

Appendix I. Response to Public Comments on DG-1145

Introduction

During the development of the draft regulatory guide, the NRC held several public meetings that provided an explanation of the process being used to develop the guidance and to discuss draft work-in-progress sections. The draft work in progress sections were posted on the NRC website at the same time as meeting notices were issued. The public was encouraged to review the draft work in progress sections prior to each public meeting and to submit comments and questions by using the “Contact us Page” on the NRC website. The NEI COL task force also submitted comments and questions electronically prior to and after each public meeting. The members of the public were also encouraged to submit comments and questions during the public meetings. All questions and comments submitted by the members of the public were posted on the NRC website after each meeting.

The NRC staff addressed as many questions and comments as they could prior to the issuance of the draft regulatory guide. The remaining questions will be addressed in the final guide. The public is encouraged to submit comments and questions. These comments and questions will be integrated with the comments and questions that were submitted earlier. Comments on NRC responses will be integrated where appropriate. Comments related to the Part 52 rulemaking will be addressed in the final guide after the Part 52 Rule is issued.

C.I.1-1 Will the guide include a list of relevant generic issues to be addressed by the applicant (such as GSIs, USIs, Generic Letters, Bulletins, and Information Notices)? This would be very helpful and would ensure consistency in the applications.

Response: Yes. Sections C.I.1.9.3 and C.I.1.9.4 provide guidance relative to generic issues and generic communications. These sections refer to Section C.IV.8 of the guide for additional guidance on generic issues and generic communications. COL applicants may use different reactor technologies; therefore, technical relevancy of specific generic issues and communications must be addressed on an application-specific basis by the COL applicant.

Disposition: Section C.IV.8 has been added to the guide to provide a list of relevant generic issues and generic communications.

C.I.1-2 Please discuss how a combined license (COL) applicant should address differences between the structure of Part I of DG-1145 and that of the design control documents (DCD) of previously certified designs.

Response: The rules associated with the use and reference of the DCD for a certified design are provided in the appendices of Part 52 for the applicable certified design. COL applicants should comply with the format and content in Part I of DG-1145 for their application. For differences between the structure of Part I of DG-1145 and that of the DCDs, the COL applicant may identify a deviation from compliance with DG-1145. Additional guidance regarding application submittal is provided in Section C.IV.2 of this guide.

Disposition: Additional guidance associated with “incorporate by reference” and “include in the application” has been provided in Section C.IV.2.

C.I.1-3 Will the guide clearly differentiate between issues and COL application elements that are specific to different types of reactors?

Response: No. The guide is designed to be generic and applicable to all COL applicants. It will not address specific reactor technologies that have already been certified; however, where necessary, guidance may be provided to differentiate between active and passive plants.

Disposition: No change to DG-1145.

C.I.1-4 Will a separate evaluation be required for thermal-hydraulic codes for evolutionary plants? If the codes are already approved (e.g., per 10 CFR 50.46) and no testing has been done for new models (as in the case for passive plants), why would an extensive staff review be required?

Response: The staff assumes that this question refers to the use of thermal-hydraulic codes, which have been approved for use per 10 CFR 50.46, on new plant designs or design features for which no prototype was built. The staff believes that a review sufficient to ensure compliance with 52.47(b)(2)(i) is required for the staff to make its requisite finding. The extent of this review may be determined by the various factors as discussed in 52.47(b)(2)(i). The applicant should provide information sufficient for the staff to perform this review.

Disposition: No change to DG-1145.

C.I.1-5 Can the guide address closure of design acceptance criteria (DAC) via topical reports with regard to the standard review plan (SRP) revision time lines? Would a topical report be reviewed against the SRP in place six months prior to topical submittal?

Response: Yes; however, this discussion is applicable to Section C.III.1 of the guide. To maintain consistency with the assumption in Section C.III.1.3, guidance will be discussed for generic use of topical reports to close out design issues not related to DAC.

Disposition: Section III.1, Chapter 1.9.2 provides guidance with respect to compliance with SRPs when closing out design issues via Topical Reports. Additional guidance related to DAC has been provided in Section C.III.5.

C.I.1-6 For areas where there are design acceptance criteria (DAC) in a certified design, will the closure of the DAC be reviewed against a forthcoming standard review plan (SRP) revision or against the SRP revision utilized for the design certification?

Response: Certified designs have achieved finality in accordance with 10 CFR 52.63. Therefore, any DAC that were approved in a certified design were reviewed against the SRP revision utilized for the design certification. The staff expects that DAC closure will be reviewed against the SRP revision utilized for the design certification.

Disposition: See disposition for C.I.1-6, above.

C.I.1-7 Will Section C.I.1 of the guide provide guidance for satisfying the 10 CFR 52.79a requirement to address standard review plan conformance, operating experience, and other information historically discussed in final safety analysis report (FSAR)?

Response: Yes; however, the Section C.I.1 guidance is limited to addressing compliance with regulatory guides, standard review plans, generic issues and generic communications and does not provide guidance on all other information historically addressed in FSARs.

Disposition: No change to DG-1145.

C.I.1-8 Please explain NRC expectations for how the following would be addressed:

A. The Design Certification addresses one standard review plan (SRP) version for design issues and the combined license (COL) application would address a potentially different SRP version for non-design issues.

B. Topical Reports may reach closure on an issue on a potentially different version of the SRP. How would this be identified in the COL application (to address the regulation on SRP conformance) and what completion/closure would be afforded?

Response: The staff understands the above question to refer to differences between certified design issues (i.e., DCD) and non-certified design issues (i.e., site-specific design included in a COL application). There are two instances in which SRP compliance reviews are required by regulation. An application for a certified design is required to address SRP compliance for the design in accordance with 10 CFR 52.47(a)(ii). In addition, a COL applicant is required to address SRP compliance for the facility in accordance with proposed 10 CFR 52.79(a)(41). The staff expects that the COL applicant that references a certified design will evaluate SRP compliance for the portions of the facility not included in the certified design and will perform this evaluation to the SRPs in effect 6 months before the docket date of the COL application. The portions of the facility in this COL application that are included in the certified design have finality and re-review of the certified design against newer versions of the SRP than the version evaluated in the DCD is not required.

The staff's experience with design certification reviews includes review of topical reports that address design issues to support the DCD. The staff expects that COL applicants and certified design vendors will use topical reports to address certified design and non-certified design issues. The use of topical reports by COL applicants and/or certified design vendors to close out DAC, and for compliance with SRPs, is addressed in the response to C.I.1-5, above. The use by COL applicants of topical reports to address certified design and non-certified design issues that are not related to close-out of DAC is also anticipated by the staff. These topical reports may be submitted prior to submittal of the COL application. For consistency, the staff expects that topical reports submitted prior to COL application submittal will comply with the SRP revisions that are included in the compliance evaluation provided in the COL application.

The SRP is not a substitute for the regulations, and compliance with the SRP is not a requirement. Applicants that do not comply with the SRPs must provide adequate justification for the proposed alternative methods for complying with the regulations. See also response to C.I.1-5 above.

Disposition: Guidance has been provided in Section C.III.1 - Chapter 1.9

C.I.1-9 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.I, 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 C.I.1.4 states that "The division of responsibility between the reactor designer or certified plant designed (sic), architect-engineer, constructor, ----". Section C.I.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 C.I.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.

Response: Section C.III.1 provides guidance for a COL applicant that references a certified design. Section C.III.2 provides guidance for a COL applicant that references a certified design and an early site permit. With respect to interfaces discussed in Section C.I.1.8, the intent is that there are no site interfaces per 10 CFR 52.47 for a COL applicant that does not reference a certified design. In addition, there are no interfaces with standard designs as discussed in Appendix A to Reg. Guide 1.70 for a COL applicant that does not reference a certified design.

Disposition: The staff has clarified that Section C.I provides guidance for a COL applicant that does not reference a certified design; Section C.III.1 provides guidance for a COL applicant that references a certified design, and Section C.III.2 provides guidance for a COL applicant that references a certified design and an early site permit. Additionally, Section C.I.1.4 has been revised to delete reference to "certified plant designed."

C.I.1.1.6.2-1 Section C.I.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?

Response: No. The staff does not intend to expand regulatory requirements through guidance documents.

Disposition: The bullet in Section C.I.1.1.6.2 has been reworded to be consistent with the discussion in Section C.I.1.9.2.

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

Response: The list of acronyms is for the FSAR only.

Disposition: Section C.I.1.1.6.6 has been revised to indicate that the list of acronyms is for the FSAR and that documents that are not part of the FSAR but are part of the application should include their own list of acronyms.

C.I.1.6-1 Are topical reports intended to act as additions to the design control document that will be finalized and incorporated by reference? Or, will each combined license (COL) applicant have to draw from the topical report in their own application?

Response: Topical reports that are referenced in the design control document (DCD) for a certified design do not need to be referenced separately by a COL applicant referencing that certified design. Unless otherwise provided for in the proposed revision to 10 CFR Part 52, topical reports for the certified design that are prepared in addition to those referenced in the DCD (e.g., topical reports that may be prepared to close out design acceptance criteria) must be referenced separately by each COL applicant referencing that certified design.

Disposition: No change to DG-1145.

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?

Response: Section C.I.1 provides guidance for a COL applicant that does not reference a certified design; therefore, a discussion of documents incorporated by reference into a DCD is not relevant. However, documents may be incorporated by reference in a COL application that does not reference a DCD. A list of such documents should be provided in FSAR Section 1.6 of the COL application. A brief summary of the information included in such referenced documents may be warranted in specific sections where it is referenced to provide clarity if necessary. Although this is a carryover from the Part 50 licensing process, it is equally applicable to the Part 52 licensing process in order to provide clarity for the NRC staff to review the license application

Disposition: No change to DG-1145.

C.I.1.6-3 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. During the June 14 public workshop, the NRC agreed that these summaries are not required in all cases. Section C.I.1.6 should be revised to indicate that summaries of information incorporated by reference may be provided as appropriate.

Response: The staff agrees with this comment.

Disposition: Section C.I.1.6 has been revised to include “as necessary.”

C.I.1.8-1 Will the proposed regulatory guide discuss the level of detail needed for site specific conceptual design engineering information that needs to be included in the combined license (COL) application?

Response: Yes. Guidance is provided in Section C.III.1, Chapter 1.8 of the guide as this issue is specific to COL applicants that reference a certified design. COL applicants that do not reference a certified design must provide a design for the entire facility without any reliance on conceptual design.

Disposition: Guidance has been provided in Section C.III.1, Chapter 1.8.

C.I.1.9-1 Sections C.I.1.9.1, C.I.1.9.2, and C.I.1.9.3 require 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 Regulatory Guides, SRPs and generic issues that are beyond the scope of the referenced DCD and/or ESP. Please confirm this understanding.

Response: The staff agrees with this comment.

Disposition: Guidance has been provided in Chapter 1.9 of Sections C.III.1 and C.III.2 related to this “timing” issue for compliance evaluations with regulatory guides, SRPs, and generic issues.

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 (COL) 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.

Response: The staff agrees that the ultimate goal of the SRP update is to incorporate operating experience into NRC staff review guidance, as well as DG-1145. In the interim period, COL applicants should have as much information as possible regarding operating experience in order to prepare complete COL applications. To this end, guidance on generic issues and generic communications on operating experience has been provided in DG-1145. In addition, the SRP update is being coordinated with the development of DG-1145 and will be compatible with the final guide when it is issued.

Disposition: Section C.IV.8 has been added to provide additional guidance for addressing relevant generic issues and generic communications.

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 (ESP). 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 standard review plans (SRPs) should be evaluated to the scope of information provided in the COL application.

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 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 ESP as applicable to the COL applicant scope.

b. The guidance and standards listed in C.I.1.9.1 through 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.

Response: The staff has provided generic guidance in Sections C.III.1 and C.III.2 on the scope of conformance evaluations that are necessary. Due to variations in current and future reactor technologies that may be included in certified designs, the staff does not believe that providing more specific guidance or lists of applicable regulatory guides and standard review plans is appropriate.

Disposition: No change to DG-1145.

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 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.

Response: The requirements in proposed 10 CFR 52.79 specifically request how operating experience information was incorporated into the plant design. It does not request how such information was incorporated into the operational aspects of the facility.

Disposition: The statement in C.I.1.9.4 has been revised to delete the phrase “including operational aspects of the facility.”

C.I.1.9.5-1 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

Response: The staff understands that convergence on the issues that need to be addressed may be an iterative process between the NRC staff and a COL applicant that does not reference a certified design. The issues that need to be addressed also depend upon the reactor technology and design provided by the applicant. At this time, the staff does not believe that providing more definitive guidance in this section is an efficient use of resources; however, the staff reserves the right to revisit the guidance in this section for future improvement.

Disposition: No change to DG-1145.

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.

Response: A COL application need not update siting information in an ESP to account for changes in NRC guidance issued after the ESP. However, pursuant to 10 CFR 52.6, each applicant or licensee that identifies information as having, for the regulated activity, a significant implication for public health and safety or common defense and security shall notify the Commission of this information.

Disposition: No change to DG-1145.

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

Response: COL applicants that reference an ESP are not required to revise the information included in the ESP. However, pursuant to 10 CFR 52.6, each applicant or license that identifies information as having, for the regulated activity, a significant implication for public health and safety or common defense and security shall notify the Commission of this information.

Disposition: No change to DG-1145.

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?

Response: The Commission has determined that this information is not sensitive.

Disposition: No change to DG-1145.

C.I.2.1.2.1-1 Section C.I.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.

Response: The requirement for an EAB for reactor site applications filed on or after January 10, 1997 is 10 CFR 100.21(a).

Disposition: "100.3(a) of Part 100" is replaced by "100.21(a) of Part 100" in the respective Section 2.1.2.1, "Authority."

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?

Response: The intent of Section 2.2.3.1 is to define design-basis events internal and external to the nuclear plant that frequent enough and have consequences serious enough to potentially affect the safety of the plant. For those facilities with intake structures located on navigable waterways, the COL applicant should consider the probability and potential effects of intake structure collisions on the plant cooling water to determine if this is a design-basis event. If the proposed facility does not rely on an intake structure for safe shutdown, then the applicant may state that the loss of intake structure has no safety impact.

Disposition: No change to DG-1145.

C.I.2.3-1 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 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.

Response: The intent of revising Regulatory Guide 1.23 is to provide updated guidance regarding tower and instrument siting criteria, system accuracy, and data processing, recording, and displays. Compliance with regulatory guides is not required. If the onsite pre-operational meteorological monitoring program has begun before Regulatory Guide 1.23 is revised, the revised regulatory guide could still be used to help define the onsite operational meteorological monitoring program.

Disposition: No change to DG-1145.

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 combined license (COL) application review.

Response: The staff expects that the COL applicant will provide at least one annual cycle of meteorological data collected onsite with the application. These data should be used by the COL applicant to calculate (1) the short-term atmospheric dispersion estimates for accident releases discussed in DG-1145 Section C.I.2.3.4 and (2) the long-term atmospheric dispersion estimates for routine releases discussed in DG-1145 Section C.I.2.3.5. The COL applicant should continue to monitor the data and submit the complete 2-year data set when it has collected all the data. This supplemental submittal should also include a reanalysis of the Section C.I.2.3.4 and C.I.2.3.5 atmospheric dispersion estimates based on the complete 2-year data set.

Disposition: No change to DG-1145.

C.I.2.3.4.1-1 Section C.I.2.3.4.1 indicates that the combine license (COL) application should provide both conservative and realistic estimates of atmospheric dispersion factors. What is the purpose for providing realistic estimates?

Response: Although realistic estimates of short-term (accident release) atmospheric dispersion factors are used in the Environmental Impact Statement to evaluate the environmental impacts of postulated accidents, they are not required for the final safety analysis report (FSAR).

Disposition: Section C.I.2.3.4.1 will be revised to eliminate the request to provide realistic estimates of short-term (accident release) atmospheric dispersion factors.

C.I.2.4-1 In reference to 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.

Response: Assuming that a COL application selects a reactor design technology with radwaste storage design that precludes release of liquid effluents containing radioactive materials, the COL applicant would not need to present analysis of transport of radioactive materials through soil and groundwater from accidental release in Section 2.4.13. Discharge of radioactive materials from abnormal/accidental events are addressed elsewhere in the application or the design of the selected reactor technology.

Disposition: No change to DG-1145.

C.I.2.4.3-1 Section C.I.2.4.3 of Regulatory Guide 1.70 references Reg. Guide 1.59. Is this still an appropriate reference or has it been superseded?

Response: Regulatory Guide 1.59 is incomplete in many areas such as, tsunami guidance and it references a standard that has been withdrawn. However, Regulatory Guide 1.59 is of historical interest. Relevant SRP updates are in progress to provide necessary discussion.

Disposition: No change to DG-1145.

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 C.I.2.3?

Response: The design basis wind is related to the normal wind associated with building design, and is based on 3-second gust wind speeds measured at 33 ft above ground. In coastal sites hurricane wind speeds (e.g. 185 miles per hour (mph) at coastal sites) can be higher than the design basis maximum winds (e.g. 97 mph for inland sites), and the tornado wind speeds can be higher yet (e.g. 300 mph at tornado prone sites). Probable maximum meteorological winds influence the hurricane surge heights at coastal sites, therefore, the flood elevation at the site..

Disposition: No change to DG-1145.

- 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?
- Response:** Areas with potential for a dry channel bed due to atmospheric thermal conditions, either in the past or during the design life of the plant, need to be evaluated for channel diversion effects.
- Disposition:** No change to DG-1145.
- 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.
- Response:** In sections C.I.2.4.11.1 and C.I.2.4.11.5 the drought condition should have a recurrence period of 100 years.
- Disposition:** No change to the guide.
- C.I.2.5-1** Is the Regulatory Guide (RG) 1.70 .2.5.6 on embankments and dams no longer required or will it be included elsewhere in DG-1145?
- Response:** Embankments and dams are now covered by different sections. Dams are included in the C.I.2.4.3.4, "Probable Maximum Flood Flow," and C.I.2.4.4.1, "Dam Failure Permutation." Embankments are covered under the C.I.2.5.4.5, "Excavations and Backfills."
- Disposition:** No change to DG-1145.
- 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.
- Response:** Regulatory Guide 1.165, "Identification and Characterization of Seismic Sources and Determination of Safe Shutdown Earthquake Ground Motion," endorses both the EPRI-SOG and LLNL PSHA and source databases. Since these PSHA were developed in the 1980s, many components such as the seismic source and ground motion models need to be updated. RG 1.165 also provides guidance on how to update the PSHA source and ground motion models. The guidance provided in RG 1.165 is still an acceptable approach to meet the seismic siting regulations (10 CFR 100.23). The guidance provided in DG 1145 focus on the material needed by the NRC to perform a complete review and evaluation of a siting application. Both RG 1.165 and DG 1145 should be used a guidance documents for seismic siting.
- Disposition:** No change to DG-1145.
- C.I.2.5.2.4-1** 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).
- Response:** After extensive review of a previous early site permit (ESP) application, which implemented the performance based approach, the NRC staff has determined that the

performance based approach described in ASCE 43-05 for seismic design basis category SDB-5D provides an acceptable approach to determine the Safe Shutdown Earthquake ground motion (SSE) spectrum for nuclear power plant sites. The staff also considered using a performance based method that targets seismic core damage frequency (SCDF); however, a specific target SCDF and other necessary seismic fragility parameters have not been determined. In addition, the staff prefers the ASCE 43-05 method since it targets a minimum damage state rather than core damage.

Disposition: No change to DG-1145.

C.I.2.5.2.4-2 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?

Response: From the perspective of the seismology, it is always beneficial to compare the site controlling earthquake magnitudes and distances with the controlling earthquakes used in licensing (1) other facilities, (2) near by plants or (3) plants licensed in the similar seismogenic regions. The comparison can help to identify potential difference in source characterization, attenuation relationships, hazard deaggregation processes. Table 1 in Section 2.5.2 of NUREG 0900 provides magnitudes and distances within seismogenic source regions that can be used for comparison.

Disposition: No change to DG-1145.

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."

Response: Rock or hard rock are relative terms. NRC staff has accepted a method using the reference rock or hard rock, i.e., the rock with a shear wave velocity of 2.8 km/sec, to calculate seismic wave transmission characteristics, adopted in the three early site permit (ESP) applications. All the site-specific amplification effects, linear or non-linear, specific to the local soil conditions, could be calculated based on this reference rock.

Disposition: No change to DG-1145.

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.

Response: Detailed faulting investigations are required by Appendix S, "Earthquake Engineering Criteria for Nuclear Power Plants," to 10 CFR 50 under subtitle IV "Application to Engineering Design."

Disposition: No change to DG-1145.

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.

Response: The phrase “ potential piping conditions” refers to the condition where seepage occurs under embankments or retaining walls. When the seepage velocity is great enough, erosion of the soil can occur. Erosion of the supporting soil is known as piping and can lead to failure of the embankment or retaining wall.

Disposition: No change to DG-1145.

C.I.3-1 Sections C.I.3.2.1, C.I.3.7.1 and C.I.3.9.3.2 make reference to the Operating Basis Earthquake (OBE). As indicated in standard review plan (SRP) 3.9.3, (Draft Rev 2, April 1996) Section III.1 and note 78, for evolutionary plants like ABWR and those for which combined license (COL) applications will be filed, the NRC has accepted the elimination of the OBE from design consideration. It is recommended that the OBE be deleted from DG-1145, or, as a minimum, a statement similar to the one in SRP 3.9.3 be added to DG-1145. We note that Section C.I.2.5.2 of DG-1145 supports the need only to define the safe-shutdown earthquake (SSE).

Response: Usually, OBE is not considered a design consideration for combined license (COL) or early site permit (ESP) applications. Per 10 CFR 50.34(b)(10), from text of proposed new rule: "on after January 10, 1997, stationary power reactor applicants who apply for an operating license of this chapter, as partial conformance to General Design Criterion 2 of appendix A to this part, shall comply with the earthquake engineering criteria of appendix S to this part. However, for those operating license applicants and holders whose construction permit was issued before January 10, 1997, the earthquake engineering criteria in section IV of appendix A to part 100 of this chapter continue to apply."

Disposition: No change to 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?

Response: This item elaborates on flooding protection considerations for safety related components and systems located in structures that are buried substantially below grade. Construction defects, degradation over time, and other factors can lead to in-leakage.

Disposition: No change to regulatory guide DG-1145.

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?

Response: The definition of “surface deformation” and how it must be considered is provided in 10 CFR Part 50, Appendix S. Appendix S was included in 10 CFR Part 50 when the regulations were amended in 1996, and it applies to applicants for a design certification or combined license pursuant to 10 CFR Part 52 or for a construction permit or operating license pursuant to 10 CFR Part 50 on or after January 10, 1997.

Disposition: No change to DG-1145.

C.I.3.2.1-2 Section C.I.3.2.1, the 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?

Response: As stated in 10 CFR Part 50, Appendix S, the operating basis earthquake (OBE) is the vibratory ground motion for which those features of the nuclear power plant necessary for continued operation without undue risk to the health and safety of the public will remain functional. The OBE Ground Motion is only associated with plant shutdown and inspection unless specifically selected by the applicant as a design input. Therefore, some plant structures, systems, and components (SSCs) may include the OBE as part of their design basis. Section C.I.3.2.1 requests only that a list of these SSCs be provided. No other specific design details regarding consideration of the OBE are being requested by Section C.I.3.2.1.

Disposition: No change to DG-1145.

C.I.3.2.1-3 The 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, system, 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.

Response: The NRC agrees with this statement. Also, see the response to question C.I.3.2.1-2.

Disposition: No change to DG-1145.

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 adequate. Please clarify.

Response: NRC expects that a current version of any applicable reference be used. When the applicant uses a reference that is not current or not endorsed by the NRC, an explanation or justification for the adequacy should be included in the application.

Disposition: No change to DG-1145.

C.I.3.3.2-1 Please 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 lay down areas and warehouses of current nuclear plants; only effects of structural collapse of non-safety buildings on safety buildings need to be addressed.

Response: Missile Spectra I and II from Revision 2 of SRP 3.5.1.4 limit consideration of massive design basis missiles (i.e., automobile and telephone pole) to elevations up to 30 feet above grade level anywhere within one-half mile of safety-related plant structures. To the extent that protection against massive design-basis missiles does not extend to the full height of structures, the potential for non-safety buildings to become sources of missiles comparable to the design-basis massive missiles should be evaluated. Such potential missiles should be located at plant grade or be designed to withstand tornado loads without becoming a missile.

Disposition: No change to DG-1145.

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?

Response: The scope of SSCs that should be protected against flooding is described in Regulatory Guide (RG) 1.59, "Design Basis Floods for Nuclear Power Plants." RG 1.59 describes the scope as those systems necessary to achieve and maintain cold shutdown and references RG 1.29 as guidance in identifying SSCs that should be protected from flooding. The NRC policy on regulatory treatment of non-safety systems for evolutionary passive plants accepts higher temperature states for safe shutdown and permits some SSCs necessary for maintaining safe-shutdown or to provide defense-in-depth in achieving safe shutdown to be designated as non-safety related. These selected non-safety related systems that are identified through the regulatory treatment of non-safety systems process as providing important contributions to achieving or maintaining safe shutdown conditions should be protected from flooding and identified as such.

Disposition: No change to DG-1145.

C.I.3.4.1-2 Section 3.1.4.1(3) {sic} 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?

Response: The NRC staff believes this comment applies to section C.I.3.4.1(3). The section was drawn essentially unchanged from RG 1.70, rev. 3. This item applies to equipment that requires flood protection, but the equipment is located such that permanent structural flood protection is not provided. This configuration is consistent with Regulatory

Position C.2 of RG 1.59 for certain safety-related SSCs not necessary to achieve safe shutdown. In this case, in-leakage through cracks in structural walls may be postulated because the structure is not designed to provide permanent flood protection and pumping systems are intended to remove the in-leakage.

Disposition: No change to DG-1145.

C.I.3.5.1.3-1 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.

Response: Section C.I.3.5.1.3(1)(f) requests information on characteristics of postulated missiles in terms of missile size, mass, shape, and exit speed for design overspeed and destructive overspeed in postulated turbine failures (describe the analysis used in estimating the missile exit speeds, and identify the direction of rotation with respect to each turbine-generator under consideration). Section C.I.3.5.1.3(2) requests information on the methods, analyses, and results for the turbine missile generation probability calculations.

Since the mid-1980's, the NRC staff has evaluated the turbine missile issue on the basis of plant owners' demonstration of an acceptable probability of turbine missile generation and of turbine orientation. The probability of unacceptable damage resulting from turbine missiles, P_4 , is expressed as the product of (a) the probability of turbine failure resulting in the ejection of turbine rotor (or internal structure) fragments through the turbine casing, P_1 ; (b) the probability of ejected missiles perforating intervening barriers and striking safety-related structures, systems, or components, P_2 ; and (c) the probability of struck structures, systems, or components failing to perform their safety function, P_3 . Stated in mathematical terms, $P_4 = P_1 \times P_2 \times P_3$. The staff has focused its attention on the plant owners' demonstration of an acceptable P_1 to minimize the potential of turbine missile generation. It seems that the information requested under C.I.3.5.1.3(1)(f) would be part of the technical basis to support the derivation of P_1 . As stated above, Section C.I.3.5.1.3(2) requests that COL applicants provide the methods, analyses, and results for the turbine missile generation probability calculations. Therefore, the information requested under C.I.3.5.1.3(1)(f) should be contained in the probability calculation report of turbine missile generation, which should be submitted to satisfy Section C.I.3.5.1.3(2), regardless of whether the missile generation probably is acceptably small or the inservice inspection and testing program for the turbine is acceptable.

Disposition: No change to DG-1145.

C.I.3.5.1.6-1 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).

Response: The staff agrees with the comment.

Disposition: "10CFR 100" is replaced by "10CFR 50.34 (a) (1)" in the respective Section 3.5.1.6, "Aircraft Hazards."

C.I.3.5.1.6-2 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 section C.I.3.5.1.6?

Response: The last paragraph of Section C.I.3.5.1.6 states

“All the parameters used in these analyses should be explicitly justified. Wherever a range of values is obtained for a given parameter, it should be plainly indicated and the most conservative value used. Justification for all assumption made should also be clearly stated.”

The intent is to ensure that parameters used in the reference analyses are “explicitly justified”, that a “range of values”, if used, be identified as such, and that the most conservative value in a range would be used in the analyses.

If an applicant happens to be using the DOE standard and its technical support documents as a source of parameters in its analyses, the specifications in the above paragraph still apply.

In any event, it should be noted that the acceptance criterion of 10^{-7} per year is applied to a distinct type of hazard (e.g., missile impact, overpressure, toxic gas exposure, thermal fire effects, etc.). As such, it is intended to cover the aggregate probability of occurrence of a specific type of insult to a nuclear power plant. In the case of aircraft hazards, 10^{-7} is used as an acceptance criterion with respect to the likelihood of an onsite aircraft crash due to all possible aircraft mishaps in its vicinity. This includes all aircraft parameters relevant to a proposed site (e.g., aircraft size, weight, altitude, speed, flight frequency).

As noted in the Standard Review Plan (NUREG-0800), because of the low probabilities of the site hazards analyzed, sufficient data are often not available to permit accurate calculation of event probabilities. Accordingly, the expected rate of occurrence of potential exposures in excess of 10CFR50.34(a)(1) guidelines of an order of magnitude of 10^{-6} per year is acceptable if, when combined with reasonable qualitative arguments, the realistic probability can be shown to be lower.

Disposition: No change to DG-1145.

C.I.3.5.3-1 For Section C.I.3.5 the NRC indicated during the workshop that the "to-do list" for C.III.1.3.5.3 would include "For each 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.

Response: If the site is found to be vulnerable to aircraft missiles, the structural barriers incorporated in the certified design plus any safety-related SSCs outside the scope of the certified design would have to be reanalyzed for this design basis missile.

Disposition: No change to DG-1145.

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

Response: DG-1145, Section C, Part I, provides guidance for COL applicants that do not reference a certified design. COL applicants that do not reference a certified design should provide a level of design information for their entire facility that is sufficient in detail for the NRC to resolve all safety issues. ITAAC is a verification program that a licensee must successfully complete, after license issuance, to demonstrate that their facility has been constructed and will operate in conformity with the license. As such, for a COL applicant that does not reference a certified design, ITAAC may not be used to provide COL application information that is necessary to issue the license.

For a COL applicant that references a certified design, the ITAAC that are included in the certified design become a part of the COL application. These ITAAC may include design acceptance criteria (DAC) that specify an approved process for completing design information and verifying the implementation of the completed design. DAC are approved on an application-specific basis and are the only approved method for completing portions of the facility design after issuance of the combined license. Unless the COL application references a certified design which includes DAC, there is no mechanism available to the applicant to “extend” ITAAC. For consistency, the selection methodology for ITAAC included in a certified design should be used by a COL applicant referencing that certified design to select site-specific structures, systems, and components to be included in ITAAC.

Disposition: No change to DG-1145.

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.

Response: GDC 4 requires that nuclear power plant structures, systems, and components (SSCs) important to safety be designed to accommodate the effects of, and be compatible with, environmental conditions associated with normal operation, maintenance, testing, and postulated accidents, including loss-of-coolant accidents. These SSCs shall be appropriately protected against dynamic effects associated with postulated pipe ruptures, including the effects of pipe whipping and jet impingement. Staff evaluates requested information for reasonable assurance that the proposed facility will meet the regulatory requirements of GDC 4 - environmental and dynamic effects design bases. For example, in ESBWR DCD Tier 2, Section 3.6.5, GE stated that sketches of applicable piping systems showing the location, size and orientation of postulated pipe breaks and the location of pipe whip restraints and jet impingement barriers shall be provided by the COL applicant.

Disposition: No change to 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.

Response: The NRC staff agrees with the comment. See Response to C.I.3.6.3-2 for the detailed discussion.

Disposition: Section 3.6.3(1)(a) will be modified.

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 leak before break (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.

Response: The information described in Sections 3.6.3(1)(a), 3.6.3(1)(b), and 3.6.3(2)(a) is related to plant-specific, piping system-specific, and as-built conditions. The as-built criteria in C.I.3.6.3 will not be changed because they represent the technical basis upon which the LBB concept was approved by the staff as discussed in the Statement of Consideration of the LBB Final Rule (Federal Register, 41288, October 27, 1987) and SRP 3.6.3.

However, the NRC staff understands that the as-built information may not be available at the time of the COL application. The NRC will accept actual material properties and design information in accordance with ITAAC during plant construction. Representative material properties may be used in the LBB analysis submitted with the COL application. Sections 3.6.3(1)(a), 3.6.3(1)(b), and 3.6.3(2)(a) will be changed to address the timing of submitting the as-built information.

Disposition: Section 3.6.3(1)(a) will be modified.

C.I.3.6.3-3 Section C.I.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.

Response: It is acceptable to use representative material properties in the COL application, that will be updated to as-built material properties during construction. See Response to C.I.3.6.3-2. If the representative, in lieu of as-built, material properties are used in the leak before break (LBB) analyses, the representative material properties should be selected such that they would bound the as-built material properties.

Disposition: Section 3.6.3(1)(b) will be modified.

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." 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 since they are not considered in an leak before break (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.

Response: See response to C.I.3.6.3-2. As for the comment that reads "...detailed nozzle properties should not be required since they are not considered in an LBB analysis...", the staff notes that nozzles have been considered and analyzed in many LBB analyses submitted by the current PWR licensees. A nozzle of a piping system should be considered in the LBB analysis and its properties should be submitted if the nozzle sustains significant stresses when compared to other nodal locations of the pipe as a result of the pipe stress analyses.

Disposition: Section 3.6.3(1)(b) will be modified.

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.

- Response:** If the as-built drawings of pipe geometry are not available at the time of comined license (COL) application, the NRC staff would accept design piping isometric drawings in the COL application. The staff will verify the as-built piping systems in accordance with ITAAC during construction. C.I.3.6.3(2)(a) will be modified to address this issue.
- Disposition:** Section 3.6.3(2)(a) will be modified.
- 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).
- Response:** If the as-built drawings of pipe geometry are not available at the time of COL application, the NRC staff would accept design piping isometric drawings in the COL application. The staff will verify the as-built piping systems in accordance with ITAAC during construction. The word "as-built" remains in C.I.3.6.3(2)(a) to reflect the technical basis upon which the LBB approach was approved by the staff. See Response to question C.I.3.6.3-2
- Disposition:** Section 3.6.3(2)(a) will be modified.
- C.I.3.6.3-7** Section C.I.3.6.3(2) requires a discussion of snubber reliability including any technical specification requirements. Typically, snubbers are no longer addressed in the technical specifications.
- Response:** The NRC agrees with the above comment. Section 3.6.3(2)(c) will be revised to read: Discuss snubber reliability.
- Disposition:** Section 3.6.3(2)(c) will be modified.
- C.I.3.7.2.4-1** The last sentence in section C.I.3.7.2.4 states, "Provide discussion of any other methods used for SSI analysis or the basis for not using SSI analysis." The AP1000 design control document (DCD) simply states that SSI is not significant for the nuclear island founded on rock with a shear wave velocity greater than 8000 ft/sec. Is a reference to this section of the DCD adequate justification for a combined license (COL) application?
- Response:** The answer is "yes," if the COL applicant provides site specific geotechnical data to demonstrate that the shear wave velocity of the foundation material is greater than 8,000 ft/sec.
- Disposition:** No change to DG-1145
- C.I.3.7.2.5-1** During the workshop discussion of section C.I.3.7.2.5, the staff stated that a combined license (COL) application that references a certified design that envelops the floor response spectra (FRS) for COL site does not need to provide information beyond the statement that the site is enveloped. Please confirm this.

Response: The statement is not quite correct. There are two ways to demonstrate that a specific site meets the enveloping criteria: (1) by following the guidelines described in DG-1145, Section C.III.3.7.1.1.1 to meet the ground motion enveloping criteria, or (2) by demonstrating that the site specific FRS at all locations of interest (e.g., locations of major component supports, piping supports, floors, etc.) are enveloped by those of the generic design.

Disposition: No change to DG-1145.

C.I.3.9-1 The titles of sections C.I.3.9.7 and C.I.3.9.8 suggest content will be provided later for risk-informed in-service testing and inspection. Will this guidance be for optional risk-informed programs?

Response: These sections should not be part of section 3.9 of the guide.

Disposition: Sections C.I.3.9.7 and C.I.3.9.8 will be reserved for future use in the regulatory guide.

C.I.3.9.2.4-1 The last sentence of section C.I.3.9.2.4 implies that the subject testing may be completed at the time the combined license (COL) application is submitted. Is this in reference to prototype reactor testing? If so, what additional testing is required for a non prototype reactor?

Response: The answer to the first part of the question is " Yes". The additional testing for the non-prototype reactor internals would depend on which Category of the non-prototype reactor it falls under (as defined in Regulatory Guide 1.20, " Comprehensive Vibration Assessment Program for Reactor Internals during pre-operational and Initial Startup Testing"). Various levels of testing are applicable to Categories I, II, III, and IV. In addition for BWRs, the staff will evaluate testing of the steam dryers and main steam system components, which may or may not have been performed on the prototypical reactor. Therefore, this additional testing should be completed on the non-prototype reactor internals.

Disposition: No change to DG-1145.

C.I.3.11.3-1 The wording in the first sentence in section C.I.3.11.3, "Qualification Test Results", requires documentation of test results while the wording in the same section of Regulatory Guide 1.70 required test results. What is intended by this wording change? Current operating plants provided environmental qualification test results in the safety analysis report (SAR) and maintained documentation packages on site for NRC inspection.

Response: The expectation is to provide only a summary of the test results. The actual documentation packages could remain at the site for audit.

Disposition: No change to DG-1145.

C.I.3.12-1 What topics will be covered section C.I.3.12 that are different from the piping design information required in sections C.I.3.6, C.I.5.2, etc.?

Response: The section on piping will be a compilation of SRP acceptance criteria already existing under various Standard Review Plan (SRP) sections that are applicable to piping design including the criteria relative to thermal oscillations and thermal stratification as stated in Bulletins 88-08 and 88-11. In addition, the SRP will contain acceptance criteria on intersystem loss-of-coolant accident, various design certification reviews to supplement piping Design Acceptance Criteria, and issues related to environmental fatigue.

Disposition: Section C.I.3.12 of the guide will be revised.

C.I.3.13- 1 During the workshop discussion of section C.I.3.13, "Threaded Fasteners", it was pointed out that some COL applicants would be referencing the AP1000 DCD and that there was no section 3.13 in that document. The Staff responded that a COL applicant referencing a certified design that was not required to address this section would not be required to address it in the COLA. Please confirm that this position is correct.

Response: The staff agrees with the comment.

Disposition: Section C.I.3.13.1.4 of DG-1145 will be removed from the guide.

C.I.3.13.1.4-1 For section C.I.3.13.1.4, pre-service inspection results will not be available at the time the COL application is submitted.

Response: The Pre-service Inspection referenced here is the fabrication inspection of fasteners performed under ASME Code, Section III. It is likely that the results of the inspection may not be available at the time the COL application is submitted. In some cases, the results may be available. The staff feels that it is not necessary to submit the results at the time of the COL application. In such circumstances, the review of results could be performed under ITAAC.

Disposition: No change to DG-1145.

C.I.4-1 Is the level of detail regarding the program to manage aging of reactor internal components that has typically been submitted for license renewal applications considered sufficient for a combined license (COL) application?

Response: The level of information provided in the COL application should be consistent with the level of information that is being sought in response to the development of reactor internals aging management programs for license renewal applications. For example, as the industry program to develop guidelines for PWR reactor internals aging management completes, the staff would expect the recommendations of that program to be directly incorporated into COL applications.

Disposition: No change to DG-1145.

C.I.4-2 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?

Response: The staff agrees with this comment. The fuel design in the DCD meets all of the Tier 1, Tier 2*, and Tier 2 design requirements and is capable of being used without further staff review. Therefore, the fuel design in the DCD is the default design for the COL applicant for Cycle 1. If the COL applicant chooses to use a fuel design that is different from the fuel design in the DCD, the COL applicant must follow the change process for Tier 2* information (license amendment) which includes staff review and approval.

Disposition: No change to DG-1145.

C.I.4-3 DG-1145 should be modified to make clear that details of the fuel design and the core design such as those identified in section C.I.4 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. Section C.I.4 should provide a summary description of the mechanical, nuclear and T&H designs of the various reactor components including fuel.

Response: The staff agrees that the details of the fuel design and the core design can be provided in the COL application by referencing an approved DCD. Alternatively, the COL applicant may submit, for staff review, a different fuel design and/or core design. The licensee may not use approved methods or a vendor's fuel design change process to modify the Cycle 1 fuel design or core design. The fuel design and its placement for Cycle 1 must be specifically reviewed by the staff. If the DCD refers to an equilibrium core design, then the COL applicant must provide the Cycle 1 loading patterns and related core physics patterns for staff review in accordance with the applicable change process (i.e., typically changes to Tier 2* information). DG-1145, Section C.III.1, Chapter 4, provides guidance for COL applicants that reference a DCD. Section C.I.4, however, is intended for COL applicants that do not reference a certified design. For such COL applicants, referencing NRC approved methods and fuel reference topical reports is not a sufficient basis upon which to resolve all safety issues. The COL applicant must specify a fuel design and a core design.

Disposition: No change to DG-1145

C.I.4-4 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?

Response: In certified designs, certain fuel design acceptance criteria have been designated as Tier 2* information. Changes to Tier 2* information must follow the change process associated with certified designs. For a COL applicant that references a certified design, changes to Tier 2* information will be governed by the certified design change process for the life of the plant.

Disposition: No change to DG-1145.

C.I.5.2.1.2- 1 Section C.I.5.2.1.2 specifies that a list of "ASME Code Case interpretations that will be applied to components within the RCPB" to be provided. Clarification should be added to indicate that this list is for Section III or code cases that are related to construction, and not Section XI code cases. Code cases are different from interpretations. Either delete the word interpretations or somehow separate them in the sentence.

Response: The word "interpretations" will be deleted, since this section addresses only applicable Code Cases.

Disposition: Delete the word "interpretations" from the referenced sentence.

C.I.5.2.4-1 Section C.I.5.2.4.1(9) requires discussion of procedures used to meet Code requirements. What kind of procedure or information is required to be identified here? If a list of nondestructive examination (NDE) procedures is required, then this requirement should be deleted. The list can become outdated rather quickly because a utility can either use its own NDE procedures or its NDE vendor(s), and it may not use multiple NDE vendors or switch NDE vendors often.

Reference to Regulatory Guide (RG) 1.150 should be revisited. Current examination ultrasonic testing of Reactor Vessel Welds requires the use of ASME Section XI, Appendix VIII. Our understanding is that Appendix VIII (or approved alternate) is superior to RG 1.150 and should address issues/concerns identified by RG 1.150.

Response: The NRC believes the subject comment refers to Section C.I.5.2.4.1(3), not Section C.I.5.2.4.1(9). Item (3) does not require a detailed description of each NDE procedure to be used for examination, since the applicant may not have such information at the time of COL application. Therefore, the response to Item (3) should focus on to what extent the methods, techniques and procedures used for examinations will be qualified to the Code requirements and its bases for acceptance.

For performing ultrasonic testing (UT) examinations not covered by ASME Section XI, Appendix VIII, the applicant should address the issues/concerns identified in RG 1.150 to ensure the UT methods, techniques and procedures used for Code examinations are consistent with that recommended in the subject Regulatory Guide. There is no need to address RG 1.150, if the UT examinations comply with ASME Section XI, Appendix VIII.

Disposition: (1) Replace the second sentence in Item (3) as:

“For performing ultrasonic testing (UT) not covered by ASME Section XI, Appendix VIII, the applicant should address the issues/concerns identified in Regulatory Guide 1.150, “Ultrasonic Testing of Reactor Vessel Welds During Preservice and Inservice examinations” to ensure the UT methods, techniques and procedures used for Code examinations are consistent with that recommended in the subject Regulatory Guide.”

C.I.5.2.4.1-1 The last sentence in Section C.I.5.2.4.1 refers to the inservice inspection (ISI) program in Chapter 16, "Technical Specifications." ISI programs are no longer included in the Tech Specs.

Response: The last sentence in Section C.I.5.2.4.1 refers to the ISI program in Chapter 16, “Technical Specification” of the SAR will be removed because the technical specifications are no longer require to contain ISI program information.

Disposition: Remove the last sentence in Section C.I.5.2.4.1.

C.I.5.2.4.1-2 Section C.I.5.2.4.1, "ISI and IST Programs" provides a list of 9 items to be provided in the combined license (COL) application to allow the NRC to make a reasonable assurance finding. Some of the 9 items will not be available at the time the COL application is submitted. For example, items 1, 2, 7 and 8 would not be complete at COL application. Item 1 can be completed for major components of the reactor coolant pressure boundary (RCPB). For item 2, it is not expected that all remote access equipment would be identified several years before the examinations. Also, items 7 and 8, code exemptions and relief requests will not be developed at the time the application is submitted. The list should be modified to indicate that all such items that have been identified will be included in the application.

Response: Additional guidance will be provided in this section for the described situation. The added guidance will stipulate that when some detailed information for inservice inspection and testing program as required in this section is not available at the time of submitting the application, the COL applicant should make a commitment in the application that such information will be provided at a later date for NRC review prior to fuel load. Consistent with the discussion in SECY-05-0197 on operational programs, the COL application should provide sufficient information to “fully describe” the program. It is acceptable to submit a general description as long as it “fully describes” the programs and references any applicable standards regarding ISI and IST programs. The programs should be updated with the specific information at least one year prior to scheduled fuel load.

Disposition: Add the following to the end of this section as a separate paragraph:

“It is acceptable to submit a general description of the programs as long as it “fully describes” the programs, as defined in SECY-05-0197, and references any applicable standards regarding the ISI and IST programs. When some detailed information for the ISI and IST programs as required in this section is not available at the time of submitting the application, the COL applicant should make a commitment in the application that such information will be provided at a later date (at least one year prior to fuel load) for NRC review prior to fuel load.”

C.I.5.3.1.1-1 The last sentence in section C.I.5.3.1.1, "Material Specifications" states that "Information provided in Chapter 5 of the final safety analysis report (FSAR) may be incorporated by reference". This section is guidance for Chapter 5. The same comment applies in other locations.

Response: The NRC agrees that the text should be clarified. The intent is that information applicable to Chapter 5 that is contained in other chapters of the FSAR may be cross-referenced rather than duplicated.

Disposition: Section C.I.5.3.1.1, and other sections for which this comment is applicable, will be revised to clarify the staff's intent.

C.I.5.3.2.2-1 Section C.I.5.3.2.2, "Operating Procedures": This section requests a comparison with intended operating procedures. The operating procedures will not be complete at the time the combined license (COL) application is submitted. The section should require a commitment that the procedures will include provisions to assure the limits are met.

Response: The NRC agrees that operating procedures would not be available at the time of COL application submittal.

Disposition: Section C.I.5.3.2.2 will be revised to address the comment (e.g., "The FSAR should contain a commitment that plant operating procedures will ensure that the pressure-temperature limits identified in Section C.I.5.3.2.1 will not be exceeded during any foreseeable upset condition."]

C.I.5.4-1 Sections C.I.5.4.4, C.I.5.4.5, C.I.5.4.9, C.I.5.4.10, C.I.5.4.13 and C.I.5.4.14. These sections are reserved. What are the subjects and when is the guidance expected?

Response: These Sections are identified as "reserved" for administrative convenience. The numbering scheme within Section C.I.5.4 is carried over from Regulatory Guide 1.70 in order to retain internal document consistency and correlation with the Standard Review Plan numbering scheme. For the identified Sections, Regulatory Guide 1.70 contained no definitive guidance.

Disposition: The NRC does not currently anticipate including definitive guidance in Sections C.I.5.4.4, C.I.5.4.5, C.I.5.4.9, C.I.5.4.10, C.I.5.4.13 or C.I.5.4.14. No change to the guide.

C.I.6.1.1.1-1 Item (1) in Section C.I.6.1.1.1 requests "List the material specifications for all pressure-retaining ferritic materials, austenitic stainless steels, and nonferrous metals, including bolting and welding materials, in each component (e.g, vessels, piping, pumps, and valves) that are part of the ESF systems." It was only "principle" materials in RG 1.70. What is the basis for the expansion?

Response: The word "principal" used in the RG 1.70 is ambiguous and subject to interpretation. Therefore, clarification is needed to define what constitutes "principal." In DG-1145, the word "all" is used in lieu of "principal" to provide the needed clarification. This is based on the consideration that all materials that are used to construct pressure-retaining

components in the ESF systems are considered to be principal materials, since these components are needed for safety related operating functions. The use of the word "all" is not an expansion of the guidance in RG 1.70, because it clarifies the intent of the guidance in RG 1.70

Disposition: No change to DG-1145.

C.I.6.1.1.1-2 Item (2) in section C.I.6.1.1.1 requests "List the ESF construction materials that would be exposed to the core cooling water and containment sprays in the event of a loss-of-coolant accident (LOCA). Provide test data and service experience to show that the construction materials used are compatible with the core cooling and containment spray solutions." Service experience should be sufficient in many cases, e.g, familiar/common materials and solutions. Test data should only be required where insufficient experience is available.

Response: In the staff's review of the materials selected for the ESF systems of the plant, it is always desirable to have the COL applicant submit both the relevant test data and the service experience to support the material selection. The staff recognizes that in some cases, when service experience is not available, the subject review of materials compatibility with the ESF fluids will be based solely on the test data. Additional test data may be requested if the submitted test data is determined not to be adequate. Similarly, when only service experience is submitted, the staff may request the submittal of additional test data if it is determined that the submitted information is not adequate to support the application.

Disposition: No change to DG-1145.

C.I.6.1.1.1-3 Item (3)(c) in Section C.I.6.1.1.1 requests "Cold-worked austenitic stainless steel should not be used for pressure boundary applications. It may be used for other applications when there is no proven alternative available. Use of such materials should be supported by service experience and laboratory testing that simulates the environment to which the components will be exposed." If no use of these materials for pressure boundary is a new restriction, please provide the basis. Also, the request for both service experience and laboratory testing seems excessive. Service experience should be sufficient in many cases, e.g, familiar/common materials and solutions. Laboratory testing should only be required where insufficient experience is available.

Response: It is well known that austenitic stainless steel materials in cold-worked state is susceptible to corrosion related degradation such as stress corrosion cracking. This phenomenon has been demonstrated in laboratory testing and supported by plant operating experiences. The residual stresses created from cold working such as rolling and extrusion in material forming and abusive machining and grinding of components provide the driving force to accelerate the initiation of cracking in a corrosive environment. Therefore, it is necessary to restrict the application of cold-worked materials to ensure the maintenance of the structural integrity of the pressure boundary made of austenitic stainless steel. Regarding the need to submit the laboratory testing data when cold worked austenitic stainless steel materials are used, this is due to the concern that stress corrosion cracking is a time-dependent degradation mechanism, and is also sensitive to the aggressive conditions of the environment as well as the nature and extent of cold working which may not be fully represented in the past service experience.

Disposition: No change to DG-1145.

C.I.6.1.1.2-1 Item (2) in Section C.I.6.1.1.2-1 requests "Provide the following information regarding the composition and compatibility of the core cooling water and containment sprays and other processing fluids, as they relate to the materials of the ESF systems..." Please provide additional guidance with regard to "other processing fluids."

Response: The other processing fluids refers to any other fluids used during the process of fabrication and cleaning of the components. The concern is aggressive processing fluids may create pitting, or contaminants on the surface of the components which subsequently may lead to cracking during service.

Disposition: No change to DG-1145.

C.I.6.1.1.2-2 Item (3) in Section C.I.6.1.1.2 requests "Provide information to verify the compatibility of materials used in manufacturing ESF components with the ESF fluids." Item (4) then requests "Describe the process used to verify that ESF components and systems are cleaned in accordance with RG 1.37." If the processes used as described in Item (4) are sufficient, then request (3) seems to moot. What is the technical basis for item (3)?

Response: The information requested in Item (3) and Item (4) is different. In Item (3) the information requested pertains to the compatibility of materials used in manufacturing ESF components with the ESF fluids. In Item (4) the information requested pertains to the compliance with RG 1.37 in the cleaning of the ESF components.

Disposition: No change to DG-1145.

C.I.6.1.1.2-3 Item (6) in Section C.I.6.1.1.2 requests "Provide information concerning the proposed approach to control the chemistry of the water used for the ECCS and containment spray solutions (CSS) and during the operation of the systems. Describe the methods and bases to evaluate the short-term compatibility (during the mixing process) and long-term compatibility of these sprays with all safety-related components within the containment." The first sentence refers to both emergency core cooling system (ECCS) and core spray system (CSS), but the second only refers to sprays. Confirm the information requested in the second sentence does not apply to ECCS, but only CSS.

Response: The second sentence should also apply to ECCS because similar concern also exists for spray solutions in ECCS.

Disposition: The second sentence in C.I.6.1.1.2 (6) has been revised to: "Describe the methods and bases to evaluate the short-term compatibility (during the mixing process) and long-term compatibility of the water used for the ECCS and CSS with all safety-related components within the containment."

C.I.6.2-1 Section C.I.6.2 notes "CD acceptable" in a several places. Please clarify then intent of this notation. Does this imply that the information could be provided via CD outside the content of the final safety analysis report (FSAR)? Note that the FSAR is likely to be on CD.

Response: The intent of “CD acceptable” was to allow the applicant to provide voluminous data on a CD rather than a hard copy. However, because the FSAR will most likely be provided on a CD, “CD acceptable” may lead to confusion. It did not imply that the information could be provided via a CD outside the content of the FSAR.

Disposition: The phrase “CD acceptable” has been removed from Section 6.

C.I.6.2.1-1 Section C.I.6.2.1 requests "Describe how the basic functional design requirements for the containment meet GDCs 4, 16, and 50 in Appendix A to 10 CFR Part 50 and 10 CFR 50.46." Please provide additional guidance on how 50.46 ECCS evaluation criteria should be related to containment design basis.

Response: 10 CFR 50.46 applies to LOCA analyses. There are two connections between 10 CFR 50.46 and containment analyses. 10 CFR Part 50 Appendix K D.2, "Containment Pressure," requires that the containment pressure calculated during the reflood and spray cooling portions of the LOCA be minimized. Guidance for this requirement is given in SRP 6.2.1.5, "Minimum Containment Pressure Analysis for Emergency Core Cooling System Performance Capability Studies."

In addition, licensees use 10 CFR Part 50 Appendix K, I.A., "Sources of Heat During the LOCA," as guidance on the sources of heat to be included in LOCA and main steam line break containment analyses.

This is current practice and is not a new requirement.

Disposition: No change to DG-1145.

C.I.6.2.1.1-1 Item (1) in Section C.I.6.2.1.1 requests "Discuss the design bases for the containment to withstand a spectrum of LOCA and main steam line break accidents." Subitems (a) and (b) then request information regarding "the postulated accident conditions and the extent of simultaneous occurrences (e.g., seismic event...." This seems to imply that a simultaneous seismic event and LOCA should be evaluated for containment analysis. Please clarify and confirm that this is NOT the intent of these statements.

Response: The NRC does not intend to formulate a new requirement. The wording will be revised to make it clearer. The intent was to say that only seismically qualified equipment should be credited for accident mitigation in containment safety analyses

Disposition: Revised C.I.6.2.1.1 (a) and (b) to state:

a) Discuss the postulated accident conditions and the extent of simultaneous occurrences (e.g., loss of offsite power and single active failures) that determine the containment accident pressure (including both internal and external design pressure requirements). Only seismically qualified equipment should be credited for accident mitigation in containment safety analyses. State the maximum calculated accident pressure and temperature.

(b) Discuss the postulated accident conditions and the extent of simultaneous occurrences (e.g., loss of offsite power and single active failures) that determine the accident pressure and temperature requirements for the internal structures of pressure-

suppression-type containments, with reference to the design evaluation in Item 3(b) of this section. Only seismically qualified equipment should be credited for accident mitigation in containment safety analyses.

C.I.6.2.1.1-2 Item (2)(a) in Section C.I.6.2.1.1 requests "Describe the qualification tests proposed to demonstrate the functional capability of the structures, systems, and components in pressure-suppression-type containments and nonpressure-suppression type containments." Please provide additional guidance on the type of qualification testing that might be expected for nonpressure-suppression type containments.

Response: The type of testing would depend on the containment design of the proposed power plant. Testing of containment heat removal systems and isolation systems would be two potential candidates.

Disposition: No change to DG-1145.

C.I.6.2.1.1-3 Item (3)(a) in Section C.I.6.2.1.1 similarly states "Tabulate (and electronically provide) the results of each accident analyzed, as shown in Table 6-3 at the end of this section of DG-1145," and Item (3)(b) states "Provide tables (or transmit electronically)...." Please clarify then intent of these notations. Does the first note imply that the information should also be provided in some electronic format outside the content of the final safety analysis report (FSAR)? Does the second imply an option that the information could be provided in some electronic format outside the content of the FSAR? Note that the FSAR is likely to be "electronically provided" on CD.

Response: As part of the review of a new design or COL application, the staff may want to perform independent calculations to audit the calculation results obtained by the applicant. This may be done as part of the review of a new computer code or to assess the assumptions made by the applicant in performing safety analyses. The staff has found it most efficient to obtain the applicant's information electronically (by transmitted files or CD, for example).

This is not a new requirement. The exact mode of transmittal of the requested information would be agreed to between the staff and the applicant.

Disposition: To avoid confusion, the words "and electronically provide" and "or transmit electronically" has been removed from Section 6.

C.I.6.2.1.1-4 Item (3)(b) in Section C.I.6.2.1.1 requests "Provide large-size plan and section drawings of the containment...." Provide clarification of how this is accomplished consistent with the electronic submittal guidance in Section IV.2.

Response: This request has been removed from Section C.I.6.2.1.1

Disposition: This sentence in Section C.I.6.2.1.1 (3) (b) has been revised to state, "Illustrate all equipment and structural surfaces that could be subjected to pool dynamic loads in the containment drawings."

C.I.6.2.1.3-1 Section C.I.6.2.1.3 requests the accident be described in four phases, including a new "refill phase." Please clarify the distinction between the "refill phase" and the "core reflood phase" and provide a regulatory basis for the change from RG 1.70.

Response: The response of the reactor pressure vessel to a loss-of-coolant accident (LOCA) is divided into four phases. These are the blowdown in which the reactor coolant is discharged from the vessel, the refill phase in which the ECCS restores the reactor vessel water level to the bottom of the core but prior to contact of the water injected by the ECCS with the fuel, reflood in which the core is flooded and the fuel rods quenched, and long term cooling. In containment mass and energy release calculations, the refill phase is usually not included because this conservatively allows the injected water to contact the fuel sooner which leads to a more rapid mass and energy release to the containment.

By adding the refill phase here, the staff is eliciting the applicant's assumptions of how the refill phase is modeled. This is not a new requirement.

Disposition: No change to DG-1145.

C.I.6.2.1.4-1 Section C.I.6.2.1.4 refers to "electronically" providing information. Does the second imply that the information is expected to be provided in some electronic format outside the content of the final safety analysis report (FSAR)? Note that the FSAR is likely to be "electronically provided" on CD. Item (6) states "tabulate (and electronically provide)...." Does this latter note imply that the information should also be provided in some electronic format outside the content of the FSAR? Please clarify then intent of these notations.

Response: See Response for C.I.6.2.1.1-3.

Disposition: See Disposition for C.I.6.2.1.1-3

C.I.6.2.2.2-1 Section C.I.6.2.2.2 states "Specify the time elapsed for the CHRS to be fully operational following postulated accidents." The rewording of this sentence is less clear than the wording in RG 1.70. It now seems to imply that the CHRS may not be fully operational at the time of the event and that some time could elapse before it becomes fully operational to respond to the event. Please clarify the intent of the rewording.

Response: The NRC agrees that the new wording is unclear

Disposition: The sentence Section C.I.6.2.2.2 is revised to the RG 1.70 version, "Specify the times following postulated accidents that the containment heat removal systems are assumed to be fully operational."

C.I.6.2.3.4-1 Section C.I.6.2.3.4 requests "Provide results of tests performed, as well as a detailed updated program. Subsequent test results should be provided as they become available." These tests won't be performed during the combined license (COL) application review. Does this imply that testing results should be included in the bi-annual periodic updates? If so, what is the regulatory basis for the information request?

- Response:** The NRC agrees with this comment. COL applicants are not expected to perform the testing described in this section prior to submittal of their application or to provide any test results in the application.
- Disposition:** The subject statement has been deleted.
- C.I.6.2.4.4-1** Section C.I.6.2.4.4 requests "Provide the results of tests performed, as well as a detailed updated testing and inspection program." These tests won't be performed during the combined license (COL) application review. Does this imply that testing results should be included in the bi-annual periodic updates? If so, what is the regulatory basis for the information request?
- Response:** See Response for C.I.6.2.3.4-1
- Disposition:** See Disposition for C.I.6.2.3.4-1.
- C.I.6.2.5-1** During the workshop discussion of section C.I.6.2.5, it was pointed out that regulatory Guide 1.7, revision 2, the current issued revision, does not reflect the current version of 10 CFR 50.44. Regulatory Guide 1.7, draft Rev. 3 is written to be consistent with the regulation. What is the schedule for issuing RG 1.7, Rev. 3?
- Response:** Regulatory Guide 1.7, Revision 3, is scheduled to be issued by September 2006.
- Disposition:** No change to DG-1145.
- C.I.6.2.5.4-1** Section C.I.6.2.5.4 requests "Provide the results of tests performed, as well as a detailed updated testing and inspection program." These tests won't be performed during the combined license (COL) application review. Does this imply that testing results should be included in the bi-annual periodic updates? If so, what is the regulatory basis for the information request?
- Response:** See Response for C.I.6.2.3.4-1.
- Disposition:** See Disposition for C.I.6.2.3.4-1.
- C.I.6.3.2.2-1** Section C.I.6.3.2.2 requests "Describe provisions with respect to control circuits for motor-operated isolation valves in the ECCS, including consideration of inadvertent actuation prior to or during an accident" and C.I.6.3.2.5 requests "Identify the functional consequences of each possible single failure, including the effects of any single failure or operator error that causes any manually controlled electrically operated valve to move to a position that could adversely affect the ECCS." The industry understands these to include requests for failure modes and effects analysis (FMEA) considerations of operator error. Please confirm this understanding or clarify the request and its regulatory basis.
- Response:** Yes. The intent is to use the failure modes and effects analysis to systematically search for potential single failure points and their effects on prescribed functions caused by electrical failures, mechanical failures, or operator errors.
- Disposition:** No change to DG-1145.

C.I.6.3.2.2-2 Sections C.I.6.3.2.2 and 6.3.5 refer to IEEE Std 609. Should these references be to IEEE 603. If not, the 609 standard does not seem to be readily available. It is not available from the IEEE web site, nor in other typical standards purchasing locations. Please identify where this document can be obtained.

Response: IEEE Std 609 is a typographic error. The correct reference is IEEE Std 603, "Trial Use Standard Criteria for Safety Systems for Nuclear Power Generating Stations," 1998.

Disposition: C.I.6.3.2.2 and C.I.6.3.5 has been revised to reference is IEEE Std 603.

C.I.6.3.2.5-1 Section C.I.6.3.2.5 requests "Discuss how all potential passive failures of fluid systems, as well as single failures of active components, were considered for long-term cooling." Please clarify this request and provide its regulatory basis. Specifically, clarify that the passive failures are also considered on a single failure basis and not "all" together.

Response: Passive failure are considered for long-term cooling on a single failure basis the same way as active single failures. SECY-77-439 stated that during the long-term ECCS recirculation cooling mode the most limiting active failure, or a single passive failure equal to the leakage that would occur from a valve or pump seal failure, is assumed.

Disposition: No change to DG-1145.

C.I.6.4-1 Section C.I.6.4-1 states "The control room is also the entire zone serviced by the control room ventilation system." However, the 1996 draft revision of SRP 6.4 Section I.1 states; "The zone serviced by the control room emergency ventilation system is examined to ascertain that all critical areas requiring access in the event of an accident are included within the zone (control room, kitchen, sanitary facilities, etc.) and to ensure that those areas not requiring access are generally excluded from the zone." This SRP description is preferred since it would allow for isolation of areas not serviced by the recirculation mode of the control room ventilation system. The site should have the opportunity to determine the control room habitability zone, provided it would be tested as appropriate. Alternatively, the statement in DG-1145 could be revised to read "The control room is also the entire zone serviced by the control room ventilation system when in the recirculation mode."

Response: The Second Paragraph in Section C.I.6.4, "Habitability Systems," is revised as follows:

As defined in Regulatory Guide 1.197, "Demonstrating Control Room Envelope Integrity at Nuclear Power Reactors," May 2003, on Page 1.197-2, the "Control Room" is the plant area, defined in the facility licensing basis, in which actions can be taken to operate the plant safely under normal conditions and to maintain the reactor in a safe condition during accident situations. It encompasses the instrumentation and controls necessary for a safe shutdown of the plant and typically includes the critical document reference file, the computer room (if used as an integral part of the emergency response plan), shift supervisor's office, the operator wash room and kitchen, and other critical areas to which frequent personnel access or continuous occupancy may be necessary in the event of an accident.

Also, as defined in Regulatory Guide 1.197, "Demonstrating Control Room Envelope Integrity at Nuclear Power Reactors," May 2003, on Page 1.197-2, the "Control Room

Envelope (CRE)” is the plant area, defined in the facility licensing basis, that in the event of an emergency can be isolated from the plant areas and the environment external to the CRE. This area is served by an emergency ventilation system, with the intent of maintaining the habitability of the control room. This area encompasses the control room and may encompass other non-critical areas to which frequent personnel access or continuous occupancy is not necessary in the event of an accident.

Disposition: Section C.I.6.4 has been revised.

C.I.6.4.1-1 Item (4) in Section C.I.6.4.1 requires criteria for "food, water, medical supplies, and sanitary facilities". Although RG 1.70 requires this, SRP 6.4 says nothing about food, water, or medical supplies. Please confirm that these supplies must only be available to control room personnel in an accessible area, but need not be stored in the control room.

Response: A new third paragraph is included in Section C.I.6.4.1, “Design Basis,” as follows:

Food, water, medical supplies, and sanitary facilities must be located inside an accessible area within the Control Room Envelope.

Disposition: Section C.I.6.4.1 has been revised.

C.I.6.4.5-1 Section C.I.6.4.5 requests "The application should also include results of any tests performed to support specification of the test program, as well as a detailed update of the program." There won't be any testing performed during the COL application review. Does this imply that testing results should be included in the bi-annual periodic updates? If so, what is the regulatory basis for the information request?

Response: See Response for C.I.6.2.3.4-1.

Disposition: See Disposition for C.I.6.2.3.4-1.

C.I.6.5.5-1 Section C.I.6.5.5 provides guidance for suppression pool fission product cleanup evaluation. This seems inconsistent with the Regulatory Guide 1.183 Appendix A statement of "Reduction in airborne radioactivity in the containment by suppression pool scrubbing in BWRs should generally not be credited." However, it is recognized that the RG also says "However, the staff may consider such reduction on an individual case basis."

Response: “Suppression Pool as a Fission Product Cleanup System,” is provided as guidance in DG-1145 for any type of future designs which may credit suppression pool scrubbing in its analyses.

Disposition: No change to DG-1145.

C.I.6.6.7-1 Section C.I.6.6.7 requests "Indicate whether the program for Class 2 system pressure testing will comply with the criteria in Article IWC-5000 of Section XI of the ASME Code. Also indicate the extent to which the program for Class 3 system pressure tests will comply with those criteria." Shouldn't the Class 3 pressure tests be compared to the IWD-5000 criteria?

- Response:** Yes, Class 3 pressure tests should meet the criteria of IWD-5000.
- Disposition:** The second sentence referenced above should be modified to reflect the criteria of IWD-5000 for Class 3 system pressure tests as follows:
Also indicate whether the program for Class 3 system pressure testing will comply with the criteria in Article IWD-5000.
- C.I.7-1** This document frequently refers to IEEE Std 7-4.3.2-2003, "IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations." 10 CFR 50.55a(h) requires protection systems to meet the requirements of IEEE Std 603-1991, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations." IEEE 603-1991 references IEEE 7-4.3.2-1982. Please Clarify the proper regulatory path to use the 2003 version and show compliance with the CFR requirements.
- Response:** 10 CFR 50.55a(h) requires safety systems to meet the requirements of IEEE Std. 603-1991 and the correction sheet dated January 30, 1995. Federal Register/ Vol. 64, No.70/April 13, 1999/ Rules and Regulations clarified that as a matter of law, the other IEEE standards referenced in IEEE Std. 603-1991 are not rulemaking requirements. Although IEEE-603-1991 references an older version of IEEE 7-4.3.2, Regulatory Guide 1.152, "Criteria for Use of Computers in Safety Systems of Nuclear Power Plants," references IEEE Std 7-4.3.2-2003, as the present "IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations."
- This standard specifies additional computer-specific requirements (incorporating hardware, software, firmware, and interfaces) to supplement the criteria and requirements of IEEE Std 603-1998. The criteria contained in IEEE Std 603-1998, in conjunction with criteria in IEEE Std 7-4.3.2-2003 as endorsed by NRC Regulatory Guide 1.152, Revision 2, establish minimum functional and design requirements for computers used as components of a nuclear power generating plant safety system.
- Disposition:** DG-1145 Section C.I.7 is revised to clarify the regulatory position.
- C.I.7-2** Section C.I.7 references IEEE 603-1991, 603-1998, and 603 with no revision date. While we endorse the concept of using the latest revisions of the various standards, consistency is needed within the document regarding the various standards.
- Response:** IEEE 603-1991 criteria is the requirement stated in 10 CFR 50.55a(h). The DG-1145 guidance references this revision unless another specific revision is stated. The revision for other IEEE standards should be the revision endorsed by the current revision of a regulatory guide unless a specific revision in the document is provided.
- Disposition:** No change in the DG-1145.
- C.I.7-3** DG-1145 references EPRI TR 102323 (page 4) - however, no revision is given. Industry would prefer revision 3 of the document be referenced for use in these applications. One example of why EPRI 102323, Rev. 3, should be used or be the basis for a revision to Regulator Guide. 1.180 Rev. 1 is Test CS-114 (conducted susceptibility). Experience in qualification testing of platforms and components has shown that the CS-114 test levels

are still particularly problematic and cause considerable effort to either justify why what the equipment meets is acceptable or to develop special filters. The established levels for this test were based on EPRI data collected in 1993-4, but the consensus of both the industry and NRC experts is that the data was applied incorrectly, resulting in overly conservative test levels. Rev. 3 of 102323 has corrected the test levels for this test. It also includes the justification for these revised levels.

Response: Regulatory Guide (RG) 1.180, Rev.1 references EPRI TR 102323, and states that NRC staff accepted the EPRI document in a Safety Evaluation Report (SER) dated April 17, 1996, as one method for addressing issues of EMC for safety-related digital I&C systems in NPPs. RG 1.180 complements the position set forth in the SER. In addition to the EPRI guidance, RG1.180, Rev. 1, provides additional acceptable methods for addressing EMC issues and includes guidance on testing to address signal line susceptibility and very high frequency (above 1 Ghz) phenomena.

Since RG 1.180 , Rev. 1, provides several acceptable methods for addressing NPP EMC issues, including the guidance of EPRI TR 10323. Hence the SRP Chapter 7 guidance references RG 1.180, Rev.1 for addressing EMC issues for NPPs.

Disposition: The draft regulatory guide (DG) is changed to reference RG 1.180, "Guideline for Evaluating Electromagnetic and Dadio-frequency Interference in Safety-Related Instrumentation and Control Systems," instead of referencing EPRI TR 102323.

C.I.7-4 Chapter 8 of DG-1145 references Regulatory Guide (RG) 1.180 directly; Chapter 7 references the EPRI TR. Inconsistency between chapters needs to be corrected.

Response: The DG-1145 is changed to reference RG 1.180.

Disposition: The DG-1145 is changed to reference RG 1.180

C.I.7-5 Lightning is now grouped with other environmental factors in Chapter 7. This does not seem to be the right place for this guidance - seems to fit better under system integrity. It was not mentioned in the Chapter 8 guidance on environmental factors. Also, ANSI 665 is referenced in this section - we believe that IEEE 1050 should be referenced as well. Both of these are endorsed in RG 1.204. There should be consistency between Chapters 7 and 8 in this area.

Response: The DG-1145 is changed to reference RG 1.204.

Disposition: The DG-1145 is changed to reference RG 1.204.

C.I.7-6 Section C.I.7 states, "The adequacy of the software life cycle process implementation - A sample of verification and validation, safety analysis, and configuration management documentation for various life-cycle phases should be provided..." Should revise to "provide description of V&V process and have documentation available for audit and review."

Response: This item is revised as follows: An index of the life cycle documents should be provided. A statistically valid sample of system requirements should be selected to demonstrate that the applicant/licensee's life cycle activities have been implemented as planned (The

guidance for lifecycle activities see Section C.I.7 Appendix 7A, item (b)). The sample size should be such that the staff can conclude with 95% assurance that the quality of the design has been validated. BTP 7-14 describes functional characteristics and software development process characteristics that can be verified by staff audits.

Disposition: DG-1145 has been revised.

C.I.7-7 NEI 04-04 was recently endorsed by NRC regarding cyber security programs. This document should be mentioned in the draft regulatory guide in terms of having a cyber security program that meets the guidance of 04-04 Needs to be in the appropriate section of the guidance. Also, RG 1.52 is referenced instead of 1.152 (typo).

Response: Because the document NEI 04-04 is not available for general public, this DG can not reference the NEI 04-04 document. The staff has considered the issues in the NEI 04-04 document and integrated them in RG 1.152 Revision 2.

Disposition: No change in the DG-1145 except the typo is corrected.

C.I.7-8 How will the cyber security sections be reconciled with the ongoing Part 73 rulemaking? The use of RG-1.152 for Cyber Security is still problematic considering that all current and future platforms are commercial off-the-shelf (COTS). While these concepts can be applied to application development, the platform and platform software have long since been "developed". No current platform safety evaluation report (SER) addresses RG 1.152, R2. In addition, the staff should clarify reviews of cyber security issues beyond safety related items that will occur during the combined license (COL) process.

Response: The cyber security concern has been included in the Standard Review Plan Chapter 7, Revision 4. The staff will review cyber security according to RG 1.152, Rev. 2 guidance.

Disposition: No change to DG-1145.

C.I.7-9 Several standards are referenced with no date revision noted. Are the referenced standards considered to be the latest ones published or the latest endorsed? Industry would prefer that the guidance make clear that the latest published standards should be utilized.

Response: An IEEE standard's revision should be the revision endorsed by the current revision of a regulatory guide unless a specific revision in the document is provided.

Disposition: A Clarification is added to DG-1145

C.I.7-10 Item K in appendix 7B in Section C.I.7 states in part, "...For computer-based system, configuration management plan should describe for maintaining the identification of computer software." This sentence does not appear to make sense and should be revised. Is this sentence trying to indicate that the configuration management plan should describe the mechanism(s) for maintaining identification?

Response: This item has been revised as follows: "For computer-based systems, the configuration management plan should describe the identification process for computer software."

Disposition: DG-1145 has been revised.

C.I.7-11 Appendix 7C, "Evaluation of Conformance with IEEE Std 7-4.3.2" (Reference: SRP Chapter 7, Appendix 7.1-D) - this reference is to a new SRP section that has not been made publicly available. As such, we are unable to comment on this section, and we understand that the SRP updates will not be available until March 2007. We believe it would be appropriate for the NRC to publish this SRP section as soon as possible. In the case of brand new SRPs like this one, we recommend the NRC issue the SRP in draft form as soon as possible. This will increase the likelihood that the SRP will be commonly understood when the final is issued in March of next year.

Response: SRP Chapter 7, Appendix 7.1-D will be publicly available after completion of its approval process. It is a guidance for evaluation of conformance to IEEE Std. 7-4.3.2.

Disposition: No change to DG-1145.

C.I.7-12 The industry understands that it must produce detailed documentation for all sections of Chapter 7. Since a lot of this material was not completed during the Certification it is covered under the design acceptance criteria (DAC) and inspection, test, analyses, and acceptance criteria (ITAAC). This documentation is expected to be reviewed and approved by the licensee and held for audit by the NRC; it is not expected to be submitted to the NRC. The industry needs additional guidance on what the NRC expects the applicant to actually submit for NRC review and approval. Since all near term applications will reference certified designs (or soon to be certified designs), the NRC should be clearly addressing the certified design as their highest priority.

Response: Additional guidance is provided in DG-1145, Section C.III.5, "Design Acceptance Criteria."

Disposition: No change to DG-1145.

C.I.7-13 In the whole discussion, RG's 1.168, 1.173, 1.172, 1.169, 1.170, 1.153 and Item A-19 (NUREG 0933) are notably absent as references. At least one of these RG's was "draft" but are nonetheless applicable to the design, configuration and testing of the SW and HW components. It may be that the reference is implied through other standards and documents but it isn't obvious. Clarification is needed on treatment of these guides.

Response: DG-1145, Section C.I.7.1.2, "Identification of Safety Criteria," stated that the specific information identified in SRP Chapter 7, Appendix 7.1-A, "Acceptance Criteria and Guidelines for Instrumentation and Control Systems Important to Safety." The RGs listed in the comment above are referenced in SRP Chapter 7, Appendix 7.1-A.

Disposition: No change to DG-1145

C.I.7-14 It is recommended that clarification be added that some of the more detailed information in the list of 7 topics in Appendix 7A will be made available for NRC review rather than submitted. Note that the current corresponding SRP section uses the word "reviewed" rather than "provided".

Response: DG-1145, Section Appendix 7A stated that the following seven topics should be

addressed in digital I&C system applications. Additional clarification has been provided in the revised version. Some topics require submittal as part of the licensing process or as topical reports. Some topics should be made available for staff review and audit.

Disposition: DG-1145 Section 7A items 6 and 7 are revised.

C.I.7-15 Section C.I.7 discusses the defense-in-depth and diversity (D3) analysis. Clarification is needed on how leak-before-break fits into the best estimate analyses used the D3 work. A followup comment on Sections C.I.7.1, Review Process for Digital Instrumentation and Control Systems (Reference: SRP Chapter 7, Appendix 7.0-A), Item 3, Defense-in-depth and diversity: In response to this industry comment the NRC staff indicated that as a result of the Davis Besse event the staff does not consider leak before break as a viable analysis approach for BTP-19 evaluations. The staff further indicated that the staff position paper on BTP-19 is in the review and concurrence process. Industry believes further technical discussions in this area are warranted. The industry believes that the NRC response during the July 12 workshop indicating that leak before break is not a viable approach for BTP-19 given the Davis-Besse event is not consistent with staff positions regarding leak before break concepts used in other evaluations. For example, leak before break analyses are still used for risk-informed ISI. The staff should not remove this allowance for BTP-19, especially given the augmented reactor head (top and bottom) inspections imposed by order until the ASME code is revised. NRC should not set different standards for use of technology by different branches. If leak before break is still a valid analysis technique for RI-ISI it should also be good for use in BTP-19 evaluations. NRC staff should not reverse positions for unusual events that have happened that have been appropriately remedied. Industry believes that the augmented inspections adequately address the D-B lessons learned such that leak before break remains a valid analysis assumption.

Response: GDC 4, Environmental and dynamic design bases, stated that the dynamic effects associated with postulated pipe ruptures in nuclear power units may be excluded from the design basis when analyses that have been reviewed and approved by the Commission demonstrate that the probability of fluid system piping rupture is extremely low under conditions consistent with the design basis for the piping. Therefore, the leak-before-break credit was authorized for a very narrow application - consideration of dynamic effects of pipe ruptures.

The staff position on BTP 7-19 is being updated. The guidance will be stated in the update to BTP 7-19.

Disposition: RG on defense-in-depth and diversity (D3) analysis is referenced to BTP 7-19. The guidance will be stated in the update to BTP 7-19.

C.I.7-16 Appendix 7A discusses NRC Regulatory Guide (RG) 1.152, Revision 2, "Criteria for Use of Computers in Safety Systems of Nuclear Power Plants," as establishing the minimum functional and design requirements for computers used as components of a nuclear power generating plant safety systems. The revision level for IEEE 603 in the RG is different than the one cited in 10 CFR 50.55a. Also, the RG endorses IEEE 7.4.3.2-2003 whereas NRC has said to a licensee (Oconee) that 10 CFR 50.55a does not explicitly allow use without a relief request. Clarity is needed on the proper regulatory path for use of the later version of these technical documents. IEEE 603-1991 references

IEEE 7.4.3.2-1982. RG 1.1.52 endorses IEEE 7.4.3.2-2003. And, this document references IEEE 603-1998, which references IEEE 7.4.3.2-1993. Clarity is needed on the proper regulatory path to use the latest versions and still show compliance with the CFR requirements.

Response: See response to item C.I.7-1.

Disposition: See response to item C.I.7-1.

C.I.7-17 Appendix 7A, "Digital Instrumentation and Control Systems Application Guidance"(Reference: SRP Chapter 7, Appendix 7.0-A), Item 3, discusses defense-in-depth and diversity. The latest NRC positions seem to indicate that the use of leak-before-break in analyses is not acceptable. Need clarification on how leak-before-break fits into the best estimate analysis. Also, we have been told in an earlier meeting that the staff is updating the BTP-19 diversity and defense-in-depth positions through a SECY paper. Please update us on the status of this work and the potential impact on BTP-19.

Response: See response to item C.I.7-15.

Disposition: See response to item C.I.7-15.

C.I.7-18 Section C.1.7.1 - It is recommended that clarification be added that some of the more detailed information in the list of 7 topics will be made available for NRC review rather than required to be submitted. Items 6 & 7 are examples. Note that the current corresponding SRP section uses the word "reviewed" rather than "provided".

Response: See response to item C.I.7-14.

Disposition: The DG-1145 has been revised.

C.I.7-19 Paragraph 5 and 7 on page two in Section C.I.7.1, the staff may want to consider segregating the platform from the application with regards to lifecycle planning and include both hardware and software. The platform (hardware host, Operating System and built in libraries, application building environment) has a distinctly different lifecycle and different management requirements than does the application (feed water, turbine control, reactor trip, etc). Segregation will also allow these two items to be managed independently and for regulations to be applied independently. For instance, we will not want to apply BTP 7-14 to the platform components directly if possible. Software development output should address the application vs. the platform. The platforms interaction with the application would be specified and validated in various V&V processes.

Response: The staff will review each application on case by case bases. No guidance will be provided at the present time. The staff will take consideration of this comment for the SRP update.

Disposition: No change to DG-1145.

C.I.7-20 In Appendix 7B, Item D, "Equipment Qualification," needs to identify specific standards that are considered acceptable in designing the system to minimize EMI/RFI. Only general guidance is given, except for testing guidance where EPRI TR-102323 is referenced.

Response: See response to item C.I.7-3.

Disposition: The DG-1145 is changed to reference RG 1.180.

C.I.7-21 RG 1.204 is referenced in DG-1145 Chapter 8; Item D in Appendix 7B of Chapter 7 references NFPA 78. Difference between chapters should be reconciled.

Response: The DG-1145 is changed to reference RG 1.204.

Disposition: The DG-1145 is changed to reference RG 1.204.

C.I.7-22 Item E, system integrity section in Appendix 7B is written such that the preferred method is for the Reactor Trip System to fail in a tripped state. While we agree that the RTS safe position is normally the tripped state, we believe that the ESFAS wording: "...should fail to a pre-defined state. For many ESFAS functions this predefined safe state will be that the actuated component remains as-is." or the GDC-23 wording: "The protection system shall be designed to fail into a safe state or into a state demonstrated to be acceptable on some other defined basis..." would be more appropriate.

Response: DG-1145, Section 7B is revised to use the same wording as GDC-23.

Disposition: DG-1145, Section 7B is revised to use the same wording as GDC-23.

C.I.7-23 Item G, capability for test and calibration in Appendix 7B states: "Any failure that is not detectable must be considered concurrently with any random postulated, detectable, single failure." IEEE 338 does not contain this language. Suggest removing both the second and third sentences.

Response: This guidance is from IEEE 603 safety system criterion 5.1, not from IEEE 338.

Disposition: The DG-1145 has been revised to take consideration of this comment.

C.I.7-24 Next to last sentence of item G in Appendix 7B says, "Test procedures that require disconnecting wires, installing jumpers, or other similar modifications of the installed equipment are not acceptable test procedures for use during power operation." This a new requirement that does not have an adequate technical basis. Although this may be a preference, no standard requires this. Suggest removing this language.

Response: DG-1145 Section Appendix 7B item (7) is revised to take consideration of this comment.

Disposition: DG-1145 Section Appendix 7B item (7) is revised to take consideration of this comment.

- C.I.7-25** The staff should clarify what credit they are allowing for automated self-testing. We recognize that this depends on the test coverage provided within the platform. However, the staff has approved three standard platforms, so this guidance should be able to be provided with reference to these pre-approved platforms (or for other platforms that will be pre-approved in the future).
- Response:** See response to C.I.7-19.
- Disposition:** No change in the DG-1145
- C.I.7-26** Additional guidance is needed on the qualification requirements for HSI to support manual actions. Manual actions credited in the safety analysis for accident mitigation are clearly covered by 603 and must meet the same requirements as for the RPS/ESFAS. But what about longer term actions (e. g. achieving hot shutdown, achieving cold shutdown)? What about HSI for safety related support systems such as electrical, cooling water and HVAC? These safety related aux systems typically run in auto with no manual intervention required. Historically their HSI was Class 1E, but this was for design convenience. Is Class 1E HSI still required just because the system performs a safety function?
- Response:** Additional clarification is required for this comment. No guidance will be provided at the present time. The staff will take consideration of this comment for the SRP update.
- Disposition:** No change to DG-1145.
- C.I.7-27** C.I.7.2 paragraph H, The last sentence should be changed todescribe a method for maintaining....
- Response:** RG 1.47, "Bypassed and Inoperable Status Indication for Nuclear Power Plant Safety Systems," is one acceptable method to comply with IEEE Std. 603 Safety System Criterion 5.8.3
- Disposition:** No change to DG-1145.
- C.I.7-28** C.I.7.2, paragraph M, RG 1152 security requirements are still untenable. Consideration should be given here to proposing a criteria for platform reliability apart from RG-1.152 and IEEE 7-4.3.2.
- Response:** The purpose of DG-1145 is to develop a framework for development of COL applications. References to other regulatory guides, such as RG 1.152, are made to identify a method acceptable to NRC to address an issue. Those regulatory guides undergo a public comment process that include stakeholder inputs. In addition, regulatory guides present a method, acceptable to NRC staff, to meet requirements. An applicant may elect to submit and justify another method.
- Disposition:** No change to DG-1145.
- C.I.7-29** C.I.7.2 page 6. There should be a heading between "M. Reliability" and "A. Automatic Control" or the paragraph numbering should continue with "N".

Response: DG-1145 Section Appendix 7B is revised.

Disposition: DG-1145 Section Appendix 7B is revised.

C.I.7-30 The discussion of IEEE 7-4.3.2 in Appendix 7B, Item C has the section numbers confused. These need to be corrected.

Response: DG-1145 Section Appendix 7C is revised

Disposition: DG-1145 Section Appendix 7C is revised

C.I.7-31 The last sentence of item G in Appendix 7B should be removed. We are not likely to be able to craft periodic tests for "data errors" and "deadlocks". Separate guidance in the design process will drive mitigation of these items. If a digital or computer related statement is desired here by the NRC, additional thought should be given and more valid requirements stated.

Response: DG-1145 Section Appendix 7B is revised.

Disposition: DG-1145 Section Appendix 7B is revised.

C.I.7-32 Section C.1.7.2 - L there is a passing reference to Chapter 18. This may be adequate as long as Chapter 18 embraces the same RG's and standards for software configuration control and testing requirements. However, RGs and standards are notably absent from Chapter 18. System displays and the software that governs their construction and operation are integral to the software life cycle process.

Response: The staff will consider this comment for the SRP update.

Disposition: The staff will consider this comment for the SRP update.

C.I.7-33 In appendix 7B, item M, the staff requires reliability analysis to include software. This is a change from previous NRC policy which accepted that the unreliability contribution of software is insignificant in an overall system reliability analysis, as long as that software was developed in accordance with 10CFR50 Appendix B and 7-4.3.2. Therefore, there should be no need for an additional software reliability analyses.

Response: Additional clarification is required for this comment. No guidance will be provided at the present time. The staff will consider this comment for the SRP update.

Disposition: No change to DG-1145

C.I.7-34 C.I.7.3 paragraph F: The extra requirements beyond IEEE 603 should be left to other documents as this will lead to conflicts later.

Response: DG-1145 Section Appendix 7C is revised.

Disposition: DG-1145 Section Appendix 7C is revised.

- C.I.7-35** Item M in Appendix 7C needs clarification as to the relationships of the various documents cited and the statement "Software error recording and trending maybe used in combination...." What does that mean?
- Response:** This is one method to analyze software reliability.
- Disposition:** No change to DG-1145.
- C.I.7-36** Item D in Appendix 7B, Equipment Qualification, the statement, "The applicant/licensee should confirm that there is independence between environmental control systems and sensing systems which would indicate the failure or malfunctioning of environmental control systems" is not a requirement of IEEE Std. 603 and should be deleted.
- Response:** Because the loss of environmental control systems does not usually prompt changes in environmental conditions, the design bases may rely upon monitoring environmental conditions and appropriate action by operators to ensure that mild environmental conditions are maintained. The applicant/licensee should confirm that the design satisfies the single failure criterion such that there is independence between environmental control systems and sensing systems which would indicate the failure or malfunctioning of environmental control systems.
- Disposition:** No change to DG-1145.
- C.I.7-37** Section C.1.7.2, Criterion D in Appendix 7B, Equipment Qualification, the last two sentences in this section about lightning should be moved to section E, system integrity, to match IEEE 603. This change removes the inappropriate imposition of IEEE Std. 323 equipment qualification requirement for lightning effects.
- Response:** DG-1145 Section 7B is revised.
- Disposition:** DG-1145 Section 7B is revised.
- C.I.7-38** Criterion E in Appendix 7B, System Integrity, delete, "Reactor trip system (RTS) functions should typically fail in the tripped state. Engineered safety feature actuation system (ESFAS) functions should fail to a predefined safe state. For many ESFAS functions this predefined safe state will be that the actuated component remains as-is." These statements are not requirements of IEEE Std. 603 and should be deleted.
- Response:** DG-1145 Section 7B is revised to use the wording of GDC-23.
- Disposition:** DG-1145 Section 7B is revised to use the wording of GDC-23.
- C.I.7-39** Criterion E in appendix 7B, System Integrity states, "Failure of computer system hardware or software should not inhibit manual initiation of protective functions or the operator performance of preplanned emergency or recovery actions" is not a requirement of IEEE Std. 603 and should be deleted. The requirements of Section 6.2 of IEEE Std. 603 are sufficient to ensure proper manual control.

Response: This guidance comes from BTP 7-19 acceptance criteria, which stated that the manual controls are connected to safety equipment that should be downstream of the plant's digital I&C. BTP 7-19 is developed based on Commission SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Design," dated July 15, 1993.

Disposition: No change to DG-1145.

C.I.7-40 Criterion G in appendix 7B Capability for Test and Calibration states, "The extent of test and calibration capability provided bears heavily on whether the design meets the single-failure criterion," is confusing since the design must meet the single failure criterion. The statement, "Any failure that is not detectable must be considered concurrently with any random postulated, detectable, single failure" is out of context and is a variation of the single failure criterion words in section 5.1 of IEEE Std. 603. Therefore, delete these two statements to eliminate any possible confusion with the statement of the single failure criterion in section 5.1 of IEEE Std. 603.

Response: DG-1145 Section 7B-1, item (7) is revised.

Disposition: DG-1145 Section 7B-1, item (7) is revised.

C.I.7-41 Section C.1.7.2, Criterion G in appendix 7B, Capability for Test and Calibration states, "Test procedures that require disconnecting wires, installing jumpers, or other similar modifications of the installed equipment are not acceptable test procedures for use during power operation" is not a requirement of IEEE Std. 603, IEEE 338, or Regulatory Guide 1.118 and should be deleted.

Response: DG-1145 Section 7B is revised to take consideration of this comment. However, the concern of disconnecting wires, installing jumpers, or other similar modification was addressed in RG 1.118. The guidance in Section 7B on this concern is provided as a reminder.

Disposition: DG-1145 Section 7B is revised.

C.I.7-42 Criterion G in appendix B Capability for Test and Calibration states, "For digital computer-based systems, test provisions should address the increased potential for subtle system failures such as data errors and computer deadlock" is not a requirement of IEEE 603, IEEE 338, IEEE 7-4.3.2, or Regulatory Guide 1.118 and should be deleted.

Response: DG-1145 Section 7B is revised.

Disposition: DG-1145 Section 7B is revised.

C.I.7-43 Delete "simple failure" and substitute "single failure" in the second sentence of item C in appendix 7B

Response: DG-1145 Section Appendix 7B is revised.

Disposition: DG-1145 Section Appendix 7B is revised.

- C.I.7-44** Criterion A in appendix 7C, Single Failure Criterion states, "(3) To verify that the displays and manual controls for critical safety functions initiated by operator actions are diverse from the computer systems used in the automatic actuation of plant safety systems" is not a requirement of IEEE Std. 603 or IEEE Std. 7-4.3.2 and should be deleted.
- Response:** The DG-1145 Section 7C-1 item (1) is revised as follows:
Single-Failure Criterion: Clause 5.1 in IEEE Std 603 defines single failure criterion.
- Disposition:** The DG-1145 is revised as stated above.
- C.I.7-45** Criterion C in appendix 7C, Quality - The listing of life cycle activities and attributes are somewhat tutorial and paraphrase the requirements in IEEE Std. 7-4.3.2 and referenced standards. Descriptions of life cycle attributes are more accurately described in the standards and should be deleted from this review guidance. Substitute a requirement to describe the life cycle process.
- Response:** The staff considers these life cycle activities an acceptable approach to provide the necessary steps to meet the quality criteria.
- Disposition:** No change to DG-1145.
- C.I.7-46** Criterion D in appendix 7C, Equipment Qualification is confusing since portions of the requirements of IEEE 7-4.3.2 are repeated word for word but other portions are not mentioned or referenced. The only new information is the reference to EPRI TR-106439, "> Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications.>> Therefore, delete the entire section and substitute a statement on the acceptability of using EPRI TR-106439 for commercial grade equipment.
- Response:** The basic guidance for equipment qualification is stated in Appendix 7B, item (4). The additional guidance stated in Appendix 7C, item (4) is a clarification of staff's concerns with respect to qualifying digital computers for use in safety systems.
- Disposition:** No change to DG-1145
- C.I.7-47** The section that discusses cyber security should state that NEI-04-04, "Cyber Security Program for Power Reactors," provides an acceptable basis for addressing cyber security issues.
- Response:** See response to C.I.7-7
- Disposition:** No change in DG-1145
- C.I.7-48** No section number is given for cyber security and then the numbers revert to previously used numbers. Revise the numbers to be sequential.
- Response:** The cyber security is addressed in Section Appendix 7C-2.
- Disposition:** DG-1145 has been revised.

C.I.7-49 During the July 12 workshop, and just prior to the workshop, the industry and other stakeholders were informed that the initial version of C.I.7, posted on the website June 30, 2006, was not the correct version. The NRC informed us that the new section was now on the website. We noted during that workshop, and again with these comments, that our focus in reviews was on the initial, incorrect document. During the July 12 workshop, we thought we heard that the majority of the differences in the documents were due to reorganizing the document. In our reviews since the workshop, we have noted several changes that appear to be substantive technical changes. As a result of this error in posting the correct document, the industry has not had enough time to properly review and comment on the revised section. We will continue to review this section and provide comments to the NRC.

Response: The initial version is following SRP Chapter 7 review guidance. The revised version follows RG 1.70 format. In the revised version, guidance on submittal related to digital instrumentation and control systems is in Appendix 7A (old version section C.I.7.1); guidance on submittal related to conformance with IEEE Std 603 is in Appendix 7B (old version section C.I.7.2); and guidance on submittal related to conformance with IEEE Std 7-4.3.2 is in Appendix 7C (old version section C.I.7.3). There are no substantive technical changes.

Disposition: Explained in response.

C.I.7-50 General and appendix B: In numerous cases throughout this document, IEEE 603 is referenced without a revision. Given that a later version of IEEE 603 exists than 10 CFR 50.55a(h) endorses, the industry believes that the NRC should move to expedite rulemaking that would clarify and allow the use of the latest version of IEEE 603 and referenced standards without use of any regulatory relief process. This approach will ensure clarity in future applications and avoid unnecessary regulatory submittals.

Response: See responses to C.I.7-1 and C.I.7-2.

Disposition: No change to DG-1145.

C.I.7-51 Appendix C (new document number): further confuses the issue of how licensees should proceed with respect to IEEE 603 and 7-4.3.2, given 10 CFR 50.55a(h) requires conformance to IEEE 603-1991. The NRC must provide licensees clear regulatory guidance with respect to licensing upgrades relative to the various standards. For example, if the NRC expects licensees to submit exemption requests or other forms of regulatory relief to utilize IEEE 7-4.3.2 for safety related applications, this needs to be clearly stated in this document. In addition, the staff needs to, in an expeditious manner, pursue rulemaking that will ensure the use of later standards can happen without unnecessary regulatory confusion and relief.

Response: See responses to C.I.7-1 and C.I.7-2.

Disposition: See responses to C.I.7-1 and C.I.7-2.

C.I.7-52 Current Section 7B-1, Item F in appendix 7B-1 This section, in the initial version posted to the website, indicated "Annex G of IEEE Std 7-4.3.2 describes an acceptable means for providing communications independence." We noted in our original comments that

Annex G was wrong. The revised C.I.7, page C.I.7-13 states: "Annex E of IEEE Std 7-4.3.2-2003 describes approaches to computer communications independence, however it is not endorsed by the NRC because it provides insufficient guidance." While we recognize this new guidance is consistent with RG 1.152, this section is substantially different than the previous version. Industry believes that the NRC should provide us with details of why the staff believes that Annex E does not provide sufficient guidance. Also, references in the regulatory guide and the new draft guide section are to sections of the SRP that are undergoing change. Industry will not have a chance to comment on these changes in a timely manner unless these sections are provided well in advance of the March 2007 SRP update target.

Response: Appendix 7B-1, item (6) stated that transmission of signals between independent channels should be through isolation devices, and should be such that signals from one channel do not adversely affect the proper operation of other channels. Additional guidance will be provided in SRP Chapter 7. NRC staff recognizes that this updated guidance is not currently available. NRC will make it available as revisions are finalized. This was discussed at the May 18, 2006, public meeting.

The purpose of DG-1145 is to develop a framework for development of COL applications. References to other regulatory guides, such as RG 1.152, are made to identify a method acceptable to NRC to address an issue. Those regulatory guides undergo a public comment process that addresses stakeholder concerns.

Disposition: DG-1145 has been revised.

C.I.7-53 Appendix 7C (new document number): In the original version of this document, the following statement was used on numerous occasions (see old letters G, H, I, J, and L): "No requirements beyond IEEE Std 603-1998 are necessary." The later version of C.I.7 removed this statement, but in each case adds text. The industry is reviewing these sections to ensure that the text is consistent with the current regulatory requirement (IEEE Std. 603-1991). Any additional text should be removed by the staff.

Response: The additional text was added to provide clarification of the staff's concerns. When the COL application addresses these concerns, there will be fewer questions during the review stage.

Disposition: No change to DG-1145

C.I.7-54 The SER's for the approved platforms were developed prior to Revision 2 of RG-1.152. Since the reviewed platforms blur the line between COTS and purpose-built systems, can the staff clarify how the new requirements in RG-1.152 should be applied to platforms with existing SER's?

Response: The SER of the platforms mainly addresses the staff's approval of the design requirements. The staff needs to verify the implementation phase of the design. RG 1.152 requirements will be considered during the design implementation phase of review.

Disposition: No change to DG-1145.

C.I.7-55 C.I.7.9.3 Appendix 7A items 5 and 7. First, these two sections address lifecycle issues. Industry experience is that the lifecycle of the platform is distinct from the lifecycle of the application. Clarification in these sections to allow the lifecycle planning to be segregated for clarity into two parts, one for the platform and one for the application, will facilitate both design and review. Second, some allowance or option for combining the software and hardware requirements and design information into an integrated document is preferred rather than requiring a rigid segregation of hardware and software. Experience has shown that the software and hardware are functionally integrated and greater clarity can be achieved by discussing them together. The requirements of BTP-14 can be easily met with integrated documents. This should be an option.

Response: BTP-14 provides guidance on software life cycle process reviews for digital computer-based instrumentation and control systems. It covers the life cycle of the platform and the life cycle of the application. The staff considers that the review of the life cycle of the platform only covers the design requirement phase, and the review of the implementation phase will be conducted during the COL application stage that may include the software and hardware functional integration.

Disposition: No change to DG-1145.

C.I.7-56 C.I.7.1, Review Process for Digital Instrumentation and Control Systems (Reference: SRP Chapter 7, Appendix 7.0-A), Item 3, Defense-in-depth and diversity: In response to this industry comment the NRC staff indicated that as a result of the Davis Besse event the staff does not consider leak before break as a viable analysis approach for BTP-19 evaluations. The staff further indicated that the staff position paper on BTP-19 is in the review and concurrence process. Industry believes further technical discussions in this area are warranted. The industry believes that the NRC response during the July 12 workshop indicating that leak before break is not a viable approach for BTP-19 given the Davis-Besse event is not consistent with staff positions regarding leak before break concepts used in other evaluations. For example, leak before break analyses are still used for risk-informed ISI. The staff should not remove this allowance for BTP-19, especially given the augmented reactor head (top and bottom) inspections imposed by order until the ASME code is revised. NRC should not set different standards for use of technology by different branches. If leak before break is still a valid analysis technique for RI-ISI it should also be good for use in BTP-19 evaluations. NRC staff should not reverse positions for unusual events that have happened that have been appropriately remedied. Industry believes that the augmented inspections adequately address the D-B lessons learned such that leak before break remains a valid analysis assumption.

Response: See response to item C.I.7-15.

Disposition: See response to item C.I.7-15.

C.I.7.1.2-1 In Section C.I.7.1.2, Identification of Safety Criteria, the following is stated, "Provide a description of the technical design bases for all the various functions of the protection system." The design bases for the protection system is addressed in SRP appendix 7.1-C, SRP 7.2, and SRP 7.3. Does the design bases for the protection system need to be addressed in all the sections specified? Is it acceptable to consolidate this discussion in one section?

Response: DG-1145, Section C.I.7.1.2 stated that the application should provide a regulatory requirements applicability matrix that lists all design bases, criteria, regulatory guides, standards and other documents that will be implemented in the design of the systems listed in Section C.I.7.1.1. The Design basis information should be provided in all the Sections.

Disposition: No change to DG-1145.

C.I.7.2.1-1 In Section C.1.7.2.1, "System Description" should be numbered C.1.7.2.1.1 versus C.1.7.2.1

Response: DG-1145 has been revised.

Disposition: DG-1145 has been revised.

C.I.7.5-1 Section C.1.7.5, Safety-Related Display Instrumentation is confusing. Albeit the lead-in sentence states that this section applies to "required manual safety functions," the only required manual safety functions listed in this section are the subset of accident monitoring instrumentation that is type A per revision 4 of Reg. Guide 1.97. Although the title of the section states that the section applies to safety-related display instrument, only type A, B, and C accident monitoring instrumentation is safety related. The remainder of the instrumentation listed is non-safety-related instrumentation. This non-safety-related instrumentation should be deleted from section C.1.7.5 and relocated to an appropriate section that discusses instrumentation not required for safety. When relocated, provide references to the criteria applicable to the listed instrumentation.

Response: DG-1145, Section C.I.7.5 title is revised to "Information System Important to Safety."

Disposition: DG-1145 has been revised.

C.I.7.5.1-1 Section C.I.7.5.1 scopes in the Emergency Response Facility instrumentation into "Safety Related Display Instrumentation"- this does not appear to be consistent with the referenced SRP section. Seems to be more appropriate in C.I.7.9.

Response: The Emergency Response Facility instrumentation is part of the Information System Important to Safety. C.I.7.9 is for data communication systems that are part of or support the system described in sections C.I.7.2 through C.I.7.8.

Disposition: No change to DG-1145.

C.I.7.6-1 For section C.I.7.6 the 1997 version of the SRP defines the scope of interlock systems as follows:

- Interlocks to prevent overpressurization of low pressure systems - See BTP HICB-1.
- Interlocks to prevent overpressure of the primary coolant system during low-temperature operations of the reactor vessel - See BTP RSB 5-2.
- Interlocks for ECCS accumulator valves - See BTP HICB-2.
- Interlocks required to isolate safety systems from non-safety systems
- Interlocks required to preclude inadvertent inter-ties between redundant or diverse safety systems.

DG 1145 C.I.7.6.2 specifies:

- Analyses should include, but not be limited to, consideration of instrumentation installed to prevent or mitigate the consequences of:
 - Cold water slug injections,
 - Refueling accidents,
 - Over-pressurization of low-pressure systems, and
 - Fires

Although the DG 1145 introductory paragraph does list the same areas as the SRP noted above, except for over-pressurization, the remainder of the items in the DG-1145 list appear to be new guidance.

Response: DG-1145 is intended for light water reactor designs. The areas listed in Section C.I.7.6 are the examples for consideration. The system designer should determine which interlock systems are required.

Disposition: DG-1145 is revised to delete the systems not in the SRP Section 7.6.

C.I.7.6.2-1 In section C.1.7.6.2, Analysis of interlock systems important to safety, delete "fires" from the list. Appendix R exposure fires are outside of the scope of this section on interlock systems important to safety.

Response: See response to C.I.7.6-1

Disposition: DG-1145 is revised to delete the systems not in the SRP Section 7.6.

C.I.7.7-1 Due to the segmented nature of analog systems, control system failures are typically considered one at a time in the plant's safety analysis (e. g. loss of feedwater is considered independently of inadvertent rod withdrawal). But as control systems are integrated together, the potential for multiple concurrent events may increase. The NRC should provide guidance in section C.I.7.7 for redundancy and failure requirements within integrated control systems that allows the current single event analysis strategy to be maintained.

Response: DG-1145, Section C.I.7.7.2, "Design Basis Information," requires the applicant to address applicable topics that include redundancy and failure requirements within integrated control systems.

Disposition: No change to DG-1145

C.I.7.8.3-1 Delete "protection systems" and substitute "safety systems" in the second sentence of section C.I.7.8.3.

Response: DG-1145 has been revised.

Disposition: DG-1145 has been revised.

C.I.7.9-1 All of the information discussed in section C.I.7.9 has already been covered in the previous sections. Therefore, it recommended that section C.1.7.9 be deleted.

Response: C.I.7.9 is for data communication systems that are part of or support the system described in sections C.I.7.2 through C.I.7.8. If some of the information has been provided in other section, the application document can cross reference these sections for staff to review.

Disposition: No change to DG-1145

C.I.8-1 First sentence states electric power system is source of power to reactor coolant pumps and other auxiliaries. RCPs are a PWR specific design item, thus the sentence should be revised to be more generic; e.g. "...source of power for station auxiliaries and for the protection system..."

Response: The staff agrees with this comment.

Disposition: DG-1145 has been revised.

C.I.8.1-1 Introduction states the need to show compliance with various regulations and standards (e.g. Reg Guides, GLs). This is a similar requirement to section 1.9 of the DG. Should this discussion be a duplicate of section 1.9 information, or should 1.9 refer to this section?

Response: The COL applicant may provide a detailed discussion of compliance (or exceptions) with Reg Guides (RG) associated with the electrical areas in Section 8.1. In so doing, Section 1.9 of the FSAR should provide a reference to Section 8.1. COL applicants may also provide the RG compliance discussion as part of an appendix to Chapter 1 or as a topical report that is incorporated by reference.

Disposition: No change to DG-1145.

C.I.8.1-2 Introduction refers to AAC as part of SBO response. Not all plant designs will need an AAC, thus this sentence should be revised, e.g.; "... the onsite electric system should be described briefly in general terms, and a brief description provided for station blackout mitigation, and the associated ..."

Response: The staff expects all new power plant designs to install an AAC power source for SBO mitigation rather than using batteries for coping duration. Therefore, no change to this sentence is necessary.

Disposition: No change to DG-1145.

C.I.8.1-3 Introduction discusses systems "important to safety"; What is the scope of this group? Can a more specific definition be provided?

Response: Any supporting system that is used to mitigate the consequences of an accident is considered a system important to safety. For example, although not designed to Class 1E requirements, an offsite power system is regarded as a system important to safety.

Disposition: No change to DG-1145.

C.I.8.1-4 Regulatory Guide (RG) 1.6 is applicable to safety related / 1E onsite power sources (e.g. safety related diesel-generators); This RG will not be applicable to passive plant designs such as AP-1000/ESBWR

Response: Onsite power systems include dc power systems as well. Thus, RG 1.6 will be applicable to passive plants because these plants use safety-related dc power systems for accident mitigation. Therefore, dc power systems in passive plants should meet the recommendations of this guide with regard to providing independence between redundant dc power systems.

Disposition: No change to DG-1145.

C.I.8.1-5 Reg Guides 1.29 & 1.100 on seismic issues, RG 1.108 for EDG testing and RG 1.62 for manual initiation were originally listed in RG 1.70 for chapter 8, but they are not listed here; Were they dropped intentionally?

Response: RGs 1.29, 1.100 and 1.62 will be added to the list. RG 1.108 was withdrawn and its recommendations were incorporated in RG 1.9, Rev. 3.

Disposition: DG-1145 has been revised.

C.I.8.1-6 Regulatory Guide 1.153 is called out in the body of section 8, and IEEE 603 is listed in this section; Need to add 1.153 to list of Reg Guides.

Response: The staff agrees with this comment. RG will be revised to include RG 1.153.

Disposition: DG-1145 has been revised.

C.I.8.1-7 Reg Guide 204 should be 1.204 for Lightning Protection.

Response: The staff agrees.

Disposition: DG-1145 has been revised.

C.I.8.1-8 BTP ICSB 2 & 8, as well as GL77-07, 79-17, 84-15, and 94-01 should only apply to safety related diesel generators (1E).

Response: The staff agrees. However, BTP ICSB 8, should be applicable even if no Class 1E DGs are used.

Disposition: No change to DG-1145.

C.I.8.1-9 Generic Letter 2006-02 solicited industry input on grid reliability issues. Requirements / guidance from the NRC on this issue has not been finalized in this area, thus this should not be included in this section.

Response: We expect that the resolution of the Generic Letter (GL) 2006-2 will be completed before the final guide is issued. Therefore, inclusion of this GL is appropriate.

Disposition: No change to DG-1145.

C.I.8.1-10 Listing of IEEE Standards separately from the Reg. Guide may lead to some difficulties. If a newer revision of a standard is called out in the DG, the applicant may be required to provide a "gap analysis" against a Reg. Guide justifying the use of the newer standard. Revise Reg. Guides to reflect newer standards acceptable to the NRC.

Response: The staff is in the process of revising RGs to reflect a newer version of IEEE standards acceptable to the NRC.

Disposition: No change to DG-1145.

C.I.8.1-11 IEEE 946 standard for design of DC systems may be applicable, but we believe that a regulatory guide has not endorsed this standard. The list of IEEE standards does not list all standards endorsed by the Reg. Guides e.g. RG 1.158 endorses IEEE 535-1986 which is not listed. Was this an oversight? We need clarification of the intent of listing IEEE Standards in this section. It seems redundant to require a description of conformance to all IEEE Standards endorsed by the Reg Guides, since they would be addressed as part of conformance to the Reg. Guide.

Response: The RGs generally endorse a standard in its entirety or with some exceptions. The staff is concerned that requiring a description of conformance to only RGs may not include a description of all recommendations of an IEEE standard endorsed by a guide. Therefore, a description of conformance to IEEE standards as well as RGs in the SAR is necessary. IEEE 535-1986 will be added to the list.

Disposition: DG-1145 has been revised.

C.I.8.2.1-1 Description states "...offsite power is preferred source of power for the protection system..."; This discussion needs to be re-worded to be more generic, e.g.;

" The offsite power system MAY BE the preferred source..."

"If required to meet GDC 17, then two or more physically independent..."

Response: This RG is a base document that is written for all plant designs. If some of the recommendations of the guide are not applicable to a particular design then the applicant needs to say it is not applicable to its design.

Disposition: No change to DG-1145.

C.I.8.2.1-2 Section should require a Failure Modes and Effect Analysis (FMEA) for the switchyard. This requirement should only apply to sites that must comply with GDC 17 (i.e. exclude passive plants). The FMEA may not be complete at time of combined license (COL) application submittal.

Response: Performance of a FMEA of the switchyard is required to avoid plant centered causes of loss of offsite power failures regardless of the type of power plant design. Passive plants that are exempted from requiring two offsite sources must demonstrate that the required single offsite power source is not lost due to a single event in the switchyard.

In addition, if a FMEA of the switchyard is not complete at the time of COL application submittal, it may be submitted during the review process. COL applicants not providing a FMEA at time of COL application submittal should provide a schedule for submittal. In order for the staff to resolve all safety issues, the FMEA must be submitted and reviewed by the staff prior to issuance of the COL license.

Disposition: No change in DG-1145.

C.I.8.2.1.2-1 These sections require a significant amount of detail on the offsite transmission system, much of which appears to be predicated upon the GDC 17 requirement for two physically independent circuits. For COL applications that reference a DCD for a design which has been granted an exemption to the requirement for two offsite sources, what is the required subset of information on the transmission system that is required, and what is the basis for the requirement for that information?

Response: If an applicant has been granted an exemption to the requirement for two offsite sources, then it needs to prove that a single qualified offsite power source satisfies the requirements of GDC 17 with regard to capacity and capability. It must also be physically independent from other transmission lines so that a single event does not fail this source. The basis for these requirements is that during power operation the safety-related loads are powered from this offsite power source.

Disposition: No change in DG-1145.

C.I.8.3.1.1-1 The requirement to discuss how RG 1.75 recommendations are met is redundant to section 8.1 requirements. Should only have to do once. Same comment applies to pg C.I.8-14 for DC cables. This comment applies to two entire paragraphs on each section, and not just the sentence containing RG 1.75.

Response: The staff agrees with this comment. The COL applicant may provide a detailed discussion of compliance (or exceptions) with Reg Guides (RG) associated with the electrical areas in Section 8.3. In so doing, Section 1.9 of the FSAR should provide a reference to Section 8.3. COL applicants may also provide the RG compliance discussion as part of an appendix to Chapter 1 or as a topical report that is incorporated by reference. If it is desirable to include the details of the RG 1.75 discussion in Sections 8.1 and 8.3, the COL applicant may do so in one section and have the other section reference

Disposition: No change in DG-1145.

C.I.8.3.1.1-2 System Capacity & Capability section discusses suitability of diesel generators for standby power source. Not all plant designs utilize diesels, thus the wording should be more generic, e.g.; "...suitability of the standby power sources to ensure sufficient..."

Response: Diesel Generators are widely used in the nuclear industry as onsite emergency power sources. No change to the RG is necessary.

Disposition: No change in DG-1145.

C.I.8.3.1.1-3 What is meant by "complete form"? What level of detail is required?

Response: This sentence in the DG will be clarified.

Disposition: DG-1145 has been revised.

C.I.8.3.1.3-1 Is it necessary to provide software titles? Codes may change over life of plant; "Electronic models" of software are not typically submitted to the NRC as a part of the application. Models will be available for inspection by NRC. Comment also applies to DC sections.

Response: The staff acknowledges that electronic models of software are not typically submitted to the NRC as part of the application. However, the staff needs to know the software platform, including revision, used for the analysis of the electrical systems so that the staff can independently verify the applicants design decisions. For example, if the licensee uses an ETAP revision that has QA pedigree, then the staff has confidence the platform is acceptable. By requiring the base system model, the staff can be assured that the software was correctly used. Also, the staff requests that this information be submitted rather than available for inspection at the applicant's facility.

Disposition: No change in DG-1145.

C.I.8.3.1.3-2 a. Section 4 for Equipment Protection is assumed to only apply to safety-related equipment.

b. Does this section cover "associated circuit analysis" type issues that are required by the Fire Protection plan?

Response: Section 4 requirements for equipment protection and coordination study is applicable to safety-related systems.

b. No

Disposition: No change in DG-1145.

C.I.8.3.1.3-3 Section 6 on Power Quality does not specify any industry guidance (e.g. IEEE 519, RG 1.180); What parameters are a concern, e.g. frequency, voltage, harmonic content (THD)? What acceptance criteria for VFDs are a concern (THD, notch depth)? (same comment for DC section)

Response: The application of adjustable speed drive system in power plants will result in harmonic currents in the distribution systems. The harmonic currents may cause instrumentation and control systems to operate erroneously. Therefore, it is necessary to evaluate the effects of harmonics on equipments as well as controls and instrumentations. Some controls and instrumentations are susceptible to frequency and voltage variations and the staff wants to assure that these parameters are adequately addressed in the applications. IEEE 519 will be added to the RG. RG1.180 is already included in the list of RGs.

Disposition: DG-1145 has been revised.

C.I.8.3.1.3-4 Item one in Section C.I.8.3.1.3 requires that a combined license (COL) applicant provide "an electronic copy of the model of the electrical distribution system ----." During the workshop, the NRC stated that this statement was intended to include the inputs and results and not the code used for the analysis. Please confirm that this statement will be clarified in the guidance.

Response: The RG as currently written does not ask for the code used for the analysis. The staff needs to know the software platform, including revision, that the COL applicant used for the analysis of the electrical systems so that the staff can independently verify the applicant's design decisions. The staff will revise the guide to clarify this guidance.

Disposition: DG-1145 is revised.

C.I.8.3.1.3-5 Section C.I.8.3.1.3 - AC, & C.I.8.3.2.3 - DC

Section C.I.8.1 lists RG 1.180 that covers EMI/RFI for safety related I&C systems as a reference.

Item six in Sections C.I.8.3.1.3 and item five in C.I.8.3.2.3 contain requirements to address power quality. There are no existing regulatory guides on power quality for power systems. IEEE 519 was developed for harmonic control on power systems, but its intended scope was transmission and distribution systems, not plant internal systems. The draft regulatory guide does not call out IEEE 519, and there is no discussion on power quality or harmonics in the draft SRP sections. The AP1000 design control document (DCD) chapter 8 does not discuss harmonics or power quality at all. This analysis and discussion would be a new requirement for combined license (COL) applications referencing the AP1000 DCD and this information should not be required for those applications.

Response: If a power plant design includes equipment and components that are susceptible to voltage or frequency variations or has non-linear loads that produce harmonics, then those equipment and components must be identified and considered for the effects of poor power quality and harmonics. The SRP sections will be revised to include discussions on the power quality and harmonics. The staff acknowledges that the scope of this standard established guidelines for transmission and distribution systems, not plant internal systems. However, in the absence of other available guidance in this area, the staff will use this standard as the basis for establishing the adequacy of electrical equipment to operate in the presence of harmonic distortion. RG will be revised to include reference to IEEE 519.

Disposition: DG-1145 has been revised.

C.I.8.3.2.1-1 Section 4 requires battery characteristic curves; this appears to be a level of detail that would not be available for a COL application.

Response: If battery characteristic curves cannot be provided at the time of COL application submittal, they may be submitted during the review process. COL applicants not providing these curves at time of COL application submittal should provide a schedule for submittal. In order for the staff to resolve all safety issues, the battery characteristic curves must be submitted and reviewed by the staff prior to issuance of the COL license.

Disposition: No change in DG-1145.

C.I.8.3.2.2-1 Section refers to RG 1.9 which is applicable to diesel generators. Should this be here?

Response: Reference to RG 1.9 will be removed.

Disposition: DG-1145 has been revised.

C.I.8.3.2.2-2 Section 6 calls out 125 & 250 VDC batteries. New plant designs may not use these voltage ratings; thus the statement should be more generic.

Response: These are only examples. Moreover, 125 and 250 VDC voltage levels for batteries are widely used in nuclear power plants. No changes to the RG are necessary.

Disposition: No change in DG-1145.

C.I.8.3.2.2-3 Section 7 on grounding should NOT refer to 8.3.1.2. DC systems are typically ungrounded, so what should be discussed is:

- grounded or ungrounded
- ground detection system
- load grounding
- referenced consensus standards

Response: The RG will be revised to reflect this change.

Disposition: DG-1145 is revised.

C.I.8.4.1-1 The level of detail for training and procedure discussion should be the same as accepted by the NRC for section 13.5, i.e. functional description of required operator actions vs. detailed procedures.

Response: If the details for training and procedure discussion is provided somewhere else, then that section may be referenced in this section.

Disposition: No change to DG-1145.

C.I.8.4.1-2 Local power sources and transmission paths for re-supply may be under the control of a Transmission System Operator (TSO) that is independent of the licensee. This information may not be available at the time of COL application submittal.

Response: The licensee must also be aware of these local power sources and transmission paths available to re-supply a power plant following loss of a grid or an SBO and should provide training to its operators in this regard.

If this information is not complete at the time of COL application submittal, it may be submitted during the review process. COL applicants not providing this information at the time of COL application submittal should provide a schedule for submittal. In order for the staff to resolve all safety issues, this information must be submitted and reviewed by the staff prior to issuance of the COL license.

Disposition: No change in DG-1145.

C.I.8.4.1-3 Some confusion between the DG guidance and RG 1.155 and 10 CFR 50.63. The words that are in the DG are paraphrased out of 1.155 and 10CFR50.63, but it's not presented in a logical manner. The key items of this section per RG 1.155 and NUMARC 87-00:

-What is the required SBO coping duration? Provide analysis based upon NUMARC 87-00 guidance for determining coping duration-

-Does the plant utilize an ac independent approach, or alternate ac (AAC) approach (per Section 7.1.1 of NUMARC 87-00) for demonstrating capability to cope for the period of the coping duration? If ac independent, provide results of the analyses that demonstrate that parameters identified in Section 7 of NUMARC 87-00 are addressed. (can spell out the parameters from NUMARC 87-00 if want). Provide a functional description of any extraordinary operating procedures.

-If coping utilizes AAC, provide functional description of procedure and time required to establish AAC. If time required is greater than 10 minutes, provide analyses that parameters identified in Section 7 of NUMARC 87-00 are addressed for the first hour of the SBO event.

Response: This section of the RG will be revised for clarity.

Disposition: DG-1145 has been revised.

C.I.8.4.2-1 Last sentence on passive system designs should be moved to the beginning of this section. More general discussion about passive plants should also be included in other applicable sections (e.g. Offsite & Onsite AC requirements not all applicable to passive designs).

Response: This particular sentence on passive plants asks for an analysis to identify the minimum duration for operating only on the safety-related batteries and to identify the paths available to recharge the batteries. This should remain under analysis section and not discussion section. The staff will consider revising the RG to include discussion on passive plants in other sections of the RG.

Disposition: No change in DG-1145.

C.I.9.1.2-1 The last sentence in Section C.I.9.1.2, "Spent Fuel Storage" requires a description of the "design features and or controls for density of spent fuel assembly storage to address the potential for zircaloy cladding ignition of recently discharged fuel in the case of a spent fuel pool draining event. This event is not a design basis event for any of the designs currently anticipated to be referenced in COL applications. What is the regulatory basis for including this requirement in a COL application?

Response: Consistent with SRP 9.1.2, Revision 3, July 1981, the review of high density storage configurations will be on a case-by-case basis. Applications should include an evaluation of the thermal performance of the racks for the most limiting design basis configurations, including partial drain-downs due to failures of gate seals or connected piping systems. Acceptance is based on satisfying coolant parameters used in the

criticality analysis, which typically assume a subcooled liquid within the fuel bundles. However, a complete pool draining event is not within the design bases events considered in the current SRP, and need not be addressed.

Disposition: The last sentence in Section C.I.9.1.2 will be modified to replace the discussion of a spent fuel pool draining event and potential zircaloy cladding ignition with a discussion of rack thermal performance, as described above.

C.I.9.2.5.2-1 In the last sentence in Section C.I.9.2.5.2, Regulatory Guides 1.27 and 1.72 are more appropriate than Regulatory Guides 1.29 and 1.72. Regulatory Guide 1.27 “Ultimate Heat Sink”. Please confirm.

Response: Yes, the reference should be to RG 1.27, Ultimate Heat Sink,” instead of RG 1.29.

Disposition: The reference will be revised as indicated.

C.I.9.5-1 Sections C.I.9.5.4, C.I.9.5.5, C.I.9.5.6, C.I.9.5.7, and C.I. 9.5.8, Diesel Generator Auxiliary Systems, should address the case for designs that do not rely on diesel generators for safety-related functions. An introductory sentence that states that the sections are only applicable for designs that incorporate safety-related diesel generators would clarify the guidance.

Response: The guidance is applicable to both safety-related and non-safety related diesel generators in that passive designs with non-safety related diesel generators may use the diesels for long-term recovery and defense-in-depth functions. Also, the diesel generators may be subject to the policy on Regulatory Treatment of Non-Safety Systems

Disposition: No change to DG-1145.

C.I.9.5.1.3-1 Section C.I.9.5.1.3, "Safety Evaluation". The last sentence before the two bullets states that the analyses described in the two bullets should be provided, as a minimum. (emphasis added). The second bullet states, "When provided, a summary description of the design specific fire probabilistic risk assessment (PRA) that uses ----". The effect of the two sentences makes it unclear as to whether a fire PRA is required. The risk information required to address fire hazards is not yet resolved. It is recommended that the information requirements related to fire risk be addressed in Section C.II.1 of the guidance and that the second bullet be deleted.

Response: A detailed fire PRA is not necessarily required for a new reactor. However, if a licensee references a certified design and if that certified design includes a fire PRA, then the COL applicant, per proposed 52.80(a), is to use that PRA and update it to reflect site and plant-specific information that may not have been available at the design stage. In addition, a licensee that has a risk-informed, performance-based fire protection program (similar to an NFPA 805 program) or that plans to evaluate plant changes using a risk-informed approach must have a fire PRA.

The minimum requirement for fire risk assessment for a new reactor that does not need a detailed fire PRA (in accordance with the above) is a Fire-Induced Vulnerability Evaluation (FIVE) type analysis. However, if fire is a significant contributor to plant risk, then a detailed fire PRA is required.

The term “fire PRA” encompasses all levels and types of PRAs, ranging from a simplified bounding analysis to a detailed analysis in accordance with NUREG/CR-6850 and the draft ANS Fire PRA Standard.

A new reactor plant PRA should be subjected to a peer review to the extent that adequate industry guidance is available in a timely manner to support the licensing process. The industry guidance will be reviewed for acceptability by the NRC prior to its application to specific fire PRAs. The NRC will also review the results of the plant-specific peer reviews. A peer review should be conducted for all types and levels of fire PRAs. In the event that adequate industry guidance is not available for conducting a fire PRA peer review, the NRC will review the fire PRA for acceptability.

DG-1145 Section C.I.9.5.1 will be revised to remove any specific discussion of fire PRA and will refer to Section C.I.19 (Probabilistic Risk Assessment Information and Severe Accidents) and Section C.II.1 (Probabilistic Risk Assessment) for guidance on fire PRAs.

Disposition: DG-1145 Section C.I.9.5.1 has been revised as described in the response.

C.I.9.5.2-1 Sections C.I.9.5.2.1 and C.I.9.5.2.2 require information to be provided related to the Security Communications System. Since much of this information may be treated as Safeguards information, it is recommended that it be addressed as part of the Security Program in Section C.I.13.

Response: The staff agrees that the security communication system should be addressed as part of the security program in Section C.I.13. The reference to the security communications systems in Section C.I.9.5 will be removed. Section C.I.9.5.2 will point the applicant to Section C.I.7.9 for guidance on data communication.

Section C.I.7.9.1 addresses the data communication system description, Section C.I.7.9.2 addresses design basis information, and Section C.I.7.9.3 addresses analysis. COL applicants should follow the guidance in Section C.I.7.9 for preparation of the data communication system portion of the application, regardless of whether the system being described is a plant (data) communication system or a security (data) communication system.

Disposition: DG-1145 revised as discussed in response.

C.I.10-1 It appears that all the information required by this section of the guidance is included in the generic design control document (DCD) for a combined license (COL) application referencing the AP1000 certified design with the exception of the circulating water system design, and the program descriptions required by COL information and actions items identified by final safety evaluation report (FSER) for Chapter 10. Does the Staff agree with this assessment?

Response: The staff understands this to be an application-specific question. DG-1145 is intended to provide guidance on a generic basis to COL applicants that reference a certified design, or early site permit, neither, or both.

Disposition: No change to DG-1145.

- C.I.10-2** Can you identify any significant differences between this guidance and the requirements of the SRP for Chapter 10?
- Response:** DG-1145 is intended to provide guidance for COL applicants on providing information for the staff to perform its review. The SRP is guidance for the staff to perform its review of the application and contains the acceptance criteria. The two sets of documents are complementary.
- Disposition:** No change to DG-1145.
- C.I.10-3** Section C.I.10.4.7 requires the applicant to , "Demonstrate consistency with the requirements of GDC 5, 44, 45 , and 46 of Appendix A 10 CFR Part 50", it appears that this should apply to more than just section C.I.10.4.7. Is this just a formatting issue, i.e., do these apply to sections C.I.10.4.1 through 7?
- Response:** Based on the SRP (1981 Revision), this set is only applicable to 10.4.7 and 10.4.9 (PWR only).
- Disposition:** No change to DG-1145.
- C.I.10.2.3.3-1** A general comment is that some guidance on the timing for providing information would be very helpful. For example, section C.I.10.2.3.3 asks for a description of the pre-service inspection procedures and acceptance criteria for turbine rotors. It is expected that the combined license (COL) application would contain a general description and reference any applicable standards with the information available at the time of the application. The procedures and acceptance criteria would probably be finalized during construction and be available for NRC inspection. Does that meet the expectation of section C.I.10.2.3.3?
- Response:** It is acceptable to submit in the COL application a general description and reference any applicable standards regarding pre-service and in-service inspection of the turbine rotor, provided that the COL application contains a commitment to submit the finalized pre-service and in-service inspection procedures and acceptance criteria during the construction but one year before loading the fuel.
- Disposition:** C.I.10.2.3.3 of the regulatory guide will be revised to incorporate the above guidance.
- C.I.11-1** Many of the Chapter 11 to-do list items call for the combined license (COL) application to "update or confirm" radioactive waste system descriptions in the generic design control documents (DCD). While COL applications must identify any departures from the generic DCD, COL applicants are not required to include additional design description or analyses beyond that approved in the generic DCD. Verification that the plant-specific design is consistent with the design certification is a function of the NRC's engineering design verification (EDV) process. Also, several Ch. 11 to-do list items pertain to information about operational programs beyond those identified in Section C.1.13.4 that is not necessary for COL and will not be available for COL. As discussed during the workshop, complete information about these programs will be developed and available for NRC inspection prior to fuel load. COL applications will provide a high level prospective description of these programs that will be developed fully after the COL is issued.

These "to-do" list items appear to present requirements well beyond the expected information scope of a COL application. Please clarify the purpose and basis for these documents.

Response: The staff recognizes that this comment was received during the earliest interactions with the at public at the scheduled workshops. Since that time Section C.III.1 of DG-1145 was developed to provide guidance for COL applicants that reference a certified design. Section C.III.1 - Chapter 11 provides guidance for a COL applicant with respect to radioactive waste treatment systems.

Disposition: DG-1145 has been revised to include guidance in Section C.III.1 - Chapter 11

C.I.11-2 During the workshop on May 17, 2006, the staff distributed two handouts entitled "Review Areas to be Addressed in a COL Application Referencing a Certified Design". One of these was for Chapter 10 and the other for Chapter 11. These were referred to as the "to do" lists for those chapters and it was indicated they would be incorporated into DG-1145, section C.III.1. The content of these two documents is very detailed and includes information requirements that are not in the corresponding sections of DG-1145 Part 1. The information is related to the design approved in the design certification process for AP1000. The information is much more detailed than that which provided the basis for NRC approval of the generic DCD and would not be available at the time a combined license (COL) is filed.

Response: The staff recognizes that this comment was received during the earliest interactions with the at public at the scheduled workshops. Since that time Section C.III.1 of DG-1145 was developed to provide guidance for COL applicants that reference a certified design. Section C.III.1 - Chapter 11 provides guidance for a COL applicant with respect to radioactive waste treatment systems.

Disposition: DG-1145 has been revised to include guidance in Section C.III.1 - Chapter 11.

C.I.11-3 The level of detail specified in Section C.I.11 is well beyond the level found to be acceptable for the AP1000 design control document (DCD). For example, C.I.11.2.1 requests information in the COL application for the liquid radioactive waste system components and design parameters. It specifies design and expected flows, design and expected temperatures, design and expected pressures, materials of construction, capacities, expected radionuclide concentrations, expected decontamination factors for radionuclides, and available holdup times. This information was not necessary to support the NRC safety finding on the liquid radioactive waste system for design certification, and there are no COL Information Items associated with these details. Section C.I.11.2 of the AP1000 DCD includes some of this information for the system and components; design flows, design temperatures, design pressures, materials of construction, capacities, expected activities, and decontamination factors. For this example, the guidance requires additional design information not required for approval of the DCD. A similar disparity exists for the gaseous radioactive waste system in Section C.I.11.3.

- Response:** The staff recognizes that this comment was received during the earliest interactions with the at public at the scheduled workshops. Since that time Section C.III.1 of DG-1145 was developed to provide guidance for COL applicants that reference a certified design. Section C.III.1 - Chapter 11 provides guidance for a COL applicant with respect to radioactive waste treatment systems.
- Disposition:** DG-1145 has been revised to include guidance in Section C.III.1 - Chapter 11.
- C.I.11-4** Many of the reactor vendors are proposing the use of modular skid mounted systems for rad waste processing and treatment. Will the combined license (COL) guidance factor in this approach?
- Response:** The staff recognizes that this comment was received during the earliest interactions with the at public at the scheduled workshops. Since that time Section C.III.1 of DG-1145 was developed to provide guidance for COL applicants that reference a certified design. Section C.III.1 - Chapter 11 provides guidance for a COL applicant with respect to use of temporary radioactive waste treatment systems.
- Disposition:** DG-1145 has been revised to include guidance in Section C.III.1 - Chapter 11.
- C.I.11.3.1-1** Section C.I.11.3.1 requests that the combined license (COL) applicant submit information related to the bases governing seismic design criteria and the analytical procedures for equipment support elements and structures housing the gaseous waste treatment system. COL applicants should not be required to provide design details for systems included in a certified design that go beyond the level of detail provided in the referenced design control document (DCD). The design certification process included a finding by the staff that the generic DCD included adequate information for approval. Therefore, additional information about structures, systems, and components (SSCs) within the scope of the DCD at the time of COL application is not needed to authorize construction and operation of that plant.
- Response:** The staff agrees with this comment. Certified designs have achieved finality in accordance with 10 CFR 52.63.
- Disposition:** DG-1145 has been revised to include guidance in Section C.III.1 - Chapter 11.
- C.I.11.4.2-1** Section indicated that the combined license (COL) application should “include in the discussion the use the mobile systems and provide the process control programs demonstrating conformance wit GL-080-009 and GL-81-039 and consistency with the guidance in Regulatory Guide 1.143. Since most of the information will be developed after the application is filed, the guidance should indicate that the criteria for selection of mobile systems and a summary of the process control document should be provided in the application.
- Response:** The staff recognizes that this comment was received during the earliest interactions with the at public at the scheduled workshops. Since that time Section C.III.1 of DG-1145 was developed to provide guidance for COL applicants that reference a certified design. Section C.III.1 - Chapter 11 provides guidance for a COL applicant with respect to use of temporary radioactive waste treatment systems.

- Disposition:** DG-1145 has been revised to include guidance in Section C.III.1 - Chapter 11.
- C.I.12-1** Section C.I.12 references neither RG 1.70 nor NEI-04-01. Please clarify the relationship between DG-1145 and these documents.
- Response:** Two main documents serve as the technical basis for DG-1145: RG 1.70 and the most recent SRP revision. Much of the text of DG-1145 is drawn from these documents. In the specific case of section C.I.12.5, discussion of the radiation protection operational program includes significant contributions from NEI 04-01E and the series of 2005 public meetings concerning the development of NEI's guidance document.
- The degree to which other DG-1145 sections reflect NEI 04-01E input will vary. Section C.IV.9 specifically addresses the applicability of industry guidance. Any formal endorsement of NEI 04-01E by the staff will be documented in this section.
- Disposition:** No change to the guide.
- C.I.12-2** Many of the items on the 'combined license (COL) with DCD To Do List' should have been addressed in the AP1000 design control document (DCD) (e.g., dose levels for tank rooms should be defined in Tier 1 or 2 criteria). Should this information not be addressed separately from the COL application, the COL application review would be made more of an inspection to verify implementation. Please clarify how such information will be treated in the review and/or post-COL stage.
- Response:** The list of Chapter 12 COL items contained in Sections C.III.1 and C.III.2 of DG-1145 is significantly different than the original list ("Review Areas to be Addressed in a COL Application Referencing a Certified Design," ML060800400) which was presented at the March 15, 2006 workshop on DG-1145. Many of the items in the original list have been removed from the list and are not included in the Chapter 12 portion of Sections C.III.1 or C.III.2 of DG-1145. The items contained in the Chapter 12 portion of Sections C.III.1 and C.III.2 of DG-1145 are closely associated with the DCD COL Action Items for the AP1000.
- The NRC, as part of its engineering design verification activities (first-of-a-kind inspections), will audit or inspect additional engineering design detail regarding the implementation of the certified standard design.
- Disposition:** Several of the Chapter 12 COL items that were presented at the March 15, 2006 workshop on DG-1145 ("Review Areas to be Addressed in a COL Application Referencing a Certified Design," ML060800400) have been revised or deleted. The current list of COL items for Chapter 12 appears in Sections C.III.1 and C.III.2 of DG-1145.
- C.I.12-3** It appears that there were many items identified in Section C.I.12 that were not derived from design control document combined license (COL) action Items. Is it reasonable to assume that the regulatory guide will correspond closely enough to the standard review plan and staff's expectations such that properly addressing each issue in the regulatory guide will constitute a satisfactory final safety analysis report (FSAR) chapter? Or, is it likely that other unspecified issues will arise? If so, how will they be addressed?

Response: Yes, it is reasonable to assume that DG-1145 will be in close compliance with both the SRP and staff expectations. The DG-1145 preparation and SRP update efforts work in tandem, with technical reviews being performed by the same set of staff members. In addition, the recent reorganization of the Office of Nuclear Reactor Regulation's Division of New Reactor Licensing relocated both of these project management responsibilities under a single branch.

The list of Chapter 12 COL items contained in Sections C.III.1 and C.III.2 of DG-1145 is significantly different than the original list ("Review Areas to be Addressed in a COL Application Referencing a Certified Design," ML060800400) which was presented at the March 15, 2006 workshop on DG-1145. The items contained in the Chapter 12 portion of Sections C.III.1 and C.III.2 of DG-1145 are closely associated with the DCD COL Action Items for the AP1000.

In the event that an issue arises which is specified in neither DG-1145 nor the SRP, the staff will inform potential applicants, in accordance with 10 CFR 52.79(a)(44).

Disposition: Several of the Chapter 12 COL items that were presented at the March 15, 2006 workshop on DG-1145 ("Review Areas to be Addressed in a COL Application Referencing a Certified Design," ML060800400) have been revised or deleted. The current list of COL items for Chapter 12 appears in Sections C.III.1 and C.III.2 of DG-1145.

C.I.12-4 While the concern over the omission of review coverage relating to 10 CFR 20.1406 for the AP1000 is understood, 10 CFR Part 52 has provisions for such issues. This is a generic item that would apply to all COL applications. The AP1000 Design Certification Rule (Part 52, Appendix D) notes that generic changes are governed by the provisions in 10 CFR 52.63(a)(1). NRC should follow the process outlined in 10 CFR 52.63(a)(1) to include this as a change to the AP1000 Design Certification. This should not simply be "slipped in" as part of the combined license (COL) process.

Response: 10 CFR 20.1406 requires applicants for a license to describe how the facility design and procedures for operation will minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste. Sections C.I.12.1.2 and C.I.12.5.3 of DG-1145 address compliance with both the design and operational aspects of 10 CFR 20.1406. The NRC staff realizes that the DCD for the AP1000 does not directly address how the AP1000 design will address the design related aspects of 10 CFR 20.1406. If necessary (i.e., if the issue is not resolved before the AP1000 design is referenced in a COL application), the NRC will follow the process set forth in 10 CFR 52.63(a)(1) to ensure that the COL application includes a description of how the AP1000 design will comply with the design related aspects of 10 CFR 20.1406.

Disposition: No change to the guide.

C.I.12.1-1 Please clarify the criteria that will be used to judge compliance with the requirement to provide "incorporation and use of experience from past designs and operating plants" in design and as low as is reasonably achievable (ALARA) programs. Please also provide the context of the regulatory basis for this requirement.

Response: The fifth item listed under Section C.I.12.1.1 of the March 15, 2006, public meeting handout (“Review Areas to be Addressed in a COL Application Referencing a Certified Design,” ML060800400) states: “Describe how experience from past designs and operating plants is used to develop an improved radiation protection design to ensure that occupational radiation exposures are ALARA.”

The regulatory basis for this statement is 10 CFR Part 20.1101 which states that “the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA.” ALARA is defined, in part, as “making every reasonable effort to maintain exposures to radiation as far below the dose limits in [10 CFR Part 20] as is practical...taking into account the state of technology, the economics of improvements in relation to state of technology, [and] the economics of improvements in relation to benefits to the public health and safety...”

Regulatory Guide 8.8 states that “information gained in operations can provide a basis for modifying equipment selection and design features of new facilities.” In reviewing the DCD for the AP1000, it is noted that Section C.I.12.1.1 states that “the design is reviewed for ALARA considerations and updated and modified as experience from operating plants is applied.” Furthermore, Section C.I.12.1.2 of the AP1000 DCD lists simplifying plant design features compared to past designs.

Disposition: In light of the fact that the AP1000 DCD contains examples to show that operating plant experience has been incorporated into the plant design, the fifth bullet listed under Section C.I.12.1.1 (as described above) has been withdrawn with respect to COL applications referencing the AP1000 DCD.

C.I.12.1-2 In the discussion of Section C.I.12.1, the NRC stated that operating experience would be addressed in the context of future design activities. This issue appears to relate more to design certification than the combined license (COL).

Response: See response to Question C.I.12.1-1.

Disposition: See disposition fo Question c.I.12.1-1.

C.I.12.1-3 The following items in Section 12.1.2 are not believed to be "review areas to be addressed in a combined license (COL) application referencing a certified design." Rather, it is believed that they should be considered to have been closed through the AP1000 Design Certification:

- "Describe the as low as is reasonably achievable (ALARA) design guidance and training ... during initial plant design."
- "Also, describe the design considerations implemented to ensure that occupational radiation exposures during decommissioning will be ALARA."

Response:

- a. Section 12.1.1.1 of the AP1000 DCD discusses how the ALARA policy is applied during the design of the AP1000.
- b. See response to Question C.I.12-4.

Disposition: a. The first item under Section 12.1.2 (“Review Areas to be Addressed in a COL Application Referencing a Certified Design,” ML060800400) has been revised to read, "Describe provisions for continuing ALARA facility design reviews once the plant is operational (e.g., for plant changes and/or modifications)" and now appears in Section C.III.1.12.1.2 and C.III.1.12.1.2 of DG-1145. This item will have to be addressed by the COL applicant.

b. No change

C.12.2-1 How does one reconcile the recognition by the staff that the design will not necessarily be 100% complete with the DG-1145 language that “all” sources will be identified and “all” equipment will be located in a COL application?

Response: DG-1145 is written to apply to a "custom" COL application. A custom COL application is a COL application where the licensee does not reference a standard design certification. Since a custom COL application does not reference a standard design, a custom application must include a description of contained and airborne radioactive material sources. DG-1145 does not state that "all" radiation sources must be identified, but that only those sources that form the basis for the shielding design calculations and the sources of airborne radioactivity used for the design of personnel protection measures and dose assessment. For a COL application that references a standard design certification, the description of radioactive sources should have been provided in the design certification document (DCD).

The NRC realizes that a COL application cannot list "all" radioactive sources. However, the DCD referenced by a COL application should contain a complete list of those sources that form the basis for the shielding design calculations and the sources of airborne radioactivity used for the design of personnel protection measures and dose assessment. Any sources in this category that were not listed in the DCD should be addressed in the COL application. (See Sections C.III.1.12.2.1 and C.III.1.12.2.1 which state “Describe any additional contained radiation sources that are not identified above, including radiation sources used for instrument calibration or radiography.”)

The NRC realizes that the plant design may not be 100% complete at the time of COL submittal and therefore not all radiation sources may not be known at that time. If this is the case, then the COL applicant shall submit a listing of any additional radiation sources not listed in the DCD so that these can be reviewed during the pre-operational inspections.

Disposition: No change to the guide

C.I.12.2-2 Is it a regulatory requirement that the final safety analysis report (FSAR) contain identification of all sources and all equipment?

Response: 10 CFR 52.79(b) states that the (COL) application “must contain the technically relevant information required of applicants for an operating license by 10 CFR 50.34.” 10 CFR 50.34(b)(3) states that the application must include "the kinds and quantities of radioactive materials expected to be produced in the operation and the means for

controlling and limiting radioactive effluents and radiation exposures within the limits set forth in Part 20 of this chapter."

Also see response to Question C.I.12.2-1.

Disposition: No change to the guide

C.I.12.2-3 In regards to the third item under Section C.I.12.2 ("Review Areas to be Addressed in a COL Application Referencing a Certified Design," ML060800400), explicitly identify this item as relating to confirmed shield design only.

Response: The third item under Section 12.2.1 has been deleted and is not included in Section C.III.1.12 or Section C.III.2.12 of DG-1145. However, for those cases where the contained source term information referenced in the DCD for the referenced plant design has changed, updated source term information must be provided. This only applies to those contained sources of radiation that form the basis for shielding design calculations.

Disposition: The third item under Section 12.2.1 has been deleted and is not included in Section C.III.1.12 or Section C.III.2.12 of DG-1145.

C.I.12.2-4 In regards to Section C.I.12.2, what makes up the source term (e.g., waste, sources, fuel, fixed contamination on pipes, activated components)? How would NRC expect this to be tracked?

Response: As described in RG 1.70 and DG-1145, for contained sources, the DCD should contain a listing of the sources of radiation that form the basis for the radiation protection design. These sources should be described in the manner needed as input to the shield design calculation. The DCD for the AP1000 contains a listing of these contained sources. The only contained sources (i.e., those sources of radiation that form the basis for the radiation protection design) that need to be referenced in the COL application are those sources that were either not referenced in the DCD (such as radiation sources used for instrument calibration or radiography or any required radiation sources containing byproduct, source, or special nuclear material that may warrant shielding design consideration) or those sources where the source term may have changed such that it would affect the shield design.

Also see response to Question C.I.12.2-1.

Disposition: No change to the guide

C.I.12.2-5 The following item in Section C.I.12.2.1 ("Review Areas to be Addressed in a COL Application Referencing a Certified Design," ML060800400) is not believed to be a "review area to be addressed in a combined license (COL) application referencing a certified design." Rather, it is believed that it should be considered to have been closed through the AP1000 Design Certification:

"Describe any required radiation sources ... that exceed 100 millicuries." Assuming the COL applicant does not have new sources not envisioned by the design control document and final safety evaluation report (FSER), this matter would not be open for additional consideration.

Response: The first item under Section 12.2.1 has been deleted and is not included in Section C.III.1.12 or Section C.III.2.12 of DG-1145. The only contained sources (i.e., those sources of radiation that form the basis for the radiation protection design) that need to be referenced in the COL application are those sources that were either not referenced in the DCD (such as radiation sources used for instrument calibration or radiography or any required radiation sources containing byproduct, source, or special nuclear material that may warrant shielding design consideration) or those sources where the source term may have changed such that it would affect the shield design.

Disposition: The first item under Section 12.2.1 has been deleted and is not included in Section C.III.1.12 or Section C.III.2.12 of DG-1145.

C.I.12.3-1 Section 12.3.4 refers to ANSI N13.1-1993 for effluent monitor design. Design Control Document Section 11.5 indicates the radiation monitoring system was designed to ANSI N13.1-1969. Based on recent experience at Salem and Surry, there is a very significant difference between the two versions of the standard, completely changing the design approach. Is the NRC going to require compliance with the 1993 version of the standard? If so, the design and operation of the system may be significantly affected.

Response: Section C.1.11.5 of DG-1145 references ANSI/HPS N13.1-1999, the most recent version of this ANSI standard. As was pointed out in this question, Section C.1.12.3.4 of DG-1145 makes reference to ANSI N13.1-1993. ANSI N13.1-1993 simply reaffirms the earlier version of the standard, ANSI N13.1-1969-there are no changes to the this version of the standard from the earlier version. The version of the standard referenced in Section C.1.11.5 of DG-1145, ANSI/HPS N13.1-1999, differs significantly from the earlier versions in that it is now a performance-based standard rather than one based on prescriptive rules. As is stated in the Forward to ANSI/HPS N13.1-1999, "Although the approach to achieving representative effluent sampling presented in this standard represents a substantial departure from the methodology recommended by a previous version of this standard, it is practical and the expected performance is attainable." The NRC staff is in the process of revising Section C.1.12.3.4 of DG-1145 so that it makes reference to the most recent version of the ANSI standard, ANSI/HPS N13.1-1999, and is consistent with Section C.1.11.5 of DG-1145.

Section 11.5 of the AP1000 Design Control Document (DCD) states that the radiation monitoring system for the AP1000 will be designed to ANSI N13.1-1969 standards. Since the NRC staff has certified the DCD for the AP1000, a COL applicant referencing the AP1000 design will be able to use a radiation monitoring system which was designed to meet ANSI N13.1-1969 standards. The NRC cannot require that a COL applicant, who references the AP1000 design, comply with a more recent version of ANSI N13-1 (such as ANSI/HPS N13.1-1999) without following the process outlined in 10 CFR 52.63(a)(1). However, a COL applicant referencing the AP1000 design can choose to submit a COL application which references the most recent version of the ANSI standard- ANSI/HPS N13.1-1999.

Disposition: Section C.1.12.3.4 of DG-1145 will be revised so that it makes reference to the most recent version of the ANSI standard, ANSI/HPS N13.1-1999, and is consistent with Section C.1.11.5.

C.I.12.3-2 What is the minimum set of radiation protection facilities that must be described either in a design certification (DC) or COL application?

Response: The minimum set of radiation protection facilities that must be described either in a design certification (DC) or COL application is listed in Section C.I.12.5.4 (Equipment, Instrumentation, and Facilities) of DG-1145. This list is duplicated below:

The radiation protection facilities to be described should include:

- men's and women's locker and shower rooms;
- radiation protection program offices;
- access control stations;
- laboratory facilities for radioactivity analyses;
- decontamination facilities (for both equipment and personnel);
- portable instrument calibration facility;
- facility for issuing and storing protective clothing;
- facility for issuing, storing, and maintaining respiratory protection equipment;
- machine shop for work on activated or contaminated components and equipment;
- area for storing and issuing contaminated tools and equipment;
- area for storing radioactive materials;
- facility for dosimetry processing and bioassay;
- laundry facility; and,
- other contamination control equipment and areas.

Disposition: No change to the guide.

C.I.12.3-3 The following items in Section C.I.12.3.1 are not believed to be "review areas to be addressed in a combined license (COL) application referencing a certified design." Rather, it is believed that it should be considered to have been closed through the AP1000 design certification:

- a. "Describe each very high radiation area ... and radiation monitor locations for each of these areas."
- b. "Provide an illustrative example of each of the following components (including equipment and piping layouts), when applicable, and describe any associated design features intended to minimize personnel dose during operation or maintenance of the component ... minimize personnel exposure." Some of this information is included in the AP1000 design control document (DCD); other design information which was not provided or requested to be in the DCD should not be considered anew in the COL process.
- c. "Provide scaled layout and arrangement drawings of the facility. ... Accurately locate positions, indicating the approximate size and shape of each source." Again, the AP1000 DCD includes a significant amount of information in this regard; the matter cannot be reconsidered during the COL process.

Response: In order for the staff to evaluate the licensee's compliance with 10 CFR 20.1602, Control of access to very high radiation areas, the staff needs to review the administrative controls for use of the design features provided to control access to these radiologically controlled areas. Since a description of these administrative controls is outside the

scope of the DCD, this information must be addressed by the COL applicant. Because the regulations require additional measures for such areas to ensure that an individual is not able to gain unauthorized or inadvertent access to these areas, the staff is requesting that the COL applicant provide detailed drawings showing isometric views of each very high radiation area and indicate the location of radiation monitors for these locations so that the staff can adequately evaluate the additional controls put in place for these areas by the licensee.

- b. This item is in reference to Section C.I.12.3.1 of DG-1145 and is intended to apply to a "custom" COL application (see response to Question 12.2-1). As such the information requested should be described in the DCD (or custom COL application in the case where no DCD is referenced).

After evaluation of the AP1000 DCD, the staff determined that the information contained in Sections 12.1 and 12.3 of the AP1000 DCD was sufficient to address the information requested in Section C.I.12.3.1 of DG-1145.

- c. The scaled layout and arrangement drawings contained in Figures 12.3-1, 12.3-2, and 12.3-3 of the AP1000 DCD do not indicate the location of the contained radiation sources described in Section 12.2 of the AP1000. Since the locations of these sources may not have been known at the DCD stage, the staff is asking that they be provided at the COL stage. If the source locations are not known at the COL stage, then the location of these sources may have to be reviewed during the pre-operational inspections. By providing the locations of the radiation sources on the scaled layout and arrangement drawings, the staff would be able to further evaluate the licensee's operational controls for maintaining radiation exposures ALARA as well as the licensee's access control procedures.

Disposition:

- a. The first bullet under Section 12.3.1 ("Review Areas to be Addressed in a COL Application Referencing a Certified Design," ML060800400) has been deleted. Guidance to COL applicants on access control for very high radiation areas is provided in Section C.1.12.5.3 of DG-1145 under the heading "Access Control".
- b. No change.
- c. No change.

C.I.12.3-4

Major components, such as heat exchangers, pumps, large piping and valves, would likely be located on arrangement drawings in the design control document (DCD). With those equipment locations established, various radiation zones would be established and described in the DCD for NRC review during the design certification review stage.

Since, in the case of the AP1000, the subject radiation zones were provided in the DCD, it is not clear as to why this information would be requested by the Section 12.3 review guidance for a COL application referencing the AP1000 certified design. In general, it is expected that design matters within the scope of the standard design would be reviewed during design certification. Additional engineering design detail regarding the implementation of the certified standard design would be audited or inspected by the NRC as part of its engineering design verification activities (first-of-a-kind engineering inspections). Please clarify the basis for this guidance in the proposed DG-1145.

Response: DG-1145 is written to apply to a "custom" COL application (see response to Question 12.2-1). A custom COL application is a COL application where the licensee does not reference a standard design certification. Since a custom COL application does not reference a standard design, a custom application must include a description and the location of the plant radiation zones on the plant scaled layout and arrangement drawings. For a COL application which references a standard design certification, such as the AP1000 COL application, the description and the location of the plant radiation zones have already been provided in the design certification document (DCD).

As stated in the above comment, the NRC, as part of its engineering design verification activities ("FOAKE" inspections), will audit or inspect additional engineering design detail regarding the implementation of the certified standard design.

Disposition: No change to the guide

12.3-5 For location information regarding minor equipment locations, such as radiation area monitors, it is expected that the design control document (DCD) would describe the types of monitors to be used and their general locations, such as by naming the rooms or plant areas. Exact monitor placement represents a level of design detail that may not be available in the DCD or at the time of combined license (COL) application development. However, the DCD should describe the general process or criteria that would be used for radiation monitor placement.

In the case of the recently certified AP1000 design, the DCD describes general locations of radiation monitors, as well as the criteria for establishing exact monitor locations. An example of criteria for defining monitor locations is provided in DCD (Tier 2) Section 11.5.6.2 for the TSC Area Monitor. Please clarify application content guidance in regards to this issue.

Response: The staff agrees, in part, with this comment. In the case of the AP1000 DCD, Section 11.5.6.1 of the AP1000 DCD describes design objectives for locations of the area monitor detectors and Table 11.5-1 lists the service area for each of the area radiation monitors. To the extent that this information is available at the time of the COL application, the licensee should indicate the general locations of the area, airborne radioactivity, and portal radiation monitors on the scaled facility layout drawings.

During the pre-operational inspections, NRC inspectors would confirm that the process and criteria described in the certified DCD and/or COL application's FSAR Chapter 12 were implemented faithfully (as described in the DCD and/or COL application) in establishing the exact locations of the subject radiation monitors.

Disposition: No change to the guide.

C.I.12.5-1 The operational program described in Section C.I.12.5 appears to include the program to implement the certified design into the detailed design. Please clarify.

Response: Section C.I.12.5 of DG-1145 provides guidance on what the NRC expects to see in a COL application to describe the licensee's operational radiation protection program so that it meets the radiation protection standards set forth in 10 CFR Part 20 and is consistent with the guidance given in the appropriate regulatory guides, where the practices set forth in such guides are used to implement NRC regulations.

The first part of Section C.I.12.5 of DG-1145 addresses the licensee's operational radiation protection program (Subpart B of 10 CFR Part 20). Because the staff does not expect the licensee to be able to have this program fully implemented at the time of the COL review, this section contains a series of four milestones over which the licensee is expected to implement the operational radiation protection program on a phased basis.

The next part of Section C.I.12.5 of DG-1145 is divided into three areas: organization; equipment, instrumentation, and facilities; and procedures. The section on procedures is further broken down into ten categories of procedures which address compliance with Subparts C through K of 10 CFR Part 20.

Disposition: No change to the guide.

C.I.12.5-2 What is an example of the additional level of detail required in the COL concerning equipment type and location versus that provided for design certification?

Response: With respect to major pieces of radioactive source containing equipment, such as tanks, vessels, pumps, and large diameter piping runs, the staff expects these components to be shown on the scaled facility layout drawings. To the extent that the locations of certain components are not yet accurately known at the time of the COL application, then staff will evaluate the location of those components during the pre-operational inspections.

With respect to equipment and instrumentation, as described in Section C.I.12.5 of DG-1145, the staff expects the licensee to include the criteria for selection, locations (to the extent known at time of the COL application), quantity (considering equipment unavailability), and types for each type of instrument. To the extent that the locations, quantity, and types of equipment and instrumentation are not fully known at the time of the COL application, the licensee should provide the criteria for selection and location in the COL application and the staff will evaluate the equipment and instrumentation location, quantity, and types during the pre-operational inspections.

Disposition: No change to the guide.

C.I.12.5-3 Does the staff understand and expect that combined license (COL) applications may not identify equipment selections and locations within rooms? This is first of a kind engineering (FOAKE) that is not required for COL. Rather, COL applications may state that "Radiation protection equipment will be selected and located within the plant with appropriate consideration for as low as is reasonably achievable (ALARA) and operating experience." This would be an inspection matter for the staff post-COL issuance.

Response: See response to Question C.I.12.5-2.

Disposition: No change to the guide.

C.I.12.5-4 In Section C.I.12.5, how would an applicant describe personnel responsibility for implementation and documentation radiation protection program reviews, if such personnel have not been selected at the time of COL?

Response: 10 CFR 20.1101c) requires the licensee to periodically (at least annually) review the radiation protection program content and implementation. In the COL application, the licensee should commit to following 10 CFR 20.1101 and describe the administrative organization of the radiation protection program, including the authority and responsibility of each identified position (key positions are identified in Section C.I.12.1 of DG-1145), including those positions which will have the responsibility for reviewing the radiation protection program content and implementation.

Disposition: No change to the guide.

C.I.12.5-5 In regards to the Equipment and Instrumentation discussion in Section C.I.12.5.1, are the quantities, sensitivities, ranges, alarms and calibration frequencies of detectors and monitors needed at the combined license (COL) application phase? This information will not be known until much later.

Response: It is recognized that the exact quantities, sensitivities, ranges, alarms, and calibration frequencies of detectors and monitors may not be known at the time of the COL application. The COL application should describe the criteria for selection, quantity (considering equipment unavailability), and types for each type of instrument and provide as much information about the detectors and monitors as is known at the time of COL application. Section C.I.12.5 provides a list of implementation milestones for the phased implementation of the radiation protection program. This list provides the milestones for when various parts of the radiation protection program (including the instrumentation and equipment) must be implemented and in place.

Disposition: No change to the guide.

C.I.12.5-6 In regards to the second bullet on the Section C.I.12.5 slide, Equipment, Instrumentation and Facilities, is Section C.I.12.5.3 of NEI 04-01E template guidance acceptable to the staff as the content of Section 12.5.3 of a combined license (COL) application final safety analysis report (FSAR)?

Response: The NRC staff worked in conjunction with NEI on the compilation of the radiation protection portion (Section 12.5 Operational Radiation Protection Program) of NEI 04-01 which discusses equipment, instrumentation, and facilities. This has been incorporated into Section 12.5 of Sections C.III.1 and C.III.2, as well as in Section C.I.12.5 of DG-1145. If an applicant for a combined license included the information specified in Section 12.5.2 of Sections C.III.1 or C.III.2 of DG-1145 in the COL application as Section 12.5.2 (Equipment, Instrumentation, and Facilities), the staff would review it and would most likely find it acceptable if it addressed all the information described in Section C.I.12.5.2 of DG-1145 and the comparable section of NUREG-0800 (Standard Review Plan).

Disposition: No change to the guide.

C.I.12.5-7 What are the application portions of NUREG-1736 that must be addressed by combined license (COL) applicants?

Response: NUREG-1736 consolidates numerous guidance documents relating to 10 CFR Part 20 into a single, comprehensive source. For each section in Part 20, this document includes a statement and discussion of the requirement, a statement of its applicability, a guidance statement, and a list of existing regulatory guidance and implementation guidance that is meant to assist the reader in further understanding the purpose and meaning of each section of Part 20.

10 CFR 20.1101 states that “each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part.” In incorporating the various provisions of Part 20 in the development of the combined license applicant’s radiation protection program, the combined license applicant can consult the corresponding portions of NUREG-1736 for guidance.

Disposition: No change to the guide.

C.I.13-1 Experience with applications currently being developed is that it would be more efficient to locate organization and staffing requirements for other plant organizations such as Radiation Protection and Fire Protection in Chapter 13 rather than in the program description sections of the safety analysis report (SAR) (e.g., 12.5 and 9.5.1). Is this an acceptable alternative to the guidance provided in the current draft of DG-1145?

Response: Yes. COL applicants should, however, provide references to FSAR Chapter 13 of their application for these types of programs.

Disposition: No change to DG-1145

C.I.13.1-1 As discussed in the May 18th workshop, industry is considering development of a generic safety analysis report (SAR) section 13.1 that could be referenced by several applicants. The concept would include use of generic position titles and a table that shows the correlation of the generic titles and site-specific positions. Would the staff accept this approach for Section C.I.13.1?

Response: Yes. This approach is acceptable to the staff provided that sufficient information is included in the application for the staff to make its license determination.

Disposition: No change to DG-1145

C.I.13.1.1-1 Item 2 in Section C.I.13.1.1.1 requires a combined license (COL) applicant to provide a description of the development and implementation of staff recruiting programs. This information should not be required if the application adequately describes the position requirements and numbers of individuals needed to staff the plant and supporting organizations. What is the reason behind and the regulatory basis for this proposed guidance?

Response: The staff agrees that information on recruiting programs is not required.

Disposition: Section C.I.13.1.1 has been revised to delete information requests for recruitment programs.

C.I.13.1.1.3-1 Section C.I.13.1.1.3 requires that resumes be provided for assigned persons identified in section C.I.13.1.1.2. The section also requires that the qualification requirements for those positions be identified. Many current operating plants have removed resumes from the safety analysis report (SAR) because of the administrative burden associated with updating those sections to reflect personnel changes resulting from rotations, reorganizations, retirements, etc. The detailed qualification requirements for key positions are licensee commitments and must be met or alternatives justified as these positions are filled. At the time a combined license (COL) application is filed, the requirements for these positions can be identified in accordance with regulatory guidance, such as Regulatory Guide 1.8, but many of the positions may not be filled. It is recommended that the requirement for resumes be removed since the position qualification requirements will allow the staff to assess organization qualification adequacy. The qualifications of individuals filling those positions can be assessed through inspections at the sites after the application is filed. This same issue exists for plant operating personnel in section C.I.13.1.3.2.

Response: The staff agrees with this comment.

Disposition: Sections C.I.13.1.1.3 and C.I.13.1.3.2 have been revised to delete any resume requirements.

C.I.13.1.2-1 Item 3 in Section C.I.13.1.12, requires a commitment to meet the applicable requirements for a Fire Protection Program. Those commitments are also located in Section C.I.9.5.1. This item seems out of place for Section C.I.13.

Response: The staff disagrees with this comment. The commitment in this section is consistent with the SRP.

Disposition: No the change to DG-1145

C.I.13.1.2.1-1 During the May 18 workshop on draft DG-1145, the staff discussed the wording of sections C.I.13.1.2.1 that would require an applicant to provide an organization chart showing the title of each position, number of persons assigned, etc. An industry comment proposed that a high-level organization chart be provided in the combined license (COL) application since the details needed for the requested chart would not be known at the time the application is filed. Our understanding of the discussion of this issue is that the staff agrees that a high-level organization chart is adequate for the application and that the regulatory commitments associated with the applicant organization could be confirmed through inspections after the COL application is filed.

Response: The staff confirms this understanding.

Disposition: No change to DG-1145.

C.I.13.1.2.1-2 Section C.I.13.1.2.1 requires an applicant to provide an organization chart showing the title of each position, the number of persons assigned common or duplicate positions, number of operating shift crews, etc. It is anticipated that this level of detail may not be

known at the time the combined license (COL) application is submitted. A high level organization chart could be prepared and submitted in the application with more detail developed later and made available for inspection. The guidance should be modified to indicate that this information will be developed after the application is submitted. This position is consistent with SRP 13.1.2-13.1.3, Rev. 5 issued July 2005

Response: The staff agrees with this comment. See also response to C.I.13.1.2.1-1 above.

Disposition: No change to DG-1145.

C.I.13.2-1 The industry believes that Section C.I.13.2 should be written as a either a generic or standardized combined licenses (COL) application section. Please identify any concerns that the NRC may have with the industry taking this approach.

Response: The staff agrees with this approach; however, COL applicants must ensure that sufficient information is provided for the staff to make its license determination. In addition, staff will still need to review follow-on applications to ensure consistency with the generic or standardized section.

Disposition: No change to DG-1145.

C.I.13.2-2 Throughout Section C.I.13.2, NRC refers to "titles of positions". To facilitate standardization of Section C.I.13.2, does the NRC staff agree that it would be acceptable to provide "functional position descriptions" whenever the phrase "titles of positions" is used? This would allow development of a generic section without making applicant specific title distinctions that will be inconsistent from utility to utility.

Response: The staff agrees that "functional position descriptions" are acceptable alternatives to "position titles".

Disposition: No change to DG-1145.

C.I.13.2-3 Throughout this section C.I.13.2, NRC refers a number of formal instruction techniques including "classroom instruction" and "lecture". Does the NRC agree with use of the term "formal instruction" to encompass classroom instruction, lecture and other formal instruction techniques like e-learning applications to avoid limitation in delivery techniques?

Response: The staff agrees with this comment.

Disposition: Sections C.I.13.1 and 13.2 revised as necessary

C.I.13.2-4 In Section C.I.13.2, the NRC refers to the development of "contingency plans" in the event of delays in fuel loading. The industry believes that implementation of re-qualification or retraining programs suffice for the contingency plans requested. Does the NRC agree? If not, why?

Response: The staff agrees with this comment.

Disposition: Section C.I.13.2 clarified to add "(i.e., requalification and/or retraining)."

C.I.13.2-5 Currently Industry's 10 CFR 50.120 training programs and licensed personnel training programs undergo accreditation by the National Academy for Nuclear Training. Would the NRC be open to explore a license condition to have an accredited training program in place in lieu of a more detailed final safety analysis report (FSAR) section C.I.13.2?

Response: The staff does not concur with this approach.

Disposition: No change to DG-1145.

C.I.13.2-6 DG-1145 specifies that license applicants should identify the proposed course durations in the final safety analysis report (FSAR) section 13.2. Industry believes that it is not possible to prescribe course durations prior to implementation of the systems approach to training as describe in 10 CFR 55.4. Industry believes that predetermination of course is inconsistent with systems approach to training (SAT) and that should be removed from DG-1145. Does NRC concur?

Response: The staff concurs with this approach.

Disposition: No change to DG-1145.

C.I.13.2.1.1-1 Item 4 in Section C.I.13.2.1.1 identifies Regulatory Guide 1.149 along with several other regulations and refers to all of them as "requirements." The NRC Regulatory Guide is only guidance, not a requirement. Does the NRC agree that DG-1145 should be revised to reflect the distinction between the requirements and guidance?

Response: The staff agrees with this comment.

Disposition: Item 4 has been revised to provide a distinction between requirements and regulatory guidance.

C.I.13.2.1.1-2 Item 6 in Section C.I.13.2.1.1 discusses implementation milestones. Does the NRC agree that these milestones could be identified relative to fuel load as opposed to calendar dates?

Response: The staff agrees with this comment. Milestones should be provided relative to fuel load in accordance with the information requirements for operational program implementation discussed in Section C.I.13.4

Disposition: No change to DG-1145

C.I.13.2.1.1-3 Item 2 in Section C.I.13.2.1.1 indicates that the application should include "a commitment to meet the requirements of 10 CFR 50.120 at least 18 months before fuel load." As this is a regulation that must be met, why is it necessary to include a commitment in the final safety analysis report (FSAR)?

Response: For completeness and consistency, the staff is requesting information regarding implementation milestones for operational programs in Section C.I.13.4 regardless of whether the implementation milestone is a regulatory requirement or is a license condition.

Disposition: No change to DG-1145.

C.I.13.2.1.1-4 Item 3 in Section C.I.13.2.1.1, please identify the training programs that they envision including in this section

Response: These are programs not covered by 10 CFR 50.120. It is the responsibility of the licensee to identify these programs. The staff does not believe additional guidance is necessary.

Disposition: No change to DG-1145.

C.I.13.2.1.1-5 Item 3 in Section C.I.13.2.1.1, the industry proposes to write a description of the systems approach to training (SAT) process to address the elements of this process that will provide assurance that operation and plant staff are trained to perform difficult, important, and infrequently required tasks as well as those required by regulation. This will include:

- Analyze Training Needs , starting with Job Task Analysis,
- Design training programs and training courses to address task objectives and the skills and knowledge needed,
- Develop training content, presentation, and learning techniques, and
- Evaluations to ensure that the learner retains sufficient knowledge and skills to perform the tasks as well as measuring and monitoring training effectiveness.

Please identify any concerns that the NRC may have with this approach.

Response: The staff agrees with this approach.

Disposition: No change to DG-1145.

C.I.13.2.1.1-6 Item 3 in Section C.I.13.2.1.1, please clarify the level of detail expected in the "subject matter of each course"? Does the NRC agree that it is sufficient to identify "proposed topics" instead of "syllabus" as this will be consistent with other portions of this chapter?

Response: The staff makes no distinction between “proposed topic” and “syllabus”. COL applicants must provide sufficient information for the staff to make its license determination.

Disposition: No change to DG-1145.

C.I.13.2.1.1-7 Item 3 in Section C.I.13.2.1.1 indicates that training programs for three different levels of prior staff experience be detailed. As all programs will be designed for an individual without prior training, qualification or experience, does the NRC agree that a description of the systems approach to training as described above would be adequate to address this issue?

Response: The staff agrees with this approach; however, the COL applicant should clearly identify that the training program will accommodate different levels of experience.

Disposition: No change to DG-1145.

C.I.13.2.1.1-8 Item 3 in Section C.I.13.2.1.1 indicates that the application should include "a commitment to conduct an onsite formal training program and on-the-job training such that the entire plant staff will be qualified before the initial fuel loading." Industry believes that there is no requirement, or need, to have the entire plant staff qualified before fuel load. Such a condition will rarely occur over the lifetime of the plant due to continuous hiring of new personnel. The new personnel become a part of the plant staff immediately but often require some period of time to become "qualified." It is necessary only to have a sufficient number of qualified plant staff to operate the plant. Does the NRC agree that it would be appropriate in DG-11454 to replace the phrase "the entire plant staff" with the phrase "sufficient plant staff to ensure safe plant operations"?

Response: The staff agrees with this comment.

Disposition: Item 3 has been revised to replace the phrase "the entire plant staff" with "sufficient plant staff to ensure safe plant operations."

C.I.13.2.1.1-9 Item 4 point e in Section C.I.13.2.1.1 includes the sentence "The program description is verified to include the course of instruction, the number of hours of each course and the organization conducting the training." Why is this sentence included in subpoint e as opposed to being included after the final sentence of Item 4? It would be more consistent with the Regulatory Guide if it was included with the final sentence of the item.

Response: These training requirements are particular to the fire protection staff members rather than the general plant staff.

Disposition: No change to DG-1145.

C.I.13.2.1.1-10 The last sentence of item 4 in Section C.I.13.2.1.1 indicates a commitment to verify that initial fire protection training be completed prior to receipt of fuel. This is not consistent with fire protection program implementation guidance schedule (currently in 13.4). Please identify any concerns that the NRC may have with the industry taking this phased approach.

Response: The implementation milestone for fire protection program training in item 4 of Section C.I.13.2.1.1 is correct.

Disposition: Section 13.4 has been changed from "fuel load" to "fuel on-site".

C.I.13.2.1.1-11 As a job task analysis is an element of the systems approach to training, as described in the question for item 3 in this section. Industry proposes using the description of a systems approach to training to address item 5 in section C.I.13.2.1.1. Please identify any concerns that the NRC may have with the industry taking this approach.

Response: The staff agrees with this approach; however, COL applicants should provide sufficient information for the staff to make its license determination.

Disposition: No change to DG-1145.

C.I.13.2.1.1-12 Item 6 in Section C.I.13.2.1, please clarify whether this item refers to a program description or a course description.

Response: The staff makes no distinction between “program description” and “course description.” COL applicants should provide sufficient information for the staff to make its license determination.

Disposition: No change to DG-1145

C.I.13.2.1.1-13 Industry believes that the separate emergency planning section addresses item 7 in section C.I.13.2.1.1. Please identify any concerns NRC may have with this approach.

Response: The staff agrees with this approach; however COL applicants should ensure that any standardization of this approach is consistent.

Disposition: No change to DG-1145

C.I.13.2.1.1-14 Please clarify item 7 in Section C.I.13.2.1.1. The first sentence refers to radiological emergencies and the second sentence and sub-points (a) and (b) don't seem to be related.

Response: The staff agrees with this comment.

Disposition: Sub-points (a) and (b) are not related to item 7 and have been revised as items 8 and 9.

C.I.13.2.2.1-1 Item 3 in Section C.I.13.2.2.1, NRC uses the phrase "should include the content described in 10 CFR 55.59 or should be based on the use of a systems approach to training (SAT)". Why is the use of a systems approach to training not included in this section as it refers to the same re-qualification program?

Response: The staff has determined that Section C.I.13.2.2, Replacement and Retraining, is not required as it is adequately covered in C.I.13.2.1.

Disposition: The information contained in Section C.I.13.2.2 on “Replacement and Retraining” has been replaced with “References.”

C.I.13.2.2.3-1 Section C.I.13.2.2.3 discusses replacement training. Industry believes that all replacement personnel would be required to go through initial training to become qualified and re-qualification training to maintain their qualification. Please identify any concerns NRC may have with using an approach that includes initial and re-qualification only, why is there a separate section on replacement training?

Response: See response to C.I.13.2.2.1.

Disposition: See disposition for C.I.13.2.2.1.

C.I.13.3-1 In the last sentence of the third paragraph, discuss how the information submitted for section C.I.13.3 will demonstrate compliance with 10CFRPart 100?

Response: The information submitted for Section 13.3 is not intended to demonstrate compliance with 10 CFR Part 100. Those determinations will be made through applicable sections of the Standard Review Plan (SRP). The 04/26/06 version of DG-1145 (section 13.3) identifies 10 CFR Part 100, and specifically 10 CFR 100.21(g). Some sections within 10

CFR Part 100 (i.e., 100.1, 100.3, 100.20, and 100.21(g)) duplicate some emergency preparedness criteria in 10 CFR Parts 50 and 52. It is acceptable to reference the sections of the FSAR that address site characteristics to satisfy the significant impediment criteria.

Disposition: No change to DG-1145.

C.I.13.3-2 The last sentence of the paragraph states, “In addition to NRC’s (described above), the COL applicant needs to include State and local plans that address the relevant DHS requirements contained in 44 CFR Part 350, 351, and 352, as well as associated guidance documents. For a “Green Field” COL submittal, at best only an existing State plan will be available. What is the expectation for submittal of State and local plans for a Green Field submittal where possibly no State and/or local plans exist?”

Response: 10 CFR 50.33(g), through 10 CFR 52.77, requires that the applicant for a combined license shall submit radiological emergency response plans of State and local governmental entities. A reasonable assurance finding by NRC is based in part on a determination by the Department of Homeland Security (DHS) that the State and local plans are adequate and whether there is reasonable assurance that they can be implemented (see 10 CFR 50.47). In regard to the COL application, all State and local emergency response plans must be submitted. The only exception would be submission of a “utility plan,” pursuant to 10 CFR 50.47(c)(1). Absent complete and integrated emergency plans, which must include both State and local emergency plans, the COL application would be considered incomplete, and would not be accepted for docketing.

Disposition: No change to DG-1145.

C.I.13.3-3 Does the NRC have a list of the pertinent documents included in “guidance documents, generic communications, and other criteria that would be used to develop the application”?

Response: Yes. A draft table of these documents was provided as a handout at the May 18, 2006, public meeting. Some of the documents listed in the table may not be applicable to a COL application submittal (e.g., EPPOS 1 through 5).

Disposition: The table has been incorporated into section 13.3 in the list of references.

C.I.13.3.1-1 Our understanding is that section C.I.13.3 would reference the site Emergency Plan as a stand alone document as opposed to a stand-alone document identified as Section C.I.13.3 of the application.

Response: The staff agrees.

Disposition: As DG-1145 goes through the technical editing process, the reference to the SAR should be clarified.

C.I.13.3.1-2 Discuss the level of detail required in the E-plan submitted at the COL stage. For instance, plant staffing level detail may not be available at the time of COL application submittal. Can this information be submitted later and this action tracked as an ITAAC, license condition or other tracking mechanism?

Response: A complete and integrated emergency plan must be submitted at the COL stage. Information that is not available at the COL stage, may be reflected as an ITAAC, consistent with Table 13.3-1. However, plant staffing levels are not included as a generic ITAAC in Table 13.3-1. This is information that should be available, and part of the emergency plan submitted, at the time of COL application. In general, the use of commitments or other tracking mechanism will not be allowed.

Disposition: No change to DG-1145.

C.I.13.3.1-3 The last sentence of this paragraph states “For example, an applicant could propose an ITAAC for the licensee’s onsite procedures and a license condition for the offsite procedures.” Is not the requirement to submit offsite procedures a departure from current requirements?

Response: The subject sentence has been removed, and the requirements have not changed.

Disposition: The subject sentence has been removed.

C.I.13.3.1-4 Does this section pertain to NUREG-0933 III.A.1.1? There should be no outstanding safety items for each site related to this section. Should a statement be provided in this section, referencing the SER for these safety items? Please verify.

Response: NUREG-0933 presents the priority rankings for generic safety issues, and is periodically updated. Item III.A.1.1 in NUREG-0933 is resolved, and no new requirements are needed. There are, however, TMI-related emergency planning requirements that may apply to some applications (i.e., 10 CFR 50.34(f)(2)(iv), (viii), (xvii), and (xxv)). These are addressed separately in DG-1145.

Disposition: DG-1145 has been revised to only identify NUREG-0933 as a general reference in Section 13.3.4.

C.I.13.3.1-5 Are the inspection, test, analyses, and acceptance criteria (ITAAC) in Table 13.3-1 the base ITAAC? May other ITAAC, license conditions or other tracking mechanisms be submitted and is it appropriate to modify the wording in the existing ITAAC?

Response: Yes, the ITAAC in Table 13.3-1 are the base, generic ITAAC. Applicants are expected to modify the wording to be site-specific. However, they should retain the basic intent of the specific generic ITAAC. Other ITAAC may be proposed, and will be reviewed on a case-by-case basis. In general, the use of license conditions or other tracking mechanisms will not be allowed.

Disposition: No change to DG-1145.

C.I.13.3.2-1 For multi-unit sites, letters of agreement at the time of combined license (COL) application submittal may not reflect the new plant. Is it acceptable to submit letters of commitment (i.e., other certification)? The word "all" should be removed; it's implied. Also, it might be interpreted to apply to all correspondence referring to agreements, for example, B.5.b-specific letters which might be withheld from public disclosure.

Response: Letters of commitment or other certifications are acceptable. However, a proposed schedule for completion of the revisions to the letters of agreements should be included in the application. This could be an ITAAC. For example, a local response organization agrees to honor a local plan or procedures for responding to an emergency. A “commitment” (only) to develop emergency plans at some time in the future, in lieu of submitting the completed plans in (or referenced by) the COL application, would not be acceptable. The staff agrees that the word “all” should be removed.

Disposition: No change to DG-1145, except for the removal of the word “all.”

C.I.13.3.4-1 Minor comment - At the time of this agreement the agreement was with FEMA (vice DHS) and should be referenced as such.

Response: The staff agrees.

Disposition: DHS was changed to FEMA.

C.I.13.3.4-2 The footnote after D-1 in the EP Program Elements column under planning standard one in Table 13.3-1 might be misinterpreted as referring to NUREG-0654 for EALs. If that were the case, then it should Regulatory Guide 1.101. However, since this footnote simply identifies that the bracketed information [A-#] following each program element is a NUREG-0654 Section II cross-reference, it is recommended that this footnote be attached to the heading so it is clear that it applies to the entire column.

Response: The staff agrees.

Disposition: A footnote to the heading has been added.

C.I.13.3.4-3 Take out the hyphen in 2.3, “stated in the emergency”, in Acceptance criteria column of Table 13.3-1.

Response: The staff agrees.

Disposition: The hyphen has been removed.

C.I.13.3.4-4 For the emergency planning (EP) Program Elements column in Table 13.3-1 pertaining to Planning Standard 4.0: Can it be clarified that the reference to the emergency operations facility (EOF) providing space for news personnel can be addressed by applicants making reference to a JIC. Note that the ITA & AC columns make no reference to the EOF.

Response: Yes.

Disposition: The words “at the EOF” have been deleted.

C.I.13.3.4-5 In regards to planning standard 5.0 in Table 13.3-1, "TSC is within 2 minutes of the Control Room" - A number of utilities have located their technical support center (TSC) outside of the two minute walking distance with provisions for advanced communications between the Control Room and TSC. Some applicants at multi-unit sites may want to have a single TSC. It is unlikely that the travel time from the TSC to all control rooms can be less than 2 minutes. Can advanced communications satisfy the 2 minute requirement?

Response: Yes. Advanced communications capabilities may be utilized in lieu of the two minute requirement.

Disposition: The ITAAC has been revised to reflect that advanced communications capabilities may be used to satisfy the two minute travel time.

C.I.13.3.4-6 In regards to planning standard 5.0 in Table 13.3-1, current practices allow for a combined technical support center (TSC) and operational support center (OSC). Why not allow for this practice? This should be an acceptable practice for combined license (COL) application .

Response: The staff agrees.

Disposition: The ITAAC has been revised to reflect that the TSC and OSC may be combined at a single location.

C.I.13.4-1 The sample Table 13.4-X, "Operational Programs Required by NRC Regulation and Subject to the License Condition on Program Implementation", includes implementation dates that are based on the Part 50 licensing process and should be updated to recognize that the COL is issued before plant construction begins. Items 12, 13 and 14 should have milestones related to fuel loading instead of issuance of the operating license.

Response: The staff agrees with this comment.

Disposition: The milestones for items 12, 13, and 14 have been revised to relate to fuel load instead of COL issuance.

C.I.13.4-2 Based on the proposed content, it is suggested that this section should be titled "Operational Program Implementation.

Response: The staff agrees with this comment.

Disposition: Section C.I.13.4 has been revised as noted.

C.I.13.4-3 The scope of this section was discussed in April workshop under DG-1145, Section C.IV.4. It is anticipated by industry that resolution of comments presented for that section may result in some corresponding changes to this section.

Response: The staff agrees that resolution of comments on C.IV.4 may impact C.I.13.4.

Disposition: No change to DG-1145.

C.I.13.5-1 The fourth sentence in the introduction of Section C.I.13.5 requires that the combined license (COL) application identify persons (by position) who have the responsibility for writing procedures and the persons who must approve procedures. As discussed in the May 18, 2006 workshop, the detailed applicant organization (including the positions described above) will not be known at the time the application is filed. Procedural revision and approval will be delineated in administrative procedures as defined in Section 13.5.1.1.

Response: The staff agrees with this comment.

Disposition: Section C.I.13.5 has been revised to require that the functional position for procedural revision and approval be delineated in the description of administrative procedures.

C.I.13.5-2 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 QA program. Section C.I.17.5 does not require the application to address these requirements. Is it the NRC's expectation that all this information would be provided in Section 13.5 of the COL safety analysis report (SAR)?

Response: See response to C.I.13.5.2.1-1, below.

Disposition: See disposition to C.I.13.5.2.1-1, below.

C.I.13.5.2.1-1 The second sentence in Section C.I.13.5.2.1 requires that each procedure performed by licensed operators be identified by title and included in a described classification system. It is not expected that this level of detail will be known at the time the combined (COL) application is submitted. The application can include a list of procedures by class and function. The more detailed listing of procedures would be developed subsequent to the filing of the application. Suggest rewording to "Operating procedures should be identified by type and included in a described classification system."

Response: The staff agrees with this approach. Detailed procedures will be verified during construction.

Disposition: Section C.I.13.5.2.1 has been revised as suggested.

C.I.13.5.2.1-2 In regards to the the third sentence in Section C.I.13.5.2.1, the general content of each class of procedures should be available at the time the application is filed. The format of procedures will be developed as part of the procedure writers' guide and will occur after the application is filed.

Response: The staff agrees with this approach. Detailed procedures will be verified during construction.

Disposition: No change to DG-1145.

C.I.13.5.2.1-3 For the second sentence in Section C.I.13.5.2.1.A, comments C.I.13.5.2.1-2 and 3 above apply to this sentence. The part of the organization responsible for maintaining procedures and the general content of procedures can be identified at the time of application. The specific group(s) responsible for procedure maintenance and the format of procedures will be developed subsequent to the application filing.

Response: The staff agrees with this approach. Detailed procedures will be verified during construction.

Disposition: No change to DG-1145.

C.I.13.5.2.1-4 The purpose of section C.I.13.5.2.1.B is not understood. It appears to duplicate the information that is required in C.I.13.5.1.1 related to administrative controls for procedure development.

Response: Section C.I.13.5.2.1.B says the FSAR will describe the operating procedure program whereas C.I.13.5.1.1 deals with administrative procedures.

Disposition: No change to DG-1145.

C.I.13.5.2.1-5 Since the second sentence in Section C.I.13.5.2.1.C states that the PGP should be submitted at least 3 months prior to the commencement of formal operator training, we understand that the first sentence means that a description of the commitment to develop the emergency operating procedures (EOPs) and the appropriate regulatory guidance to be used should be described in the application. Does the staff agree with this understanding?

Response: The staff concurs with this understanding.

Disposition: No change to DG-1145.

C.I.13.5.2.1-6 Could the second sentence of C.I.13.5.2.1 be deleted? The sentence states that procedures should be identified title. This information may not be known at time of application

Response: See response to C.I.13.5.2.1-1.

Disposition: See disposition to C.I.13.5.2.1-2.

C.I.13.5.2.2-1 It is recommended that the phrase ", what groups or groups within the operating -----class of procedures," in the first in Section C.I.13.5.2.2 be deleted. The intent of "the group or groups with responsibility for following ----" is not clear. The information on the general organization responsibility is required to be provided in the introduction

Response: The last sentence of C.I.13.5.2.2 says that if "their general objectives and character" are described elsewhere, include the reference in this section (i.e., if organizational is described in 13.5, refer to section 13.5 in this section).

Disposition: No change to DG-1145.

- C.I.14-1** Does the NRC expect to update Regulatory Guides 1.16 and 1.68 in the near term?
- Response:** The NRC staff is reviewing all Regulatory Guides to identify and prioritize those that are considered necessary to support new reactor licensing efforts. The results of this review will be provided separate from DG-1145 activities.
- Disposition:** No change to DG-1145.
- 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 COL application? What is the definition?
- Response:** The term "organizational unit" is consistent with the language used in draft SRP Section 14.2. The expectation is that the applicant will provide a full description of the test organization and how other organizations may support or otherwise contribute to the initial test program.
- Disposition:** The sentence has been revised to read "The combined license applicant should provide a description of the organization that will manage, supervise, or execute any phase of the test program."
- 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?
- Response:** Draft SRP 14.2 states that, "The applicant should describe the education, training, and experience requirements established for each management and operating personnel, including the NSSS [nuclear steam supply system] vendor, architect-engineer, and other major contractors, subcontractors, and vendors, as appropriate, that will conduct the preoperational and startup tests and will develop testing, operating, and emergency procedures." Additionally, Regulatory Guide (RG) 1.68 states, "Hiring and training schedules for the plant operating and technical staff need to be established so that experienced and qualified personnel will be available for the development of testing, operating and emergency procedures."
- Disposition:** No change to DG-1145.
- 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.
- Response:** The staff does not expect an applicant to provide specific details of the participation of the plant operating and technical personnel in the initial test program. However, an application should include enough information that the staff can make a determination and reasonable conclusion on the applicant's plans for personnel participation in the initial test program.

- Disposition:** DG-1145, Section C.I.14.2.2 has been revised to include the response above.
- 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.
- Response:** The NRC staff agrees with this comment. The staff is requesting a “description” of the administrative controls. There is no discussion of procedural details being required.
- Disposition:** DG-1145, Section C.I.14.2.4 has been revised to note that COL applicants are not expected to provide detailed procedures with the application.
- 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?
- Response:** The tests required for ITAAC involve many that are considered pre-operational tests, which are part of the initial test program. Therefore, any controls for retesting to ensure that pre-operational testing was not invalidated, should be addressed in this section. A description of the specific testing is not being required. The staff does agree that a general description as proposed above would be sufficient to ensure that the applicant is going to consider that the ITAAC will not be invalidated by modifications or maintenance and the subsequent testing that would be performed.
- Disposition:** No change to DG-1145.
- 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.
- Response:** The NRC agrees with this comment.
- Disposition:** The last two sentences in Section C.I.14.2.5 have been moved to 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.

Response: Operating experience can only be applied from past experience. The staff would expect that the applicant consider past operating experience and more recent experience. The staff's expectation is that operating experience from the previous construction 'era' should be considered, as well as more recent information gained from the current operating fleet that may be applicable to the proposed facility.

Disposition: No change to DG-1145.

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?

Response: The NRC agrees that the level of detail typically provided in the SAR test abstracts is adequate.

Disposition: No change to DG-1145.

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 agree that the information provided in these documents is the expected level of detail for a combined license (COL) application?

Response: The applicants for a design certification are not responsible for initial fuel loading and initial criticality. A COL applicant should provide what its controls will be for the initial fuel loading and initial criticality procedures.

Disposition: No change to DG-1145.

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.

Response: The NRC is only asking for the applicant to identify preoperational tests that verify ITAAC. The NRC is not asking the licensee to provide the applicable inspection procedures.

Disposition: No change to DG-1145.

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.

Response: The NRC understands that procedures may be revised as necessary to properly implement the initial test program. However, the staff expects that working procedures will be issued in the 60 days prior to use for the initial test program. This is not just for staff consideration, but also is requested to give personnel adequate time to become familiar with the procedure.

Disposition: No change to DG-1145.

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.

Response: The NRC agrees with this comment.

Disposition: The sentence has been revised to read "The FSAR should also provide an overview of the initial test program and should identify each test required to be completed before initial fuel loading."

C.I.14.3-1 The third sentence in the fourth paragraph in Section C.I.14.3 references Section C.I.13.6 for Security inspection, test, analyses, and acceptance criteria (ITAAC), and Section C.I.13.6 references Section C.I.14.3.

Response: The NRC staff agrees with this comment. Guidance on physical security ITAAC will be provided in Section C.II.2.

Disposition: Section C.I.14.3 has been revised to reference Section C.II.2.

C.I.14.3-2 Section C.I.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 final safety analyses report (FSAR) info that has a limited FSAR lifetime, such as the Start-up Test Program, Technical Specifications and Construction Quality Assurance Plan (QAP). Are there other reasons why ITAAC should be submitted separately from the FSAR?

Response: ITAAC is a requirement of *proposed* Part 52.80, Contents of applications; additional technical information, whereas *proposed* Part 52.79 identifies technical information in FSAR. The NRC staff agrees that ITAAC is not unlike other FSAR information that has a limited lifetime; however, the staff is trying to maintain consistency between DG-1145 and the information requirements of the *proposed* Part 52 rule.

Disposition: No change to DG-1145.

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, tests, analyses and acceptance criteria (ITAAC). Substantial guidance in this regard is provided in draft SRP 14.3 (1996) and in Section 14.3 of the AP1000 design control document (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 application that references a design certification may consist largely of a reference to design control document DCD Section C.I.14.3?

Response: The guidance is provided in Section C.II.2. It was originally intended for Inclusion in C.I.14.3; however, the staff relocated the information to C.II.2 and created a new section C.III.7 to ensure consistency with the *proposed* Part 52 rule. The relationship of the sections is as follows:

- Section C.I.14.3 provides guidance on including ITAAC in a COL application.
- Section C.II.2 provides guidance on the development of a complete set of ITAAC for the entire facility described in the COL application.
- Section C.III.7 provides guidance on the ITAAC “To Do” list for each potential COL application scenario and discusses the various categories of ITAAC.

The NRC staff agrees that Section 14.3 for a COL application may consist largely of a reference to DCD Section 14.3. In addition, by regulation, if the COL application references a certified design it must reference DCD Section 14.3. However, the additional ITAAC necessary to provide a complete set of ITAAC for the facility must also be provided.

Disposition: No change to DG-1145.

C.I.15.0-1 The first paragraph in section C.I.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?

Response: This paragraph has been removed

Disposition: Section C.I.15 has been revised.

C.I.15.0-2 The fourth paragraph in section C.I.15.0 lists a number of Three Mile Island (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.

Response: The items listed in the lists for the TMI Action Plan, unresolved safety issues, Generic safety Issues, Generic Letters, and Bulletins in C.I.15.0 are applicable to the LWR designs. Some items may be applicable to one design but not applicable to other design. All the items listed were applied to the new reactor license applications submitted under Part 52, including the design certification of ABWR, System 80+, AP600 and AP1000, where applicable. A COL application referencing a certified design would not be required to address the generic design issues in this list that are not applicable to the specific design

Disposition: No change to the guide.

C.I.15.0-3 Section C.I.15.0 includes a number of lists of Three Mile Island (TMI) items, unresolved safety issues (USI), generic safety issues (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.

Response: The generic issues, i.e., TMI Action Items, USI/GSI, Bulletins, and Generic letters, listed in Section C.I.15.0 are applicable to the transient and accident analyses. The combined license (COL) applicant may provide the information to the generic issues in one place and reference it in the others.

Disposition: No change to the guide.

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?

Response: This paragraph has been removed.

Disposition: The section C.I.15 has been revised.

C.I.15.0-5 Why aren't the generic letters and bulletins which preceded design control document (DCD) certification excluded from combined license (COL) consideration? The certification by NRC must have considered these issues, they don't need to be re-addressed. The list includes some from the 1980's which predate all the DCD's. The draft regulatory guide (DR) should clarify that only generic communications subsequent to DCD certification need be addressed in COL.

Response: The guide was written for all COL applicants, not necessarily those referencing a certified design. The COL referencing a certified DCD is addressed in Section C.III.1 and C.III.2.

Disposition: No change to the guide.

C.I.15.0-6 Please clarify in the draft regulatory (DR), the basis for what is considered "applicable" for the lists of unresolved safety issues, and generic safety issues.

Response: The “applicable” generic issues are those issues pertaining to the transient and accident analyses for the specific design for the COL application.

Disposition: The guide will be revised as follows:

“Applicable TMI Action Plan Items include I.C.1, II.B.3, II.E.1.1, II.E.1.2, II.E.5.1, II.F.1, II.F.2, II.F.3, II.K.2.16, II.K.2.17, II.K.3.1, II.K.3.5, II.K.3.7, II.K.3.13, II.K.3.30, II.K.3.31, II.K.3.44, and II.K.3.45.”

“Applicable USIs and GSIs include USI-A-9, USI-A-47, USI-B-17, USI-C-4, USI-C-5, USI-C-6, USI-C-10, GSI-3, GSI-22, GSI-23, GSI-24, GSI-40, GSI-75, GSI-125.II.7, GSI-135, GSI-185, and GSI-191.”

“Applicable GIs and Bls include GL-80-019, GL-80-035, GL-83-11, GL-83-22, GL-83-32, GL-85-06, GL-85-16, GL-86-13, GL-86-16, GL-88-16, GL-88-17, GL-93-04, GL-97-01, GL-98-02, BL-80-04, BL-80-12, BL-80-18, BL-86-03, BL-93-02, BL-95-02, BL-96-01, BL-96-03, and BL-2001-01.”

C.I.15.1-1 "only limiting cases in each group need to be quantitatively analyzed" - cannot apriori determine the limiting event - quantification of multiple events is usually necessary. Implies something amiss when multiple events quantified.

Response: The initiating events for each combination of category and frequency group should be evaluated to identify the events that would be limiting. The intent is to reduce the number of initiating events that need to be quantitatively analyzed. That is, not every postulated initiating event needs to be completely analyzed by the applicant. In some cases a qualitative comparison of similar initiating events may be sufficient to identify the specific initiating event that leads to the most limiting consequences. Only that limiting initiating event should then be analyzed in detail.

Disposition: No change to the guide

C.I.15.3-1 "cover all expected changes predicted for the entire life of the plant" - where cycle specific reload analyses are defined, it's not required for analyses to bound future indeterminate future core/fuel designs. Addressing the present design is sufficient, e.g. initial core, and equilibrium core.

Response: The statement will be modified as: “Assure that the range is sufficiently broad to cover expected changes predicted for the fuel cycles to the extent practicable based on the fuel design and acceptable analytical methodology at the time of the DC or COL application.”

Disposition: Section C.I.15.3 will be revised.

C.I.15.4-1 The draft regulatory guide should require an approved methodology, values for specific uncertainty components. GE & BWROG has an NRC accepted methodology for trip uncertainty, for reference in combined license (COL). GE has had public discussion with TS staff on when specific components of uncertainty should be evaluated and documented. Much of the data will come after procurement and EQ testing, ie after COL, not possible to include in COL.

Response: The third paragraph of section C.I.15.4 will be modified as: “List the expected limiting delay time for each protection system function, and describe the acceptable methodology for determining uncertainties (from combined effect of calibration error, drift, instrumentation error, etc.) to be included in the establishment of the trip setpoints and allowable values specified in the plant technical specifications.”

Disposition: Section C.I.15.4 will be revised.

C.I.15.5-1 Section C.I.15.5 is inconsistent with section C.I.15.1 "1) assure that a sufficiently broad spectrum of initiating events has been considered;" it's not required to document the infinite possibility of initiating events.

Response: Section C.I.15.5 does not specifically request the applicant to document the infinite possibility of initiating events. The number of the initiating events to be documented depends on the specific plant design and the analytical methods used to categorize the events to be analyzed, and is subjected to the NRC review and approval for any methods different from the current approach for the event categorization.

Disposition: No change to the guide.

C.I.15.6.2-1 Item f in section C.I.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.

Response: The statement 15.6.2(6) will be clarified as: “Assure consistency between the safety analyses and the emergency response guidelines/emergency procedure guidelines (ERGs/EPGs) or EOPs with respect to the operator response (including action time) and available instrumentation.”

Disposition: Section C.I.15.6.2 will be revised.

C.I.15.6.2-2 What is the intent of the requirement to evaluate the effect of operator errors?

Response: The intent is to address the effects of operator errors that result in failing to carry out the required actions identified in the response to C.I.15.6.2-7.

Disposition: No change to the guide.

C.I.15.6.2-3 What is a “plant operational analysis?”

Response: A plant operational analysis is a sensitivity study to determine the effects of a system or component failure on plant response.

Disposition: No change to the guide.

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

Response: The statement 15.6.2(6) will be clarified as: "Assure consistency between the safety analyses and the emergency response guidelines/emergency procedure guidelines (ERGs/EPGs) or EOPs with respect to the operator response (including action time) and available instrumentation

Disposition: Section C.I.15.6.2 will be revised.

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?

Response: SECY-77-439 is publically available in ADAMS (ML060260236). DG-1145 references are publically available documents. References to industry standards are publically available and NRC references, such as regulatory guides, standard review plans and generic communications, are available from the NRC's public website (<http://www.nrc.gov/reading-rm/doc-collections>).

Disposition: DG-1145 has been revised to provide the ADAMS Accession No. for SECY-77-439.

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.

Response: The last sentence of 15.6.2(1) will be modified as: "Identify all operator actions credited in the transient and accident analyses for consequence mitigation."

Disposition: Section C.I.15.6.2 will be revised.

C.I.15.6.2-7 Clarification needed of "required operator actions". There are extensive scram procedure actions, however in passive designs few operator actions are credited in the safety analysis. "Required" should be those required to achieve the acceptable safety analysis consequences. Plant investment protection actions are not required. This will provide more focus, versus repeating the same actions repetitively.

Response: The last sentence of 15.6.2(1) will be modified as: "Identify all operator actions credited in the transient and accident analyses for consequence mitigation."

Disposition: Section C.I.15.6.2 will be revised.

C.I.15.6.2-8 Item f in section C.I.15.6.2 should be moved to a different chapter, dealing with emergency operating procedures (EOP's)

Response: The statement 15.6.2(6) will be clarified as: “Assure consistency between the safety analyses and the emergency response guidelines/emergency procedure guidelines (ERGs/EPGs) or EOPs with respect to the operator response (including action time) and available instrumentation.”

Disposition: Section C.I.15.6.2 will be revised.

C.I.15.6.2-9 Chapter 15 anticipated operational occurrence (AOO) analyses in previous final safety analysis reports (FSARs) and design control document (DCD) included non-safety systems, e.g. feedwater (FW), pressure regulator, recirc system. AP1000 safety evaluation report (SER) contains some guidance on when non-safety systems can be credited.

Can we assume that values which operate at rated pressure, e.g. FW check valves are not "low differential pressure". Suggest using some fraction of the containment design pressure for the definition of "low pressure"

Response: (A) The first three sentences on the second paragraph will be modified as the following:

“Only safety-related systems or components can be used to mitigate transient or accident conditions. However, non-safety related systems or components may be assumed operable in analyses for the following cases:

- (1) when a detectable and non-consequential random and independent failure must occur in order to disable the system, and
- (2) when non-safety related components are used as backup protection.

For example, under case (1), continued operation of the main feedwater control system (MFCS) may be assumed in those design-basis events not related to feedwater malfunction, loss of ac, or turbine trip, if it can be shown that a failure in the MFCS is not a consequence of the initiating events, and the probability of a random, independent failure occurring in the MFCS within the time of the initiating event is extremely low. Under case (2), the turbine stop and control valves can be credited in the design-basis analyses for backup protection if the valves are demonstrated to be reliable and subject to surveillance requirements in the Technical Specifications.

For any non-safety related systems or components credited in the design-basis analyses for mitigating the event consequences, proper justification must be provided. Non-safety related systems or components that may adversely affect transient or accident analyses must be taken into account. List the non-safety related systems or components assumed in the analyses for each event in a tabular form as recommended in Appendix J.”

(B) The basis for treating the check valves in the passive safety system designs as active components was stated in SECY-94-084, Section B, “Definition of Passive Failure,” that “redefine[s] check valves, except for those whose proper function can be demonstrated

and documented, in the passive safety systems as active components subject to single failure consideration.” An example of possible exemption is the accumulator check valves installed in applications identical to those for the currently licensed plants where the accumulator pressure will eventually create a large pressure differential to force open the valves as the reactor coolant system pressure falls.

Disposition: Section C.I.15.6.2 will be revised.

C.I.15.6.3-1. Does "Actual computer listing" means source code? Source listing are not in any final safety analysis report (FSAR) or LTR.

Response: The statement “and include figures showing the analytical model, flow path identification, actual computer listing, and listing of major input data” in the first paragraph of C.I.15.6.3.1 will be removed from the DG-1145.

Disposition: Section C.I.15.6.3 will be revised.

C.I.15.6.4-1 Does barrier performance mean containment performance? Clarify that time histories are only needed for events which approach design limits.

Response: Yes, barrier performance means containment performance. Provide detailed information only for the limiting events.

Disposition: No change to the guide.

C.I.15.6.5-1 f GE groups events by frequency, AOO, Infrequent Events, Accidents

Response: Deviations from the guidance are acceptable on a case by case basis.

Disposition: No change to the guide.

C.I.15.6.5-2 A, B, D are not separate events but different aspects in the analysis of 1 event

Response: Staff is unclear of the meaning of the comment. The current SRP Chapter 15.6.5, Appendices A, B and D separately discuss the different release pathways within the design-basis LOCA radiological consequences analysis. The staff does not intend to rewrite and renumber the current SRP sections, therefore the reference in Appendix A of DG-1145, Section C.1.15 is correct. The applicant may provide one comprehensive discussion of the design-basis LOCA radiological consequences analysis in the COL application.

Disposition: No change to the guide.

C.I.15.8-1 Table 15.8-1 In ESBWR design control document (DCD), failures are considered in the event frequency determination, AOO vs. Infrequent Event

Response: The recommended table is only a typical table and the applicant may provide the same information in another format.

Disposition: No change to the guide.

C.I.16-1 The draft guidance for this section addresses the requirements for providing proposed technical specifications and bases. It also provides guidance related to the use of approved generic technical specifications for applications referencing certified designs and standard technical specifications (NUREG-1430 through 1434) for applications that do not reference a certified design.

The section also requires that an application provide a description of the procedures developed for including probabilistic risk assessment (PRA) in the process for developing technical specifications and for processing changes to regulatory requirements including technical specifications. Another part of the draft requires that the application include a description of controls to assure that changes to technical specifications ensure that the current regulations, orders, and license conditions are met, consistent with the principles of risk-informed regulation.

There are three concerns with the process related requirements. First, the C.I sections of the guidance should specify the desired content of corresponding application sections. Guidance for development and change processes should be located in Section IV of the guidance. Second, the process guidance, as written, indicates that a risk assessment of proposed Technical Specification changes is required. Regulatory Guide 1.177 provides an optional, risk-informed means for justifying Technical Specification changes but is not a requirement. Third, the guidance on change processes is not clear on differentiating between departing from the approved generic technical specifications and changes to a COL licensee's technical specifications. There are different regulatory requirements for each of these. Also, we understand that bracketed information in the generic Tech Specs represents information not completely reviewed and approved and that replacement of bracketed information with plant specific design information does not require an exemption

Response: The second and third concerns have been addressed through clarification of the subject language. The NRC staff agrees that Section IV is the appropriate location for guidance for development and change processes, but prefers to maintain the paragraph following the quotation from 10 CFR 50.36(c)(2)(ii) of the four criteria for establishing limiting conditions for operation in TS.

Disposition: No changes were made to the guidance in response to the first concern. The second and third concerns were addressed through clarification of the subject language.

C.I.16-2 A combined license (COL) application final safety analysis report (FSAR) Chapter 16 must include the proposed Technical Specifications and Bases in accordance with 10CFR 50.36, 50.36a, and 52.79. This draft guidance requires, in addition, that an application describe the procedures and controls for preparation of Technical Specifications and processing Technical Specification changes. This information is not required by 10 CFR 52 as part of the application except the general requirement to discuss administrative controls of processes. Current rules (10 CFR 50.59, 50.90, DCR VIII.C) provide very specific requirements for license amendments and departures from generic technical specifications. The description of (1) "procedures ... for developing the technical specifications"; (2) "controls used to prepare risk information"; and (3) administrative controls to assure future license amendments comply with the regulations are details that are not considered appropriate for a COL application. Internal processes

and procedures that ultimately result in submittal of an application (initial or for future amendment) are more appropriately the subject of inspections during construction and operation. Particularly, in the case of future license amendment requests (including future Technical Specification change requests), where the regulatory requirements are clear and well understood, expecting descriptions of compliance processes several years in advance of their use should not be required in the COL application or any docketed correspondence.

Response: Deviations from the referenced certified generic TS or the applicable standard TS (NUREG-1430 through 1434) should be justified in the COL application, and also in exemption requests if required. Description of the processes and controls used by the COL applicant to prepare the proposed plant-specific TS would facilitate the NRC staff's review, particularly regarding whether the TS are comprehensive. These processes would likely be incorporated in subsequently developed procedures for proposing changes to the approved plant-specific TS following issuance of the COL.

Disposition: No changes were made in response to this comment.

C.I.16-3 This guidance section implies that use of Regulatory Guide 1.177 to support "technical specification changes" is a requirement. There is no current regulatory requirement to risk-inform technical specifications. Regulatory Guide 1.177 provides an optional process for risk-informing Technical Specification changes and the status of this Regulatory Guide should remain consistent with other NRC guidance. The language in this section should indicate that it is optional consistent with Regulatory Guide 1.177.

Response: The NRC staff agrees with the comment and clarified the subject language to make clear when the COL application should contain information on the use of risk insights in support of proposed TS.

Disposition: The NRC staff revised the guidance to make clear when the application should include information describing the use of risk insights in support of proposed TS.

C.I.16-4 The first paragraph in Section C.I.16 states that a combined license (COL) should include technical specifications and associated bases "conforming to the approved generic technical specifications for the certified design (if applicable) and consistent with the standard technical specifications in NUREG-1430 through 1434, as appropriate, with appropriate site-specific deviations." Paragraph 3 of page 1 of 4 states that "Justification should be provided for deviations from the certified design generic or standard technical specifications -----". Development of the generic technical specifications for the currently certified designs included evaluation against the standard technical specifications for the applicable reactor vendor. DCRs require the site-specific technical specifications to be developed with specific deviations from the generic design control document (DCD) technical specifications justified by exemption requests. A separate justification of the differences from the standard technical specifications would not make sense. In the case of an application made without referencing a certified design, it may be appropriate to present comparative information against some other approved standard Technical Specifications, however, the appropriate standard could be a prior certified design or NUREG-1430 through 1434. Please confirm that this is the intent of these two paragraphs.

Response: The NRC staff agrees that the language regarding guidance on justifying deviations from the referenced model TS is not clear, and that the intent as stated in the comment is correct.

Disposition: The subject language in the guidance was clarified.

C.I.16-5 In general, the guidance is not clear on different processes and expectations for applications that do or do not reference a certified design. It appears that some portions may be addressing one situation while other portions address the other. As such, clear guidance is not achieved. This appears to present the same problem as we have discussed with previous draft guidance sections.

Response: This comment appears to address the same issue as comment C.I.16-4.

Disposition: The subject language in the guidance was clarified.

C.I.16.1-1 Section C.I.16.1 is the only section identified in the guidance for this chapter. Does the staff intend to add other sections in the future to address related topics such as Technical Requirements Manual, Availability Controls, etc.?

Response: Current practice at operating plants is to place relocated TS requirements in the technical requirements manual (TRM) and to incorporate the TRM in the FSAR by reference. The NRC staff will consider adding guidance regarding whether to include information about the TRM, which is not included in the certified design review, in the COL application. The TRM is distinct from availability controls, which are addressed elsewhere in the guidance.

Disposition: No changes were made to the guidance in response to this comment.

C.I.16.1-2 The third sentence in the third paragraph of Section C.I.16.1 should be revised to state "References to the applicable sections of the SAR/COL application that support the bases and provide clarifying details of each specification should be supplied in the Reference section of the COL technical specification bases, consistent with the level of detail of references provided in the approved generic technical specifications bases for the certified design." This statement provides additional guidance on where to provide the information and on the appropriate level of detail.

Response: The NRC staff agrees with the comment.

Disposition: The guidance was revised to state that the proposed TS bases should list references used in support of writing the bases.

C.I.16.1-3 The last sentence in the third paragraph of Section C.I.16.2.1 indicates "Justification should be provided for deviations from the certified design generic or standard technical specifications pertinent to the selected nuclear steam supply system (NSSS) vendor." This should be clarified to indicate that the justifications for differences need not be in the final safety analysis report (FSAR)/design control document (DCD), but could be provided as a separate document.

- Response:** The NRC staff acknowledges that the guidance could be misconstrued regarding the location of justifications for deviation from the referenced model TS.
- Disposition:** The guidance was revised to state that the COL application should justify deviations from the referenced model TS, either a certified design generic TS or the applicable standard TS.
- C.I.16.1-4** In the second and seventh lines in paragraph 10 in Section C.I.16.1, a reference is made to manuals, reports, and program document identified in technical specifications administrative controls section "or other applicable governing regulations." Since this draft SRP section only addresses technical specifications, references to "or other applicable governing regulations" should be deleted.
- Response:** Some TS administrative control requirements are derived from regulatory requirements other than TS; the guidance simply notes this fact.
- Disposition:** No changes to the guidance were made in response to this comment.
- C.I.16.1-5** The industry believes it may be appropriate for combined license (COL) applications to address the applicability of Technical Specifications between COL issuance and fuel load so that there is a documented, mutual understanding of the implementation process during this period. This discussion may not be appropriate for Section 16.1 but should be documented. Under a Part 50 Operating License, Tech Specs became effective when the license was issued. Under Part 52, the license will be issued before major construction begins, so there will be discrepancies between the Tech Specs and the "plant" when the COL is issued. It may also be necessary to reflect this understanding in the license.
- Response:** This NRC staff acknowledges that the COL should contain a condition regarding when the plant-specific TS must be complete, that is, when all bracketed information must be supplied. The NRC staff will consider whether the guidance should address this implementation issue.
- Disposition:** No changes to the guidance were made in response to this comment, but may be in the next draft.
- C.I.17.4-1** Industry provided a pre-workshop comment that an operational reliability assurance process (ORAP) was not required to be implemented based on the standard requirements memorandum (SRM) for SECY 94-084 and SECY 95-132. In a written response, the staff stated that it disagreed and that an ORAP was required. No regulatory basis for the position was cited. The staff has not presented positions consistent with SECY 94-084 [“The Commission (with all Commissioners agreeing) has disapproved the staff’s proposal to require that an O-RAP be continued for the life of the COL license. The staff should ensure that the objectives of the O-RAP are incorporated into existing programs for maintenance or quality assurance.”] and SECY 95-132. [“The staff removed the requirement that a separate O-RAP exist for the life of the plant”]. Further the staff in SECY 95-132 concluded that the objectives of operational reliability assurance are adequately addressed by maintenance rule and quality assurance programs compliant with existing regulations with the exception of one small scope issue which would be

addressed by a COL action item. Industry would be interested in discussing this issue further with the staff when industry SMEs are available.

Response: See response to C.I.17.4.1-1.

Disposition: No change to DG-1145

C.I.17.4-2 The combined license (COL) DRAP for an application referencing a certified design will consist of the generic design control document (DCD) DRAP and the COL scope DRAP. Since the generic DCDs include the bulk of the information for the plant design, the COL scope should be much smaller and focus on the design scope outside the certified design. Does the Staff agree, for this case, that the COL application should reference the applicable generic DCD and add specific information related to the applicant scope design? Of course, the DRAP for the entire plant scope would be the responsibility of the COL holder.

Response: The NRC agrees with the comment.

Disposition: No change to DG-1145.

C.I.17.4-3 In general, the guidance is written similar to an SRP with direction for the staff to review certain material in an application. Directing the guidance to the applicants would make it more clear what is expected in an application versus the information maintained outside the final safety analysis report (FSAR) that the NRC staff may audit.

Response: The NRC agrees that guidance in DG-1145 should be for the applicants to help them understand what information should be provided in a COL application. This section is written with input from the SRP and is intended to be consistent with the SRP. If the section appears to include staff guidance, this will be edited to make it consistent with the approach the staff is taking in the rest of the chapters of C.I. During this process NRC staff will seek to clarify, wherever possible, that information which would be expected in the SAR versus information in the COL application that would be maintained outside the SAR, and of course, subject to NRC audit and inspection.

Disposition: The NRC will review this section and make edits where appropriate to be consistent with the approach the NRC is taking in the rest of the chapter of C.I in the Regulatory Guide.

C.I.17.4.1-1 Section C.I.17.4.1 states that a combined license (COL) applicant is responsible for developing and implementing an operational reliability assurance process (ORAP). This statement is inconsistent with the Staff's response to the Commission SRM for SECY 94-084 as indicated in SECY 95-132, Attachment 2. In those documents, the staff agreed that the objectives of a stand-alone ORAP could be accomplished through implementation of existing regulatory requirements such as the Maintenance Rule, 10 CFR 50.65, and 10 CFR 50, Appendix B, quality assurance (QA) Program. The requirement to "develop and implement" an ORAP seems to be inconsistent with the Commission direction and previous staff guidance.

Response: The NRC disagrees with the comment which states that the requirement for COL applicants to develop and implement an ORAP is inconsistent with the position in SECY 95-132. COL applicants (or holders) will have to develop and implement an ORAP and

they may choose to use Maintenance Rule and 10 CFR 50, Appendix B, QA Programs, or other programs. However, COL applicants (or holders) will have to supplement Maintenance Rule and QA Programs (over what is in current programs) if they choose to use them to implement the ORAP.

Disposition: No change to DG-1145.

C.I.17.5-1 The industry made a number of significant comments on SRP Section 17.5. The industry has similar concerns about Section 17.5 of DG-1145. See NEI letter dated April 11, 2006.

Response: Comment noted.

Disposition: The NRC will review the NEI letter dated April 11, 2006.

C.I.17.5-2 The level of detail that is being proposed for this Section of DG-1145 is normally covered in utility implementing procedures. If this level of detail needs to be in the combined license (COL) application there won't be a need for implementing procedures. The industry would expect to have program level information in the COL application. Utilities are typically reference Standards that they commit to in the quality assurance program document (QAPD) and does not discuss the details contained in the standards in the QAPD. The details of implementation are typically left to implementing procedures.

Response: The purpose of SRP Section 17.5 was to place all QA provisions in one place to ensure the quality and uniformity of staff safety reviews. SRP Section 17.5 is mainly based on American Society of Mechanical Engineers (ASME) Standard NQA-1 (1994 Edition). The detail in SRP Section 17.5 is similar to the detail in NQA-1. As with other chapters in DG-1145, Section 17.5 of the DG was written to be consistent with the latest SRP section. Committing to use NQA-1 would significantly reduce the level of detail in the QAPD. However, in some instances, the NRC cannot reference a standard because there is no standard available.
10 CFR 50.34(b)(6)(ii) requires that the information on the controls to be used for a nuclear power plant include a discussion on how the applicable requirements of Appendix B will be satisfied. The applicant or holder must describe how each of the acceptance criteria is met.

Disposition: No Change to DG-1145.

C.I.17.5-3 Section C.I.17.5 does not clearly delineate between construction and operational requirements.

Response: ASME NQA-1 is for the construction or operational phase of a plant. The NRC found very few QA requirements that were only for construction or operation. In Draft Section 17.5 (of the SRP) the staff identified provisions that only applied to construction or operation. Public comments on Draft Section 17.5 identified additional provisions that would only apply to construction or operation that are being incorporated.

Disposition: No change to the Regulatory Guide.

C.I.17.5-4 The first paragraph of Section C.I.17.5.2 implies that a quality assurance program document (QAPD) submitted for both construction and operational phases must be in accordance with SRP 17.5. However, most combined license (COL) applicants already have existing nuclear plants with their quality assurance program documents QAPDs approved under standard review plan (SRP) Section 17.3. The Note on 17.5.1 indicates that SRP 17.5 will be used by NRC reviewers not Sections 17.1, 17.2, and 17.3. In light of the above, is the NRC saying that if you have an existing SRP Section 17.3 based on self assessment and performance based assessments, that it can't be used during the operational phase. Current QAPDs are already approved by the NRC and it wouldn't make any sense to have two different QA Programs in the same fleet of plants. Utilities have typically tried to have common program within a fleet of plants. Please clarify.

Response: 10 CFR 50.34(h) and 10 CFR 52.79(b) require that COL applicants or holders include an evaluation of the facility against the SRP that is in effect 6 months prior to the docket date of the application of a new facility. COL applicants may use an existing QAPD for the operational phase for current use provided that alternatives to or differences from the SRP in effect 6 months prior to the docket date of the application of a new facility are identified and justified.

Disposition: No change to Regulatory Guide.

C.I.17.5.1-1 In Section C.I.17.5.1 on page 7, provisions are made for an applicant to propose and justify using the existing quality assurance (QA) program for its operating "fleet." What is the process for using the existing "fleet" QA program? Are exceptions required to the bases documents of standard review plan (SRP) 17.5, since many existing programs are based on earlier guides and standards?

Response: 10 CFR 50.34(h) and 10 CFR 52.79(b) require that combined license (COL) applicants or holders include an evaluation of the facility against the SRP that is in effect 6 months prior to the docket date of the application of a new facility. COL applicants may use an existing QAPD for the operational phase for current use provided that alternatives to or differences from the SRP in effect 6 months prior to the docket date of the application of a new facility are identified and justified.

Disposition: No change to DG-1145.

C.I.17.5.1-2 Section C.I.17.5.1 on page 7, a statement is made that an applicant should incorporate the most recently NRC-endorsed standard. For those utilities developing a quality assurance program document (QAPD) based on NQA-1-1994, can provisions be made to accept this standard even though a later version may be endorsed by the time a combined license (COL) application is submitted? Related to this, does the NRC envision issuing new versions of RG 1.28 and RG 1.33 endorsing later versions of NQA-1 and ANS-3.2?

Response: The NRC does not plan to revise Regulatory Guide (RG) 1.28 or RG 1.33. The NRC is reviewing a later version of NQA-1. It is not known at this time when the NRC will be able to approve the later version. COL applicants would not be required use a later NRC-approved version of NQA-1 unless it is incorporated into SRP Section 17.5 six months prior to the docket date of the application of a new facility. The NRC does not plan on endorsing a later version of ANS-3.2.

Disposition: No Change to DG-1145.

C.I.17.5.1-3 On page 8 in Section C.I.17.5.1, a requirement is imposed to address planned sharing of personnel for stations that incorporate, or plan to incorporate, other nuclear or non-nuclear power generating facilities. Any planned sharing of personnel would be pure speculation at the time the combined license (COL) application is submitted. This level of detail is not necessary to implementing the QA program or programs at a respective station.

Response: The staff expects COL applicants to provide a complete description for implementation of the QA program. If changes are made to the implementation process, then the staff expects to be notified, as required.

Disposition: No change to DG-1145.

C.I.17.5.1.1-1 During the last thirty years there have been a number of items that have been eliminated through NRC and utility review and are not performed in current quality assurance (QA) programs. Items 4 and 8 (in line reviews) are examples of this. The NRC should eliminate items in section C.I.17.5.1.1 that they have reviewed and approved for utilities to reduce their QA Program commitments.

Response: The staff is conducting a review of QA Program safety evaluations to identify items that have been eliminated and will revise DG-1145 and SRP Section 17.5 to be consistent with the safety evaluations.

Disposition: The Regulatory Guide will be revised as appropriate to be consistent with the safety evaluation.

C.I.17.5.3-1 The second bullet in section C.17.5.3.B suggests that the utility provide and maintain a complete list of structures, systems, and components (SSCs). Industry uses drawings and other means to accomplish this same function. This should be written such that the utility will describe the method to identify SSCs to which the program applies.

Response: The NRC does not agree with this comment. Criterion II in Appendix B in 10 CFR 50 states that the applicant shall identify the structures, systems, and components to be covered by the quality assurance program.

Compliance with 10 CFR 52.47(a)(1)(ii) and 10 CFR 52.79(b) requires compliance with 10 CFR 50.34(f)(3)(ii) and (iii). The requirements of 10 CFR 50.34(f)(3)(ii) and (iii) are applicable because they require 1) all SSCs important to safety be listed in accordance with Criterion II of Appendix B to 10 CFR Part 50.

Disposition: No change to DG-1145.

C.I.17.5.3-2 In regards to Bullet 4 in Section C.I.17.5.3.F, quality assurance (QA) review and concurrence on procedures has been removed from current QA programs under approved NRC safety evaluation reports (SERs). Bullet 5 in section C.I.17.5.3.F describes periodic procedure reviews. This level of detail is similar to comments in item 2. Bullet 7 should be sufficient to address procedure review and feedback for improvement of procedures.

Response: The NRC will revise Bullet 4 to be more consistent with 10 CFR 50.34(f)(3)(iii). The requirements of 10 CFR 50.34(f)(3)(iii) are applicable because they require QA personnel be included in the documented review and concurrence in quality-related procedures associated with design, construction, and installation.

The NRC agrees with the comment on Bullet 7 and DG-1145 and SRP Chapter 17.5 will be revised accordingly.

Disposition: DG-1145 will be changed.

C.I.17.5.3-3 Section C.I.17.5.3.Y seems to imply that a utility would put non safety related structures, systems, and components (SSCs) into their quality assurance (QA) program. This is not required in current operating plant QA Programs. (Note: Unlike draft SRP 17.5.Y.1, DG-1145 does not make the distinction between applicants for passive advanced light water reactor designs or COL holders that choose to implement 10 CFR 50.69, and the other applicants.)

Response: The NRC agrees with this comment.

Disposition The Regulatory Guide will be revised to be consistent with SRP Chapter 17.5.

C.I.17.5.3-4 There is very little guidance in section C.I.17.5.3.Y. It is not married well to the SECY 94-084 and 95-0132 regulatory treatment of non-safety systems (RTNSS) guidance and it should be.

Response: There is no RTNSS guidance in DG-1145. The NRC is evaluating how to address RTNSS.

Disposition: No change to DG-1145.

C.I.17.5.3-5 In Section C.I.17.5.3.Y there is no explicit mention of "availability controls." The expectation was that this section would provide us with the answer as to where we put regulatory treatment of non-safety systems (RTNSS) Availability Controls. Currently D-RAP, operational reliability assurance process (O-RAP), and Maintenance Rule are part of 17.4 and 17.6. RTNSS controls can make sense here. (Although in AP1000 they are in Table 16.3-1) Recommend the actual "Specs" as an Appendix to Chapter 17, or IBCRef within 17.4 to an external document (e.g., current fleet "TRM" like document).

Response: There is no RTNSS guidance in DG-1145. The NRC is evaluating how to address RTNSS.

Disposition: No change to DG-1145.

C.I.17.5.3-6 Section C.I.17.5.3.Z is not clear. Does this mean Nuclear Safety Review Board, Independent Safety Engineering Group (ISEG), etc. Additionally, some utilities have eliminated this requirement in their quality assurance (QA) Program. This was achieved through NRC reviews and safety evaluation reports (SERs). Are we locked into the DG-1145 independent review process or can we use an existing approved process?

- Response:** NRC safety evaluations have approved revisions to independent review program requirements but have not approved the elimination of independent review programs. Draft Section C.I.17.5 provides detailed guidance on independent review which would allow a Nuclear Safety Review Board or ISEG to conduct independent review activities.
- Disposition:** No change to the guide.
- C.I.17.6-1** Does Section C.I.17.6 imply that the maintenance rule systems are scoped into the quality assurance (QA) Program.
- Response:** Not necessarily. There is no Maintenance Rule (MR) requirement to include structures, systems, and components (SSCs) that are in MR scope as defined in paragraph 50.65(b) in a quality assurance (QA) program. Conversely, there is no requirement in Appendix B to include the SSCs within its scope, i.e., safety-related SSCs, in the MR program. However, there are SSCs that by virtue of their being safety-related happen to be included in both MR scope under paragraph (b)(1) and Appendix B scope. In addition, standard review plan (SRP) 17.5 states that in passive designs, high-safety-significant SSCs that are non-safety-related should be covered by a QA program of some sort. There will likely be non-safety-related SSCs in the MR scope under paragraph (b)(2) that are classified as high-safety-significant under the MR program. Therefore, there may be non-safety related SSCs in the MR scope that happen to be under a QA program as well because of being high-safety significant and part of a passive design, but not because of being in the MR scope.
- Disposition:** No change to the guide.
- C.I.17.6-2** It is not clear exactly what needs to be in the combined license (COL) application and what can simply be in the quality assurance program document (QAPD).
- Response:** The QAPD (construction and operation) would be included in the COL application. SECY-05-0197 requires that all operational programs be fully described in a COL application.
- Disposition:** No change to the guide.
- C.I.17.6-3** This section of the draft guidance provides a comprehensive listing of everything that is required to implement a Maintenance Rule Program. In fact, there are some items, e.g., qualification and training, that are beyond the scope of the maintenance rule. The section does not provide guidance for what should be included in a combined license (COL) application versus the information maintained outside the final safety analysis report (FSAR) that the NRC staff may audit.
- Response:** The comment is correct. The reason the first draft was as described by the commenter has been explained.
- Disposition:** The maintenance rule section will be revised to explain what should be in the COL application, what should be maintained outside the FSAR and what will be inspected.
- C.I.17.6-4** Some of the information required by this section will not be available at the time the combined license (COL) is prepared. The guidance should reflect that some maintenance rule program information will be developed post COL application and will

be maintained outside the final safety analysis report (FSAR).

Response: The staff recognizes that much of the information listed in the Maintenance Rule section may not be known or developed by the time of the application.

Disposition: The draft guide will be revised to call for information to be provided that is known at the time of the COL application. For information requested that is not yet known, the applicant will be requested to explain why it is not yet known and estimate when it will be known.

C.I.17.6-5 The content specified in the draft guidance and discussed in the presentation exceeds what should be necessary for a combined license (COL) application review and reasonable assurance finding. The staff presenter agreed that much of the information was not appropriate for a COL application. That leaves the question of what should be included in an application. Industry would like to review the next draft of this section and provide input when it is available. NUMARC 93-01 has been endorsed by the NRC as an acceptable method for implementing the Maintenance Rule. A commitment in the COL application to implement in accordance with the guidance including justification of any exceptions should be sufficient level of detail for a program description for the staff to make a reasonable assurance finding.

Response: The goal in the first draft was to include, for the benefit of applicants, everything that the NRC anticipated needing to know about an applicant's Maintenance Rule program sooner or later. The NRC recognizes that more was included than the absolute minimum needed in a COL application for a finding of reasonable assurance. However, per SECY 05-197, operational programs need to be fully described and fully described means that where applicant's make choices regarding implementation within the regulatory framework, to the extent that such choices are known, or should be known by the time a COL application is submitted, they should be explained as part of the program description in the application.

Disposition: Items in the draft guide Maintenance Rule section that are more than the absolute minimum required for a finding of reasonable assurance in accordance with the guidance in SECY 05-197 will be deleted from Maintenance Rule section.

C.I.17.6-6 The content specified in the draft guidance and discussed in the presentation exceeds what should be necessary for a combined license (COL) application review and reasonable assurance finding. The staff presenter agreed that much of the information was not appropriate for a COL application. That leaves the question of what should be included in an application. Industry would like to review the next draft of this section and provide input when it is available. NUMARC 93-01 has been endorsed by the NRC as an acceptable method for implementing the Maintenance Rule. A commitment in the COL application to implement in accordance with the guidance including justification of any exceptions should be sufficient level of detail for a program description for the staff to make a reasonable assurance finding.

Response: See response to previous comment.

Disposition: See disposition to previous comment.

C.I.17.6-7 Site personnel qualification and functional descriptions in DG-1145, Section C.I.17.6 should be consistent with Section C.I.13.1. The guidance in these two sections for describing functional positions (e.g., level of detail) should be consistent. Also, the functional position "titles" should be consistent with section C.I.13.1 (e.g., use "licensed operators" and "non-licensed operators" rather than "senior reactor operator," "reactor operator," "plant operator," etc.). The detailed personnel qualification and titles would not be in the final safety analysis report (FSAR), but would be available on-site for NRC audit prior to fuel load.

Response: The NRC recognizes that Maintenance Rule-cognizant staff titles vary among licensees.

Disposition: The level of detail discussed will be reduced to more general functional descriptions.

C.I.17.6-8 Site personnel training program descriptions in Section C.I.17.6 should be consistent with Section C.I.13.2, including guidance on level of detail for listing training courses and listing the topics covered in the courses. The detailed training documents and course content would not be in the final safety analysis report (FSAR), but would be available on-site for NRC audit prior to fuel load.

Response: No particular training courses are listed in C.I.17.6. They vary among applicants. The application should give a general description of the Maintenance Rule training to be received by the personnel listed by functions or their equivalents.

Disposition: No change to the draft guide.

C.I.17.6-9 Site procedures and database descriptions for maintenance rule (MR) implementation should be consistent with section C.I.13.5, e.g., guidance that addresses description level of detail for site procedures. Also, since MR is an operational program, the guidance in C.I.17.6 should be consistent with guidance in C.IV.4 for operational programs.

Response: The Maintenance Rule section asked for a general description of procedures, including information preparation and review, compliance, and maintenance.

Disposition: To the extent practicable, the requests for procedural descriptions will be made consistent with C.I.13.5 and C.IV.4 as applicable.

C.I.17.6-10 The risk ranking method in NUMARC 93-01 and Regulatory Guide 1.160 is not appropriate for advanced plant designs. The particular problem is with the Risk Achievement Worth criterion. This is a relative risk ranking method, and the line of demarcation was set based on plants with a core damage frequency of approximately $1e-5$. Because the Commission's safety goal is a CDF of less than $1e-4$, components whose failure could contribute 10% of this value (or even 1% of this value) should be considered risk significant; therefore the $RAW > 2$ criterion is appropriate for the operating plants. For advanced designs whose CDF is on the order of $1e-7$ to $1e-8$, the threshold is not appropriate. This would be saying that components whose failure contributes to 0.1% - 0.01% to the safety goal are significant. These types of values are typically used to justify that components or issues are, in fact, negligible.

We look forward to working with the NRC staff to develop appropriate risk ranking guidance for advanced plants with low-low CDFs.

Response: The staff agrees. The Maintenance Rule section called for explanation of and justification for deviations from NUMARC 93-01. The staff recognizes that the characteristics of advanced designs will require such explanation and/or justification as it will be sometimes necessary to deviate from the industry guidance in various areas in which it does not reflect those characteristics. Such explanations and justifications will provide valuable input to revisions to the guidance applicable to advanced designs.

Disposition: No change to the draft guide is required for this comment.

C.I.17.6-11 New plants currently under consideration have not been completely designed to the detail implied by the proposed DG-1145 maintenance rule methodology. It is universally recognized that the detailed design of the plant is not needed for certification or initial licensing applications, therefore the information needed to implement the methodology would not exist at the time of the application. Detailed information about the structure, systems, and components (SSCs) is not available until near the end of construction. As we have discussed with the NRC, to avoid this problem, we recommend an approach based on describing the maintenance rule program in the final safety analysis report (FSAR) and committing to implementation prior to fuel load.

Response: See response to Comment C.I.17.6-4.

Disposition: See disposition of Comment C.I.17.6-4.

C.I.18-1 C.I.18 states that "by the time of COL application submittal the first 11 elements should be complete" (p.2). This is infeasible, and it conflicts with prior understandings between industry and NRC.

Response: The staff understands the comment and will edit the text accordingly.

Disposition: The paragraph that contained the referenced text has been rewritten.

C.I.18-2 Of the 12 elements, those not completed in Design Certification are covered by DAC/ITAAC. Detailed documentation of the activities fulfilling DAC/ITAAC will not be submitted to NRC, but will be held for NRC inspection. The guidance should reflect the distinction between safety review of licensing submittals and NRC inspection of design implementation.

Response: Industry stated at the July 12, 2006, workshop that they would provide the staff a re-written DG-1145 Section C.I.18 at a later date. The staff will review that re-write for changes related to the comment.

Disposition: This comment will be addressed when the final guide is issued

C.I.18-3 C.I.18 should cite applicable documents as needed, and should not repeat, paraphrase, or revise available guidance.

Response: Industry stated at the July 12, 2006, workshop that they would provide the staff a re-written DG-1145 Section C.I.18 at a later date. The staff will review that re-write for changes related to the comment.

Disposition: This comment will be addressed when the final guide is issued

C.I.18-4 C.I.18 should not be used to extend NUREG-0711 guidance for Ch.18 content, scope, or analysis such as:

- a. Defining individual roles in OER for all similar predecessor plants(C.I.18.2.2.2)
- b. Treatment of new technologies as OER issues (C.I.18.2.2.2, .2.2.4)
- c. Verification of the functional requirements analysis (C.I.18.3.2.1)
- d. Verification of the function allocation... "to show that the allocations of functions result in a coherent role for plant personnel" (C.I.18.3.2.2)
- e. HRA activities in excess of PRA requirements and risk-important human actions (C.I.18.6)
- f. Identifying how HSI characteristics will minimize fatigue (C.I.18.7.2.5)

Response: It is important to note that NUREGs -0800 and 0711 PROVIDE guidance and review criteria that the staff uses to review applicant submittals. The NUREGs do not provide guidance on the content for applicant submittals, which is the purpose of DG-1145.

Industry stated at the July 12, 2006, workshop that they would provide the staff a re-written DG-1145 Section C.I.18 at a later date. The staff will review that re-write for changes related to the comment.

Disposition: This comment will be addressed when the final guide is issued

C.I.18-5 Alternative design concepts (C.I.18.7.2.4) are not appropriate in the FSAR, and if developed, they would not be described in the FSAR. In general, much of the specific material and level of detail called for in C.I.18 is excessive and would not be contained or referenced in an FSAR, but would be held available for NRC audit.

Response: Industry stated at the July 12, 2006, workshop that they would provide the staff a re-written DG-1145 Section C.I.18 at a later date. The staff will review that re-write for changes related to the comment.

Disposition: This comment will be addressed when the final guide is issued

C.I.18-6 The term "minimum inventory" is used with two different meanings. In C.I.18.4.2 it is an outcome of Task Analysis, which implies it is the total set of HSI required for all analyzed tasks. In C.I.18.7.3.2 it refers to fixed position HSI required to support plant safety, which implies it is a subset of the total set of HSI. The staff should clarify the distinction.

Response: Industry stated at the July 12, 2006, workshop that they would provide the staff a re-written DG-1145 Section C.I.18 at a later date. The staff will review that re-write for changes related to the comment.

Disposition: This comment will be addressed when the final guide is issued

C.I.18-7 Where it is left to the applicant to decide whether supporting documentation would be helpful, the word "should" is to be replaced with "may". (Consider comment for global application)

Response: Industry stated at the July 12, 2006, workshop that they would provide the staff a re-written DG-1145 Section C.I.18 at a later date. The staff will review that re-write for changes related to the comment.

Disposition: This comment will be addressed when the final guide is issued

C.I.18-8 It is suggested that the following is stated in the introduction:

-It is not the intent for the design guidance document to supercede 0711.

- Where conflicts in interpretation arise between DG-1145 and 0711/SRP Chapter 18, then 0711 and SRP Chapter 18 are the governing documents.

Response: Industry stated at the July 12, 2006, workshop that they would provide the staff a re-written DG-1145 Section C.I.18 at a later date. The staff will review that re-write for changes related to the comment.

Disposition: This comment will be addressed when the final guide is issued

C.I.18-9 If effort is to emphasize RAIs in prior submittals, then areas causing RAIs.

Response: This appears to be an incomplete question/comment.

Disposition: As this is an incomplete question/comment, no disposition is provided.

C.I.18-10 Section C.I.18 states that "by the time of COL application submittal the first 11 elements should be complete" (p.2). This is infeasible, and it conflicts with prior understandings between industry and NRC. Please confirm that the NRC agrees and will change the guide.

Response: See response to item C.I.18-1.

Disposition: See disposition in item C.I.18-1.

C.I.18-11 Of the 12 elements, those not completed in Design Certification are covered by design acceptance criteria (DAC) and inspection, test, analysis, and acceptance criteria (ITAAC). Detailed documentation of the activities fulfilling DAC and ITAAC will not be submitted to NRC, but will be held for NRC inspection. The guidance should reflect the distinction between safety review of licensing submittals and NRC inspection of design implementation. It is understood the at other sections of DG-1145 may generically clarify the DAC and ITAAC process

However, consistent with such clarification, C.I.18 should address the use of DAC and ITAAC for human factors engineering (HFE) elements not complete at combine license (COL) application.

Response: See response to item C.I.18-2.

Disposition: See disposition in item C.I.18-2.

C.I.18-12 C.I.18 should cite applicable documents as needed, and should not repeat, paraphrase, or revise available guidance. Understood from the workshop that the NRC feel some degree of repetition and some revised or additional guidance is necessary, one goal being to reduce the number of request for additional information (RAIs) resulting from applicant reviews. The industry maintains that, if the applicable review guidance is not being modified, then specific citations to the source guidance should be used wherever possible instead of restating, paraphrasing or reordering the words (and potentially the meaning) of the sources.

Response: See response to item C.I.18-3.

Disposition: See disposition in item C.I.18-3

C.I.18-13 Section C.I.18 should not be used to extend NUREG-0711 guidance for chapter 18 content, scope, or analysis. Understood from the workshop that the Staff expect NUREG-0711 to be revised again soon. Therefore, to the extent that C.I.18 text anticipates new or changed content for the forthcoming NUREG-0711 revision (e.g., to reduce RAIs), it is requested that such DG-1145 text be identified as reflecting added review guidance (i.e., beyond the source review guidance which it is hoped will be cited).

Response: Industry stated at the July 12, 2006, workshop they would provide the staff a re-written DG-1145 Section C.I.18 at a later date. The staff will review the re-write for changes related to the comment.

Disposition: This comment will be addressed when the final guide is issued.

C.I.18-14 The term "minimum inventory" is used with two different meanings. In section C.I.18.4.2 it is an outcome of Task Analysis, which implies it is the total set of human-system interface (HSI) required for all analyzed tasks. In section C.I.18.7.3.2 it refers to fixed position HSI required to support plant safety, which implies it is a subset of the total set of HSI. The staff should clarify the distinction.

Response: See response to item C.I.18-6.

Disposition: See disposition in item C.I.18-6.

C.I.18.7.2.4-1 Alternative design concepts (C.I.18.7.2.4) are not appropriate in the final safety analysis report (FSAR), and if developed, they would not be described in the FSAR. In general, much of the specific material and level of detail called for in Section C.I.18 is excessive and would not be contained or referenced in an FSAR, but would be held available for NRC audit.

Clarification: The NRC review guidance such as NUREG-0711 has been used successfully by the industry to address the content of its Ch.18 submittals to date, and the industry is aware of its technical content. "Complete" technical content and detail will be provided by the sum of applicant information that will be available to the NRC by

different vehicles (e.g., FSAR content, FSAR references, supplemental submittals, and information retained for Staff audit). Section C.I.18 should clarify (specifically, by reference to the detailed guidance on contents) the levels of reduced technical detail (versus complete details retained by the applicant for NRC audit) that would be acceptable for FSAR submittals.

Response: Industry stated at the July 12, 2006, workshop that they would provide the staff a re-written DG-1145 Section C.I.18 at a later date. The staff will review that re-write for changes related to the comment.

Disposition: This comment will be addressed when the final guide is issued

C.I.19-1 The last sentence in the last paragraph in Section C.I.19 Probabilistic Risk Assessment and Severe Accidents, states, "Chapter 19 should reference the applicable analyses and evaluations and the necessary supporting information to demonstrate compliance with the above requirements and Commission policies."

Please clarify the use of the language "should reference." We assume that a summary description of supporting information is an acceptable alternative to including all references.

Response: The NRC staff agrees with this comment. The staff does not expect the applicant to reference all supporting information that may be applicable. A summary description of the supporting information is acceptable.

Disposition: Section C.I.19 has been revised to provide clarification

C.I.19-2 In Sections C.I.19.2.3 and C.I.19.2.4 the language, "Identify important SSCs and operator actions (considering both failures and reliabilities)," is used in several subsections.

Please clarify the meaning of the word "reliabilities" in the above language.

Response: The intent of the phrasing is to ensure that important SSCs and operator actions are identified, which is typically achieved using importance measures such as risk achievement worth and Fussell-Vesley importance measures. The parenthetical statement has been replaced with the above more specific information.

Disposition: DG-1145 has been revised to provide clarification.

C.I.19.2.2.2-1 Section C.I.19.2.2.2 includes a discussion of design, COL application, construction and operational phases.

We assume the intent is for the COL applicant to describe at a summary level planned uses of PRA for the phases which occur after COL application (i.e., for the construction and operational phases.)

Please clarify the intent of the language in this section.

Response: The NRC staff agrees with this comment. The intent of these subsections is to identify the supporting uses and risk-informed applications of the PRA during the specific phases. At the time of COL application, the information provided for the construction and

operational phases will be a summary description of the planned uses and applications of the PRA. However, when in the specific phase, the staff expects the applicable section to be updated (as part of the FSAR update process) to provide a summary description of the actual uses and applications of the PRA. Thus, for example, the operational phase discussion may need to be updated when new risk-informed applications of the PRA are identified and approved for implementation (e.g., risk-informed inservice inspection, 10 CFR 50.69 implementation).

Disposition: DG-1145 has been revised to provide clarification.

C.I.19.2.2.3.1-1 C.I.19.2.2.3.1 Use of PRA in Support of Licensee Programs provides, "Describe use of the PRA in the construction phase and specifically its use in support of other licensee programs (e.g., maintenance rule, construction inspection, interface with the reactor oversight program, human factors program).

We recommend deleting the example "construction inspection" as the construction inspection program is not a licensee program. Use of PRA to support the NRC's CIP is discussed in IMC-2503.

Response: The NRC staff agrees with this comment.

Disposition: The phrase "construction inspection" has been deleted.

C.I.19.2.5-1 Section C.19.2.5, summary of Overall Plant Risk Results and Insights includes, "This section should provide the overall results and insights from the plant-specific PRA. In particular, identify the plant features, including non-safety related systems, and operator actions that are important to reducing risk and confirm that the expectation stated in 10 CFR 52.79(a) (2) is met. Include a PRA-based insights table that identifies the PRA-based insights that ensure the assumptions and plant operational features addressed in the PRA will remain valid in the as-built, as-to-be-operated plant."

We assume that the "PRA-based insights" table in this last sentence refers to "plant features" which is included in the second sentence, and that the text and tabulation would be a summary. Please clarify.

Response: The intent of the phrase "PRA-based insights" includes those insights deemed important to maintaining the validity of the PRA and includes assumptions regarding SSC and operator performance and reliability, ITAACs, interface requirements, plant features, design and operational programs, etc. The usage of this phrase is consistent with its reference to the information provided in Table 19.59-29 in the AP-600 and AP-1000 Design Control Documents (DCDs). The NRC staff expects a similar level of information to be provided in this section of the FSAR.

Disposition: No change to DG-1145.

C.I.19.4.1-1 19.4.1 Description of PRA Maintenance and Update Program: The second paragraph in this section states, "Describe how the applicant ensures the PRA maintains the appropriate scope, level of detail, and technical adequacy consistent with its uses and consistent with the prevailing PRA standards, guidance, and good practices."

This section addresses the entire operating lifetime of the plant, in addition to design, COL application and construction phases. The use and appropriateness of standards and guidance will change during the above phases. Therefore, we recommend that the language "consistent with the prevailing PRA standards, guidance, and good practices" be replaced by "consistent with the prevailing PRA standards, guidance, and good practices, as needed to support use of the PRA", and include a provision to reference an NRC review of the PRA as an alternative to explicitly addressing this language.

Response: The NRC staff agrees with this comment.

Disposition: DG-1145 has been clarified to make it clear that the plant-specific PRA should meet NRC-endorsed standards, guidance, and good practices, consistent with the Commission's phased approach to improving PRA quality as needed to support the plant-specific PRA uses and risk-informed applications.

C.I.19.4.1-2 19.4.1 Description of PRA Maintenance and Update Program: The last paragraph states, "Identify how the plant-specific PRA is maintained up-to-date by including the projected frequency of updates of the plant-specific PRA to meet existing standards that will be reflected in revisions to the FSAR (e.g., the PRA will be updated to reflect plant, operational, and PRA modeling changes, consistent with NRC-endorsed standards in existence 1 year prior to issuance of the update, which will be every other fuel cycle, not to exceed 5 years)."

As noted above, this section addresses the entire operating lifetime of the plant, in addition to design, COL application and construction phases. The use and appropriateness of standards and guidance will change during the above phases. We recommend the language, "(e.g., the PRA will be updated to reflect plant, operational, and PRA modeling changes, consistent with NRC-endorsed standards in existence 1 year prior to issuance of the update, which will be every other fuel cycle, not to exceed 5 years)" either be deleted, as it is unnecessary, or be replaced with "(e.g., the PRA will be updated to reflect plant, operational, and PRA modeling changes, consistent with PRA practices and NRC-endorsed standards, as needed to support use of the PRA, prior to issuance of the update, which will be every other fuel cycle, not to exceed 5 years)."

Response: The NRC staff agrees with this comment.

Disposition: DG-1145 has been clarified to make it clear that the plant-specific PRA should meet NRC-endorsed standards, guidance, and good practices, consistent with the Commission's phased approach to improving PRA quality as needed to support the plant-specific PRA uses and applications.

C.I.19.4.2-1 19.4.2 Description of Significant Plant, Operational, and Modeling Changes: This section includes a discussion of design, COL application, construction and operational phases.

We assume the intent is for the COL applicant to describe at a summary level planned uses of PRA for the phases which occur after COL application (i.e., for the construction and operational phases.) Note that this section appears to address the entire operating lifetime of the plant, in addition to design, COL application and construction phases. See, for example, Section "19.4.2.N Nth Operational Phase Changes." Therefore this section extends beyond COL application and issuance.

Please clarify the intent of the language in this section.

Response: The NRC staff agrees with this comment. The intent of this subsection was to identify the plant, operational, and modeling changes that significantly impact the plant-specific PRA results and insights over the life of the plant. However, this information does not need to be contained in the FSAR, as it should be provided in the applicant's description of FSAR changes, per the applicant's FSAR change process, when PRA results and insights identified in Section 19.2 are revised.

Disposition: DG-1145 has been revised to delete the associated subsections.

C.I.19.4.2-2 What is the regulatory basis for maintaining the historical list of probabilistic risk assessment (PRA) changes required in Section C.I.19.4.2? The final safety analysis report (FSAR) should describe the plant as it is, not how it was in the past. It is anticipated that the FSAR change process will include an evaluation of the change and this information will be retained as required.

Response: The NRC staff agrees with the comment and has deleted the associated subsections. The intent of this subsection was to identify the plant, operational, and modeling changes that significantly impact the plant-specific PRA results and insights over the life of the plant. However, this information does not need to be contained in the FSAR, as it should be provided in the applicant's description of FSAR changes, per the applicant's FSAR change process, when PRA results and insights identified in Section 19.2 are revised.

Disposition: DG-1145 has been revised as discussed in the response above.

C.I.19.4.2.3-1 19.4.2.3 Construction Phase Changes: This section states that "The plant-specific PRA should reflect the plant as it was constructed and in preparation for operations."

Any update of the plant-specific PRA, as necessary and appropriate, will lag the actual status of the plant, as time is required to complete and document the evaluation. Therefore, we recommend that this sentence be replaced with "The plant-specific PRA should reasonably reflect the plant as it is to be constructed and in preparation for operations."

Response: The NRC staff agrees with the comment regarding the lag time associated with maintenance updating or upgrading, as appropriate, the plant-specific PRA to reflect changes and has incorporated this perspective into the example text presented in Section 19.4 (i.e., the example includes the statement that the PRA maintenance update will be completed based on "... information available 6 months prior to the issuance of the maintenance update ..."). The specific subsection referred to has been deleted, but some of the text in this subsection has been brought into the main text of Section 19.4. Specifically, the text regarding the NRC staff expectation that the plant-specific PRA reasonably reflect the plant prior to startup, including incorporating previously deferred changes and findings during the PRA-related walkdowns during and immediately after construction.

Disposition: DG-1145 has been revised as discussed in the response above.

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.

Response: Comment noted.

Disposition: The title of Section C, Part II has been changed to “Additional Technical Information” to be consistent with the proposed 10 CFR 52.80.

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.

Response: The NRC staff agrees with this comment.

Disposition: DG-1145 has been revised to replace “needs to” with “should” throughout as appropriate.

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.

Response: The NRC staff disagrees with this comment. For the situation involving a COL application without a referenced design certification, the submitted PRA may involve COL action items or interface requirements since some PRA aspects may not be achievable at the time of the COL application, but may only be achieved during subsequent phases of construction or prior to initial startup (e.g., performing fire and seismic walkdowns). Therefore, it is expected that some action items or interface requirements will be identified for the COL plant-specific PRA that require resolution prior to operations, but after the COL application phase.

Disposition: No change to DG-1145.

C.II.1-3 During the workshop it was stated that a combined licence (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.

Response: The NRC staff agrees with this comment. The NRC staff agrees with the intent, but not all specific aspects, of the comment. It is not the NRC staff intention that the COL applicant address issues that were resolved in the design certification review or have to update the certified design PRA simply because there is more detailed information. Rather, the intent of the statement in the presentation was to make it clear that the starting point for a COL application PRA that references a certified design is the certified design PRA. The focus of the applicant, and the NRC staff review, should be on updating and upgrading, as appropriate, the PRA to reflect the specific site information, design and operational changes, aspects of the design and operations that are at a greater level of development detail than was available when the design was certified, and addressing COL issues (e.g., COL action items). For example, an update may need to address the ultimate heat sink configuration, switchyard and grid configurations, proposed procedures that may lead an operator to initiate a reactor trip or new procedures that may be relied upon for accident prevention or mitigation, design changes that have a positive or negative impact on the risk profile (e.g., adding another diesel generator or replacing diesel generators with a different offsite power source), or resolution of COL action items and interface requirements.

Disposition: No change to DG-1145.

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 COL applicants.

Response: The NRC staff agrees with this comment.

Disposition: DG-1145 has been revised to properly reflect that COL requirements are from 10 CFR 52.79 and 10 CFR 52.80. In addition, it is revised to clarify that, in the context of this part of DG-1145 (i.e., a COL application that does not reference a certified design), the applicant should ensure that the requirements of 10 CFR 52.47 are satisfied for the design being proposed in their COL application.

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 unacceptable levels". Is this measured with respect to the goals or the application-specific CDF? The NRC 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-1145. Please confirm that vulnerabilities are limited to those failures or combinations of failures that could cause the design to fail to meet stated objectives.

Response: The NRC staff agrees with this comment.

Disposition: DG-1145 has been revised to clarify that the applicant's PRA is used in the design process to: 1) identify and address potential design and operational vulnerabilities (i.e. failures or combinations of failures that are large risk contributors that could drive the risk to unacceptable levels with respect to the Commission's goals), 2) reduce or eliminate known weaknesses of existing plants that are applicable to the new design, by introducing

appropriate features and requirements, and 3) select among alternative features, operational strategies, and design options.

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?

Response: The NRC staff's basis for requiring a COL applicant to show that a design represents a reduction in risk over existing plants, is provided by the Commission's policy statement, entitled "Severe Reactor Accidents Regarding Future Designs and Existing Plants," issued on August 8, 1985. This policy statement, which is discussed in Appendix A, focuses on the guidance and procedures that the Commission has been using to certify new designs for nuclear power plants that have evolved from light water reactor (LWR) technology existing at that time. This policy statement affirms the Commission's belief that a new design for a nuclear power plant can be shown to adequately address severe accident concerns by demonstrating compliance with the requirements of Commission regulations, including the appropriate TMI requirements and the resolution of applicable unresolved safety issues (USIs) and generic safety issues (GSI). Therefore, the Commission expects new designs to achieve a higher standard of severe accident safety performance than plants contemporary with the issuance of the Commission's Severe Accident Policy Statement on August 8, 1985. The fact that severe accident concerns have been adequately addressed in the new design should be reflected in the PRA results as a reduction in risk.

Disposition: No change to DG-1145.

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.

Response: The NRC staff disagrees with this comment. The Commission directed the staff in the SRM on the proposed revisions to the 10 CFR Part 52 rule to include specific guidance regarding the PRA in the regulatory guide. In addition, there are numerous objectives for the use of the PRA, as identified in Section C.II.1.2. Demonstration that the QHOs are met is not an explicit objective, and has not been addressed in prior design certification reviews. The use of the 1E-6/year large release frequency (LRF) goal is consistent with Commission guidance. Meeting the LRF goal will generally assure that the early fatality QHO is met. As explained in the referenced footnote, the cited Commission goals of less than 1E-4/year for CDF and less than 1E-6/year for LRF were established in the Commission SRM dated June 26, 1990, in response to SECY-90-016. All certified designs approved by the NRC to date have addressed the LRF metric. Although not explicitly defined in the regulations, LRF represents the broader set of releases of which LERF is a subset. The difference between LRF and LERF is that LRF addresses the frequency of all large releases, not just those that occur "early." As an example of how LRF has been addressed by prior certified design applicants, the AP600 divided at-power LRF-related containment failures into two types: (1) initially failed containment, in which the integrity of the containment is either failed due to the initiating event or never achieved from the beginning of the accident (e.g., bypass events), and (2) containment failure induced by high-energy severe accident phenomena. The total frequency of these types of these failures constitutes the LRF for the AP600 analyses.

Disposition: No change to DG-1145.

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.

Response: The NRC staff disagrees with this comment. The Commission directed the staff in the SRM on the proposed revisions to the 10 CFR Part 52 rule to include specific guidance regarding the PRA in the regulatory guide. In addition, there are numerous objectives for the use of the PRA, as identified in Section C.II.1.2. Demonstration that the QHOs are met is not an explicit objective, and has not been addressed in prior design certification reviews. The use of the 1E-6/year large release frequency (LRF) goal is consistent with Commission guidance. Meeting the LRF goal will generally assure that the early fatality QHO is met. As explained in the referenced footnote, the cited Commission goals of less than 1E-4/year for CDF and less than 1E-6/year for LRF were established in the Commission SRM dated June 26, 1990, in response to SECY-90-016. All certified designs approved by the NRC to date have addressed the LRF metric. Although not explicitly defined in the regulations, LRF represents the broader set of releases of which LERF is a subset. The difference between LRF and LERF is that LRF addresses the frequency of all large releases, not just those that occur "early." As an example of how LRF has been addressed by prior certified design applicants, the AP600 divided at-power LRF-related containment failures into two types: (1) initially failed containment, in which the integrity of the containment is either failed due to the initiating event or never achieved from the beginning of the accident (e.g., bypass events), and (2) containment failure induced by high-energy severe accident phenomena. The total frequency of these types of these failures constitutes the LRF for the AP600 analyses.

Disposition: No change to DG-1145.

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. 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.

Response: The NRC staff disagrees with the comment. There are numerous objectives for the use of the PRA, as identified in Section C.II.1.2. Demonstration that the QHOs are met is not an explicit objective, and has not been addressed in prior design certification reviews. The use of a LRF goal and a containment performance goal (CPG) is consistent with Commission guidance, as explained in the referenced footnote. Use of the CPG was reaffirmed by the Commission in July 1993 (SRM on SECY-93-087), subsequent to receipt of the AP600 application for design certification. The CPG provides insights into the balance of preventive and mitigative features of the design. The need for a CPG was not driven by uncertainties due to unanticipated sequences. Rather, the CPG was developed to assure that appropriate balance between mitigative and preventive features is achieved. Advanced designs that achieve a reasonable balance between preventive and mitigative features based on consideration of anticipated sequences, would be better able to accommodate unanticipated sequences. Use of the QHOs and subsidiary goals in lieu of the CPG would not provide the same valuable insights.

The NRC staff does recognize the industry concerns that may arise in trying to meet the CPG. Specifically, in addressing the CPG, applicants should not intentionally increase the frequency of core damage events that do not challenge containment integrity simply to meet the CPG CCFP. In this context, the applicant should recognize that these are performance goals and not requirements for containment performance. Therefore, the discussion on CPG has been expanded to further clarify the intent of the CPG deterministic and probabilistic goals to ensure applicants understand the role of the CPG in properly balancing preventive and mitigative features.

Disposition: No change to DG-1145.

C.II.1.2-6 The last two paragraphs in section C.II.1.2 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 COL application and COL issuance phases.

Response: The NRC staff agrees with this comment.

Disposition: DG-1145 has been revised. The discussion regarding construction and operational phases has been deleted from this section and incorporated into Section C.I.19, regarding the content and format for Chapter 19 of the applicant's FSAR, as appropriate.

C.II.1.2.-7 The last sentence in Section C.II.1.2 states, "Such changes [i.e., licensing basis changes during the combined license (COL) application, construction and operation phases] need to be submitted for NRC review and approval and reflected in the updated probabilistic risk assessment (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.

Response: The NRC staff agrees with this comment. The intent of this discussion was to ensure that when there is a change in the licensing basis that significantly impacts the PRA results and insights, that the appropriate information is reflected in an update to the PRA and the information is communicated to the NRC (see C.I.19 discussion regarding the PRA maintenance and update program within the applicant's FSAR).

Disposition: DG-1145 has been revised to delete the specific discussion regarding construction and operational phases from this section.

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.

Response: The NRC staff agrees with this comment. The intent is that the design certification PRA may need to be expanded to support additional risk-informed applications that the COL applicant voluntarily seeks to implement. This perspective is already reflected in Section C.II.3 per the footnote.

Disposition: DG-1145 has been revised for clarity.

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.

Response: The NRC staff agrees with this comment.

Disposition: DG-1145 has been revised to change "realistically reflect" to "reasonably reflect."

C.II.1.4-2 Is it acceptable to reference a separate topical report for this detail?

Response:

Disposition:

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."

NEI agrees that 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 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 NRC 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 combined license (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."

Response: The NRC staff agrees that the text regarding quality assurance was too general and has revised this section on technical adequacy (and overall quality) consistent with other existing regulatory guides associated with risk-informed decisionmaking (e.g., RG 1.174 Section 2.5 regarding quality assurance/controls). The specific aspects associated with determining technical adequacy has also been substantially revised to reflect the various means an applicant may use for establishing the technical adequacy of their PRA

Disposition: DG-1145 has been revised for clarity.

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.

Response: The NRC staff disagrees with the comment and has clarified Section C.II.1.6 (and Section C.II.1.2) to make it clear that this comparison can be qualitative. A new design for a nuclear power plant is expected to incorporate features and operational requirements to address severe accident concerns (e.g., TMI issues, unresolved safety issues, and generic safety issues). Such concerns are reduced or eliminated in new designs by the introduction of features, such as redundancy, diversity, separation, defense-in-depth, improved equipment reliability, design changes to eliminate known failures, and less

reliance on operator actions. The incorporation of such features are expected to result in a reduced risk with respect to operating plants. The risk reduction can be demonstrated qualitatively, for each initiating event category identified in the PRA, by comparing the means that are available to perform the required functions to prevent and mitigate accidents. In addition, quantitative risk information for operating LWR plants is available in NUREG-1560, "Individual Plant Examination Program: Perspectives on Reactor Safety and Plant Performance." This information can be readily used to compare the risks, by initiating event category, assessed for the new design to the corresponding risks for operating plants. However, such a quantitative comparison of risks is not required by the staff.

Disposition: DG-1145 has been revised for clarity.

C.II.1.6-2 The seventh paragraph in 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 COL applicant assure that assumptions 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, RTNSS, ITAAC, RAP, and COL Action Items is not clear. These items are covered elsewhere in the guidance with different bases. Please clarify this relationship.

Response: The NRC staff agrees with the comment:

- a) The last sentence only applies to the second bullet. The second bullet refers to assumptions made in the design-specific PRA that must remain valid in the as-built, as-operated plant. Such assumptions are associated with specific requirements for the design, construction, and operation of the plant (e.g., ITAAC, TS, RAP, RTNSS, and COL Action Items). The first bullet refers to design and operational changes made to address weaknesses. However, changes usually result in additional or modified assumptions, which, in turn, result in new or modified requirements for the design, construction, and operation of the plant.
- b) The term "future plant" refers to the subject COL applicant's "as-built, as-operated" plant; not to another plant by another licensee/applicant. The second bullet will be changed to make the intent clear by replacing "a future plant" with "the as-to-be-built, as-to-be-operated plant."
- c) The risk evaluation results and insights are not the only means used to identify design and operational requirements (e.g., technical specifications, RTNSS, ITAACs, RAP, and COL action items). In general, these requirements are identified by either deterministic or a combination of both deterministic and probabilistic considerations. The implied tie between risk evaluation results and "specific requirements" refers to those "specific requirements" that ensure that important assumptions made in the PRA will remain valid in the as-to-be-built,

as-to-be-operated plant and that significant uncertainties in the PRA have been addressed. These “specific requirements” may or may not be identified by deterministic considerations and criteria alone. The important PRA assumptions include those associated with risk-significant features (i.e., features having significant risk achievement and/or risk reduction worth) as determined by risk importance measures and those identified by sensitivity studies as having a significant impact on the PRA results and insights.

Disposition: DG-1145 has been revised for clarity.

C.II.1.7-1 Section C.II.1.7, 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 probabilistic risk assessment (PRA) (which may not be in the format of Appendix B).

Response: The NRC staff disagrees with this comment. It should be noted that this part of DG-1145 applies to COL applicants that do not reference a certified design and thus, there may not be a design certification PRA upon which to develop the COL application PRA. Further, for a COL application that references a certified design, the format of the PRA information to be submitted per Appendix B is not a requirement of 10 CFR 52.80(a), which requires the COL applicant that references a certified design to submit a plant-specific PRA that "...must use the PRA for the design certification ... as applicable, and must be updated to account for site-specific design information and any design changes, departures, or variance." This requirement does not mandate the format of the submittal to be identical to that submitted under 10 CFR 52.47 for the design certification PRA, but does require that the COL applicant's plant-specific PRA be derived from the actual design certification PRA and updated and upgraded, as appropriate.

Disposition: No change to DG-1145.

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.

Response: The NRC staff disagrees with the comment. The staff notes that the guidance is consistent with other guidance regarding the use of PRA information (e.g., RG 1.174 Section 3.2 regarding archival documentation).

Disposition: No change to DG-1145.

C.II.2-1 Section C.II.2, Attachment A - ITAAC General Development Guidance: Instrumentation and Control Systems, refers to compliance with 10 CFR 50.55a(h), Criteria for Protection Systems for Nuclear Generating Stations, and IEEE Standard 603-1991 (and the correction sheet dated January 30, 1995). DG-1145 section C.I.7 bases all guidance on IEEE 603-1998. These two sections need to be in sync to avoid confusion during ITAAC inspections.

- Response:** The regulations require compliance with IEEE Standard 603-1991. A discussion regarding conformance with IEEE Standard 603 is provided in DG-1145, Section C.I.7, Appendix 7B.
- Disposition:** Section C.II.2.2.5 and Attachment A will be annotated to refer to DG-1145, Section C.I.7, Appendix 7B for additional discussion regarding conformance with IEEE Standard 603.
- C.II.2-2** Section C.II.2, Attachment A, refers to SRP Chapter 7, BTP 7-14 for software quality design controls. It does not mention IEEE 7-4.3.2-2003. DG-1145 section C.I.7 includes software quality guidance based on on IEEE 7-4.3.2-2003. These two sections need to be in sync to avoid confusion during ITAAC inspections.
- Response:** A discussion regarding conformance with IEEE Standard 7-4.3.2 is provided in DG-1145, Section C.I.7, Appendix 7C.
- Disposition:** Attachment A will be annotated to refer to DG-1145, Section C.I.7, Appendix 7C for additional discussion regarding conformance with IEEE Standard 7-4.3.2.
- C.II.2-3** Section C.II.2, Attachment A, specifies verification of each of the many functional characteristics listed in the document. A sampling process would make sense here. Otherwise, the 'each' term can be interpreted as a requirement to review 100% of the software code to determine that each characteristic was addressed for all cases.
- Response:** Verification of the functional characteristics is essential to the development of high quality software. The NRC may perform sample inspections to verify that software development was performed in accordance with a quality program.
- Disposition:** No change to DG-1145.
- C.II.2-4** Item (1) of section 14.3.5, ITAAC for Instrumentation and Controls, and section C.I.7 need to be in sync on revision levels and design criteria to avoid confusion during ITAAC inspections. DG-1145 section C.I.7 bases all I&C guidance on IEEE 603-1998.
- Response:** See response to C.II.2-1 above.
- Disposition:** See disposition to C.II.2-1 above.
- C.II.2-5** Item (2) of section 14.3.5 and section C.I.7 need to be in sync to avoid confusion during ITAAC inspections. Note that DG-1145 section C.I.7 bases all software guidance on IEEE 7-4.3.2-2003.
- Response:** See response to C.II.2-1 above.
- Disposition:** See disposition to C.II.2-1 above.
- C.II.2.1-1** Section C.II.2.1, page C.II.2-4 includes a bulleted list of items to be considered in development of inspection, test, analyses, and acceptance criteria (ITAAC) for a combined license (COL) application. The list includes items that should be "carefully considered", "emphasized", "included" or "consistent with". This seems to be good background for the development of ITAAC but does not provide specific criteria for the

selection of SSCs that require detailed ITAAC. The list seems to broaden the scope of ITAAC beyond that identified in draft DG-1145, Section C.III.7 for a scenario 4 or 5 COL application. Applicants covered by these two scenarios anticipate that ITAAC in the COL application will be based on the selection criteria identified in the generic design control document (DCD). Please confirm that this approach meets the guidance.

Response: The staff agrees with this approach. It is expected that COL applicants that reference a certified design would use the same selection methodology as provided in Section 14.3 of the DCD for the referenced certified design. COL applicants should supplement the selection methodology, as necessary (e.g, insights from plant-specific PRA).

Disposition: DG-1145 revised to include the response above.

C.II.2.1-2 The fourth sentence in Section C.II.2.1 should be modified as follows to be consistent with the purpose of ITAAC described in Draft SRP 14.3 (1996) and other documents: "The design descriptions contained in a Tier 1 document provide a summary level design basis the top level design criteria and performance standards for the SSCs that isare derived from the Tier 2 document."

Response: The staff agrees with this comment.

Disposition: DG-1145 revised as noted in the comment.

C.II.2.1.1-1 In Section C.II.2.1.1, the definition of "Design Requirement/Commitment" should be modified so that it does not say that the [Tier 1] design requirement is a commitment of the licensed facility and is equivalent to the design basis for an structures, systems, and components (SSCs). Design bases are defined in 10 CFR 50.2 and are not equivalent to Tier 1 design requirements, which are the top level design criteria and performance standards for SSCs.

Response: The staff agrees with this comment.

Disposition: Definition has been revised to delete reference to design basis.

C.II.2.2-1 Suggest deletion of Section 14.3.1, on ITAAC for Site Parameters. This section in not necessary, and introduces the non-existent concept of ITAAC on site parameters.

Response: The disagrees with this comment. Section will be retained to provide clarity and consistency with standard review plan.

Disposition: No change to DG-1145.

C.II.2.2-2 Please clarify the sub-section numbering in Section C.II.2.2. Sub-sections are numbered 14.3.1-12. Is this guidance to be located in C.II.2.2 or C.I.14.3?

Response: The staff agrees with this comment. Guidance is located in Section C.II.2.

Disposition: The subsection numbering has been clarified to be consistent with C.II.2.

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)?

Response: Regulatory Guide (RG) 4.2, "Standard Format and Content of Environmental Reports," and NUREG-1555, the environmental standard review plan (ESRP), are regulatory guidance documents. However, RG 4.2 is intended for NRC stakeholders, including applicants, and the ESRP is intended for the staff. RG 4.2 has not been updated since 1976 and, therefore, does not address more recent matters, such as severe accident mitigation design alternatives (SAMDAs), cumulative impacts, and environmental justice; nevertheless, RG 4.2 still represents an acceptable approach for submitting information in environmental reports (ERs). The ESRP was updated in 2000 and contains guidance for both ESPs and COLs.

The staff follows the environmental review guidance in NUREG-1555, the environmental standard review plan (ESRP), when conducting its environmental reviews for major Federal actions. Following the direction from the Commission, the staff's review guidance outlined in RS-002, "Processing Applications for Early Site Permits," was to provide the flexibility to deal with the industry's "Plant Parameter Envelope" (PPE) concept and information that may not be available absent a specific design, and to reflect the Commission's direction regarding alternative energy source evaluations with ESPs subsequent to the issuance of the ESRP. Therefore, in complying with RS-002, the staff indeed departed from the ESRP in those circumstances where specific design information was not available using the PPE concept. For those ESP applications that will not utilize a PPE concept, the staff expects to maintain fidelity to the ESRP.

Regulatory Guide 4.2 presents an acceptable approach for applicants to submit environmental information sufficient for the staff to undertake its independent review and to develop its environmental impact statement (EIS). It is not the only way for an applicant to provide information, but it does provide insight regarding the scope of information and the level of detail expected by the staff to determine whether the application is acceptable to establish a review schedule and to conduct the review. If the COL applicant elects to follow the guidance of Regulatory Guide 4.2 and does not reference an ESP, then the staff will find the approach acceptable. If the COL applicant elects to follow the guidance of Regulatory Guide 4.2 and reference an ESP, then the applicant need not reproduce information conforming with the Guide that was previously provided as part of the ESP application.

Disposition: No change to DG-1145.

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?

Response: The update of Regulatory Guide 4.2 is part of the NRC's infrastructure improvement activities. The NRC has not yet determined whether resources should be invested on the update before the remaining environmental rulemakings (i.e., Table S-3, Table S-4, and alternative site reviews) are completed. If the update is made before the rulemakings, then the staff would plan to complete the update in 2008; if the rulemakings are completed first, the staff would plan to update the Regulatory Guide in 2010. Based on

stakeholder interest, the staff is investigating whether these schedules should be and could be accelerated.

Disposition: No change to DG-1145.

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?

Response: The NRC already recognized the changing power market when it issued NUREG-1555 in 2000; it was in a state of flux then and, while maturing, it is still developing today. The staff is assessing the updates that may be warranted to NUREG-1555 and expects to complete the update of all identified chapters in 2008. Each chapter of the environmental standard review plan (ESRP) that the NRC will update will be prioritized and higher priority chapters will be updated first. The staff intends to seek input from stakeholders regarding which chapters warrant updating and their priority.

Disposition: No change to Regulatory Guide.

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.

Response: As discussed above, Regulatory Guide 4.2, presents an acceptable approach for applicants to submit environmental information sufficient for the staff to undertake its independent review and to develop its environmental impact statement (EIS). It is not the only way for an applicant to provide information, but it does provide insight regarding the scope of information and the level of detail expected by the staff to determine whether the application is acceptable to establish a review schedule and to conduct the review. If the COL applicant elects to follow the guidance of Regulatory Guide 4.2 and is referencing an ESP, then the applicant need not reproduce information conforming with the Guide that was previously provided as part of the ESP application.

Disposition: No change to Regulatory Guide.

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 NRC 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?

Response/Disposition:

A response to this question will be provided in the final guide after the final Part 52 Rule is issued.

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?

Response: The update of Regulatory Guide 4.2 is part of the NRC's infrastructure improvement activities. The staff has not yet determined whether resources should be invested on the update before the remaining environmental rulemakings (i.e., Table S-3, Table S-4, and alternative site reviews) are completed. If the update is made before the rulemakings, then the staff would plan to complete the update by the end of 2008; if the rulemakings are completed first, the staff would plan to update the Regulatory Guide in 2010. Based on stakeholder interest, the staff is investigating whether these schedules can be accelerated. A Review Standard is guidance for the staff; a Regulatory Guide is guidance for stakeholders. In updating ESRP sections, the staff will consider priorities based on the significance of changes to statutory and regulatory practices, as well as changes in the power market; staff progress updating the ESRP may obviate the need for a review standard.

Disposition: No change to Regulatory Guide.

C.II.3-7 Consideration of severe accident mitigation design alternatives (SAMDA) is resolved via design certification and documented in an NRC environmental assessment (EA). The staff environmental reviewers indicated that they will tier off the design certification environmental assessment to address severe accident mitigation alternatives (SAMA) in a combined license (COL) environmental impact statement (EIS). The regulations allow a COL application to reference a design certification application (10 CFR 52.55(c)). Thus, a COL application may reference a design certification application, including SAMDA evaluation, for which the NRC has not yet issued its environmental assessment. In this case, does the staff agree, and will DG-1145 make clear, that SAMDA would continue to be resolved via the design certification proceeding and that the COL application would be amended to incorporate the design certification, including the EA, when it is completed?

Response: The timing of applications and their reviews introduces a regulatory challenge if reviews and actions are not yet complete.

If the COL (or ESP) applicant at its own risk elects to reference a design not yet certified, then the SAMDA information to be provided in its COL application would still need to analyze the particular population distribution and site-specific dispersion characteristics that would otherwise be needed to conclude that it would have been bounded by that considered in the design certification SAMDA analysis.

While the SAMDA issue may be resolved for the purposes of the COL, it is a subset of the severe accident mitigation alternatives (SAMAs), which also includes procedures and training alternatives that may not have been addressed in the design certification.

Disposition: No change to Regulatory Guide.

C.III-1 Will Part III of the regulatory guide discuss how the NRC staff expects a combined license (COL) applicant to address COL action items in the final safety evaluation report (FSER) of AP1000?

Response: No. The staff has developed DG-1145 as a generic guidance document and will not provide guidance on treatment of issues that are specific to a particular certified design. Generic guidance on COL action items is provided in Section III.C.4.

Disposition: No change to DG-1145.

C.III-2 C.I addresses a COL application that references neither a DC or ESP. C.III.1 addresses a COL application that references a DC only. C.III.2 addresses a COL application that references both a DC and an ESP. However, there is no similar section that addresses a COL application that references only an ESP. Why was this possible scenario omitted?

Response: The staff considered that a DC involved resolution of a larger scope of safety issues than an ESP. The staff believed that the scenario for a COL that references an ESP only could be more easily derived by providing guidance for a COL, a COL that references a DC, and a COL that references DC and an ESP. In addition, the staff was challenged to provide guidance on the three scenarios in a time frame that responded to stakeholder needs.

Disposition: No change to DG-1145.

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

Response: A regulatory basis exists to address all aspects of the question. The basis is that sufficient information needs to be provided to resolve all safety issues.

Disposition: No change to DG-1145.

C.III.1-2 How will NRC communicate the level of detailed design information required for the non-COL action items that are on the combined license (COL) "To-Do" list and are related to design?

Response: The staff has provided guidance on these items in Section C.III.1. The level of detail must be sufficient to resolve all safety issues.

Disposition: No change to DG-1145.

C.III.1-3 The translation of a certified design into the detailed design should be part of the NRC inspection program. The current draft of section 12 appears to step into the inspection activities. Can a boundary be established between items that must be in a COL application and those that will be part of NRC inspection ?

Response: The staff has provided guidance on this issue in Section C.III.1. In addition, design information contained in a certified design is afforded finality in accordance with 10 CFR 52.63.

Disposition: No change to DG-1145.

C.III.1-4 It would be very constructive to differentiate between areas where detailed design is being requested versus non-design-oriented items. The detailed design items would be component selection and layout issues. The non-design-oriented items would be operational issues, site specific issues, or new requirements.

Response: The staff has provided guidance in Section C.III.1 consistent with format of Section C.I rather than on a design vs. non-design basis.

Disposition: No change to the guide.

C.III.1-5 NRC should clearly separate design inspections from combined license (COL) content. Design inspections should be handled by the vendor. The detailed design information provides implementation of the design certification. These detailed design related inspections should not be any different than construction inspections. Please provide guidance which characterizes how this information will be dealt with in licensing space versus inspection/verification space.

Response: Information sufficient to resolve all safety issues must be provided in the application. Design information contained in a certified design is afforded finality in accordance with 10 CFR 52.63. DG-1145 is not the appropriate regulatory document for a discussion of the scope of the inspection program.

Disposition: No change to DG-1145

C.III.1-6 As a general comment, our understanding of the meaning of design certification is that a combined license (COL) applicant who references a certified design is only required to address COL Open Items which were identified as part of the design certification. Design related issues which were not identified as COL Open Items are not required to provide additional or more detailed information as part of the COL process. There may be areas which are subject to NRC audits and inspection, but these should be handled outside of the COL process.

Response: The staff does not agree with this comment. There may be design related issues that are associated with site-specific features of the facility design that are not included in a COL action/information item.

Disposition: No change to DG-1145

C.III.1-7 Please confirm our understanding that combined license (COL) applicants referencing a design certification should focus solely on C.III.1 (or C.III.2 if an ESP is also referenced), and not on the Part 1 guidance.

Response: The staff confirms this understanding; however, guidance provided in Sections C.III and C.IV may also be applicable to COL that references a certified design.

Disposition: No change to DG-1145

C.III.1-8 What is the intent of paragraph 2 of Section C.III.1.2 and sentence two of Section C.III.1.10?

Response: Paragraph 2 of C.III.1.2 is intended to reflect the bounding nature of the guide. It is intended to cover both active and passive safety system designs as well as the scope of light water reactor designs. For example, guidance has been placed in Section C.III.1 concerning review of certain systems that may not be contained in certain facilities. The guide is intended to provide generic information to combined license (COL) applicants to prepare their applications. C.III.1.10 is intended to be an introduction to the main body of the section. The second sentence is merely a reminder that all the information included in Section C.III.1 may not need to be included in the COL application.

Disposition: No change to DG-1145.

C.III.1-9 a) Where does DG-1145 discuss the acceptability of incorporating by reference the DCD into the COL application? We suggest that IBR could be discussed in Section C.III.1.8 in conjunction with the guidance about "facilitating" NRC staff review. b) Apart from IBR, please clarify what is meant by the staff recommendation that the COL application "facilitate" the staff review wherever possible.

Response: Guidance has been included in Section C.IV.2 on "incorporate by reference" and "include in the application." The staff believes that COL applicants can "facilitate the review" by providing sufficient information in the application that is both clear and concise, minimizes the complexity of the review, minimizes the need to consult multiple references during the review, minimizes the need for RAIs, etc. More simply, "facilitating the review" means helping to make the staff's review as efficient as possible.

Disposition: DG-1145 has been revised to include the requested guidance.

C.III.1-10 It is unclear whether the information identified in Section C.III.1 is required to be submitted with the combined license (COL) application or later in the review process. For example, the first item in Section C.III.1.10.2.3 asks for a description of the turbine rotor in-service test and inspection program. These programs, as with other inservice inspection (ISI) and inservice testing (IST) programs, will be identified with the requirement to supply the program after the initial application.

Response: The information identified in Section C.III.1 must be submitted with the COL application. In certain instances information not available at the time of application submittal may be provided during the COL review process but prior to license issuance. Where operational programs are involved (e.g., ISI, IST, etc.), information sufficient to fully describe the program must be provided. It is acceptable to provide a general description of the program so long as a commitment to update the program with specific information at least one year prior to scheduled fuel load is included in the application (see SECY-05-0197). In other instances ITAAC may be necessary for information not available to support license issuance.

Disposition: No change to DG-1145.

C.III.1.1.5-1 Combined license (COL) Action/Information Items are not treated consistently. In Section C.III.1.1.5, the need to provide construction schedule info - a COL Item common to all design control documents (DCDs) - is identified. There are common COL items in Chapter 4 of DCDs, but these are not identified in C.III.1.4. We think it would be useful to identify common/generic COL items (like the construction schedule item) in Section C.III.1.

Response: Although it may have been identified as a COL action/information item, the COL applicant is required to provide construction schedule information per 10 CFR 52.77 and 10 CFR 52.79(a)(39). The staff understands that the scope of design and level of design completeness may vary for certified designs and involves, in part, commercial decisions between certified design vendor and COL applicant. The staff does not agree on the usefulness of identifying common/generic COL items at this time.

Disposition: No change to DG-1145

C.III.1.3-1 The last sentence in Section C.III.1.3 states that "The development of Section C.III.1 of this guide assumes the design was reviewed and certified without the use of design acceptance criteria (DAC). This seems to contradict the rest of the section which recognizes the use of DAC in the current certified designs.

Response: Information and guidance related to DAC has been provided in Section C.III.5.

Disposition: No change to DG-1145.

C.III.1.6-1 Section C.III.1.6 uses the term "deviations from the certified design". 10 CFR 52 refers to "departures from Tier 2 information" in the DCR Appendices, Section VIII. Please clarify the significance of the different terminology.

Response: Deviation was used in the same manner as departure.

Disposition: This section has been revised to use "departure" rather than "deviation" for consistency with the rule language

C.III.1.CH.3.5.1.4-1

Section C.III.1.3.5.1.4 provides the following guidance for COL applicants referencing a certified design:

"Identify all missiles generated as a result of high-speed winds such as tornadoes, hurricanes, and any other extreme winds. For selected missiles, specify the origin (including height above plant grade), dimensions, mass, energy, velocity, trajectory, and any other parameters required to determine missile penetration. Guidance for selecting the design-basis tornado-generated missiles is provided in Revision 2 of Regulatory Guide 1.76, "Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants."

Show that all the missiles generated as a result of the site's high-speed winds are bounded by the equivalent DC missile site parameters. If the DC missile site parameters do not bound the site's missile characteristics, demonstrate by some other means (e.g.,

re-analyzing or redesigning the proposed facility) that the proposed facility is acceptable at the proposed site."

This guidance and the discussions in the NRC's workshop of June 13, 2006 appear to impose a search for site-specific tornado-borne missiles upon the combined license (COL) applicant. This approach to assuring the protection of the safety-related structures, systems, and components (SSCs) departs from the enveloping missile spectrums that have been used in the current design certifications and incorporated in recent NRC staff guidance documentation:

Section II, "Acceptance Criteria" of Draft Revision 3 (January 2006) of SRP 3.5.1.4 "Missiles Generated by Tornadoes and Extreme Winds," states the following relative to GDC 2 and 4:

- "Acceptance is based on meeting the guidelines in Regulatory Guides 1.76 and 1.117."
- "Regulatory Guide 1.76 describes a design basis tornado that is acceptable to the NRC staff."
- "Designing a nuclear power plant to withstand the design basis tornado and tornado missiles discussed in Regulatory Guide 1.76 ensures that there will be no undue risk to the health and safety of the public in the event of most severe tornado conditions."
- "The design basis tornado generated missile spectrum in Regulatory Guide 1.76 is acceptable to the staff for the design of nuclear power plants."

Proposed Revision 1 to RG 1.76 (DG-1143), issued for comment at the same time as the draft SRP, states:

(Section B, Discussion): "Protection from a spectrum of missiles (exemplified by a massive missile that deforms on impact at one end of the spectrum and a rigid penetrating missile at the other) provides assurance that the necessary structures, systems, and components will be available to mitigate the potential effects of a tornado on plant safety. Given that the design-basis tornado wind speed has a very low frequency, to be credible, the representative missiles must be common around the plant site and must have a reasonable probability of becoming airborne within the tornado wind field."

Therefore, the DG-1145 guidance and the workshop discussions represent a significant departure from the current staff guidance. The design basis tornado missile spectrum in Regulatory Guide 1.76 is considered a representative sample of missiles (acceptable to the NRC staff) for the design of safety related structures. The design parameters (geometry/shape, weight, velocity, direction of strike, elevation of strike, etc.) of these missiles are considered bounding. Furthermore, a site specific tornado missile identification/analysis may prove to be impractical due to changing plant conditions (for example, at any given time during construction/maintenance/outages there could be different components/items present at the site). Lastly, the effort required to identify "all missiles" is subject to individual interpretation and could result in the expenditure of resources on issues marginally related to plant safety.

Response: The workshop comments were intended to address the following two issues:

- (1) Some standard plant designs have been certified with design missile spectrums that limit the consideration of the automobile missile in plant design to elevations within 9.2 meters (30 feet) above design plant grade, while the currently effective SRP 3.5.1.4, Rev.

2, July 1981, specifies that the automobile missile be considered at elevations up to 9.2 m (30 ft) above all grade levels within 0.81 km (½ mile) of the facility structures. Existing sites include nearby parking locations elevated with respect to the grade adjacent to plant structures. For certified designs that limited consideration of design missile impacts to certain elevations, the COL applicants should provide information addressing the potential for objects similar to design basis missiles to strike at elevations where such impacts were not considered in the design of the structure. Using the guidelines of SRP 3.5.1.4, Rev . 2, elevated parking areas within 0.81 km of site structures should be addressed.

(2) Proposed reductions in the design basis tornado wind speed create the potential for other weather phenomena in certain areas of the country (e.g., hurricanes along the Gulf and Atlantic coasts) to produce higher wind speeds and, thus, higher missile speeds. For the limited site locations where the design basis tornado wind speed used in the certified design is not limiting, COL applicants should address the difference in design wind speed as it relates to design basis missile speed.

These issues result from potential discrepancies between the topography and meteorology assumed for the certified design and the actual site conditions. Application of regulatory guidelines in the site evaluation should identify conditions where the missile parameters used in the certified design do not bound commonly considered design missiles, but categorization and evaluation of every potential missile on the site is not intended.

Disposition: The staff will clarify the proposed guidance to COL applicants to focus on site parameters that could affect the elevation, trajectory, and velocity of design basis missiles considered in the certified design. The inherent characteristics of tornado-generated design basis missiles (e.g., materials of construction, mass, and geometry) are not subject to re-evaluation at the COL stage.

C.III.1.CH.3.5.1.4-2

Please confirm that the proposed revision to Regulatory Guide 1.76 and the tornado missiles cited in the certified designs provide standard approaches acceptable to the NRC staff for the identification of design basis (bounding) tornado and tornado generated missile spectra for the design of safety-related SSCs. If NRC agrees please revise the language of DG-1145

Response: Certified designs assume parameters for missile speed and, in some cases, elevation. As described above, COL applicants should address the potential for site meteorology and topography to increase the speed or elevation of design basis missiles.

Disposition: The staff will clarify the proposed guidance to COL applicants to focus on site parameters that could affect the elevation, trajectory, and velocity of design basis missiles considered in the certified design. The inherent characteristics of tornado-generated design basis missiles (e.g., materials of construction, mass, and geometry) are not subject to re-evaluation at the COL stage.

C.III.1.CH.3.5.1.4-3

Should the site specific high-wind velocity (determined by the COL applicant) be less than the tornado wind velocity from the certified design or the velocity determined in accordance with RG 1.76, there will be no need to perform a site specific tornado missile identification study and/or evaluation. If the NRC agrees, please revise the language of DG-1145.

Response: The COL applicant should still address the potential effect of site topography on design basis missile elevation.

Disposition: The staff will clarify the proposed guidance to COL applicants to focus on site parameters that could affect the elevation, trajectory, and velocity of design basis missiles considered in the certified design. The inherent characteristics of tornado-generated design basis missiles (e.g., materials of construction, mass, and geometry) are not subject to re-evaluation at the COL stage.

C.III.1.CH.3.7-1

The language in Sections C.III.1.3.7.2.4 and C.III.1.3.7.2.5 requires the combines license (COL) applicant to perform a site specific soil-structure interaction (SSI) analysis and develop floor response spectra (FRS).

Please confirm that if the COL applicant demonstrates that the design parameters used in the SSI analyses performed as part of the design certification envelope the site specific parameters, there will be no need to perform a site-specific SSI analysis. This justification will include the comparison of ground input motion, soil characteristics (shear wave velocity, etc.), layering and other parameters that are required to establish the validity of this comparison. As such, the site specific FRS need not be developed since they will be enveloped by the FRS developed as part of the design certification.

Response: The staff has provided guidance on acceptable comparison methods.

Disposition: No change to DG-1145.

C.III.1.CH.1.9.1-1

Section C.III.1.9.1 notes that the COL applicant (referencing a certified design) should address compliance with regulatory guides with the purpose of indicating if methods found acceptable to the NRC staff for implementing principal design criteria (of Appendix A to Part 50) are met. It is understood that DG-1145 itself is a unique regulatory guide which addresses content of the application rather than specific methods for compliance to principal design criteria. Therefore, the COL application would not be expected to contain a compliance evaluation for DG-1145. Rather, the COL application FSAR Chapter 1 would provide a statement that the appropriate portion of DG-1145 was used in defining and developing the content of the COL application FSAR. For example, an application referencing both a certified design and early site permit would state in FSAR Chapter 1 that the FSAR complies with DG-1145 Section C.III.2 regarding content. Any significant departures from Section C.III.2 would be described and justified, as needed.

This approach should be clarified in DG-1145 Sections C.I.1, C.III.1, and C.III.2.

Response: The staff agrees with this comment.

Disposition: DG-1145 has been revised to provide this guidance.

C.III.1.CH.1.10.1.8-1

Section C.III.1.10.1.8 requires a COL applicant to identify areas "which deviate or are in variance from" the certified design and list them in Section 1.8 of the combined license (COL) final safety analysis report (FSAR). 10 CFR 52, DCR Appendices IV.A.2.b require a COL applicant to submit a report on departures from and updates to the plant-specific design control document (DCD) with the application. The requirement to include this information in the FSAR is redundant

Response: The staff agrees with this comment.

Disposition: DG-1145 has been revised to remove this item.

C.III.1.CH.19-1

Section C.III.1 - Information Needed for a COL Application Referencing a Certified Design, 19.1 Plant-Specific PRA states, in the second paragraph, last two sentences "The COL applicant may use, or incorporate by reference, the PRA for the Certified Design. However, the COL applicant should ensure the provided information is current, complete and accurate relative to plant-specific, site specific conditions and parameters. The applicant should identify and resolve the COL Action Items applicable to the PRA for the Certified Design."

We assume that "re-submittal" of the PRA for the Certified Design would not be needed. Please clarify.

Response: The NRC staff agrees. It is not necessary to re-submit the Certified Design PRA.

Disposition: DG-1145 has been revised for clarity.

C.III.1.CH.19-2

Section C.III.1 - Information Needed for a COL Application Referencing a Certified Design, Section C.II.1, Probabilistic Risk Assessment states, "The applicant should adhere to the guidance provided in Section C.II.1 of this guide for the plant-specific PRA. In cases where it can be shown that assumptions in the Certified Design PRA bound certain site-specific or plant-specific parameters (or it can be shown that any differences have no significant impact on the PRA results and insights), indicate "No change from the certified design PRA" in the appropriate section. The same is true for any changes or deviations from the Certified Design, as long as it can be shown that they do not have a significant impact on the PRA results and insights."

Clarification is needed, as noted below.

We assume that 1) the certified design PRA would not need to be "re-submitted," and 2) that rather than providing language that "No change from the certified design PRA" in the appropriate section" that language could be, instead, included where there are changes, and that sections containing no changes could be discussed collectively in one section/paragraph.

For the language, "The same is true for any changes or deviations from the Certified Design, as long as it can be shown that they do not have a significant impact on the PRA results and insights," we assume that such changes can be provided in a summary (either in a summary PRA report or in Chapter 19.) There is no need to submit a detailed PRA report on a plant-specific basis when any differences are not significant.

Response: The NRC staff agrees that it is not necessary to re-submit the Certified Design PRA. However, to enable the staff to perform an efficient review, the format guidance in Section C.II.1, Appendix B, should be followed (i.e., follow the format and content guidance, but it is acceptable to state "No significant change from the Certified Design" at the highest section-level possible in which it can be shown that the differences between the Certified Design and plant-specific PRAs are not important and do not have a significant impact on the PRA results and insights).

The NRC staff also agrees that differences from the Certified Design that are not important can be provided in a summary document (such as a PRA summary report or PRA revision/change report). In this context, the applicant should also define their criteria for what is important.

Disposition: DG-1145 has been clarified regarding the Certified Design PRA and that, in addition to updating the risk insights, only important differences/changes need to be explicitly included in the plant-specific PRA submittal information.

C.III.1.CH.19-3

Section C.III.1 - Information Needed for a COL Application Referencing a Certified Design, Risk Insights states, "During plant construction, the COL applicant should consider as-built information to acquire updated insights to strengthen programs and activities in areas such as training, emergency operating procedures development, reliability assurance, and maintenance. As plant operational data is accumulated, the licensee should update assumptions and analyses (e.g., assumed human errors; structures, systems, and component failure rates) and incorporate updated safety insights into quality assurance and operational programs."

Portions of this paragraph should be deleted as redundant to COL application sections which address the noted areas (e.g., EOPs, training, RAP, and Maintenance.) In addition, the paragraph addresses plant operations which extends beyond COL issuance or initial operations, and should be modified accordingly.

Response: The NRC staff agrees.

Disposition: DG-1145 has been revised to delete the subject paragraph since it is not related to the COL application phase.

C.III.1.CH.19-4

Section C.III.1 - Information Needed for a COL Application Referencing a Certified Design, Format and Content, states that "COL applicants should adhere to the format and content identified in Appendix B to Section C.II.1 of this guide for the plant-specific PRA."

This language needs clarification. For a COL applicant referencing a certified design a "re-submittal" of the PRA, with a discussion of any departures or site specific considerations is not needed. Instead, a summary of any differences and their impact is appropriate. The language in this draft should be modified to more clearly discuss the expectation.

Response: The NRC staff agrees that it is not necessary to re-submit the Certified Design PRA.

Disposition: DG-1145 has been revised for clarity.

C.III.2-1 In general, the industry expects that the finality provisions of 10 CFR 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.

Response: Section 52.39 governs finality of ESPs, not contents of applications for COLs referencing an ESP which is covered by proposed § 52.79(b). That being said, the staff generally agrees that, or those matters addressed in the ESP application and resolved in the ESP

proceeding, no additional information need be provided in the COL application final safety analysis report (FSAR) Chapter 2, except for those items specified in the list provided by the commenter. However, one important item missing from the list is the requirement to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit. The COL applicant would also include requests for any variances from the ESP in the COL application.

Disposition: No change to DG-1145.

C.III.2-2 Last sentence of 1st paragraph should say "...and an ESP." "[A]nd an ESP" should also be added to the last sentence of this section.

Response: The staff agrees with this comment.

Disposition: The guide has been revised as noted in the comment.

C.III.2-3 For a combined license (COL) application referencing an early site permit (ESP), the Part 52 (current or proposed) indicates that the final safety analysis report (FSAR) need not contain analyses or information submitted to the NRC with the ESP. While this appears to be clearly addressed in Part 52, the treatment of the ESP site safety analysis report (SSAR) relative the COL application is not explicitly addressed. It is the industry understanding that issues addressed during the ESP proceeding are considered resolved. The supporting information submitted in the ESP proceeding associated with resolved issues need not be resubmitted, included or incorporated in the COL application. The COL application FSAR would indicate that the subject information was provided at ESP and is resolved. Please address and confirm this understanding in DG-1145 C.III.2.

Response: The staff interprets the language in proposed § 52.79(b) that the final safety analysis report (FSAR) need not contain analyses or information submitted to the NRC with the ESP slightly differently than the commenter. The staff believes that the COL application should at least incorporate the ESP SSAR by reference, consistent with the allowance in § 50.32 which states that applicants may incorporate by reference information contained in previous applications, statements or reports filed with the Commission provided that such references are clear and specific. The staff believes this approach is consistent with the concept that the COL applicant need not resubmit ESP information, and that it would provide for a complete COL application. The staff also believes that, while not required, it may provide greater review efficiency if the ESP SSAR is included (rather than just incorporated by reference) in the COL FSAR.

Disposition: No change to DG-1145.

C.III.2.1-1 Why does C.III.2.1 repeat rather than refer to C.III.1 where appropriate? Note - some adjustments to C.III.1 language (e.g, C.III.2.1.8) would be needed

Response: In the timeframe established to develop this guide, repeating the information was the most efficient. The staff acknowledges the changes necessary to C.III.2.1.8.

Disposition: Section C.III.2.1.8 has been revised as necessary.

C.III.2.2 -1 The last sentence of the first paragraph in Section C.III.2.2 reads "For design topics that have been resolved in the design certification, the guide will state that the COL applicant does not need to include additional information." This sentence should be followed by a sentence which reads similar to, "For siting topics that have been resolved in the early site permit, the guide will state that the COL applicant does not need to include additional information." In general, C.III.2 subsections need to be modified from their analogues in Section C.III.1 to address ESPs.

Response: The staff generally agrees with this comment.

Disposition: Section C.III.2.2 has been revised as discussed in the comment. In general, the C.III.2 subsections and chapters have been modified, as necessary.

C.III.2.1.8-1 Section C.III.2.1.8 (and/or C.III.2.5) should discuss/acknowledge the PPE approach.

Response: The staff agrees with this comment.

Disposition: A discussion acknowledging use of the PPE approach has been provided in Section C.III.2.1.8.

C.III.2.CH.2-1

In C.III.2.2, several sections say no additional info is needed, while others say to revise ESP info if there are any known significant changes to ESP info. The need to update ESP info when there is significant new info is a given and applies to all site characteristic info approved in the ESP, not just the sections where DG-1145 says to revise ESP if needed. Why does DG-1145 treat some sections differently in this regard from others?

Response: The staff generally agrees with the comment on the need to update ESP information when there is significant new information. Issues of ESP finality are being addressed in the current rulemaking for 10 CFR Part 52. Additional guidance will be provided in the final guide following completion of rulemaking on 10 CFR Part 52.

Disposition: No change to DG-1145.

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.

Response/Disposition:

A response to this question will be provided in the final guide after the final Part 52 Rule is issued.

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?

Response/Disposition:

A response to this question will be provided in the final guide after the final Part 52 Rule is issued.

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.

Response: While Regulatory Guide 4.2 (current version) may not align perfectly with the evolutionary practice in recent EISs, it still represents an acceptable approach. Should the applicant elect to present the material in an alternate fashion, then it can explain why it elected to do so, for example, to align with the environmental standard review plan (ESRP) or the referenced EIS. As it prepares for the future applications, the staff is also considering whether its EISs should follow the format of the ESRP.

Disposition: No change to the guide.

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.

Response/Disposition:

A response to this question will be provided in the final guide after the final Part 52 Rule is issued.

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.

Response: The NRC expects that a reasonable representation of the project, all of its associated equipment (e.g., transmission lines) and interfaces with the environment, and the status of all authorizations, permits, licenses, etc. (other than from NRC) will be described with the application. The NRC recognizes that there may be circumstances where such approvals may need to be obtained, but cannot be finalized until decisions plans mature. Some of the information to perform the environmental analyses may be "business sensitive" or privileged; such information may need to be generalized prior to public release. In the absence of such final approvals, the NRC will establish in conjunction with the permitting

authority (or on its own) the bases for the NRC's impact analyses and will need to judge that it has a reasonable expectation that final authorizations, permits, licenses, etc. (other than from NRC) can be obtained. If the final approvals depart from those described in the Final EIS prior to the issuance of the COL, then the NRC will determine whether the EIS must be supplemented. If the COL has been issued, then, based on the significance of the departure from the earlier analyses, the NRC will need to determine whether safety or security issues require that the COL be amended.

Disposition: No change to the guide.

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.

Response: The NRC was directed by the Commission to provide insight on the attributes of an acceptable process for an applicant to determine whether "new and significant information" may exist on a previously resolved issue. The NRC has attempted to articulate the analogous process that has been successfully implemented in the license renewal arena. While subtle differences exist, the NRC believes that it is necessary for all stakeholders to recognize that this description is consistent with a well-established process and those unfamiliar with the concept can observe or be informed by its implementation elsewhere.

Disposition: No change to the guide.

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 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?

Response: First, the July 6, 2005, correspondence outlines the NRC's intended practice and discusses the similar approach used for license renewal environmental reviews for approximately 25 EISs to date. NRC does not plan to depart from these practices. NUREG-1555 and Regulatory Guide 4.2, Supplement 1, are important resources.

While the NRC staff plans to observe activities during the pre-application phase, the staff will not make any determinations regarding the adequacy of an applicant's approach or its effectiveness in preparing its application until the application is received. The pre-application activities are intended to (1) familiarize the NRC team with the activities conducted by the applicant prior to receipt of the application, (2) ensure that the NRC staff is aware of the interactions made with other stakeholders and their views on environmental issues, and (3) ensure that the applicant is aware of NRC expectations of a full and complete application.

Pre-application activities will be documented in trip reports, records of communications, and summaries of information collected and will be placed in the NRC ADAMS. Numerous activities will be conducted prior to the preparation of a draft and final EIS; appropriate documentation will be included in the NRC's ADAMS system.

Disposition: No Change to the guide.

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).

Response/Disposition:

A response to this question will be provided in the final guide after the final Part 52 Rule is issued.

C.III.3-9 The NRC 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.

Response/Disposition:

A response to this question will be provided in the final guide after the final Part 52 Rule is issued.

C.III.3-10 During the workshop, the NRC 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.

Response: The type of information provided by the three ESP applicants using the PPE concept that may not have been considered by the staff does vary. However, the fact that the staff did not "utilize" the information does not equate to information that "could be eliminated" from the ESP ERs and the EISs.

A good example of this is the treatment of the fuel cycle impacts. The applicants presented their analyses. However, the NRC found it to be incomplete even after responses to requests for additional information. The NRC staff had to reframe the analyses necessary to make its conclusions for the variety of LWR designs. The applicant's sought finality for other-than-ILWRs as well, but it did not provide sufficient information to achieve that goal. Such information could be eliminated if ESP applicants choose not to seek approval for other-than-LWRs.

Disposition: No changes to the guide.

C.III.3-11 The NRC 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.

Response/Disposition:

A response to this question will be provided in the final guide after the final Part 52 Rule is issued.

C.III.3-12 During the workshop, the NRC 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 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.

Response: The NRC expressed its willingness to continue to discuss this issue. The staff also indicated that elements of the July 6, 2005, letter were included in the March 13, 2006, re-proposed rule.

Disposition: No change to the guide.

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.

Response: The NRC expects that a reasonable representation of the project, all of its associated equipment (e.g., transmission lines) and interfaces with the environment, and the status of all authorizations, permits, licenses, etc. (other than from NRC) will be described with the application. The NRC recognizes that there may be circumstances where such approvals may need to be obtained, but cannot be finalized until decisions plans mature. Some of the information to perform the environmental analyses may be “business sensitive” or privileged; such information may need to be generalized prior to public release. In the absence of such final approvals, the staff will establish in conjunction with the permitting authority (or on its own) the bases for the NRC’s impact analyses and will need to judge that it has a reasonable expectation that final authorizations, permits, licenses, etc. (other than from NRC) can be obtained. If the final approvals depart from those described in the Final EIS prior to the issuance of the COL, then the NRC will determine whether the EIS must be supplemented. If the COL has been issued, then, based on the significance of the departure from the earlier analyses, the NRC will need to determine whether safety or security issues require that the COL be amended.

Disposition: No change to the guide.

C.III.3-14 The NRC 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.

Response/Disposition:

A response to this question will be provided in the final guide after the final Part 52 Rule is issued.

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).

Response: Section C.III.4.1 has been revised to state that Section C.III.1 of the guide provides both a generic and comprehensive set of information a COL applicant should provide in the FSAR of a COL application that references a certified design.

Section C.IV.1 is provided for the benefit of COL applicants. During its acceptance review of a combined license (COL) application, the NRC will use the information in this section to ensure that the applicant provides the information required to be included in the application.

Disposition: The guide has been changed as described above.

C.III.4-2 In Section C.III.4.3, the NRC 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?

Response: Section C.IV.4.3 has been changed to provide a set of situations in which COL information items can be addressed prior to the issuance of a COL. These include 1) identifying redundant ITAAC; 2) commitments; 3) license conditions after fuel load; 4) reference to operational programs reviewed in the COL application; and 5) proposing site specific ITAAC.

Disposition: The guide has been changed as described above.

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 design control document (DCD) information/action items?

Response: COL action items included in the ESP were included to provide a regulatory framework to address these items in a COL application. COL action items associated with the ESP will be treated the same as COL action and information items associated with a design certification.

Disposition: No change to the guide.

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.

Response: A COL applicant needs to address the complete COL action or information item, regardless if it has one or more parts. Toward that end, one COL action item may have multiple dispositions.

Disposition: No change to the guide

C.III.4-6 Will the guidance provide expectations for timeliness of combined license (COL) application information submittals (i.e COL Action Items or Information Items) for items

not complete at the time that the COL application is submitted? Examples are procedure descriptions, qualification of personnel and results of as-built verifications.

Response: The regulatory requirement in the design certification rules is for COL action or information items to be addressed in the application. Part of addressing COL action or information items should include any timing aspect associated with the COL action or information item. If this timing aspect is not addressed, the COL applicant should expect the staff to request a clarification of how this COL action or information item is being addressed.

Disposition: No change to the guide.

C.III.5-1 In the workshop, the NRC 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.

Response: The staff is in the process of discussing this issue and will provide guidance at a later date.

Disposition: No change to DG-1145 is necessary

C.III.5.1-1 The first paragraph of section C.III.5.1, Detailed Design Information and the Combined Operating License Application, contains a number of ‘shoulds’ and ‘recommends’ to “help avoid potential impacts on the combined operating licensee’s plans and schedules for loading fuel.” Flexibility needs to be maintained such that if the combined license (COL) is being banked for a later construction start, the DAC approach can be maintained. The concomitant risk to plans and schedules would be assumed by the licensee.

Response: This is a comment that does not invalidate the wording or intent of this section. Flexibility will be maintained consistent with Commission policy on the use of DAC.

Disposition: No change to DG-1145 is necessary.

C.III.5.1-2 In the second to last paragraph in section C.III.5.1, NRC discusses the design-centered review approach (RIS 2006-06) and notes that deviations to standardization may challenge this proposed “one issue, one review, one position” approach. Because of the rate of I&C technology change over the licensed life of either the design certification (DC) or combined license (COL), a second wave of orders for a given design after several years may involve later technology and require further review by the NRC staff. At that time, we would expect the staff to again apply the "one issue, one review, one position" approach.

Response: The DCRA is intended to be implemented to more efficiently review COL applications. To the greatest extent possible with this intent, the NRC will maintain flexibility should changes be made to the standard design pursuant to 10 CFR Part 52.

Disposition: No change to DG-1145 is necessary.

C.III.5.1-3 The first paragraph states that sufficient as-built and as-procured information to address DAC should be available at the time of the COL application submittal, or shortly after and that this detailed design information should be submitted during the COL application phase. This implies an unrealistic expectation of the level of detail of information available at the time of submitting the application. Further, in some design areas, as-built and as-procured information may not be available until after the COL review is completed. It should not be expected that applicants procure I&C equipment, valves, etc. prior to receipt of the COL. As-built information may not be available until the construction phase; which is authorized by the COL. One further comment is that the term "shortly after" is too vague. Based on these concerns, it is recommended that the first two sentences of this paragraph be deleted.

Response: It is clear to the staff that there will be some information that will not be available to the COL applicant prior to issuance of the combined license. Those areas should be identified by the applicant and a schedule as to when the information will be made available for NRC review should be submitted.

Disposition: Wording reflecting the response above have been incorporated into this section.

C.III.5.1-4 The first paragraph indicates that information to address DAC should be submitted during the COL application phase. This implies that the information needed to address DAC needs to be submitted to the NRC. However, it is expected that much of this information will be more detailed and lengthy than would be appropriate for inclusion in a FSAR. It is recommended that clarification be added that it is acceptable to make the information needed to address DAC available for NRC review and inspection at a site identified by the applicant.

Response: The staff have incorporated changes to reflect what information should be submitted and what information should be made available for review.

Disposition: The staff have incorporated changes to reflect what information should be submitted and what information should be made available for review.

C.III.5.1-5 It is recommended that a statement be added indicating that for design acceptance criteria (DAC) information not available at the time of the application (or during the application review) it is acceptable for the applicant to provide a schedule for completion of detailed engineering, procurement, fabrication, installation, and testing. This will support timely NRC inspection of DAC information.

Response: See response to C.III.5.1-3

Disposition: See disposition to C.III.5.1.3.

C.III.5.1-6 It appears the NRC in C.III.5.1 has assumed that there is a purchase order with the Certification Applicant by the combined license (COL) Applicants and that the Certification Applicant has advanced far enough to have "sufficient procurement and as built information available at the time of COL application". This assumption is premature, but the NRC has used the words "should be available," which indicates that there is room for exceptions.

Exceptions will be the norm since procurement activities for Digital I&C platforms would not start until the design has progressed sufficiently for a specific platform and there is an order with COL Applicant. The procurement life cycle would start when design has progressed sufficiently to support a minimal rework cycle for the systems within a specific platform. This being reality at this time for current new plants, most procurement and as-built information would not be available shortly after the COL application, but most likely a few years after the COL Application. Digital I&C procurement cycles vary from 1-1/2 to 2-1/2 years depending on suppliers and then there are still design acceptance criteria (DAC) type items that are not available until Digital I&C Supplier as- builds and test data are made available to support setpoint calculations, completing Tech Specs, etc

Response: See response to C.III.5.1-3.

Disposition: See disposition to C.III.5.1-3.

C.III.5.1.1-1 Item 2 in section C.III.5.1.1, Information Necessary to Verify Completion of Instrumentation and Control Design, lists the description of the implementation process for both hardware and software of I&C system life cycle design processes (stages) in the combined license (COL) application. Is it necessary to repeat information if the design process controls are fully described in the design certification (DC)?

Response: The staff recognizes that some information is more suitable to be made available for review rather than submitted. As such, the staff has provided clarifying language in this section. If the item states "Provide information" that means the applicant should submit information to the NRC. If the item stated "the applicant should confirm...", "the applicant should demonstrate..." that means the applicant should describe the available information and allow the staff to audit. We have also added the following statement in Section C.III.5.1.1 that stated: "If not practical to submit during the COL application, the applicant should identify those areas and provide a schedule to the NRC as to when the information will be available for NRC review." I think this statement should clarify our intent.

Disposition: See above.

C.III.5.1.1-2 Item 3 in section C.III.5.1.1, calls for the reference software design documents related to the I&C design process planning documents from the referenced certified design. Is it necessary to resubmit this information if it was provided for the DC?

Response: See response to C.III.5.1.1-1

Disposition: See disposition to C.III.5.1.1-1

C.III.5.1.1-3 It is recommended that clarification be added that the information to address design acceptance criteria (DAC) may be made available for inspection rather than submitted. Many of the 18 information items listed are more suitable for inspection than submittal.

Response: See response to C.III.5.1.1-1

Disposition: See disposition to C.III.5.1.1-1

C.III.5.1.1-4 Section C.III.5.1.1 subsection 10, Repair Provision: This section does not contain any guidance for addressing diagnostic systems for digital I&C systems. Guidance is requested in this area.

Response: There is guidance already provided for and entitled Repair Provision.

Disposition: There is guidance already provided for and entitled Repair Provision.

C.III.6 No workshop comments received for this section of the draft regulatory guide.

C.III.7-1 The last sentence of the first paragraph under design certification- inspection, tests, 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.

Response: A discussion on development of physical security ITAAC is provided in DG-1145, Section C.II.2.2.12. In addition, Appendix C.II.2-C has been created as a place holder for generic physical security ITAAC that an applicant should consider when developing their site-specific physical security ITAAC. When these generic physical security ITAAC have been established, they will be provided in Appendix C.II.2-C.

Disposition: Guidance has been added to Section C.II.2.2.12. Appendix C.II.2-C has been created.

C.III.7-2 The guidance states that combined license (COL) applications "must" include physical security (PS) inspections, tests, 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.

Response: The NRC agrees with this comment.

Disposition: The discussion of physical security ITAAC has been revised to be consistent with the above recommendation

C.III.7-3 There is a sixth inspection, test, analyses, and acceptance criteria (ITAAC) scenario: a COL application that refers to a design certification but no ESP.

Response: The NRC agrees with this comment.

Disposition: The 6th scenario, a COL application that references a certified design but no ESP, has been added.

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 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.

Response: The NRC agrees with this comment. The intent of this statement is to convey the assumption that the ESP referenced in a COL application may have included only generic EP-ITAAC that were not modified to accommodate site-specific impacts. The NRC recognizes that some ESPs may include generic EP-ITAAC that have been modified to varying degrees to accommodate site-specific impacts.

Disposition: The wording in scenario 3 has been revised to match the wording in scenario 5.

C.III.7-5 It may be simpler, and promote consistency, to present the guidance on the various inspection, test, analyses, analysis, and acceptance criteria (ITAAC) scenarios in a tabular format.

Response: The NRC agrees with this comment.

Disposition: The draft regulatory guide, Section C.III.7, has been revised to present the guidance on the various ITAAC scenarios in a tabular form.

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 DCD conceptual design information and the evaluation of SAMDAs in DCD Appendix 1B from the design certification.

Response: The NRC agrees with this comment.

Disposition: The statement has been revised to indicate that the COL applicant that references a certified design must incorporate the DCD in accordance with Section III.B of the applicable appendix to 10 CFR Part 52 for that certified design.

C.III.7-7 In reference to Section C.III.7, the Proposed 52.80(b) would require the inspection, test, analyses, and acceptance criteria (ITAAC) for a combined license (COL), including design certification ITAAC (if referenced), to be included in the application but not in the 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 constitutes 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 final safety analysis reports (FSARs) will be based on the content and organization of Tier 2 and will thus include Tier 1 design requirements. Does the NRC agree that except as a subset of Tier 2, Tier 1 design requirements are not required to be otherwise incorporated into the FSAR?

Response: The NRC does not agree with this position. Definitions for “Tier 1” and “Tier 2” are provided in Section II of the appendices to 10 CFR Part 52 that codify the certified designs. These definitions clearly reflect that the Tier 1 document is of a higher tier than Tier 2. The definition for “Tier 2” includes the following statement “compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1.” Given these definitions, Tier 1 cannot be considered a “subset of Tier 2”, as stated in the question. The requirements for incorporating the information included in a certified design are provided in Section III of the applicable appendix to 10 CFR Part 52 for that certified design.

Disposition: No change to the guide.

C.IV.1-1 The approach of requiring all information to be complete for review at combined license (COL) submittal is very restrictive and may not be necessary. For example, the plant specific probabilistic risk assessment (PRA) is done after all other COL work is done, taking an additional 3 to 6 months to complete PRA report. Will it be acceptable to submit the PRA 3 months after the final safety analysis report (FSAR)? All submittal requirements for a COL application should be thoroughly justified .

Response: By regulation, the PRA is considered a part of the COL application and is required by *proposed* 10 CFR 52.80. The staff uses the PRA to inform its review of the COL application. Allowing COL applicants to submit the PRA at a certain time period following submittal of the “FSAR” information required by *proposed* 10 CFR Part 52.79 may unnecessarily delay the staffs review. COL license applicants should develop their work schedules based upon submittal of the plant specific PRA at the same time as submittal of the other information required for a COL application to ensure a complete application. Allowing PRA submittals to occur following the “FSAR” information is not consistent with the staff and Commissions expectations for high quality, complete COL applications. A piecemeal approach to submittal of a COL application is not consistent with the high level of standardization and completeness that is necessary to instill public confidence in the new reactor licensing process defined in 10 CFR Part 52.

Disposition: No change to the COL Application Acceptance Review Checklist is required.

C.IV.1-2 How will the staff deal with areas where the design is not complete at COL?

Response: The staff understands this question to relate to designs that are incomplete at the time of COL application submittal. For a COL applicant that does not reference a certified the staff believes that there should not be any areas of the facility design that are incomplete at the time of COL submittal. The only areas where the design may not be complete are those areas in a certified design that a COL applicant references that are covered by design acceptance criteria (DAC) and included in ITAAC. Additional guidance on DAC is provided in Section C.III.5 of this guide.

Disposition: No change to the COL Application Acceptance Review checklist is required

C.IV.1-3 Does the first table that correspond to 10 CFR 52.79(a)?

Response: The staff agrees that clarification of the source of the requirements contained in the tables contained in the COL Application Acceptance Review Checklist would be useful for COL applicants and other stakeholders.

Disposition: The staff will identify the applicable subsections of *proposed* 10 CFR 52.79 and 10 CFR 52.80 to which the tables in the COL Application Acceptance Review Checklist correspond.

C.IV.1-4 In an acceptance review, the submittal of sufficient information in an application to complete NRC staff review implies that there will be no requests for additional information (RAIs), except for clarification. Should this be restated as a goal with practical guidance?

Response: This question refers to the slide presentation accompanying the discussion of the COL acceptance review checklist. The staffs intent in making this statement is to ensure that the COL application submitted is complete. In this context, “sufficient” means that there is no missing information and there are no requirements in *proposed* 10 Parts 52.79 and 52.80, and other applicable portions of the regulations, that have not been addressed. Sufficient information in the context of the acceptance review checklist is not synonymous with acceptable information necessary to make a finding necessary to issue a license. Completing the review means that all the information required by *proposed* § 52.79 and § 52.80 is provided in the application and, therefore, can be completely reviewed by the staff. Sufficient information in the context of the acceptance review is not interchangeable with adequate or acceptable information. Therefore, the staff assumes that completing its review of an application may result in requests for additional information.

Disposition: An introductory section will provided for in DG-1145, Section C.IV.1, to provide clarification and discussion on the purpose of the checklist, how the staff intends to use the checklist, and further guidance on the meaning and scope of an acceptance review, as discussed above.

C.IV.1-5 Consider changing the criteria to “Is there sufficient information to complete the review,” or articulate the real differences between the criteria and the earlier criteria.

Response: See response to C.IV.1-4 above.

Disposition: See disposition for C.IV.1-4 above.

C.IV.1-6 If all boxes are checked “Yes,” will NRC accept the combined license (COL) and begin this review?

Response: It is the NRC’s intent that the acceptance review for a COL application will be similar in process and focus to the recent acceptance review performed for the ESBWR design certification application. The acceptance review is not to the same level of detail as the license review for the application. The acceptance review will focus on whether sufficient information has been provided to perform a complete review of the application. The acceptance review may identify areas where there is insufficient or incomplete information in the application which may result in the staff seeking additional information that could result in delays to formal docketing of the application. Ideally, if the results of

the staff's acceptance review allows all the boxes in the checklist to be checked "Yes", then the application is considered to provide sufficient information for the staff to perform a complete review and the application can be docketed.

Disposition: An introductory section will be provided for in DG-1145, Section C.IV.1, to provide clarification and discussion on the purpose of the checklist, how the staff intends to use the checklist, and further guidance on the meaning and scope of an acceptance review.

C.IV.1-7 What would be the nature of RAIs for a COL application that is accepted as complete?

Response: The NRC believes it is not possible to predict the nature of requests for additional information (RAIs) based on the staff's use of the proposed COL acceptance review checklist to assist in its determination for accepting a COL application for docketing and subsequent review. Sufficient information in the context of the acceptance review checklist is not synonymous with acceptable information necessary to make a finding necessary to issue a license. Sufficient information in the context of the acceptance review is not interchangeable with adequate or acceptable information. Therefore, the staff assumes that completing its review of the application may result in requests for additional information. See also response to C.IV.1-4, above.

Disposition: See disposition to C.IV.1-4, above.

C.IV.1-8 The March 15th workshop provided insights and additional helpful information regarding the checklist. However, the current form of Part IV.1 contains only the "checklist" itself with no accompanying explanation. It would be helpful if Part IV.1 included an explanation to properly distinguish between the acceptance review and the later, more detailed technical review by the staff.

Response: The NRC agrees with the above recommendation. See also response to C.IV.1-4, above.

Disposition: The NRC will provide an introductory discussion of the purpose and goals of the checklist to properly distinguish between the acceptance review and the later, more detailed, technical review by the staff. See also disposition for C.IV.1-4, above.

C.IV.1-9 On page 8, Item 37 in Section C.IV.1 refers to Section C.II.6 which does not appear to be listed in the DG-1145 table of contents. Is Section C.II.6 to be provided later, or is this an incorrect reference? Should there also be a reference to Sections C.II.4 and 5?

Response: The reference to Section C.II.6 in Item 37 on page 8 of the proposed checklist was to a particular section of DG-1145 that was envisioned and reflected in an earlier draft of the Table of Contents for DG-1145. Item 37 corresponds to *proposed* Part 52.79(a)(37) and refers to guidance on operating experience insights. Guidance on operating experience insights will be provided in DG-1145, Section C.I.1.

Disposition: Item 37 of the COL Application Acceptance Review Checklist will be revised to provide reference to Section C.I.1 for guidance on operating experience insights.

C.IV.1-10 Page 8, Item 37 in Section C.IV.1 refers to the ESBWR design control document (DCD) application checklist which included an explicit listing of bulletins and generic letters that were expected to be addressed. As discussed in the March 15th workshop, compliance discussions for older generic communications can be quite difficult because they are

dated. Some are superceded by later generic communications and other NRC actions. It would be most helpful if the Staff were to review generic communications and reduce the number of older documents that must be addressed and provide an explicit listing as was done in the ESBWR DCD application checklist.

Response: Section C.I.1 provides a discussion on generic issues and Section C.IV.8 of this guide provides further guidance on the generic issues to be addressed by COL applicants.

Disposition: The checklist has been revised to refer to DG-1145, Section C.IV.8.

C.IV.1-11 Item 32 in Section C.IV.1 indicates that it seeks “technical qualifications” of the applicant. It is not clear as to why this item cites 10 CFR 50.57(a) which appears to relate to issuance of the operating license (specifically 50.57(a)(4) which pertains to both technical and financial qualifications). In that the checklist applies to application contents and that Item 32 refers to “technical qualifications,” a more appropriate citation would be 50.34(b)(7) which specifically applies to application content requirements.

Response: The NRC agrees with the above comment.

Disposition: For clarity, the COL Application Acceptance Review Checklist language for item 32 will be revised to be consistent with the language in *proposed* 10 CFR § 52.79(a)(32) and will not include any references to § 50.57 or § 50.34.

C.IV.1-12 On page 12, it suggested the title of this section be reworded since the section’s subject matter is broader than the final safety analysis report (FSAR). That is, Item 3 includes the Environmental Report part 51 information. This would typically be provided in a separate section or “part” of the combined license (COL) application and would therefore have an “FSAR” section reference, as implied by the column header.

Response: The NRC agrees with this suggestion. The portion of the checklist shown on page 12 corresponds to the requirements of the *proposed* 10 CFR § 52.80. The information required by *proposed* § 52.80 is additional technical information required in the application rather than additional technical information required in the FSAR.

Disposition: The portion of the checklist shown on page 12 that includes the information requirements of *proposed* 10 CFR 52.80 will be revised to be consistent with title of *proposed* § 52.80 to reflect that the information required is additional technical information required for the application.

C.IV.1-13 Item 15 indicates the following should be in the final safety analysis report (FSAR) section 13.4, “*The application contains a description of the program for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65.*” However, the standard review plan (SRP) update program schedule indicates that the Maintenance Rule would be addressed in SRP 17.x (to be issued final Dec 2007). A suggested revision is to identify Item 15 as FSAR section 17.x or TBD.

Response: The NRC agrees with this suggestion. DG-1145, Section C.I.17 will provide guidance for the licensee to fully describe their program for monitoring the effectiveness of their maintenance program as required by 10 CFR 50.65.

- Disposition:** Item 15 of the checklist will be revised to identify FSAR section 17.6 as the appropriate section of the COL application providing a discussion of the maintenance rule program.
- C.IV.1-14** Item 1 should be moved to the Administrative Requirements. The proposed rule does not require the probabilistic risk assessment (PRA) to be part of the final safety analysis report (FSAR), just part of the application. Performing a 10 CFR 50.59 evaluation of design changes with the PRA as part of the FSAR would be a significantly more difficult task than it currently is.
- Response:** *Proposed* 10 CFR Part 52.80 for additional technical information to be included in a COL application includes the requirement for a plant-specific PRA. The additional technical information required by § 52.80 are not considered part of the FSAR and they are not considered administrative requirements. See also response to C.IV.1-12.
- Disposition:** The section of the checklist containing the requirements for a the plant-specific PRA will be clarified to indicate that it is additional technical information required for the application rather than additional technical information required by the FSAR. The PRA is not considered to be part of the FSAR. See also disposition for C.IV.1-12.
- C.IV.1-15** The sufficiency standard should be information adequate to begin, not complete, the review. In addition, the sufficiency standard should not be used as an alternative means to reject applications which prefer a different technical position than the merits with which the staff agrees. Sufficiency does not equate to ultimate legal adequacy. It merely means that there must be a reasonable amount of information upon which staff can commence its review of an application that meets regulatory requirements.
- Response:** See response to C.IV.1-4 above.
- Disposition:** See disposition for C.IV.1-4 above.
- C.IV.1-16** Item 37 in the COL Application Acceptance Review Checklist seeks “comparable international operating experience.” In the same way that the NRC provides generic communications as the source of potential operating experience insights, it would seem appropriate that a domestic COL applicant would look to NRC generic communications as the source for potential foreign experience. It is suggested that the NRC clarify its position on this issue. As the lead federal agency, the NRC should provide this information to COL applicants by generic communications or other appropriate means.
- Response:** Guidance on the consideration of comparable international operating experience will be provided in Section C.I.1 of DG-1145.
- Disposition:** No change to the COL Application Acceptance Review Checklist is required.
- C.IV.1-17** 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?
- Response:** Guidance has been provided in Section C.IV.5 of this guide
- Disposition:** Section C.IV.5 added to the guide.

C.IV.2-1 Reference to the design certification (DC) in the COL application should be encouraged over incorporation of DC text in the COL application

Response: The COL application that references a certified design must include a plant-specific DCD in accordance with section IV.A.2.a, as well as siting information, plant-specific design information, and operational programs in the FSAR. Simply incorporating the generic DCD by reference will not facilitate the NRC's review of the COL application, which is the goal of this requirement. If a COL applicant does integrate the generic DCD into the FSAR submitted with the COL application, the applicant is strongly encouraged to clearly distinguish the departures from and exemptions to the generic DCD that the NRC will review in the COL application.

Disposition: The regulatory guide will be revised to include a discussion to address this comment and to explain "include in the application"

C.IV.2-2 If the reactor vendor revises the design control document (DCD), no changes would be required to the text of the combined license (COL) application since the DCD is referenced in the COL application. Does the NRC need to be informed by letter that the DCD revision does not impact the COL application?

Response: An applicant or licensee who references a design certification rule must maintain a plant-specific DCD that accurately reflects generic changes to and plant-specific departures from the generic DCD under section X.A.2. In addition, Section X.B of each appendix to 10 CFR 52 specifies requirements for submitting updates to and departures from a DCD referenced in a COL application.

Disposition: DG-1145 will be revised to include a reference to Section X for the records and reporting requirements of a COL applicant referencing a certified design.

C.IV.2-3 What is the preferred approach for updating the COL application when the design control document (DCD) is revised?

Response: The NRC requires applicants who reference a certified design to meet the requirements in section X for records and reporting.

Disposition: DG-1145 will be revised to include this requirement

C.IV.2-4 Could material that was referenced or incorporated by using the copy-and-paste method from an approved generic design control document be re-opened during the combined license (COL) review?

Response: Information in the generic DCD can only be reopened in the COL review if someone requests a change to or departure from the DCD in accordance with section VIII of the design certification rule. However, If the material from a DCD is included in the COL application by using the copy-and-paste method, it should be done in a manner that is distinct from the non-DCD material in the application, such that NRC staff reviewers can distinguish between certified design material and non-certified design material. The reason for the distinction is because different change processes apply to this information. Further guidance on change processes is provided in Section C.IV.3.

Disposition: No change to regulatory guide.

C.IV.2- 5 Section C.IV.2 as well as sections of the regulatory guide should clarify the distinction between "incorporation by reference," "including" and "physically including" information in the combined license (COL) application. Each of these terms is used in Section IV of the design certification rules, "Additional Requirements and Restrictions."

Response: The staff agrees with this comment.

Disposition: Section C.IV.2 will be revised.

C.IV.3-1 The discussion regarding parallel review combined license (COL) and design certification (DC) indicated that the DC review would be impacted if a site specific issue came up in the COL after the DC had been approved. How is this different than the case where a COL application references an existing DC, such as AP1000? The examples given were seismic loads and category 4 wind loads. These same challenges occur, but the design control document is not impacted.

Response: The discussion was intended to illustrate how site specific issues could impact the design certification review. The staff understands that the applicant for a design certification could make changes to the certified design to accommodate site specific issues if desired; however, there is no requirement to do this. The COL applicant that references a certified design for which the site characteristics are not enveloped by the site parameters in the DCD would need to implement a change to the certified design or chose a different certified design. The discussion intended only to illustrate the potential impact to design certification in review versus a completed design certification..

Disposition: No change to DG-1145.

C.IV.3-2 For the purpose of writing the departures from the DCD report, how does the NRC define "departures"? Is the information that is added to the FSAR to address COL action items considered a departure that must be justified in the departures report? Are departures only technical changes to the DCD?

Response: Guidance will be provided in the final guide following completion of the final rulemaking on 10 CFR Part 52.

Disposition: No change to DG-1145.

C.IV.3-3 The regulatory guidance uses terms such as deviations and variances. Are these equivalent to departures? It is suggested that if these terms refer to the same type of change, one term should be used throughout the guide.

Response: The staff agrees on consistent use of terminology. Departure, variance, and deviation were used interchangeably in the guide. Departure should be used consistently in the context of design changes to the certified design or "departure from a method of evaluation" as defined in the appendices to *proposed* Part 52. Variances should be used consistently in the context of early site permits.

Disposition: The guide will be revised to use consistent language.

C.IV.3-4 If we replace conceptual design information with actual design information, is the replacement a departure from the DCD? (Ref. C.III.1.5)

Response: No, the staff does not consider the replacement of conceptual design information with actual design information a departure. The conceptual design information is not certified as part of the certified design. Therefore, when the COL applicant provides actual design information it does not "replace" the conceptual design in the context of making a design change to the certified design.

Disposition: No change to DG-1145.

C.IV.3-5 The draft section C.IV.3, "General Description of Change Processes" discusses, in general terms, the provisions of the Design Certification Rule Appendices, Section VIII.B.5.c for combined license (COL) departures from Tier 2 information related to severe accident features. The NRC and industry have discussed this issue several times over the past few years and it is recommended that this section of the guidance be augmented to provide more specific guidance on the implementation of the rule regarding these changes. Specifically, the definition of "departure", "resolution of a severe accident issue", "substantial increase in the probability of a severe accident", "credible", and "substantial increase in the consequences to the public" should be expanded. Also, a more detailed change process for departures from Tier 2 information should be provided.

Response: Guidance will be provided in the final guide following completion of the final rulemaking on 10 CFR Part 52.

Disposition: No change to DG-1145.

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 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. Please reaffirm the staff's intent and discuss how the DG-1145 will be revised to address this issue.

Response: The NRC plans to codify the implementation requirements for the operational programs listed in SECY-05-0197 in the update to 10 CFR Part 52. Consequently, discussion regarding the implementation license conditions has been removed from the guide. Therefore, the programs listed in the regulations will constitute the programs that must be fully described in a COL application.

A COL applicant may choose to use a operational program to meet a future regulation (e.g., potential regulations resulting from the resolution of Generic Issue 191).

The NRC will continue to determine if any additional operational programs meet the three criteria specified in SECY-05-0197 as the update to the SRP proceeds. If any additional programs are found to meet the three criteria, the guide, SRP, and regulations will be updated as appropriate to reflect the additional operational program(s).

Disposition: The guide has been changed as described above

C.IV.4.1-1 Why is operational reliability assurance process (O-RAP) not listed in section C.IV.4.1?

Response: The operational reliability assurance program is considered to be completed prior to operation of the plant.

Disposition: No change to the guide.

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.

Response: The staff agrees with the comment.

Disposition: The guide has been changed as described above.

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."

Response: Guidance on how to fully describe an operational program and its implementation has been included in Section C, Part I, of the guide. This information is also included in Section C.III.1 of the guide.

Disposition: No change to the guide.

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.

Response: "Shall" has been changed to "must". To meet the regulations, the COL applicant must fully describe an operational program; however, the applicant has some flexibility in describing its implementation by proposing ITAAC for implementation.

Disposition: No change to the guide.

- 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 final safety analysis reports (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.
- Response:** FSAR in this context means FSAR included in a COL application
- Disposition:** The guide has been changed to provide the definition of “fully described” as provided in SECY-05-0197.
- C.IV.4.4-1** 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"
- Response:** The NRC agrees with the comment.
- Disposition:** The guide has been changed as described above.
- C.IV.5** No workshop comments received for this section of the draft regulatory guide.
- C.IV.6** No workshop comments received for this section of the draft regulatory guide.
- 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.
- Response:** Environmental issues are part of the combined license application.
- Disposition:** No change to the guide.
- 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.
- Response:** The development of this guide does not assume that topical reports will be included prior to the COL application. However, NRC regulations do not preclude the submittal of topical reports for approval by the NRC. NRC Regulatory Issue Summary 1006-06, “New Reactor Standardization Needed to Support the Design-Centered Licensing Review Approach,” recognizes that topical reports may be included in pre-application activities. Therefore, treatment of both of these topics is appropriate in this section.
- Disposition:** Revise Section C.IV.7 to add a reference to RIS 2006-06 and topical reports that may be submitted by a COL applicant to support pre-application activities.
- 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.

Response: While the question does not relate to the development of the guide, the NRC will consider coordination of public meetings with the applicant where appropriate.

Disposition: No change to the guide.

C.IV.7-4 Both the safety 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.

Response: The NRC agrees that coordination with other entities will involve both the safety and environmental reviews of the COL application. This has already been addressed in Section C.IV.7.1.3 of the guide.

Disposition: No change to the guide.

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 safety and Environmental parts of a COL.

Response: The NRC agrees that sources of this information would be appropriate to discuss sources of historical site information in pre-application.

Disposition: Guide will be changed to recommend discussion of historical site information in pre-application.

C.IV.7.1-1 The guidance does not address pre-application reviews of combined license (COL) sections for sufficiency. Applicants and NRC would benefit from developing a common, early understanding of what is acceptable for docketing.

Response: The NRC is still considering what interactions are appropriate regarding discussion of draft portions of a COL application prior to submitting a COL application.

Disposition: No change to the guide.

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.

Response: The NRC agrees that it would be appropriate to discuss the QA and DRAP program in pre-application.

Disposition: Guide will be changed to recommend discussion of the QA and DRAP program.

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.

- Response:** The scope of Section C.IV.7.1 is the entire COL application. Therefore, it is not limited to the plant specific DCD.
- Disposition:** No change to the guide
- 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.
- Response:** The NRC agrees that, in addition to site characterization and LWA activities, there may be other activities to support plant construction that would be beneficial to discuss in pre-application.
- Disposition:** Guide will be changed to recommend that other activities to support plant construction be discussed in pre-application.
- 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.
- Response:** The NRC agrees that it would be appropriate to discuss the offsite power analysis with RTO in pre-application.
- Disposition:** Guide will be changed to discuss offsite power analysis with the RTO in pre-application.
- 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.
- Response:** The NRC agrees that both COL action and information items should be discussed in pre-application.
- Disposition:** Guide will be changed to be consistent with Section C.III.4 of the guide.
- 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.
- Response:** The NRC will consider this comment in the development of the final guide and may make additional changes as appropriate.
- Disposition:** No change to the guide.
- C.IV.8-1** The third paragraph in Section C.IV.8 (p. C.IV.8-1) indicates the "benchmark for the Staff's review" was NUREG-0933, Supplement 29 (June 2005). While the Supplement 29 manuscript was completed in June 2005 (per the NRC web site), shouldn't this reference be to the publishing date of November 2005?

- Response:** The staff agrees that providing the date in addition to the supplement number may be confusing.
- Disposition:** This section will be revised to delete the date but retain the supplement number.
- C.IV.8-2** Per C.IV.8, COL applicants should review later revisions of NUREG-0933. For planning purposes, what is the general frequency for NRC updates to this NUREG?
- Response:** The staff issues an annual summary of activities related to generic safety issues in a SECY paper to the Commission that is publicly available.
- Disposition:** No change to DG-1145.
- C.IV.8-3** The C.IV.8 tabulated listing includes a column labeled "Exclusion Code." Is it correct to interpret this table such that all items provided an exclusion code are "excluded from further review" and need not be addressed in the combined license (COL) application?
- Response:** In revising Section C.IV.8 to refer to Appendix B of NUREG-0933, the question is moot. See also response to C.IV.8-7.
- Disposition:** See disposition for C.IV.8-7, below.
- C.IV.8-4** The second paragraph in Section C.IV.8 (p. C.IV.8-1) discusses the NRC review and identification of items that have been closed by other NRC actions or requirements. "In these cases, the NRC closure action and/or new requirements has been identified." Presumably, the inclusion code "RQ" (i.e., "Resolved -- new requirements issued"; p. C.IV.8.39) would apply to this statement. Yet, a considerable number of line items assigned "RQ" do not appear to identify the "NRC closure action and/or new requirement." (See items 1.B.1.1(5), I.D.1, I.D.2, II.B.1, et. al.) Are these new requirements missing or is the subject statement on p. C.IV.8-1 misunderstood?
- Response:** In revising Section C.IV.8 to refer to Appendix B of NUREG-0933, the question is moot. See also response to C.IV.8-7.
- Disposition:** See disposition for C.IV.8-7, below.
- C.IV.8-5** The final sentence of the second paragraph in Section C.IV.8 (p. C.IV.8-1) indicates that the combined license (COL) applicant should address those issues "that remain open and which are technically relevant to the COL applicant's design or the standard plant design for which certification is sought." All items under "Inclusion Code" are either "resolved" or "resolved with new requirements." No issues are labeled as "open." Please clarify the meaning of "open" in this context.
- Response:** In revising Section C.IV.8 to refer to Appendix B of NUREG-0933, the question is moot. See also response to C.IV.8-7.
- Disposition:** See disposition for C.IV.8-7, below.
- C.IV.8-6** In reviewing NUREG-0933, it is noted that numerous Three Mile Island (TMI) action items [e.g., II.B.6, II.E.4.4 (2) and (3), II.K.1(1)-(4), (6)-(9), et. al.] are listed as "NA" under "Future Plants Effective Date" (Appendix B, NUREG-0933, Supplement 29). It

appears that these TMI items were specifically applicable to operating plants at the time or were one-time actions (such as to issue a letter requiring action). In the table provided in C.IV.8, these items are given an inclusion code of "RQ." Please clarify the meaning of the "NA" for these items listed in NUREG-0933 and if the NRC intended that these items be addressed in the COL application.

Response: See response to C.IV.8-7, below.

Disposition: See disposition for C.IV.8-7 below.

C.IV.8-7 The C.IV.8 table appears to provide a comprehensive listing of Three Mile Island (TMI) items similar to that included in App. B of NUREG-0933. If the C.IV.8 "inclusion code" is understood to mean that all "included" TMI items must be addressed in the combined license (COL) application, there appears to be a discrepancy with CFR 50.34(f). This listing of "included" TMI items in C.IV.8 appears to include a number of items that are not listed in 50.34(f). Please clarify this apparent discrepancy regarding which TMI items should be addressed in either the design control document (DCD) or COL application.

Response: The staff agrees with the comment. COL applicants and design certification applicants should refer to Appendix B of NUREG-0933 for the list of generic issues that need to be addressed. In addition, applicants should also address those generic issues for which there is either no entry or "TBD" in the "Future Plants Effective Date" column. Appendix B has been verified to be consistent with the 50.34(f) items required to be addressed under 10 CFR 52.79(a)(17).

Disposition: Section C.IV.8 has been revised to refer COL applicants to Appendix B of NUREG-0933 for the list of generic issues that need to be addressed. In addition, guidance has been provided where there is either no entry or "TBD" in the "Future Plants Effective Date" column.

C.IV.9-1 The title of Part 1.B., "Codes and Testing," is apparently incorrectly interpreted as relating to standard and industry codes (such as ASME, ANS, IEEE, etc). It is recommended that the title be revised to clarify NRC intent, e.g., "Computer Codes and Verification & Validation."

Response: Comment noted

Disposition: Part 1.B, "Codes and Testing" was initially changed to Section C.IV.9, "Test Requirements for Advanced Reactors." Section C.IV.9 has been deleted and this topic has been incorporated in Section C.I.1 of the Regulatory Guide.

C.IV.10-1 What are the qualification requirements for RTNSS components? A statement was made during the public workshop that RTNSS is the same as safety related.

Response: While RTNSS systems are not safety related, Section C.IV.10 states that "the designer imposes design requirements commensurate with the risk significance of those elements involved."

Disposition: No change to the guide.

C.IV.12 No workshop comments received for this section of the draft regulatory guide.