.15.6.2-5 Section C.I.15.6.2 refers to SECY-77-439. Is this document available in ADAMS? Will all DG-1145 references, and all standard review plan (SRP) references, be made available in ADAMS?
- C.I.15.6.2-6 Section C.I.15.6.2 refers to "required operator actions". It is not clear if this is meant to be credited operator actions or operator actions based on some other requirement.
- C.II.1-1 Section C.II.1 states, in part, "An application for a combined license under 10 CFR 52 needs to include a comprehensive risk evaluation". The regulatory meaning of the verb phrase "needs to" is not clear. Since this section of DG-1145 is intended to provide guidance for combined license (COL) application content to an applicant who references neither a certified design nor an early site permit (ESP), the language should be clear if "needs to" means "shall" or if it means "should." Unless the guidance is repeating a NRC requirement, we expect that "should" would be the proper verb to use. Should and shall are well understood and have been used extensively in licensing documentation. "Needs to" is used in several places in this section.
- C.II.1-2 In several places, the guidance indicates the combined license (COL) application risk evaluation would be used to identify interface requirements and COL Action Items. These are terms that apply to design certifications and early site permits (ESPs). By definition, we would not expect the COL review to result in identification of interface requirements or COL Action Items.
- C.II.1-3 During the workshop the NRC stated that a combined license (COL) application referencing a certified design "builds off certified design reviews with focus on site specific info, design and operational changes/level of detail information, and resolution of COL issues." The underlined phrase implies that the COL application would need to address issues resolved in the Design Certification or include additional design details within the design certification scope. The underlined phrase should be deleted or clarified to make clear it that COL applications are not required to provide additional detail on the referenced certified standard design. Similarly, the plant-specific probabilistic risk assessment (PRA) need not be updated to reflect additional design detail as it is developed. However, the PRA would be updated to reflect site-specific info and changes to the standard design, as appropriate, consistent with the objective that the PRA reasonably represent the as-built, as-to-be operated facility.
- C.II.1.1-1 The last sentence before the bullets in Section C.II.1.1 should be fixed. Section 52.47 does not specify requirements for combined license (COL) applicants.
- C.II.1.2-1 Section C.II.1.2 provides the following example of vulnerability: "failures or combinations of failures which are large risk contributors that could drive risk to

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unacceptable levels". Is this measured with respect to the goals or the application-specific CDF? The Staff response in the workshop was that this requirement was based on a relative scale so that the low-hanging fruit could be addressed. This statement is inconsistent with the quoted wording in the DG. Please confirm that vulnerabilities are limited to those failures or combinations of failures that could cause the design to fail to meet stated objectives.

- C.II.1.2-2 In Section C.II.1.2, what is the regulatory basis for the combined license (COL) application to show that a design represents a reduction in risk over existing plants?
- C.II.1.2-3 DG-1145 should clarify that for passive plants regulatory treatment of non-safety systems (RTNSS) systems link the probabilistic risk assessment (PRA) to the inspection, test, analyses, and acceptance criteria (ITAACs). ITAACs are required for risk significant non-safety systems. SECY requires those systems are RTNSS.
- C.II.1.2-4 In section C.II.1.2 the following language is provided: "Determine how the risk associated with design relates to the Commission's goals of less than 1 E-4/yr for core damage frequency (CDF) and less than 1 E-6/yr for large release frequency (LRF).2 "
- The objective is to demonstrate that the QHOs are met. This can be demonstrated using the subsidiary objectives for CDF (1E-4/yr.) and LERF (1E-5/yr.). LRF is not defined in the regulations and a LRF goal is not appropriate for a regulatory guide. The draft should be changed to reference the QHOs and subsidiary goals appropriately.
- C.II.1.2-5 In Section C.II.1.2, Footnote 2 states "Commission SRM dated June 26, 1990 in response to SECY-90-016. In addition, the Commission approved the use of a containment performance goal (CPG). The CPG includes (1) a deterministic goal that containment integrity be maintained for approximately 24 hours following the onset of core damage for the more likely severe accident challenges and (2) a probabilistic goal that the conditional containment failure probability (CCFP) be less than approximately 0.1 for the composite of all core damage sequences assessed in the PRA."
- The objective is to demonstrate that the QHOs are met. This can be demonstrated using the subsidiary objectives for CDF (1E-4/yr.) and LERF (1E-5/yr.) The CPG was accepted by the Commission before risk-profile information for advanced passive plants was available. Probabilistic risk assessments (PRAs) on current designs demonstrate that nearly all credible core damage sequences have been eliminated. The uncertainty due to unanticipated sequences has driven the need for a CPG. Since CCFP is calculated based on the response to anticipated sequences, it has limited value in addressing unanticipated sequences. A CPG goal is not appropriate for a regulatory guide. The draft should be changed to reference the QHOs and subsidiary goals appropriately.

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- C.II.1.2-6 In section C.II.1.2 the last two paragraphs discuss construction and operational phases of a plant. These paragraphs are more appropriately included in a background section, as DG-1145 is focused on the combined license (COL) application and COL issuance phases.
- C.II.1.2.-7 The last sentence in Section C.II.1.2 states, "Such changes [i.e., licensing basis changes during the COL application, construction and operation phases] need to be submitted for NRC review and approval and reflected in the updated PRA updates (sic.), as necessary." This is not correct. Changes to the plant, procedures and analysis methodologies are submitted for NRC review in accordance with existing change process requirements. Many changes may be implemented without NRC approval, e.g., under 10 CFR 50.59. In accordance with current practice and standards, the plant-specific PRA will be periodically assessed to ensure that it continues to reasonably reflect the as-built, as-operated facility, and will be updated to reflect changes as appropriate. The last sentence of Section C.II.1.2 should be modified accordingly.

We agree that PRA updates are the responsibility of the COL applicant/licensee. PRA updates will not be submitted to the NRC, but rather will be maintained by the licensee in an auditable form, consistent with existing practice and standards

- C.II.1.3-1 In section C.II.1.3, please confirm that the "risk evaluation ... may need to be expanded" phrase applies to use of the probabilistic risk assessment (PRA) for optional, risk-informed programs and not to further evaluation of referenced design control document (DCD) PRAs by the NRC.
- C.II.1.4-1 Section C.II.1.4 includes the language "...realistically reflect the actual plant design." It is recommended that the word "reasonably" be substituted for "realistically" since this better reflects the situation at the time the combined license (COL) application is submitted (not all design and operation information available) and it is consistent with prevailing good practices where design and operational characteristics are "reasonably reflected" sufficiently to support the application
- C.II.1.4-2 In section C.II.1.4, is it acceptable to reference a separate topical report for this detail?
- C.II.1.5-1 In section C.II.1.5 on Technical Adequacy, the following language is provided:
"The quality of the applicant's methodologies, processes, analyses, and personnel associated with the risk evaluation need to comply with the provisions for nuclear plant quality assurance (e.g., Appendix B to 10 CFR Part 50). To this end, the applicant's risk evaluation submittal needs to meet the applicable ASME and ANS standards endorsed by the staff in Regulatory Guide 1.200 at the time of submittal."
Comment: NEI agrees that combined license (COL) applicants should apply quality assurance to the development of the probabilistic risk assessment (PRA). However, we do not believe that it is appropriate to apply the requirements in

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Appendix B to Part 50 to the PRA. Appendix B only applies to "the design, construction, and operation of those [safety-related] structures, systems, and components." In particular, Appendix B applies "to all activities affecting the safety-related functions of those structures, systems, and components." The PRA is not a design document, and it does not affect any safety-related functions. Instead, it reflects design information and the design functions that are identified in other documents. Accordingly, the PRA is not subject to Appendix B.

Also, meeting "applicable ASME and ANS Standards endorsed by the staff in Regulatory Guide 1.200 at the time of submittal" is not reasonable for the following reasons:

" A time window is required, e.g., 2 years, as the conduct of a PRA requires several years.

" As the designs used in a COL application, at least initially, will not have operational experience, e.g., plant-specific data, a direct reference to R.G. 1.200 or ASME and ANS Standards is not appropriate.

" R.G. 1.200 is a "trial" version.

" Near term COL applications are expected to be based on either a certified design or a design which is undergoing a review for certification. In either case the NRC either has reviewed or would be in the process of reviewing the PRA in detail, and thus would make the reference to RG 1.200 and ANS/ASME Standards, as appropriate and available, desirable but not necessary.

We recommend using language consistent with NEI 04-01, such as "use prevailing good practices, including Standards and guidance as they are available and appropriate, consistent with the schedule for conducting the risk evaluation."

- C.II.1.6-1 Section C.II.1.6 requires a comparison of risks of the proposed plant to those of existing plants to demonstrate that there is a reduction in risk. Such a comparison would be very difficult, if not impossible, because the specific risk information needed for existing plants is not publicly available.
- C.II.1.6-2 Section C.II.1.6 states that an applicant "needs to use the results of the risk evaluation, including those from the uncertainty and importance analyses and the sensitivity studies, in an integrated fashion, to ... identify and implement requirements to ensure that the assumptions made in the risk evaluation (e.g., regarding design and operational features of a safety system, system interactions and human actions) will remain valid in a future plant referencing the proposed design and that the uncertainties have been appropriately addressed. These are specific requirements for the design, construction, testing, inspection and operation of the plant (e.g., ITAAC, Technical Specifications, Reliability Assurance Program, RTNSS, and COL action items)." Comments are:
- a) Does the last sentence apply to both the bullets?
 - b) How does a combined license (COL) applicant assure that assumptions

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will remain valid for a future plant under the control of a different licensee/applicant?

c) The implied tie between risk evaluation results and Technical Specifications, regulatory treatment of non-safety systems (RTNSS), inspection, test, analyses and acceptance criteria (ITAAC), reliability assurance program (RAP), and COL Action Items is not clear. These items are covered elsewhere in the guidance with different bases. Please clarify this relationship.

- C.II.1.7-1 The third paragraph in Section C.II.1.7 states: "To support the NRC Staff's timely review and assessment of the documentation, applicants should adhere to the recommended format and content identified in Appendix B, ---." This section should address how this guidance is consistent with proposed Section 52.80(a) which requires the combined license (COL) application to use the design certification PRA (which may not be in the format of Appendix B).
- C.II.1.7-2 Section C.II.1.7, Format and Content, states, "Such documentation should be maintained as part of the quality assurance program such that it is available for examination and maintained as lifetime quality records in accordance with Regulatory Guide 1.33."
Instead of the above language, a reference to prevailing good practices for documentation, such as the ASME Standard, is the appropriate language.
- C.III.7-1 The last sentence of the first paragraph under design certification - inspection, test, analyses, and acceptance criteria (DC-ITAAC) says guidance on physical security ITAAC is provided in Section C.I.13.6. However, no such guidance is provided there. We agree that when generic physical security ITAAC are established, they should be presented in Section C.I.13.6.
- C.III.7-2 The guidance states that combined license (COL) applications "must" include physical security (PS) inspection, test, analyses, and acceptance criteria (ITAAC), in the same way that COL applications "must" include emergency planning (EP) ITAAC. However, EP ITAAC are unique in the way they are called out in the regulation as required. We recommend the guidance be reworded to say that COL applications will contain physical security ITAAC identified in the referenced DCD and should be supplemented as necessary consistent with guidance on generic PS-ITAAC. The balance of the guidance on development of generic PS-ITAAC is appropriate.
- C.III.7-3 There is a sixth ITAAC scenario: a COL application that refers to a design certification but no early site permit (ESP).
- C.III.7-4 The phrasing is different for discussion of the same topic under differing scenarios. In particular, under scenario 3, it says, "The COL applicant in scenario 3 that references an ESP may only include the generic emergency planning (EP) ITAAC as described in Section C.I.13.3 of this regulatory guide." While under scenario 5, it says, "the COL applicant in this scenario may only

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have included the generic EP-ITAAC provided in Section C.I.13.3 of this regulatory guide as part of the ESP referenced in the application. The differing phrasing affects the meaning of these sentences. Please clarify the intent of these statements and assure consistency of the various scenario discussions.

- C.III.7-5 It may simpler, and promote consistency, to present the guidance on the various ITAAC scenarios in a tabular format.
- C.III.7-6 Section C.III.7, under Terminology, states "The COL application references a certified design must incorporate the entire DCD..." This is not consistent with the regulations. For example, Appendix D to 10CFR Part 52 (§III.B) explicitly excludes the design control document (DCD) conceptual design information and the evaluation of SAMDAs in DCD Appendix 1B from the design certification.
- C.III.7-7 Section C.III.7: Proposed 52.80(b) would require the inspection, test, analyses, and acceptance criteria (ITAAC) for a combine license (COL), including design certification ITAAC (if referenced), to be included in the application but not in the final safety analysis report (FSAR). Tier 1 of the design control document (DCD) will be incorporated by reference into the COL application. Design certification ITAAC are that part of Tier 1 of a design control document that no longer constitute requirements on the licensee after the Commission makes its Section 52.103(g) finding prior to fuel load. Most of the rest of Tier 1 are Tier 1 design requirements which remain applicable for the life of the plant unless changed via the applicable change process. COL applicants and licensees must consider Tier 1 design requirements when implementing the "50.59-like" plant change process. Tier 1 design requirements are a subset of Tier 2. COL application FSARs will be based on the content and organization of Tier 2 and will thus include Tier 1 design requirements. Does the staff agree that except as a subset of Tier 2, Tier 1 design requirements are not required to be otherwise incorporated into the FSAR?