

U.S. Nuclear Regulatory Commission

Comment Summaries and Responses/Dispositions

Draft Guide (DG) – 1145

(Issued as Regulatory Guide 1.206)

Combined License Applications for Nuclear Power Plants (LWR Edition)

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This document summarizes the comments the U.S. Nuclear Regulatory Commission (NRC) received in response to a solicitation of public comments (71 FR 52826) on Draft Guide (DG) 1145, "Combined License Applications for Nuclear Power Plants." The following table identifies the comments received and the location of the source document in the NRC Agencywide Document Access and Management System (ADAMS).

ADAMS Accession No.	Public Comment
ML062860563	Comment (1) of K. Warnock on Request for Written Clarification for DG-1145, Section C.111.1 - Information Needed for a COL Application Referencing a Certified Design, Section 17.5.3, "Evaluation of the QAPD Against the SRP and QAPD Submittal Guidance."
ML062910164	Comment (2) of Kurt Schaefer on DG-1145 Chapters 14 and 15.
ML063000140	Comment (3) of Patricia Schroeder on Draft Regulatory Guide DG-1145, "Combined License Applications for Nuclear Power Plants (LWR Edition)."
ML063000204	Comment (4) of Adrian P. Heymer on Draft Regulatory Guide DG-1145, "Combined License Applications for Nuclear Power Plants (LWR Edition)."
ML063000144	Comment (5) of Robert E. Brown, on behalf of GE Energy Nuclear, on NRC Draft Guide 1145, "Combined License Applications for Nuclear Power Plants"
ML063000146	Comment (6) of Kathy M. Warnock on Draft Regulatory Guide DG-1145 Regarding Creation of a New SRP, With Creation of Two Organizations Within NRC, Consideration Should Be Given to Creation of New Standard Review Plan to Correlate Directly with New RG-1145
ML063030349	Comment (7) of Ronnie L. Gardner on Proposed New Regulatory Guide DG-1145, Combined License Applications for Nuclear Power Plants (LWR Edition).
ML063040327	Comment (8) of Wesley Bowers on Draft Regulatory Guide DG- 1145 re Digital Instrumentation & Controls.
ML071150149	Comment (9) of Jens Uwe Klugel on Draft Regulatory Guide DG-1145, Section C.I.2.5.2.4 Probabilistic Seismic Hazard Analysis and Controlling Earthquake and C.I.2 in General.

Comment 1 (Burns and Roe)

1. It is recommended that DG-1145, Section 17.5.3 also be revised to clarify this. Possible rewording to the second paragraph of Section 17.5.3,, could be as follows: "For COL applicants that don't have an existing NRC approved QAPD, Chapter 17 of the FSAR should also describe..."

Response/Disposition

Staff agrees and revised wording to state "If not addressed by an NRC approved QAPD..."

Comment 2 (General Electric)

1. C.1.14.3, 1st paragraph states "the COL applicant should provide its proposed *(ITAAC)* selection methodology and criteria for establishing the ITAAC that are necessary and sufficient to provide that reasonable assurance." ... Therefore, with respect to the proper content and scope of the ITAAC, there is no consistency throughout the entire industry.

A definitive set of "yes/no" criteria should be provided in Chapter 14 to consistently determine the content and scope of the Tier 1 design descriptions and ITAAC.

Response/Disposition

The NRC staff acknowledges some inconsistency in the historical development of ITAAC. Separate efforts are underway to refine the definition and ultimate closure of ITAAC items and may result in a future enhancement to this guidance document.

2. C.I.15 and numerous subsections are mis-titled on two accounts. First, the section title and various subsection titles use the slang term of "transient" (which is undefined in the 10 CFRs) to mean an "anticipated operational occurrence" (AOO), which is defined in 10 CFR 50, App. A. An undefined slang term should never be used to replace a defined term, and thus, all "transient" statements should be corrected. For example, ESBWR Tier 2 Chapter 15 correctly does not label any group of abnormal design basis events as "transients."

Second, Chapter 15 includes ATWS, which is neither an AOO nor an accident. ATWS in every BWR licensing basis and the associated ANS standard is labeled as a "special event." Therefore, the title to Chapter 15 should be changed to "Safety Analyses," and the other (non-Chapter 15) safety analyses, such as the ECCS-LOCA performance analysis in Section 6.3, should be included by reference.

Response/Disposition

See response to NEI Comment C.I.15-2

3. C.I.15.2 correctly defines the design basis events (DBEs) into AOOs and accidents. Because a PRA is already required, C.I.15.2 should provide the event probability threshold value for determining which DBEs are AOOs and which are accidents. The historic AOO annual probability threshold for the BWR is 1/100 per year. This value is conservative based on one event occurring within a plant's 60 design life.

Response/Disposition

The staff did not incorporate changes at this time in order to maintain consistency with Standard Review Plan (NUREG-0800).

4. Consistent with the regulations, C.1.15.2 correctly divides the DBEs into just two categories, AOOs and accidents. However, the use of just these two DBE categories is not currently accepted by the NRC Staff. In December 2004, GE submitted licensing topic report (LTR) NEDO-33175, Rev. 0, "Classification of ESBWR Abnormal Events and Determination of Their Safety Analysis Acceptance Criteria," for NRC acceptance. LTR Rev. 0 was consistent with the regulations and C.I.15.2 in dividing the DBEs into AOOs and accidents. The Staff did not accept that categorization, and required that DBEs which are less frequent than AOOs but are not "traditionally" called accidents be classified as "infrequent incidents or events," as reflected in the ESBWR DCD Tier 2 Chapter 15. To be consistent with the regulations the DBEs should be categorized as AOO, accidents and design basis accidents. The NRC Staff position should be made consistent with DG-1145.

Response/Disposition

No suggested change to the regulatory guide identified. The staff notes however that the Standard Review Plan (NUREG-0800) does include discussions of infrequent events as does frequently cited American Nuclear Society standards related to categorization of events.

5. The C.I. 15.6.2 paragraph should be changed to read: "Only safety-related systems or components can be used to mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in 10 CFR 50.34(a)(1). However, nonsafety-related systems and components may be assumed operable in the safety analyses for AOOs, accidents with consequences that are not comparable to the applicable guideline exposures set forth in 10 CFR 50.34(a)(1), and special events (e.g., ATWS, SBO and Safe Shutdown Fire), if an additional non-consequential random and independent failures must occur in order to disable the system(s) or component(s)."

Response/Disposition

See response to NEI Comment C.I.15-3

Comment 3 (American Nuclear Society)

1. ANS understands that DG-1145 is an update to the existing Regulatory Guide 1.70. On a historical note, current licensees of operating reactors have routinely used ANS standards to meet the provisions of RG 1.70 even though the guidance does not specifically endorse the standards in all cases. It is hoped that the next version of DG-1145 will correct this situation.

Regulatory Guide 1.206 (formally DG-1145) cites existing technical guidance in other regulatory guides, the standard review plan, or other sources to provide guidance on the content of combined license applications. As such, this regulatory guide would not be the vehicle to endorse a specific industry code or standard on the technical subjects identified in the comment. The comments have been forwarded to the staff working on the technical guidance documents for their consideration.

Comment 4 (Nuclear Energy Institute)

1. The vast majority of comments received by the NRC staff on DG-1145 was from the nuclear industry and were coordinated and submitted by the Nuclear Energy Institute (NEI). The summary of comments and their resolution are described in Attachment 1.

Comment 5 (GE Energy Nuclear)

1. The design certification rule for the ABWR, Section IV.A.3, requires that an application referencing the rule include the proprietary information and safeguards information referenced in the U.S. ABWR DCD. The NRC guidance should clarify that the information considered proprietary or safeguards for the certified design retains the same designated status in the combined license application as for the design certification and will be handled in the appropriate manner.

Response/Disposition

The staff agrees with the comment but defers to other NRC guidance for the handling of sensitive information with design reviews and COL applications. Such guidance includes the document "Guidance for Electronic Submissions to the NRC" and informal discussions during design center working group and electronic submittal working group meetings.

2. The NRC should consider including a consolidated list of important definitions already in NRC regulations, as well as others used in the guidance, and should ensure that these defined terms are used consistently throughout the document.

Response/Disposition

The staff generally agrees with the comment and added a list of acronyms and will consider expanding it to include definitions in a future revision.

3. Section C.1.14.3 includes information regarding inspections, testing, analyses, and acceptance criteria (ITAAC) that are to be addressed in a combined license application. The ITAAC for each of the four certified designs are different in the level of content and level of detail and may not be consistent with the ITAAC guidance in the current draft Standard Review Plan (NUREG-0800), Chapters 14.2 and 14.3. The guidance should note this difference.

The staff acknowledges some differences in the defined ITAAC between the certified designs but did not specifically revise the guidance.

4. Transient and Accident Analyses: Section C.1.15.6.2 states that "only safety-related systems and components may be used to mitigate transients or accident conditions." However, in both Section C.0 and in Appendix J of C.1, the guidance correctly recognizes that non-safety related components may be used to mitigate transients and accidents. We recommend that the statement in C.1 be revised to read as follows: ...

Response/Disposition

See response to NEI Comment C.I.15-3

5. We recommend that the guidance reflect the provision in each of the certified designs that, if there is a conflict between the generic DCD and either the application for a design certification or the NRC FSER, then the generic DCD controls. *See, e.g.*, 10 CFR 52, Appendix A, § II.D.

Response/Disposition

Agree – revised wording to include that in case of conflict between FSER and generic DCD, then the generic DCD controls.

Comment 6 (Burns and Roe)

1. With the creation of two organizations within the NRC (i.e., NRR and NRO), with NRR covering the current operating reactors and NRO covering the advanced reactors, consideration should be given to the creation of a new Standard Review Plan to correlate directly with the new RG-1145 (once **DG-11**45 is issued approved).

Have RG-1.70 and it's associated SRP, NUREG-0800 apply to the NRR covered reactors. But create a new SRP for the RG-1145 advanced reactors that will be covered by NRO. The current process of "band-aiding" NUREG-0800 to also apply to the RG-1145 advanced reactors is creating a very confusing process whereby some sections of NUREG-0800 don't apply to the new reactors and vice versa, some of the new information being added to NUREG-0800 does not apply to the current operating reactors. This just increases the regulatory burden and increases the potential for decreased reactor safety.

Response/Disposition

The NRC staff has coordinated the development of Regulatory Guide 1.206 and the update to the Standard Review Plan. In an attempt to maintain consistency within the agency, the NRC did not develop separate technical guidance documents for COL applicants and operating plant licensees.

Comment 7 (AREVA)

1. The comments in the letter dated October 20, 2006, from AREVA, NP, were also incorporated into the comments submitted by NEI and addressed in Attachment 1.

Comment 8 (Exelon)

1. These sections [C.1.7 related to digital instrumentation and control] should be revised to clearly state that the COL application should include a description of the software life cycle process, but that submittal of the output documents resulting from these processes is not required. Life cycle process output documents should be available for staff review.

Response/Disposition

As a result of addressing other comments and making changes to these sections related to ongoing activities in the area of digital instrumentation and control, the staff believes that the requested changes have been addressed.

2. The description section for interlock systems important to safety (section C.1.7.6.1) states that schematic diagrams should be provided. Due to the nature of a digital system, a logic diagram is considered more appropriate than a schematic diagram. Therefore, delete the requirement to submit a schematic diagram and substitute a requirement to submit a logic diagram

Response/Disposition

See response to NEI comment C.I.7-16.

Comment 9 (NPP Goesgen-Daeniken)

1. The draft regulatory guide DG-1145, section 5 has to be extended as follows:

1. In C.I.2.5.2.4 :

Provide a description of the probabilistic seismic hazard analysis (PSHA), including the underlying assumptions and methodology. Provide a detailed discussion on the link between the modelling assumptions and the available geological, geotechnical and seismological information. Discuss the potential sources of uncertainties and how they are treated in the PSHA analysis. Possible ways for treatment of uncertainties are:

- Advanced statistical techniques for parameter estimation based on the available data (e.g., NUREG/CR-6823 [14])
- Use of experts based on a formalized expert elicitation procedure based on the principles of a rational consensus [2], [3].

The methodology according to NUREG/CR-6372 "Recommendations for Probabilistic Seismic Hazard Analysis: Guidance on Uncertainty and Use of Experts" may still be applied with special consideration-to provide assurance that the results of PSHA are consistent with empirical observations especially with the information requested in section C.I.5.2.3. Furthermore, it is requested that the controlling earthquakes are

derived by deaggregation methods based on energy measures (Arias intensity, seismic input energy, or directly CAV). The energy measure(s) selected for deaggregation has (have) to be justified. The models used for the attenuation of energy measures have to be consistent with the models used for ground motion attenuation (based on the same recorded or simulated time histories).

2. The request for logic trees has to be omitted, because it is generally preferable to use regionally validated models with respect to attenuation models, simulation of time histories and seismic activity.

As a part of the validation of PSHA results, a comparison with the results of a deterministic seismic hazard analysis must be performed. The results of PSHA have to be constrained by the results of the deterministic seismic hazard analysis (regression mean + 1 *c7*). (*Remark: This must be the case for all PSHAs which are based on an instantaneous seismo-tectonic model and a stationary stochastic process model (Poissonian Model), because under these conditions uncertainties should not increase with the return period according to the modelling assumptions -for consistency reasons*).

3. Add a section on how to perform a deterministic seismic hazard analysis (as an empirical validation technique for PSHA results)

Deterministic methods are used for the design of critical infrastructures (not only nuclear) all over the world besides the USA (also for dams used) and UK. The methodology should be based on the traditional MCE (maximum credible earthquake) approach with some necessary extensions. The key requirements to be considered are:

- 1. The maximum credible magnitudes considered in the analysis should correspond to the 95%- quantile of the magnitude-recurrence distribution for the considered seismic source. Parametric and non-parametric estimation techniques should be permitted to define the 95%-quantile.
- 2. The source description should correspond to the geological, geotechnical and seismological information as used for the PSHA.
- 3. The same attenuation models (or simulation techniques) should be used as for the PSHA.

Response/Disposition

Regulatory Guide 1.206 has not been revised at this time to maintain consistency with the Standard Review Plan (SRP) and other technical guidance documents related to revised approaches to seismic analyses. The comments have been forwarded to the appropriate technical staff for their consideration in developing additional guidance.

4. An additional comment on DG-1145 was forwarded to the NRC staff from the Advisory Committee on Reactor Safeguards (ACRS) in a memorandum dated March 14, 2007 (ADAMS Accession No. ML070740683). The comment was offered by Carmen DeLong in an email to the ACRS and related to the poor image quality of some regulatory guides on the NRC public web page (documents were scanned and in some cases are difficult to read).

The staff did not revise the regulatory guide as a result of this comment. The comment has been forwarded to the Office of Research for possible enhancements to the NRC web page. In addition, many of the regulatory guides are being updated and their readability will be improved as the revisions are placed into ADAMS and the public web page.

Attachment – Summary & Disposition of NEI Comments

The comments summarized and addressed below maintain the numbering system used in the spreadsheet attached to the October 20, 2006, letter from NEI providing comments on DG-1145. The response/disposition information was input by the NRC staff into a spreadsheet and subsequently used to generate this document. The views and positions expressed are those of the NRC staff tasked to address comments on DG-1145 and, where appropriate, to prepare revisions to the regulatory guide. Whereas the regulatory guide itself has been reviewed using routine NRC processes (management and legal reviews/concurrences), the information in this document has not necessarily been vetted through those reviews and approvals. Some stakeholders have previously expressed an interest in seeing this information since it reflects the views of the NRC staff likely to be involved in actual reviews of COL applications. However, stakeholders should engage the NRC staff if the content of the regulatory guide may have been made as a result of ongoing reviews or discussions and may not have been captured in the spreadsheet used to generate this document. The staff apologies for such discrepancies and notes that preference should be given to the actual wording in the regulatory guide.

C.I.1-1 Guidance refers to the need to identify net electrical output for rated and design thermal power. Of what value is this information, and to what extent is it considered binding as part of the FSAR? The net electrical output will be influenced by many factors such as house loads that may not be known at the time of application. Also, what is the relevance? of net "design" output if different from rated output?

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised to identify net electrical output in Section 1.1.4 as approximate and for information only. Info is non-binding as facility is licensed to thermal power level. Footnote added from RG 1.70 to explain difference between rated and design power.

C.I.1-2 The phrase "whether the plant is colocated with existing operating nuclear power plants" should be clarified as to the parameters of interest. Does it apply to a new unit outside the protected area for the existing facility? Outside the exclusion area boundary? Does the unit's status matter in the definition of "operating"?

Response/ **Disposition**:

Staff agrees with this comment. DG-1145 has been revised to include the recommended wording, except it specifies exclusion area boundary only as it defines a larger area of owner control. Protected area was considered too limiting and discussions with industry have informed the staff that existing protected areas would have to be enlarged to encompass new nuclear units.

C.I.1-3 These requirements are less detailed than those in C.I.1.1 - while the value of this information and extent to which it is it considered binding as part of the FSAR is not clear, the information indicated as required should at least be consistent.

Response/ Disposition:

Staff agrees with this comment. Sections C.I.1.1 and C.I.1.1.4 have been made consistent.

C.I.1-4 Absent a clear regulatory basis or relevance of the schedule information requested here, this requirement should be deleted.

Staff does not agree with the comment. The requirement in 10 CFR 52.77 refers to 10 CFR 50.33 where Part 50.33(h) clearly requires an "applicant to state the earliest and latest dates for completion of the construction..." However, staff agrees that incorporating the recommended wording will add clarity to the guidance. DG-1145 Sections C.I.1.1.5 and C.III.1-Section 1.1.5 revised to add "As an alternative, COL applicants may include a commitment to provide the construction and startup schedules following issuance of the combined license and when a positive decision to construct the plant has been made by the licensee."

C.I.1-5 (1) "guides" is plural but DG-1145 is the only guide indicated(2) should indicated conformance with DG-1145 ensures/obviates need to address RG-1.70(3) "DG-1145" should be replaced with RG number when available

Response/ Disposition:

Staff agrees with this comment; however, staff does not believe that a discussion of obviation of Reg Guide 1.70 is necessary. DG-1145 revised to incorporate recommended wording.

C.I.1-6 Ambiguous reference to SRP conformance

Response/ Disposition:

Staff agrees with this comment; the requirement relates to SRPs "in effect" not "approved". Statement in DG-1145 clarified by adding "in effect 6 months prior to application submittal date".

C.I.1-7 In the last sentence change the word "problems" to "considerations." The example given and the context of the paragraph is to highlight issues needing special attention – these will not necessarily be problems.

Response/ Disposition:

Staff agrees. DG-1145 revised to incorporate recommended wording.

C.I.1-8 There are several examples of using a double negative sentence construction or missing words. Also several sentences are not clear. Revise the 3rd sentence to read: "By definition, there are no interface requirements between standard designs and site-specific designs for a complete facility". The 4th sentence needs to clarify what "these documents" refers to. Revise the 5th sentence: Certified design applications should reference the applicable documents. The 6th and 7th sentence: COL applicants that reference a certified design and/or early site permit are the only applicants that will have interface requirements. COL applicants that do not reference a certified design will need to submit design information on the new facility.

Response/ Disposition:

Staff agrees with these comments. DG-1145 has generally been revised to incorporate the recommended changes.

C.I.1.9 C.I.1.9.1 repeats the proposed regulation to provide an assessment of "regulatory guides" conformance. This guidance could be modified to reflect the specific RG Divisions and/or specific RGs expected to be addressed to comply with this regulation. For example, Division 2, Research and Test Reactors, would not be applicable; so, we should eliminate

Division 2 assessments since they don't address design or operation of commercial power reactors. Further, within Division 4, RG 4.2 addresses Environmental Reports and is not an appropriate topic to be addressed in the FSAR. See also C.III.1 – 1.9.1.

Response/ Disposition:

Staff agrees with this comment. DG-1145 has been revised to provide on specific RG Divisions for which conformance should be evaluated.

C.I.1-10 To determine the scope of applicable RGs, SRPs, generic issues and operating experience to be addressed in the COLA, the staff has stated that it is their current practice and intent going forward that the standard applied will be six months prior to the application date, as the applicant has no control over when the application is docketed. (This comment is typical of several instances in C.I.1.)

Response/ **Disposition**:

Staff agrees with this comment and recognizes that the applicant "submits" and the staff "dockets" an application. Section C.I.1 of DG-1145 has been revised throughout to refer to guidance "in effect 6 months before the submittal date of the COL application"

C.I.1-11 Use of "any" in "of any departures from the guidance contained in the NRC's regulatory guides," is unduly broad.

Response/ Disposition:

Staff disagrees with this comment. However, wording in DG-1145 has been changed from "any departures" to "deviations" to avoid confusion with "departure from certified design"

C.I.1-12 Use of "any" in "any differences in design features" is unduly broad

Response/ Disposition:

Staff disagrees with this comment. Part 52.79(a)(41) indicates "all differences". Wording in DG-1145 changed from "any" to "all".

C.I.1-13 Generic Issues. Improvements regarding guidance for the review of generic issues is noted in C.IV.8 (9/1/06); however, as recognized by the Staff, other related sections in C.I and C.III.1/2 have not vet been updated and are, therefore, inconsistent. In addition, guidance in C.IV.8 also requires additional clarification regarding the use of NUREG-0933, Appendix B. Additional comments are provided on C.IV.8 1. C.I.1.9.3 mentions a listing of generic issues in C.IV.8. Section C.IV.8 no longer contains a listing of generic issues. 2. C.I.1.9.3 indicates: "Those issues that remain open and are technically relevant to the COL applicant's design should be addressed in the application. Remaining "open" is not clear in that the cited proposed Part 52.79(a)(20) is understood to require COLAs to "include" the resolutions for those issues that, in fact, have NRC approved resolutions. "Open," therefore, does seem to apply. The Staff should restrict issues to those for which acceptable resolutions have been proposed.3. In general, since guidance should be stated once and then referenced as needed, it is recommended that detailed guidance on the scope of generic issue review be included in C.IV.8. Section C.I.1.9.3 should only provide a summary and reference C.IV.8 for detailed guidance.

The Staff agrees, in part, and disagrees, in part with this comment. The staff agrees to revise the writeup in Section C.I.1.9.3 to refer to Section C.IV.8 for guidance on addressing generic issues. To conform with the updated Part 52 rulemaking and the considerations contained in responses to public comments on the rulemaking, the applicant must address the USIs that are technically relevant to their design, regardless of whether they have been closed or not. Closure of the USIs was for operating plants not future plants. (See response to Part 52 rulemaking Comment 005-10)

C.I.1-14 This section states "Applicants for certified designs or combined licenses are required to address comparable international operating experience in accordance with proposed 10
 AREVA CFR 52.47(a)(19) [52.47(a)(22) in version released 27 Sep 2006] and 10 CFR 52.79(a)(37), respectively. To the extent that the design (or portions thereof), for which an applicant seeks a design certification or COL, originates or is based on international design, the application should address how international operating experience has contributed to the design process."

Response/ Disposition:

The Staff agrees with this comment. Section C.I.1.9.4 will be revised to conform with the requirement in 10 CFR 52.79(a) that applicants have an option (i.e., demonstrate how operating experience insights from generic letters and bulletins OR comparable international operation experience have been incorporated into the design. In addition, to conform with the final Part 52 rule, the generic letters

C.I.1-14 NRC's own procedures (e.g., LIC-401) require them to factor in international OE into their own generic OE program; this is implicitly addressed in our evaluation of the NRC's OE documents. Therefore an additional requirement for the applicant to evaluate international operating experience in addition to generic letters / bulletins and should not be required.
#3 (cont'd) Further, the draft guide requires this information only from some applicants; those whose design originates or is based on international design. It is inequitable to impose this additional requirement on designs of "foreign" heritage, because any assessment of "heritage" (i.e., the extent to which a domestic design is "based on" a "foreign" design) is subjective, as is the assessment of applicability of international OE to any given domestically licensed design. NRC disposition of the industry's May 30 comment in this regard on the Part 52 rulemaking is pending.

Response/ **Disposition**:

and bulletins will be limited to those "issued after the most recent revision of the applicable standard review plan and 6 months before the docket date of the application." Applicants are provided an option, as discussed above, and, thus, there is no requirement to address comparable international operating experience for applicants whose design has "foreign heritage." In addition, if the applicant so chooses, guidance is provided on organizational sources of international operating experience.

C.I.1-15 The following documents are listed twice: SECY-91-262SECY-92-053SECY-92-092 SECY-93-087SECY-94-084SECY-94-302

Response/ Disposition:

Staff agrees. DG-1145 revised to delete redundant entries.

C.I.2-1 The last sentence of the first paragraph is ambiguous and requires clarification in that it states that the "adequacy of site characteristics need to be addressed from a safety viewpoint." The plant design and operation needs to be discussed from a safety viewpoint relative to site characteristics.

Response/ Disposition:

The last sentence of the first paragraph will be changed to the following: The purpose of this information is to demonstrate that the site characteristics have been accurately described and appropriately used in the plant design and operating criteria.

C.I.2-2 RG1.70 calls for the determination of a more severe meteorological wind system than actually recorded...based upon meteorological reasoning. DG1145 does not refer to the ability to utilize meteorological reasoning to exclude "incredible" events.

Response/ **Disposition**:

Staff Agrees. Modify the related sentence to cope with RG 1.70 as: ".... wind system than actually recorded, insofar as these are deemed "reasonably possible" to occur on the basis of meteorological reasoning."

C.I.2-3 This section tends to comply with RG1.70 section 2.4.13.3 in terms of content requirements. DG1145 requires conservative analysis be performed of all groundwater pathways for a liquid effluent release; RG1.70 requires a conservative analysis of postulated accidental release of liquid radioactive material at the site. Liquid radioactive effluent may only be located in specific areas of the plant (holding tanks or along designated haul paths thereby only warranting an analysis in the general vicinity of groundwater flow. DG1145 requires analysis of all groundwater pathways.

Response/ Disposition:

What we essentially request here is a conservative analysis of the most critical potential pathways for liquid effluent rather than all potential pathways. The first sentence of C.I.2.4.12.3 in DG-1145 could be modified as: "Provide a conservative analysis of critical groundwater passways for a liquid effluent release at the site."

C.I.2-4 This Section is compliant with the requirements of RG1.70 section 2.4.13.5 with the exception that DG1145 uses the terminology "Site Characteristics in lieu of the RG1.70 terminology "Design Bases" interchangeably. This is confusing.

Response/ Disposition:

The site characteristic referred here is the maximum elevation of potential ground water head at a surficial aquifer to maintain reliably the groundwater conditions within the groundwater design bases of the safety related SSC. The first paragraph can be modified as: "For plant not employing perm ant dewatering system, describe the site characteristics, including the maximum operational groundwater level, for groundwater-induced hydrostatic loadings ,,,"

C.I.2-5 RG1.70 defines the design basis groundwater level whereas DG1145 does not.

Response/ **Disposition**:

RG 1.70 refers that the design basis groundwater level is defined as the maximum groundwater level used in the design analysis for dynamic and static loading conditions. Therefore, the statements in

DG 1145 and RG 1.70 are the same, but the statement in DG 1145 is more clear and concise, thus no action required.

C.I.2-6 The subject section calls for current "residential population" to be indicated on appropriate maps. Census data would generally be used for this population segment and would likely include not only "residential" (strictly speaking) but also other persons, such as those in boarding schools, colleges, universities, etc. A more appropriate and clearer term would be "resident population" consistent with the use of "resident" in Reg. Guide 4.2 and census bureau terminology

Response/ Disposition:

Staff agrees. Change to "resident population" as suggested.

C.I.2-7 "Accident category (1)" discusses the consideration of potential missiles generated by explosions involving hazardous material. Category (1) in Section C.I.2.2.3.1 could be read to say that an evaluation of missiles should be considered regardless of the blast overpressure prediction. However, per Reg. Guide 1.91, (referenced in Section C.I.2.2.3.1), "If the overpressure criteria of Reg. Guide 1.91 is exceeded, the effects of missiles must be considered." Furthermore, even if the blast overpressure criteria is not met, it is reasonable that missiles not be evaluated if the probability of occurrence is shown to be less than 10-7 per year, per C.I.2.2.3.1.A similar comment would pertain to accident category (2), delayed detonation of flammable vapor cloud as well.

Response/ **Disposition**:

Change the text "relationships. In the case blast overpressure criterion is not met, or if the probability of occurrence of the subject event is greater than 10 -7 /year, missiles generated by the explosion should also be considered and an analysis should be provided in section 3.5 of the FSAR. "Change the text in C.I.2.8 as follows: "vapor cloud should be provided. If the probability of occurrence of the subject event is greater than 10-7/year, an analysis of the missiles of the FSAR."

C.I.2-8 Section C.I.2.3.3 prescribes the time for which data must be collected and "provided at docketing." Docketing occurs after submittal and completion of the Staff's acceptance review. It's assumed that the Staff intended "application" and not "docketing." Furthermore, as a practical matter, data collection must conclude well before the application submittal goal to allow sufficient time for data quality review, analysis, and development of required FSAR material.

Response/ Disposition:

Staff agrees. Revise the subject section to say "should be provided at the time of the application submittal".

C.I.2-9 The industry concurs with the Staff response to comment C.I.2.3.3-1 regarding the COL applicant's providing at least one annual cycle of meteorological data with the application and subsequent submittal of the complete 2-year data set when collected. However, the Staff elected not to reflect this disposition via change in DG-1145.

Response/ Disposition:

In response to this comment, the following sentence will be added to the end of the third paragraph in Sections C.I.2.3.3 and C.III.1.2.3.3: If two years of onsite meteorological data are not available

at the time the application is submitted, provide at least one annual cycle of meteorological data collected onsite with the application. These data should be used to calculate (1) the short-term atmospheric dispersion estimates for accident releases discussed in Section 2.3.4 and (2) the long-term atmospheric dispersion estimates for routine releases discussed in Section 2.3.5. Continue to monitor the data and submit the complete 2-year data set when it has been collected. The supplemental submittal should also include a reanalysis of the Section 2.3.4 and 2.3.5 atmospheric dispersion estimates based on the complete 2-year data set.

C.I.2-10 The scale of the maps requested in the subject guidance is far too large for the needed purpose. the scale requested will require up to 4-6 large "D" size plates in the COLA FSAR. Reg. Guide 1.165 does not require such large scale maps. The guide provides the option for smaller scale maps, as appropriate.

Response/ **Disposition**:

In response to this comment, the following should be deleted (1:24,000)

C.I.3-1 Statement of (2)(a) requires to "provide as built drawing(s) of piping geometry. It is impossible to address this requirement at the time of COL application.

Response/ **Disposition**:

C.I.3.6.3.(2)(a) will be changed to read: "Provide as-built drawing(s) of pipe geometry (e.g., piping isometric drawings). Identify locations of supports and their characteristics (such as gaps). Identify the analysis nodal points. If as-built drawings are not available at the time of COL application, design piping isometric drawings may be submitted, provided that the COL application contains a commitment to submit the as-built information during plant construction but one year before fuel load." [Related NRC ID No. C.I.3.6.3-5]

C.I.3-2 Typo: in (1), change "fee" to "free"

Response/ **Disposition**:

Staff agrees with comment. DG-1145 revised as noted.

C.I.3-3 Although this section and other sections use "Seismic Category II" as one of SSCs category of seismic design, the definition is not specified.

Response/ Disposition:

The staff agrees with the comment that the definition of Seismic Category II structures, systems and components (SSCs) should be provided. The definition is: "Seismic Category II applies to plant SSCs which perform no safety-related function, and the continued function of which is not required. However, these SSCs should be designed so that the SSE does not cause unacceptable failure of or interaction with Seismic category I items." Note that the term "Seismic Category II" has been widely used in the design of advanced reactors (ABWR, AP600, AP1000, ESBWR, etc.).

C.I.3-4 All these sections have requirements for ground motion time histories to meet spectrum matching for multiple damping values and to envelop a target PSD (Power Spectral Density). These requirements are applicable if site-independent RG 1.60 ground spectra are considered as design spectra. For COL plants a site-specific SSE ground spectrum will be developed from a PSHA (Probabilistic Seismic Hazard Analysis) in accordance with RG 1.165 or equivalent. In a recent NRC-sponsored study NUREG/CR-6728, Technical Basis for Regulatory Guidance on Design Ground Motions: Hazard- and Risk-Consistent

Ground Motion Spectra Guidelines, spectrum matching for damping other than 5% and target PSD enveloping are not required.

Response/ Disposition:

The staff partially agrees with the comment that the NUREG-6728 approach is one approach that is acceptable for the case of a site specific ground response spectrum developed from a PSHA. In the current update of SRP Section 3.7.1 (which is to be published in the near future), the staff, as an other option, also provided guidelines to develop the target PSD for ground response spectra other than the RG 1.60 ground response spectra, including ground response spectra developed from PSHA.

C.I.3-5 These two sections address same subject for dams.

Response/ Disposition:

Agree. Will refer back to Section 3.7.3.8

C.I.3-6 Description of implementation program for the seismic monitoring program is not a requirement in the existing SRP.

Response/ Disposition:

The SRP has been revised to include Implementation of the seismic instrumentation plan as part of the Staff's update of Section 3.7.4 of NUREG-0800 (Standard Review Plan). The DG-1145 and SRP is revised to include, "If details of the implementation plan are not available at the time the COL application is prepared; however, the applicant should provide sufficient detail for the Staff to be able to assess the adequacy of the program implementation."

C.I.3-7 ANSI/AISC N690-1984 is mentioned. Does it mean that only the 1984 edition is acceptable?

Response/ Disposition:

The ANSI/AISC N690-1984 listed is a superseded edition. It should be replaced by "ANSI/AISC N690 (1994) including Supplement 2 (2004)." And yes, only the ANSI/AISC 1994 edition with Supplement 2 (2004) is acceptable. Note to Manny Comar: Additionally, wherever, ANSI/AISC N690 (1984) is listed in the entire C.I.3.8 and C.III.3.8 sections, the reference should be replaced by "ANSI/AISC N690 (1994) including Supplement 2 (2004)."

C.I.3-8 Clarify what sections of Regulatory Guide 1.29 provide recommendations for Seismic Category I SSCs.

Response/ Disposition:

1) The staff finds that it is not necessary to refer to specific sections of the regulatory position. If specific positions of RG 1.26 are to be identified, positions C.1 thru C.5 (ref. DG-1156 proposed rev. 4 to RG 1.26) should be identified rather than only positions C.1 and C.3. 2) DG-1145 has not been revised to incorporate this comment. 3) No corresponding changes are required.

C.I.3-9 Clarify what sections of Regulatory Guide 1.29 provide recommendations for non-Seismic Category I SSCs whose failure could reduce the functioning of a Seismic Category I SSC or could result in incapacitating injury to control room personnel.

1) The staff finds that it is not necessary to refer to specific sections of the regulatory position. If specific positions of RG 1.26 are to be identified, positions C.1 thru C.5 (ref. DG-1156 proposed rev. 4 to RG 1.26) should be identified rather than only positions C.2 and C.4. 2) DG-1145 has not been revised to incorporate this comment. 3) No corresponding changes are required.

C.I.3-10 Add Regulatory Guide 1.151 to the 3rd paragraph to be consistent with the 2nd paragraph.

Response/ Disposition:

1) The staff concurs with this comment. Reference to Regulatory Guide 1.151 is appropriate to be consistent with the second paragraph. 2) DG-1145 has been revised to incorporate this comment per the recommended wording. 3) No corresponding changes are required.

C.I.3-11 C.I.3.9.6.2 (4) states "and include this information in the technical specifications. "This level of detail is no longer included in the Improved Technical Specifications, Section 5.5.

Response/ Disposition:

Staff agrees with the comments and proposed changes.

C.I.3-12 C.I.3.9.6.3 (4) states "and include this information in the technical specifications." This level of detail is no longer included in the Improved Technical Specifications, Section 5.5.

Response/ Disposition:

Staff agrees with the comments and proposed changes.

C.I.3-13 Typographical error. The last sentence should read: "...Regulatory Guide 1.26 or Regulatory Guide 1.143."

Response/ Disposition:

Staff agrees with comment. DG-1145 revised as noted. [1) The staff concurs with this comment. 2) DG-1145 has been revised to correct typographical error by adding a comma between RG 1.26 and RG 1.143. 3) No corresponding changes are required.]

C.I.3-14 The second sentence reads as follows: "These are the SSCs whose failure could lead to offsite radiological consequences, or those required for safe plant shutdown to a cold condition assuming an additional single failure." The words in italics are confusing and do not conform to existing regulation.

Response/ **Disposition**:

Agree. Incorporate changes as proposed

C.I.3-15 The third sentence reads: "Missiles associated with over speed failures of rotating components..." The types of missiles should be clarified as those that are "credible."

Response/ Disposition:

Agree. Incorporate changes as proposed.

C.I.3-16 The requested information in this provision (i.e. details of the containment penetrations (etc), the number of pipe breaks, their locations, the presence of postulated cracks, and rupture orientation) is not expected to be available for COL and is not necessary to support COLA.

Response/ Disposition:

1) The staff disagrees with the NEI comments on C.I.3.16 THRU C.I.3.20 for the following reason: 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 postulated pipe ruptures including the effects of pipe whipping and jet impingement. For an 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. Staff requires and reviews the requested information to conclude that pipe rupture postulation and the associated effects are adequately considered in the plant design, and therefore are acceptable and meet the regulatory requirements of GDC 4 - environmental and dynamic effects design bases. 2) The associated DG-1145 sections need not be revised. 3) No changes to SRP Section 3.6.2 are needed. However, to further clarify that as-built information is not requested, a standard sentence is added to state that design or bounding assumptions may be provided and applicant should propose method to document (ITAAC, LC, FSAR).

C.I.3-17 Other than the design criteria, the requested detailed information for the guard pipe assemblies is not expected to be available for COL and is not necessary to support COLA.

Response/ Disposition:

Same staff response as response C.I.3.16

C.I.3-18 The requested information for the analyses results is not expected to be available for COL and is not necessary to support COLA.

Response/ **Disposition**:

Same staff response as response C.I.3.16

C.I.3-19 The requested information (i.e. final configurations, locations, and orientations) is not expected to be available for COL and is not necessary to support COLA.

Response/ **Disposition**:

Same staff response as response C.I.3.16

C.I.3-20 The requested information is not expected to be available in its entirety for COL and is not necessary to support COLA.

Response/ Disposition:

Same staff response as response C.I.3.16

C.I.3-21 Reference is made to the OBE. Designing for an OBE is no longer a requirement.

Response/ **Disposition**:

The comment is only partially correct and does not fully reflect the applicable NRC regulation. The reference to OBE in the above listed DG-1145 sections is appropriate and should be kept as written because as noted in 10 CFR 50, Appendix S, the operating basis earthquake (OBE) is only associated with plant shutdown and inspection unless specifically selected by the applicant as a design input. If the OBE is set at one-third or less of the safe shutdown earthquake (SSE) ground motion, an explicit response or design analysis is not required. If the OBE is set at a value greater than one-third of the SSE, an analysis and design must be performed to demonstrate that the safety related containments/structures remain functional and are within applicable stress, strain, and deformation limits. Further guidance on the use of OBE is provided in SRP Section 3.7.

C.I.3-22 Editorial. In first sentence, "Section HI" should read "Section III."

Response/ **Disposition**:

Staff agrees with comment. DG-1145 revised as noted. [The editorial comment is accepted and the suggested correction should be made.]

C.I.3-23 ANSI N45.2.5 is an inactive national standard. The replacement reference is to ASME NQA-1.

Response/ Disposition:

This comment is generally correct, but the appropriate replacement references should be the "applicable provisions of SRP Sections 3.8 and 17.5." Also, this disposition should apply to the entire section C.I.3.8 wherever references to ANSI N45.2.5 are made.

C.I.3-24 ANSI/AISC N690-1984 is a superseded edition. Use latest version

Response/ Disposition:

The ANSI/AISC N690-1984 listed is a superseded edition. It should be replaced by "ANSI/AISC N690 (1994) including Supplement 2 (2004)." Note to Manny Comar: Additionally, wherever ANSI/AISC N690 (1984) is listed in the entire C.I.3.8 and C.III.3.8 sections, the reference should be replaced by "ANSI/AISC N690 (1994) including Supplement 2 (2004)."

C.I.3-25 The requested information in items (1) to (5) is not expected to be completely available for COL and is not necessary to support COLA.

Response/ **Disposition**:

The statement is partially correct. The following sentence will be added at end of items 3 and 4 in C.I.3.9.2.1 "For those piping systems which are likely to be modified substantially during plant construction, the information may be deferred till as built locations become available."

C.I.3-26 C.I.3.9.3.1, second paragraph, item (3) seeks a summary of maximum stress, deformation, and cumulative usage factor values for all ASME Code Class I components. This information will not be available at the time of COLA and is not necessary to support COLA. The cumulative usage factor values will be contained in the ASME required design report, which requires reconciliation with the as-built configuration. Consistent with industry's position in NEI 04-01 Rev E, Appendix H, Item 3-18, the ASME required

design specification and design report should be made available for NRC audit prior to fuel load. This comment also applies to C.III.3.9.3.1.

Response/ Disposition:

Staff disagrees - 1) NEI has not provided the basis for stating that the requested design information of ASME 1, 2, 3 components will not be available at the time of the COLA, and why it is not necessary to support COLA. 2) NEI recommended that the ASME required design specification and design report should be made available for NRC audit prior to fuel load. It is the staff's position that the design reports of the ASME Class 1,2,3 piping, components and supports should be made available prior to the start of construction and prior to the issuance of the COL, to permit the resolution of any potential issues between the NRC reviewers and the design organization. The review of the design reports is necessary to ensure that the DCD design criteria have been properly implemented. 3) The staff is not requiring as-built reconciliation at the time of the COLA. This will be reviewed in the ITAAC phase. However, to further clarify that as-built information is not requested, a standard sentence is added to state that design or bounding assumptions may be provided and applicant should propose method to document (ITAAC, LC, FSAR).

C.I.3-27 The requested information in paragraph 2 (i.e. program results, stresses, deformations, EQ, etc) is not expected to be completely available for COL and is not necessary to support COLA.

Response/ **Disposition**:

Staff disagrees - see response to C.I.3.26

C.I.3-28 The requested information in the second paragraph (i.e. the results of the analysis and/or test programs) is not expected to be available for COL and is not necessary to support COLA.

Response/ Disposition:

Staff disagrees - see response to C.I.3.26. For those piping systems which are likely to be modified substantially during plant construction, the information may be deferred till as built locations become available.

C.I.3-29 Piping supports, supplementary steel, and instrumentation supports traditionally have been in compliance with ASME NF and AISC, with jurisdictional boundaries identified in the FSAR. These three sections should also address AISC N690 Code.

Response/ Disposition:

Agree. Make changes as proposed

C.I.3-30 DG-1145, Appendix I provided response to a number of issues raised about the content of C.I.3.6.3. The NRC responded that, as a result of public comments, "Section 3.6.3(1)(a) will be modified", "Section 3.6.3(1)(b) will be modified", "Section 3.6.3(2)(a) will be modified", and "Section 3.6.3(2)(c) will be modified". DG-1145 has not been revised to incorporate any changes to the above referenced paragraphs.

Response/ **Disposition**:

C.I.3.6.3.(1)(a) will be changed to read: "Identify the types of as-built materials and material specifications used for base metal, weldments, nozzles, and safe ends. If the as-built materials and

material specifications are not available at the time of the COL application, representative and bounding materials and associated specifications may be used in the LBB analysis to be submitted with the COL application, provided that the COL application contains a commitment to submit the as-built material information during plant construction but one year before fuel load." [Related NRC ID No. C.I.3.6.3-1 and C.I.3.6.3-2]. C.I.3.6.3(1)(b) will be changed to read: "Provide the asbuilt 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. If the as-built materials properties may be used in the LBB analysis to be submitted with the COL application, provided that the COL application contains a commitment to submit the as-built material properties may be used in the LBB analysis to be submitted with the COL application, provided that the COL application contains a commitment to submit the as-built material properties may be used in the LBB analysis to be submitted with the COL application, provided that the COL application contains a commitment to submit the as-built material properties during plant construction but one year before fuel load." [Related NRC ID No.C.I.3.6.3-3 and C.I.3.6.3-4]. C.I.3.6.3(2)(c) will be changed to read: "Discuss snubber reliability." [Related NRC ID NO. C.I.3.6.3-6]

C.I.3-31 The reference in the first paragraph to 10CFR50.49 and mechanical equipment, is not correct. That is because 50.49 does not address mechanical equipment.

Response/ **Disposition**:

Removed word "mechanical" from first sentence

C.I.3-32 The following comments/ observations for this section are: a. Inclusion of RG 1.30 is incorrect, as this RG pertains to QA requirements and not to EQ requirements and it is therefore, outside the scope of EQ. b. RG 1.151; same as above comment for b), regarding RG 1.30.c. RG 1.183; same as above comment for a) and b) regarding requirements of 10CFR50.67 and RG 1.30.

Response/ Disposition:

Removed references to 10 CFR 50.67, RG 1.30, RG 1.151. RG 1.183 will be retained. Provides guidance on EQ and provides guidance for Regulatory Positions 2.c.(1) and 2.c(2).

C.I.3-33 Sections 3.7.1 as written reflect pass requirements associated with use of generic design ground response spectra, e.g., RG 1.60 design ground response spectra. There are fundamental differences between generic SSE design ground response spectra and current methods to develop site-specific SSE design ground response spectra. Therefore these sections should be revised to reflect current state-of-the-art practice for developing site-specific SSE design ground response spectra are PSHA based following RG 1.165 or equivalent risk-performance base methodology. The PSHA and associated methodologies to develop the site-specific SSE are based on 5 percent damped spectra. The associated ground motion time histories therefore should only need to match the 5 percent design ground response spectra and current dequate energy over the frequency range, component correlation characteristics, etc. are provided in NUREG/CR-6728.

Response/ Disposition:

Agree. Will rewrite to clarify.

C.I.3-33 If response spectrum analysis instead of time history analysis is used to determine building response for design, then site-specific SSE design ground response spectra at appropriate damping values should be provided. Section 3.7.1 should clarify that there is a single location or control point for the SSE free-field ground motion response spectra at the free ground surface and that location depends on the soil characteristics at the site. That location, depending on site conditions, can either be the top of finish grade or an outcrop or hypothetical outcrop at a location of the top competent material for the site. NUREG-0800 provides this clarification.

Response/ Disposition:

Agree. Will rewrite to clarify.

C.I.3-34 This section requires submittal of EQ testing requirements, accident environments, and milestone schedules that won't be available at the time the COLA is submitted. The EQ program information requirements are outlined in DG-1145, Section C.I.13.4

Response/ Disposition:

Revised to be consistent with Section C.I.13.4

C.I.4-1 Given that the reactor vendors are constantly working to improve fuel and core design (Note INPO's objective of Zero fuel failure by 2010), the information requested by DG-1145 is too prescriptive. DG-1145 should clearly indicate that the information to be supplied is a reference or typical fuel design recognizing the actual fuel and core design will be developed using fuel and core design methods approved by the NRC for the intended application consistent with the Plant license. The actual fuel and core design may change, thus DG-1145 should acknowledge that any changes following a COL application should be consistent with the current process for refueling current (at the time of fuel loading) operating plants.

Response/ Disposition:

Staff agrees with the idea of this comment, but suggests slightly different wording. It is suggested that a second paragraph be added to C.I.4 of DG-1145 to state the following: "The information required to be submitted by this chapter is considered to be reference, typical, or bounding fuel design information. Prior to Cycle 1, the applicant can request an amendment to the Tier 2* information related to the fuel system design. The Cycle 1 related core fuel assembly design, control rod assembly design, core loading pattern, and related core parameters (related to sections C.I.4.3 and C.I.4.4) must be submitted for approval."

C.I.4-2 Definition of "final (FSAR) design drawing" is unclear.

Response/ Disposition:

Staff agrees with this comment. DG-1145 has been corrected per the recommended wording.

C.I.4-3 The bulleted information under the headings "phenomenological models" and "fuel system damage criteria" contain typographical errors.

Response/ Disposition:

Staff agrees with this comment. DG-1145 has been corrected per the recommended wording.

C.I.4-4 Sections are duplicated

Response/ **Disposition**:

Staff agrees with this comment. DG-1145 has been revised to deleted duplicated sections.

C.I.5-1 In the fourth line of the paragraph under this section, please clarify why the component order date of each Class 1 component within the RCPB is required to be part of the COL application. It does not appear to be relevant information for this stage of the licensing process, nor, if required, will this information be available at the time the application is submitted.

Response/ Disposition:

Staff agrees with this comment. The proposed wording is acceptable.

C.I.5-2 The fourth sentence of the paragraph discusses the use of Regulatory Guide 1.84 to identify those ASME Code Cases that are "generally acceptable" (emphasis added) to the NRC staff. The industry recognizes that RG 1.84 identifies Code Cases that are acceptable to the NRC, and that some Code Cases are acceptable only under conditions identified in RG 1.84. Additional specificity should be added to avoid ambiguity.

Response/ Disposition:

Staff agrees with this comment. DG-1145 has been revised per the recommended wording.

C.I.5-3 In the last sentence of the paragraph, the requirement to "identify the final metallurgical condition" of the material placed in service is unclear. Please clarify what the term, "metallurgical condition," means or else delete the term.

Response/ **Disposition**:

The staff agrees with providing clarity but disagrees with the recommended wording. Add the following wording to this section: "The term of "metallurgical condition" is a technical term used to describe the microstructure of the materials. Based on its phase diagram, the microstructure of a material can vary in accordance with the heat treatments applied to the materials. Different microstructures of a material will possess different mechanical properties. One example is the heat treatment of the austenitic stainless steel in a certain temperature range will create a sensitized microstructure, which is characterized by chromium depletion along the grain boundary. The austenitic stainless steel with sensitized microstructure is susceptible to intergranular stress corrosion cracking. Materials engineers with metallurgy background should be able to provide the requested information."

C.I.5-4 The third sentence of the fourth information request requires the provision of sufficient information on the concentration of chemical compounds to meet Regulatory Guide 1.36 requirements. This should be clarified to address the leachable concentrations, since only leachable ions pose a threat (Cl or F) or ameliorating benefit (Na or SiO3) to the promotion of stress-corrosion cracking of austenitic stainless steel, as described in the Regulatory Guide.

Response/ Disposition:

The staff disagrees with this comment and therefore no change is needed. The addition of the word "leachable" before the word "concentration" is not desirable because it will imply certain

concentrations are not leachable. The acceptable concentrations of the leachable ions (chloride, fluoride, sodium, and silicate) in the insulation materials are provided in Regulatory Guide 1.36.

C.I.5-5 This section identifies the requirement to submit data, test results or information that may not be available at the time of COL application. Please clarify what the requirements are for this type of information, and whether it is required to be provided at the time of COL application or at a later date, if at all.

Response/ Disposition:

The staff agrees with this comment but not with the recommended wording. Add the following paragraph at the end of the section: If data, test results, or other information are unavailable at the time of the COL application, representative or bounding data and information may be submitted for staff review as part of the COL application. The COL applicant should submit the data, test results, or other information which was not available at the time of COL application to the staff at a pre-determined time agreed upon by the both parties. The applicant may need to work with the NRC staff during the review to agree on an appropriate method (e.g., ITAAC, license condition, FSAR update) to ensure that the as-built plant is consistent with the design reviewed during the licensing process.

C.I.5-6 The numbering of the bulleted items in the listed paragraphs is incorrect.

Response/ Disposition:

Staff agrees with this comment. DG-1145 has been revised per the recommended wording.

C.I.5-7 The second sentence of the stated section is not correct. It implies that inservice inspections can demonstrate whether or not a material is susceptible to PWSCC. ISI cannot demonstrate that a material is susceptible or not, ISI can only determine if there is in-service degradation or not. The industry performs inspections of many components that are susceptible to PWSCC without finding degradation.

Response/ **Disposition**:

The staff agrees with this comment. The recommended wording is acceptable.

C.I.5-8 The numbering of the bulleted items in the listed paragraphs should be re-started from (1)

Response/ Disposition:

Staff agrees with this comment. DG-1145 has been revised per the recommended wording. This may be an inherent pdf conversion issue.

C.I.5-9 The industry does not have "exemptions" from Code requirements, but rather has Relief Requests and alternatives per 10 CFR 50.55a. The industry also works to Code Cases, as specified in Regulatory Guide 1.147. Please clarify if our understanding is correct and this item can be deleted. If this requirement is addressing components that are exempt from the inspection requirements of Section XI as defined in Section XI (usually based on size), please clarify and elaborate that this is the intent of this item.

The staff disagrees with this comment but adds the following wording to clarify the intent of this item, replace the wording after "Code Exemptions" with "Identify any components that are exempted from the ASME Code Section XI examination requirements."

C.I.5-10 The second sentence of this paragraph appears to duplicate information on operational programs contained in Section C.I.13.4, but does not comprehensively define the information that is required to enable the staff to make a reasonable assurance finding regarding the acceptability of the program.

Response/ Disposition:

The staff disagrees with this comment. No revision is needed because the information that needs to be provided is stated in the first sentence.

C.I.5-11 Please clarify the requirement to discuss the procedures used to perform nondestructive evaluations in the second sentence of this bullet. Procedures will not be developed by the time of COL application. Also, it does not seem to be advisable to submit detailed procedures which require a FSAR update if a change to the procedure is performed. We believe that a discussion of the methods and techniques used to perform nondestructive evaluations, that will be incorporated in procedures developed as part of an ITAAC, provides sufficient information for staff review.

Response/ **Disposition**:

Staff agrees with this comment. Revise DG-1145 according to recommended wording.

C.I.5-12 The third sentence of the paragraph in this section states, "Also identify the reactor vessel designer and manufacturer, and describe their experience." This requirement does not appear to be appropriate. Please clarify why this information needs to be supplied.

Response/ **Disposition**:

Staff agrees with this comment. Staff has determined this sentence should read: "COL applicant may identify a specific manufacturer, if one has been chosen, and provide a description of their experience."

C.I.5-13 Please clarify what is meant by the words used at the end of the first sentence, "...improve their properties or quality?" These words appear to imply that Code-acceptable materials need improvement in order to be acceptable to NRC.

Response/ Disposition:

Staff agrees with this comment. The sentence should be, "Identify the reactor vessel materials, including weld materials, and describe any special requirements."

C.I.5-14 Detailed information on fracture toughness properties may not be available at the time of COL

Response/ Disposition:

Staff agrees with this comment. DG-1145 to be revised according to the recommended wording.

C.I.5-15 These sections start with a general statement concerning the description of the preoperational test programs. Section C.I.5.4 is supposed to identify component and subsystem design. Requirements for descriptions of pre-operational test programs for a subset of systems in C.I.5.4 appear to be out of place and better covered in C.I.14.

Response/ Disposition:

Staff agrees with the comment. The proposed deletion of lead-in paragraphs describing preoperational test programs descriptions underneath the subsections in C.I.5.4.6 and C.I.5.4.7 is acceptable.

C.I.5-16 The last paragraph in C.I.5.4.7.2 states, "(for example, in a BWR, the RCIC condensing mode)". The RCIC condensing mode in a BWR is not a current design. For instance, the current BWR, i.e. ABWR, does not have such an outdated system. Therefore, the above description should be deleted.

Response/ Disposition:

Staff disagrees with this comment. The mode diagram comment is located in the last sentence of the first paragraph. There may be plants that still use this mode, therefore the statement will not be revised.

C.I.6-1 The C.I.6 lead-in information states "The applicant should state its intentions with regard to adopting risk-informed categorization, and treating structures, systems, and components in accordance with Title 10, Section 50.69, of the Code of Federal Regulations(10 CFR 50.69)." Generally, this should be done once in Section 3.2, not in the various sections of the FSAR discussing the SSCs

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised to move statement on applicant commitment to 50.69 to Section 3.2.

C.I.6-2 Lead-in info to C.I.6 states "Generic design control documents (DCDs) typically address the equipment and materials used to manufacture the components in the engineered safety feature (ESF) system. If applicable, this information may be incorporated by reference." Workshop discussions have led the Industry to believe that the Staff interprets Part 52 to require that the COLA include the DCD information, not "incorporate by reference."

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised to delete statement as it is not applicable to a COL applicant that does not reference a certified design.

C.I.6-3 The 3rd paragraph, 2nd sentence, reads in part, "...to serve as ESFs systems."

Response/ **Disposition**:

Staff agrees with this comment. DG-1145 revised per recommended wording

C.I.6-4 Section states "Operating experience has indicated that certain nickel-chromium-iron alloys (e.g., Alloy 690 and Alloy 182) are susceptible to primary water stress corrosion cracking (PWSCC) attributable to corrosion. Alloy 690 has improved stress corrosion cracking resistance in comparison to Alloy 600..."

Response/ **Disposition**:

Staff agrees with this comment. DG-1145 revised to correct typo per recommended wording

C.I.6-5 The first sentence of the paragraph discusses the control of the pH of ESF coolants.

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised per recommended wording

C.I.6-6 Traditional PWRs drain water to the refueling canal and during recirculation post accident the SI pumps draw from the sump to continue cooling and depressurizing containment. Not all next generation designs have a traditional sump. Discussion of the refueling canal may be misleading. The discussion in DG-1145 should be revised to make it more generic.

Response/ **Disposition**:

Staff does not agree with the comment. The staff contends that if the sump is not part of the design (no traditional sump) the discussion related to the sump does not apply.

C.I.6-7 This section contains the statement "Consider smaller break areas of steam line breaks starting with the double-ended rupture, until no liquid entrainment is calculated to occur." The approved AREVA methodology does not include this verbiage. This is typical of the Westinghouse approach and shouldn't be part of DG 1145 because it is a vendor specific approach. AREVA runs a spectrum of break sizes, but if the results of the analysis are trending toward lower containment pressure we don't continue to reduce the break size. For certain break size liquid entrainment may occur. The discussion in DG-1145 should be revised to make it more generic.

Response/ **Disposition**:

Wording will be revised to reflect more than one approach that considers entrainment as appropriate.

C.I.6-8 Typographical errors in the mass units of measure.

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised to correct typos per recommended wording

C.I.6-9 Section C.I.6.2.2 only includes fan coolers, sprays and passive systems to remove heat from the reactor containment for PWRs. The US EPR uses the passive heat structures and the Residual Heat Removal (RHR) Hx to remove energy from the In-Containment Refueling Water Storage Tank (IRWST) which is similar to a BWR removing energy from the suppression pool. The discussion in DG-1145 should be revised to make it more generic.

Staff agrees with the comment. If active containment cooling system in the design, they will not be part of the staff review.

C.I.6-10 §C.I.6.2.2.2 states "Compare the design of the recirculation intake structures to the positions in RG 1.82, Revision 3, "Sumps for Emergency Core Cooling and Containment Spray Systems."" This is not the correct title for this RG.

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised to correct title of RG 1.82

C.I.6-11 C.I.6.2.2.3 refers to RG 1.83 for analysis of NPSH for recirculation pumps, but the title identified is that of RG 1.82. The reference should be RG 1.82. RG 1.83 is titled "Inservice Inspection of Pressurized Water Reactor Steam Generator Tubes." Also, correct the "Surfaces" in the title to "Sources"

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised per recommended wording

C.I.6-12 C.I.6.2.2.4 requests "Provide the results of tests performed, as well as a detailed updated testing and inspection program." Delete this statement on the same basis as indicated in comments C.I.6.2.3.4-1, C.I.6.2.4.4-1, C.I.6.2.5.4-1, and C.I.6.4.5-1, and agreed to in the responses to the comments.

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised per recommended wording

C.I.6-13 C.I.6.3.1 states "Describe how the ECCS design meets the relevant Commission policy, as described in SECY papers and corresponding staff requirement memoranda (SRMs)." It is generally not appropriate to request applicants to discern and comply with the Commission Policy from SECY papers and the corresponding SRMs. These documents have not been through the appropriate review processes for public and stakeholder comment to be considered guidance to the applicants.

Response/ Disposition:

Staff agrees with this comment. When revising this appropriate SECY, the guidance will be included .

C.I.6-14 Section C.I.6.3.1 refers to "GL 98-0". Should these references be to GL 98-04. Please confirm.

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised to correct typo

C.I.6-15 Section C.I.6.3.2.5 states "describe how containment sump recirculation debris screen design meets the guidelines in RG 1.82, Revision 3". The statement about the screen for a BWR should be added according to the RG 1.82 Revision 3.

The staff agrees with the comment. When revising this, the same will be made similar to the guidance as found in SRP section 6.2.2.

C.I.6-16 C.I.6.3.2.5 states "Describe how the regulatory oversight of the active nonsafety systems was considered in using the process of "regulatory treatment of non-safety systems" described in SECY-94-084." The results of the SECY document, and the SRM (which indicates that the Westinghouse comments on this item, as stated in the Attachment to NTD-NRC-94-4145 should be accommodated) should be documented in some form of clear guidance to the industry. This SECY, the SRM and the WEC comments, are not readily available to the public.

Response/ Disposition:

Staff agrees with this comment. When revising this appropriate SECY guidance will be included .

C.I.6.3.4.1 refers to RG .79. The reference should be RG 1.79.

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised to correct typo

C.I.6-18 C.I.6.4 refers to "Section 15.X.X, paragraph 5." The reference should be Section 15.6.5, paragraph 5.

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised to include appropriate Chapter 15 section

C.I.6-19 C.I.6.4.2.2 – Ventilation System Design. This section should identify the ventilation system components that are located outside the Control Room Envelope and interface with unfiltered air outside the envelope, and if they are at negative or positive pressure. This information is necessary since these components are typically the main sources of unfiltered air in-leakage in a pressurized Control Room.

Response/ Disposition:

The staff does not understand the significance of this comment and would like some additional clarification from the commenters.

C.I.6-20 C.I.6.4.2.4 – Interaction with other zones and pressure containing equipment. This section needs to specifically address the interaction with air conditioning components that are pressurized with refrigerant, and interface directly with Control Room Envelope atmosphere. It may not be possible to isolate these components if they are needed for Control Room cooling. Although, most refrigerants in current use are non-toxic, they can displace air and cause asphyxiation in a confined space.

Response/ Disposition:

Staff feels that this concern is already addressed in the DG-1145 in section C.I.6.4.2.4 under item 2. Hence, staff does not propose any changes.

C.I.6-21 C.I.6.4.2.5 refers to "Section 15.X.X, paragraph 5." The reference should be Section 15.6.5, paragraph 5.

Staff agrees with this comment. DG-1145 revised to include appropriate Chapter 15 section

C.I.6-22 C.I.6.4.2 states "If chlorine has been identified as a potential hazard to the operator, specific guidance is provided by RG 1.95, 'Protection of Nuclear Power Plant Control Room Operators Against an Accidental Chlorine Release." This is no longer accurate as RG 1.78 Rev 1 has subsumed the RG 1.95 guidance.

Response/ Disposition:

Staff agrees with this comment. Update will reference new guidance provided in RG 1.78.

C.I.6-23 C.I.6.4.4.2 – Toxic Gas Protection. Typically the toxic gas detector is located in the outside air intake with an isolation damper downstream. This section should identify if the air intake isolation damper is designed to close before toxic gas reaches it.

Response/ Disposition:

Staff agrees with the comment in principle. Staff will evaluate the addition of item (3).

C.I.6-24 C.I.6.6.1 requests "A detailed inservice inspection program, including information on areas subject to examination, method of examination, and extent and frequency of examination, should be provided in the technical specifications." This sentence should be deleted since ISI is no longer included in the Technical Specifications (as the information was generally a duplication of the requirements).

Response/ Disposition:

Staff agrees with the comment.

C.I.6-25 C.I.6.6.6 requests "Describe the method to be used in evaluating examination results for Class 3 components and, until publication of IWD-3000, indicate the extent to which these methods are consistent with requirements in Article IWA-3000 of Section XI." This guidance should be updated to reflect that IWD-3000 has now been published.

Response/ **Disposition**:

Staff agrees with the comment and the proposed text will be added to show the update that reflects IWD-3000.

C.I.6-26 The Main Steam Line Isolation Valve Leakage Control System (BWRs) has been eliminated in new BWR plants. It is recommended that the description be modified to make consistent with section C.I.10.4.4 in DG-1145.

Response/ **Disposition**:

Staff agrees with this comment. When revising this appropriate SECY guidance will be included .

C.I.6, Table 6-2, Item IV.C refers to units of "106 Btu/hr." The units should be 106 Btu/hr.

Response/ Disposition:

Staff agrees. DG-1145 revised to correct typo

C.I.6, Table 6-4 contains an outdated note * that states "*Provided best estimates of these heat sinks in the PSAR stage and a detailed listing in the FSAR." This note should be deleted.

Response/ Disposition:

Staff agrees. DG-1145 revised note to read "Provide best estimates of these heat sinks in the COL application and a commitment to update the FSAR based on as-built information (this should be consistent with the values in containment analyses)"

C.I.6, Table 6-4 items (19) and (34) are both other. Item (19) should probably be removed.

Response/ Disposition:

Staff agrees. DG-1145 revised to delete Item (34) instead

C.I.6. Table 6-4, item B, states "The following data should be provided for the passive heat sinks listed in Table 6-4A (a detailed listing in the FSAR stage):" The parenthetical phrase should be omitted since there is only one phase under Part 52.

Response/ Disposition:

Staff agrees. DG-1145 revised to delete statement instead

C.I.6. Table 6-4, item D, includes a column header for density with units of "1/bft3" and a column header for Thermal Conductivity with units of "Btu/hr-ft EF". The units should likely be "lb/ft3" and "Btu/hr-ft2 EF," respectively.

Response/ **Disposition**:

Staff agrees. DG-1145 revised to correct typo

C.I.6, Tables 6-4B, 6-4C, and 6-4D have several inconsistencies with the similar table in RG 1.70.

Response/ **Disposition**:

The staff agrees with the comment. These corrections will be handled as a part of the RG update.

C.I.6, Table 6-5 Item B(11) use of "Resiction" should be Restriction.

Response/ Disposition:

Staff agrees. DG-1145 revised to correct typo

C.I.6, Table 6-11 footnote indicates plots should include time periods "to at least 106 seconds." This should be "to at least 106 seconds."

Response/ Disposition:

Staff agrees. DG-1145 revised to correct typo

C.I.6, Table 6-13 identifies two headers for differential pressure with units of "psig". These units should likely be "psid".

Staff agrees. DG-1145 revised to correct typo

C.I.7-1 In these sections, the uses of SAR and FSAR are inconsistent. For example, in 7.2, 7.3, and 7.4, the "SAR" is referenced but in 7.5, 7.6, 7.7 and 7.8, reference is made to the "FSAR." This seems to be a consistency issue throughout the new draft guide. In the previous revision of the draft guide, only the "SAR" term is used. The SAR and FSAR are related but some implications may be made if one uses SAR instead of FSAR or vice versa.

Response/ Disposition:

Staff agrees with this comment. Use FSAR for all sections.

C.I.7-2 The first paragraph leads into a bulleted list with "These system functions are:". However the bulleted list is a list of systems (such as post accident monitoring system) instead of a list of functions. The intent of the wording lacks clarity.

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised to list systems.

C.I.7-3 Under item (6), the second sentence states "A statistically valid sample of system requirements should be selected to confirm that the applicants/ licensee's life-cycle activities have been implemented as planned. The sample size should be such that the staff can conclude with at least 95% assurance that the quality of the design has been validated." This statement is an attempt to clear up the amount of information that needs to be submitted. However, the method of determining the sample size of the requirements is still ambiguous. Exactly what one requirement constitutes is debatable and the sample size to provide "95% assurance" is open to interpretation. There was discussion at the work shop in July that the NRC would require an inventory of documents to be made available to the reviewers when the application is submitted and the NRC would then review what they thought was a valid sample size. This approach would be more manageable.

Response/ **Disposition**:

Staff agrees with this comment. DG-1145 revised to state "Applicant should identify documentation available for NRC inspection that confirms implementation. The type of documents should be similar to the documents shown on SRP BTP 7-14, Figure 7-A-1, Flow of Documents Through the Software Life Cycle."

C.I.7-4 Under item (7), the second sentence states "A statistically valid sample of software design outputs should be provided to confirm with at least 95% assurance that they address the functional requirements and have been allocated to the software appropriately, and to confirm that the expected software development process characteristics are evident in the design outputs." This statement is an attempt to clear up the amount of information that needs to be submitted that was during the review of the first draft. However, the method of determining the sample size of the design outputs is still ambiguous. The sample size to provide "95% assurance" is open to interpretation.

Staff agrees with this comment. DG-1145 revised to per response to Comment C.I.7.3.

C.I.7-5 In Appendix C.I.7-B, under item (6), the last sentence references SRP Appendix 7.1-D, "Guidance for Evaluation of Conformance to IEEE Std. 7-4.3.2. This SRP Appendix currently does not exist. It is understood that the SRP's are being updated, however reference to future guidance does not provide clear guidance to applicants.

Response/ Disposition:

SRP Appendix 7.1-D will be issued in March 2007 and will coincide with issuance of RG 1.206. In addition, the staff is investigated public forums in which to share the updates to SRP Appendix 7.1-D prior to final issuance (e.g., meeting summaries, public workshops, etc.)

C.I.7-6 In Appendix C.I.7-B, under item (6), the guidance on communication independence is ambiguous and the present guidance on this matter is conflicting. Physical and electrical independence is addressed in this item but not communication independence. It states that additional guidance is provided in SRP Chapter 7, Appendix 7.1-C. When reviewing the guidance provided in SRP Appendix 7.1-C, it states in section 5.6 that Annex G of IEEE Std. 7-4.3.2 describes an acceptable means for providing communications independence. The version of the IEEE 7-4.3.2 that the SRP references must be 1993 since the SRP was published in 1997. The verbiage in this annex is exactly the same as that found in Annex E of the 2003 version of IEEE 7-4.3.2. However, RG 1.152, rev. 2, explicitly states that the NRC has not endorsed Annex E of IEEE 7-4.3.2 -2003. The regulation is conflicting.

Response/ Disposition:

SRP Appendix 7.1-D will be issued in March 2007 and will coincide with issuance of RG 1.206. In addition, the staff is investigated public forums in which to share the updates to SRP Appendix 7.1-D prior to final issuance (e.g., meeting summaries, public workshops, etc.)

C.I.7-7 In this section, under Software Life Cycle Process Implementation, there is a bulleted item labeled "Test". In BTP-14, which is the origin of this wording, the word "Validation" is used. All other items in the lists are exactly the same except this one. Why was this word changed? Also, the numbering of the items starting with Software Life Cycle Process Planning should be labeled as (a), (b), (c) instead of (1) (2) (3)

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised to use recommended wording.

C.I.7-8 Typographical error. Under item 12: Human Factors Considerations, there is a lone "e" in the text.

Response/ **Disposition**:

Staff agrees. DG-1145 revised as recommended.

C.I.7-9 In the first paragraph of this Appendix, reference is made to IEEE 603-1998. It states that IEEE 7-4.3.2 -2003 serves to amplify IEEE Std. 603-1998, yet there is no regulation that endorses IEEE Std. 603-1998. IEEE 7-4.3.2 -2003 is endorsed by Regulatory Guide 1.152 rev. 2 except for Annexes B thru F.

Staff agrees with this comment. Clarity has been provided in Section C.I.7 and confirms that IEEE Std. 603-1991 is required by 10 CFR 50.55a(h). Use of IEEE Std. 603-1998 recommended by guidance only.

C.I.7-10 The terminology in the second paragraph should be modified to be consistent with Regulatory Guide 1.97.

Response/ Disposition:

Staff agrees. DG-1145 revised to state "Instrumentation for accident monitoring...".

C.I.7-11 Since each system section (RTS, ESF, etc.) has a design basis sub-section, the third paragraph of C.I.7.1.2 is unnecessary.

Response/ Disposition:

Staff disagrees. The technical design bases should be addressed for all protection functions and the statement in Section 7.1 identifies this as a generic requirement for all sections. It is expected that the technical design bases be provided in each system section and not in Section 7.1.

C.I.7-12 Remote shutdown capability is not required to meet IEEE 603.

Response/ Disposition:

Staff agrees. DG-1145 revised to make separate discussion for Remote Shutdown Capability.

C.I.7-13 The terminology in the first bullet should be modified to be consistent with Regulatory Guide 1.97.

Response/ **Disposition**:

Staff agrees. DG-1145 revised to use recommended wording.

C.I.7-14 The fourth and fifth bullets do not have references to regulatory requirements for the safety parameter display system and information to be transmitted to the emergency response facilities and nuclear data link.

Response/ Disposition:

Staff agrees. Safety parameter display and emergency response facilities are TMI-related requirements. References made to 10 CFR 50.34.

C.I.7-15 The first sentence of C.I.7.5.2 discusses only Regulatory Guide 1.97 type A instrumentation (i.e., required manual safety functions and essential operator actions). However, the examples listed include non-safety functions (e.g., monitoring the status of safety equipment). In developing a suggested revision to this sentence, it was realized that there is no need for a separate discussion of this subset of information systems important to safety.

Response/ **Disposition**:

Staff disagrees with this comment. Section 7.5 is not specific to information obtained from RG 1.97 instrumentation. The 1st paragraph defines the scope of the analysis and should not be deleted. No change to DG-1145 has been made.

C.I.7-16 This section requires submittal of schematic diagrams, while all other instrument and controls sections require submittal of logic diagrams, piping and instrument diagrams, and location layout drawings.

Response/ Disposition:

Staff agrees. DG-1145 revised to use recommended wording.

C.I.7-17 Defense-in-depth and diversity is covered adequately in section C.I.7.1.8.

Response/ Disposition:

Staff disagrees with this comment. The 9th bullet in C.I.7.7.2 is for cross-checking the design consistency. No change to DG-1145.

C.I.7-18 This section applies to both safety and non-safety communications systems. Since there is only one list of design basis information, it is unclear which criteria should be discussed for non-safety systems. Also, approximately half of the design considerations listed will have already been discussed in the SAR section that describes the supported system in which the communications components are used

Response/ Disposition:

Staff disagrees with this comment. These items are for cross-checking the design consistency. No change to DG-1145.

C.I.7-19 Miscellaneous editorial changes

Response/ **Disposition**:

Staff is in partial agreement with comment. In 4th bullet DCA has been changed to DCS. Staff does not agree with the remainder of the editorials because.... No other changes to DG-1145 made per this comments.

C.I.7-20 The references to GDC 1 and 10 CFR 50.55a(a) (i.e., quality standards and records) appear out of place in a section about communications systems.

Response/ **Disposition**:

The Staff does not agree with this comment. The DCS of portions of the DCS perform safety functions. No change to DG-1145.

C.I.7-21 The third sentence states "The applicant/licensee should confirm that there is independence between environmental control systems and sensing systems which would indicate the failure or malfunctioning or environmental control systems." It is agreed that the single failure criterion must be met if the environmental control system is required to ensure a particular environment. However, independence is required between redundant portions of the environmental control system, not between the environmental control system and the sensing system that indicates failure or malfunction of the environmental control system.
No change to DG-1145. Power supplies should be independent between the environmental control system and the sensing system.

C.I.7-22 NRC comment C.I.7.39 on the preliminary version of this section identified that the statement, "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 Standard 603 and should be deleted. This previous comment stated that the requirements of Section 6.2 of IEEE Standard 603 are sufficient to ensure proper manual control. The NRC response to the comment was to make no change based on the justification that "This guidance comes from BTP 7-19 acceptance criteria...BTP 7-19 is developed based on Commission SECY-93-087...dated July 15, 1993." It is noted that SECY-93-087 and BTP 7-19 were developed prior to incorporation of IEEE Standard 603 into 10 CFR 50.55a(h) in 1998. Hence, this portion of these documents in not supported by current regulations. The guidance promulgated by these documents related to manual controls is inappropriate in the subject appendix entitled "Conformance with IEEE Std. 603."

Response/ Disposition:

TBD. This item is still under discussion and will be addressed by the recently established Working Group on Digital I&C.

C.I.7-23 Miscellaneous editorial changes

Response/ Disposition:

Staff disagrees with this comment. GDCs 20 through 25 still use the wording "protection system." Therefore, no changes to DG-1145 have been made.

C.I.7-24 Editorial change

Response/ Disposition:

Staff disagrees. GDC 24 use wording protection functions, therefore, no changes to DG-1145 have been made.

C.I.8-1 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

Response/ **Disposition**:

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.

C.I.8-2 Reg. Guide 1.29 is out of order.

Response/ Disposition:

The guide will be revised to place RG 1.29 in numerical order.

C.I.8-3 Introduction & section 8.4 refers to AAC as part of SBO response. Not all plant designs will need an AAC. Part of "bigger picture" issue on GDC 17 and passive plants. See comments for section C.I.8.2

Response/ **Disposition**:

This section will be revised to clarify that all plant design will not need an AAC source.

C.I.8-4 Introduction discusses systems "important to safety"; A more specific definition / scope needs be provided.

Response/ Disposition:

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. An offsite power is considered "important to safety" by the staff. Although passive plants are exempted from providing two offsite power sources are required by GDC 17, they are not exempted from having none. Therefore, the staff recommends that one offsite power source with sufficient capacity and capability from the transmission network be provided to power the safety-related systems and other auxiliary systems under normal, anticipated operational occurrences and accident conditions to ensure that safety-related batteries are not challenged unnecessarily.

C.I.8-5 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. Examples;(1) 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). (2) FMEA and Stability Analysis may not be complete at time of COLA submittal due to availability of information for switchyard design.(3) Local power sources and transmission paths for resupply 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 COLA submittal.

Response/ Disposition:

An offsite power is considered "important to safety" by the staff. Although passive plants are exempted from providing two offsite power sources are required by GDC 17, they are not exempted from having none. Therefore, the staff recommends that one offsite power source with sufficient capacity and capability from the transmission network be provided to power the safetyrelated systems and other auxiliary systems under normal, anticipated operational occurrences and accident conditions to ensure that safety-related batteries are not challenged unnecessarily. The passive plants should perform a FMEA of the switchyard to ensure that a single event does not cause failure of the single offsite power source from the transmission network. 1&2 -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.3 - 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.

C.I.8-6 This section identifies a requirement to: "Describe how the stability of the grid is continuously studied as the loads grow and additional lines and generating lines are added."

Response/ **Disposition**:

The licensees are required to provide a stability analysis of the grid to demonstrate that a loss of a nuclear unit, loss of a critical transmission line, or loss of the largest generator on the system would not cause a loss of offsite power to the plant. Since the grid conditions will continue to change over time due to load growth, this stability analysis must also be updated with the changing grid to assure that original assumptions bound the new grid conditions. Therefore, no change to this section of the guide is necessary.

C.I.8-7 The requirement to discuss how RG 1.75 recommendations are met is redundant to section 8.1 requirements. Same comment applies for DC cables. (This comment applies to two entire paragraphs on each section, and not just the sentence containing RG 1.75.)

Response/ **Disposition**:

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.

C.I.8-8 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.

Response/ Disposition:

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

C.I.8-9 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/ **Disposition**:

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.

C.I.8-10 (1) Section 4 for Equipment Protection does not specify that it only applies to safetyrelated equipment. (2) It is unclear if this section should cover "associated circuit analysis" type issues that are required by the Fire Protection plan.(3) Section 4 is under AC, but includes discussion on DC fuses.

Response/ Disposition:

1) Section 4 applies to safety related as well as systems important to safety such as offsite power system components. Therefore, no change to the reg guide is necessary. 2) The associated circuit analysis for response to fire (e.g. separation) is covered in section C.I.9.5.1. 3) The guide will be revised to delete reference to dc fuses.

C.I.8-11 Section on Power Quality (AC & DC) is a new requirement. Section does not specify any industry guidance (e.g. IEEE 519, RG 1.180); What parameters are concerns, e.g. frequency, voltage, harmonic content (THD)? What acceptance criteria for VFDs are a concern (THD, notch depth)? NRC concern on impact of VFD operation on any class 1E power systems, but no criteria provided.

Response/ Disposition:

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.

C.I.8-12 Section 4 requires battery characteristic curves; Characteristic curves will not be available until batteries are purchased, which will be after COLA submittal.

Response/ Disposition:

Recommended wording is ok

C.I.8-13 Page C.I.8-15 editorial changes; Wording under Short Circuit Studies and Monitoring and Testing

Response/ Disposition:

The guide will be revised to make these changes.

C.I.8-14 Last sentence on passive system designs should be moved to the beginning of this section.

Response/ **Disposition**:

The guide will be revised to provide discussion on passive plants.

C.I.9-1 These paragraphs address "means for maintaining a sub-clinical array." The context of the paragraph suggests that the word "clinical" should be replaced by the word "critical."

Staff agrees with comment. DG-1145 Sections C.I.1.9.1.1.1 and C.I.1.9.1.2.1 corrected to say "sub-critical"

C.I.9-2 The third sentence of the paragraph, which deals with the system description of the Fuel Handling System, states, "Component drawings, building layouts, and illustrations of the fuel handling procedures should also be provided." Please clarify what is meant by "illustrations of the fuel handling procedures."

Response/ Disposition:

Staff agrees with comment. The phrase, "illustrations of the fuel handling procedures," should be replaced with the following, "illustrations showing important aspects of the fuel handling process. For example, illustrations should show the arrangement of equipment for fuel movement within the reactor and equipment used for fuel transfer." (S. Jones)

C.I.9-3 Section C.I.9.1.5.1, "Design Basis", for Overhead Heavy Load Handling Systems: This section should be expanded to define "heavy

Response/ Disposition:

Staff agrees with comment. Add the following: "A heavy load is defined as a load weighing more than one fuel assembly and its associated handling device." (S. Jones)

C.I.9-4 Section C.I.9.1.5.1, "Design Basis", for Overhead Heavy Load Handling Systems: This section should be expanded to clarify what is being protected from a heavy load drop.

Response/ Disposition:

Staff agrees with comment. Revise Section C.I.9.1.5.1 to read: "Provide the design bases for the overhead heavy load handling system with respect to critical load handling, which involves the potential for inadvertent operations or equipment malfunctions affecting the handling system to cause a significant release of radioactivity, a criticality accident, an inability to cool the fuel within the reactor vessel or spent fuel pool, or an inability to achieve or maintain safe shutdown of the reactor. Necessary information includes parameters defining the load that, if dropped, would cause the greatest damage, the areas of the plant where the load would be handled, the design of the overhead heavy load handling system, and the operating, maintenance, and inspection procedures applied to the load handling system. (S. Jones)

C.I.9-5 Section C.I.9.1.5.2, "System Description," for Overhead Heavy Load Handling Systems: The opening sentence requires that illustrations of special lifting devices be submitted. At the time the COL application is being submitted, this information would generally not yet be available. Conformance to National Standards, such as ANSI N13.2 that is for the design of special lifting devices, should be all that is required. This provision is spelled-out in other regulatory guidance i.e. NUREG-0612.

Response/ Disposition:

Staff disagrees with comment. No change to DG-1145. Special lifting devices are critical components of the overhead heavy load handling system. Drawings of key lifting devices, such as the reactor vessel head lift rig, should be available well before plant operation. The drawings should be included in the COL application documents prior to issuance of a combined operating license. The correct national standard is ANS N14.6-1993. (S. Jones)

C.I.9-6 1. This section should use the terminology "Control Room Envelope" (CRE), consistent with Habitability Section C.I.6.4.2. 2. Add the requirement to provide details on missile protection of outside air intake and exhaust louvers in Section C.I.9.4.1.1. 3. Add "unfiltered air inleakage" in the examples given for testing in Section C.I.9.4.1.4.

Response/ **Disposition**:

Staff concurred on items #1 and #2. With respect to #3: Unfiltered inleakage testing is not related to CR HVAC system and is address as part of CR Habitability in C.I.6.4.2. (E. Forrest)

C.I.9-7 Eighth bullet regarding Failure Modes and Effects Analysis (FMEA). The text states "results of failure modes and effects analyses vis a vis single failure criteria for safe shutdown and prevention/mitigation of postulated accidents." Does this imply that if the CVCS system provides no safety-related function for safe shutdown or design basis accident mitigation, then no FMEA is required?

Response/ Disposition:

change text to "results of failure modes and effects analyses for single failure consideration of CVCS is used for prevention/mitigation of postulated accidents"

C.I.9-8 C.I.9.3.4.4 Inspection and Testing Requirements Recommend the second sentence be transferred to C.I.9.3.4.2 System Description as it does not pertain specifically to Inspection and Testing.

Response/ Disposition:

Staff concurs. The wording was moved to Section C.1.9.3.4.2. (Y. Diaz Castillo)

C.I.9-9 The 4th bullet item pertains to Operator Manual Actions (OMAs), or recovery actions, that may need to be taken to mitigate spurious actuations of equipment due to fire-induced circuit failures, or may otherwise be needed to achieve and maintain safe shutdown during and after a fire. The draft guidance states that the "acceptance criteria" for OMAs should be provided, along with the analyses (including thermal-hydraulic analysis) to demonstrate that safe shutdown can be achieved and maintained. Applicants may lack the [scenario-specific] technical input requirements developed to the necessary level of detail to adequately demonstrate the feasibility of OMAs at the COL submittal stage.

Response/ **Disposition**:

Staff concurs. DG-1145 will be revised to provide COL applicants with relief from providing certain information, analyses, etc., that cannot be finalized prior to submittal of the COL. However, the COL application must include a sufficient level of design details, design requirements, commitments, acceptance criteria, analyses, etc., to enable the staff to reach a safety finding. In addition, the COL application must include the licensee's plan and schedule to finalize any incomplete information and the finalized information must be reviewed and approved by the staff prior to fuel load. Specifically for OMAs, the guidance that has been developed for OMAs for existing plants should be applied to new reactors. As a minimum, the COL application should include the applicant's commitment to meeting the current guidance for OMAs or provide the justification for deviations. However, the staff expects that new reactor designs will require minimal reliance on OMAs for fires outside the main control room. The following text will be inserted as a new paragraph "Some of this information may not be available or possible to provide at the time the COL application is submitted. In this cases, submit the information available, justify the inability to provide the information in the COL application and provide details

describing implementation plans, milestones and sequences and/or ITAAC or commitments for developing, completing and submitting this information during the construction period, prior to fuel load."

C.I.9-10 Sections discuss detailed information requirements for diesel generator subsystems

Response/ **Disposition**:

Add "The level of information to be provided will reflect the design bases for the system; therefore, the non-safety systems will likely have reduced discussion."

C.I.10-1 Section C.I.10.1 states "In addition, for all of the following sections, include a discussion of how the system design meets the applicable regulatory requirements and is consistent with the regulatory guidance available". This statement is more appropriate for general statement of C.I.10 (before section C.I.10.1).

Response/ **Disposition**:

The staff agrees with this comment that the statement should be relocated to the end of the second paragraph in Section C.I.10. and reworded as follows: "In addition, beginning with Section C.I.10.2 and for the other sections that follow, include a discussion of how the system design meets the applicable regulatory requirements and is consistent with the applicable regulatory guidance." However, the need for adding "six months prior to application submittal" is not clear. Therefore, without understanding why this sort of logistical information is needed for this particular section, we don't agree with this part of the proposed change.

C.I.10-2 For non-code components, provide expected plant-specific material property data such as chemistry, yield strength, fracture toughness data (KIC), Charpy V-notch energy, nilductility temperature, and fracture appearance transition temperature. Identify appropriate ITAAC to verify the plant-specific material property data, including identification of manufacturer/fabricator, and heat number(s).

Response/ **Disposition**:

The staff agrees with the conclusion reached in the "Recommended Wording" section but a revision to DG-1145 on "non-code components" is not justified due to this conclusion. However, remove the last sentence, "Identify appropriate ITAAC to verify the plant-specific material property data, including identification of manufacturer/fabricator, and heat number(s)." from the C.I.10.3.6.1.

C.I.10-3 For non-code components, provide plant-specific materials property data such as chemistry, yield strength, fracture toughness data (KIC.), Charpy V-notch energy, nilductility temperature, fracture appearance transition temperature. Identify appropriate ITAAC to verify the expected material properties including manufacturer/fabricator, and heat number(s). Per past practice for design certification and Section C.II.2, ITAAC are not established to verify material properties of non-code components in the steam and feedwater systems. Rather, NRC may verify actual material properties through normal design implementation inspections.

Response/ **Disposition**:

The staff agrees with this comment. Remove the last sentence, "Identify appropriate ITAAC to verify the plant-specific material property data, including identification of manufacturer/fabricator, and heat number(s)." from the C.I.10.3.6.1.

C.I.10-4 The corresponding section of C.III.1 differentiates between the PWR and BWR issues.

Response/ Disposition:

Replace the current text with the following: "For PWRs, provide the following information with reference to fluid flow instabilities (e.g., water hammer, for steam generators using top feed):(1) A description of normal operating transients that could cause the water level in the steam generator to drop below the sparger or cause the nozzles to uncover and allow steam to enter the sparger and feedwater piping.(2) A summary of the criteria for routing or isometric drawings showing the routing of the feedwater piping system from the steam generators to the restraint that is closest, on the upstream side, to the feedwater isolation valve that is outside containment.(3) A description of the piping system analyses, including any forcing functions, or the result of test programs performed to verify that uncovering of feedwater lines could not occur or that such uncovering would not result in unacceptable damage to the system. (Demonstrate conformance with guidance for water hammer prevention and mitigation, as found in NUREG-0927.)For BWRs, provide a description of the feedwater nozzle design, inspection, and testing procedures, and system operating procedures incorporated to minimize nozzle cracking at low feedwater flow. Demonstrate conformance with the guidance in NUREG-0619 and GLs 80-95 and 81-11."

C.I.10-5 Section discusses detailed information requirements for auxiliary feedwater systems

Response/ Disposition:

The staff agrees with this comment. Add the following: "Note that this section is only applicable to auxiliary feedwater systems that perform a safety function and it is not applicable to those plant designs where this is not the case."

C.I.11-1 The highest priority for a nuclear plant is the safe, efficient generation of electricity. Liquid and solid effluent processing can usually be provided as an off site vendor service more competitively and with less distraction to the safe, efficient generation of electricity. Safety analyses for off site vendor activities is addressed as part of the vendor facility license and is not appropriate to address in the nuclear plant SAR. Moreover, the option of when to use off site processing, which waste to process off site, what quantity is processed off site, and what off site processing techniques might be selected at any given time is a business competitive and economic issue which has no bearing on the plant SAR.

Response/ Disposition:

Note that the requirements of the SRP are applicable only to an applicant for a license under Part 50 or Part 52. They do not apply to vendors, unless an evaluation of docketed topical report is requested. The reason for identifying whether some or all of waste processing functions will be done by a vendor is to determine if the systems have adequate capacity, redundancy, and flexibility in processing wastes during down time and with fuel leakage at design basis levels. For the sake of clarity, a qualifier is added, "If adopted as an operational practice," as appropriate, to address the possibility of such a waste processing option and provide supporting information to that effect.

C.I.11-2 There is some confusion as to the requirement for P&IDs to be included in the COLA or SAR. Established precedence allows P&IDs to be referenced in the SAR without actual inclusion of the P&IDs in the SAR. It seems reasonable to apply this precedent to the COLA.

Disagree with comment. Current requirements for P&IDs in COLA need to remain in light of SRP requirements to review system P&IDs. The need to provide P&IDs and process flow diagrams is essential for the staff in reviewing and evaluating system designs, methods of operation, interface with other systems, and identify process and effluent streams. Without this information, the staff cannot complete its review and evaluation, and conclude, with reasonable assurance, that the proposed systems comply with acceptance criteria, that all design commitments will be fulfilled, and that the plant will be built and will operate in accordance with its design certification and NRC regulations. Finally, nothing in the guidance prevents applicants from noting that at the time the application is being submitted that some specific information was not available and that the missing or incomplete technical information or design will be submitted at a later time. In its review, the staff will consider such a possibility during the acceptance review, make a determination as to the impact of the missing information on the conduct of its full technical review, and, if found acceptable, make it an RAI item to be issued and tracked during the technical review process.

C.I.11-3 In advanced nuclear plants, mobile (including skid-mounted) systems are expected to be a key, common component of the plant design. Since the systems and their connections are addressed in the engineered design drawings and SAR, and since the connections for such systems are included in the P&IDs, the word "temporary" and "temporary connections" adds a layer of confusion which will adversely impact routine installation, use, maintenance and replacement of such systems and connections.

Response/ **Disposition**:

ANSI 40.37 was withdrawn on 6/18/2004 but is being revised as ANSI/ANS 40.37-200x. Use of mobile or temporary equipment language is appropriate to be consistent with language in design certifications and ANSI/ANS 40.37-200x Draft. The staff agrees to add "i.e., flexible hoses and hose connections" to clarify meaning of temporary connections consistent with ANSI/ANS 40.37-200x Draft. The staff agrees with comment to include the ANSI/ANS 40.37-200x (draft) as a reference.

C.I.11-3 The problem arises because the term "temporary" as applied to nuclear plant systems is strongly associated with temporary modifications and narrowly defined time limits for temporary modifications and temporary installations. Therefore, in most nuclear plants, the word "temporary" suggests an immediate engineering review and classification as a temporary modification with clear time constraints. In sharp contrast, the mobile system concept and design is intended for short term (e.g., outage) and long term (e.g., up to 20 or more years) installations, as well as inter-unit shuttle capability. With further regard to "temporary connection" points included in the plant design for mobile systems, a more accurate and appropriate term would be "engineered, flexible connections." Reference should be made to RG 1.143 and ANSI 40-37.

Response/ Disposition:

See response above.

C.I.11-4 It should be sufficient for a plant to state that waste will be disposed when an acceptable disposal option is available. If the plant recognizes that such an option is not available at the time the SAR is submitted or at a subsequent date, then the SAR should provide appropriate information for an interim storage facility or ISFSI, as applicable. The ALWR design is intended for a 60-year licensing period, plus at least 10 years for decommissioning. This is beyond the initial application life of a commercial waste disposal

facility, which means that every new plant faces a potential for having to store some waste for short periods of time. If a disposal option is available, waste will normally go from the processor to a disposal facility. If no disposal option is available, then the waste will be processed and returned or sent to an off site vendor storage facility. If the process and return option materializes as a matter of normal operation, then the SAR should address it along with the interim storage consideration. If the disposal-site-available situation is active, then this requirement need not be addressed.

Response/ Disposition:

See response to comment C.1.11.1.

C.I.11-4 Equally important, the "fraction of waste processing contracted out" will vary as a matter of competitive routine based on disposal fees, waste characteristics, on site processing costs, and off site processing costs. It cannot be predicted reliably more than one year in advance, so it would never be reliable if stated in the SAR and would constantly need to be updated. It should be sufficient to recognize – without stating it in the SAR – that the plant will rely on safe, licensed and efficient off site processing at the discretion of the plant operator and prevailing economics.

Response/ **Disposition**:

See response above.

C.I.11-5 The plant should describe the equipment to be used and provide any appropriate data. At present, very few USA nuclear plants rely on in-house solidification, compaction, shredding, or crushing.

Response/ Disposition:

The described processing equipment is provided for illustrative purposes and not mandatory. There is nothing in the guidance preventing an applicant from considering and using other types of waste processing methods. This part of DG-1145 will remain as is. However, a qualifier was added, "If adapted as an operational practice," to clarify applicants who are required to describe specific processing equipment. Switched "solidification" to read "solidification and encapsulation" for consistency with ANSI/ANS 40.37-200x draft.

C.I.11-6 Many paragraphs and passages in DG-1145 appear to require details related to specific processes, equipment and procedures that may not be available or accurately defined at the COLA. For example the types of training, specific procedures, process control program. Such data and documentation should be incorporated in the FSAR by reference and made available for review prior to start-up.

Response/ **Disposition**:

The level of details described in the various sections of DG-1145 addressing the LWMS, GWMS, and SWMS is generally consistent with its prior version as Regulatory Guide 1.70 and 10 CFR Part 50.34a. Note that Part 50.34a (c) states that: "Each application for a license to operate a nuclear power reactor shall include (1) a description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, pursuant to paragraph (a) of this section; ..." In this context, the description of the requested information is consistent with applicable regulations and General Design Criteria 60, 61, 63, and 64 of Appendix A to Part 50. As further clarification note: a. Descriptive details are

included in DG-1145 as elaboration as to what the staff expects on specific technical or regulatory topics. This approach provides a clear understanding as to the level of details that should be included in applications. The information presented in DG-1145 parallels that of the respective sections of the SRP.

b. Given that the industry will be relying more extensively on the use of mobile or portable waste processing equipment connected to permanently installed plant system, the descriptive information discussed in DG-1145 is a reminder that this level of details is needed in applications since none of that information is included currently in Part 52 design certification requests. As can be noted from currently certified designs (CD) and ongoing certification reviews, Part 52 applicants are routinely noting that this level of detail is to be provided by future COL applicants since it is not possible to know at this stage of the process what type of portable processing systems will be available commercially in the future and what types of financial considerations will drive a utility in selecting a specific type of technology over another. c. New information is being sought in response to the requirements of 10 CFR Part 20.1406 as this requirement became effective in 1997. As a result, this requirement was not in Regulatory Guide 1.70, nor in the prior version of the SRP. The focus of Part 20.1406 is on information that demonstrates that applicants will design and develop operational procedures that will minimize contamination, facilitate decommissioning, and minimize the generation of radioactive waste.

As compared to the information presented in Regulatory Guide 1.70 and the prior version of the SRP, the further elaboration and clarification of technical and regulatory topics presented in DG-1145 are expected to ensure a greater level of standardization among applications, facilitate the staff's acceptance review process, and minimize the number of requests for additional information. The staff believes that this approach should ensure that the staff's review process is more effective, efficient, and timely. Finally, nothing in the guidance prevents applicants from noting that at the time the application is being submitted that some specific information was not available and that the missing or incomplete technical information or design will be submitted at a later time. In its review, the staff will consider such a possibility during the acceptance review, make a determination as to the impact of the missing information on the full technical review, and, if found acceptable, make it an RAI item to be tracked during the full technical review.

C.I.11-7 There are several references to "10 CFR 20.1302" dose limits. 10 CFR 20.1301 is the correct reference for the 10CFR20 dose limits.

Response/ **Disposition**:

Staff agrees with comment. Text will be reviewed and edited accordingly.

C.I.11-8 NRC Information Notice IN 91-40, Contamination of Nonradioactive System And Resulting Possibility For Unmonitored, Uncontrolled Release To The Environment, should be included along with IE Bulletin No. 80-10 throughout these documents in discussions of contamination of non-radioactive systems. Based on industry Operational Experience (OE), IN 91-40 updates information published in IE Notice 80-10, and should be appropriately referenced.

Response/ Disposition:

No changes needed to DG-1145 and SRP sections. IE Bulletin 80-10 addresses the initial NRC concern and, in that context, the issues identified in it are still relevant. IN 91-40 is a follow up reminder to licensees of the continuing possibility of unmonitored and uncontrolled releases of

radioactive materials in light of the issuance of IE Bulletin 80-10. Regarding Regulatory Guide 1.11, a reference will be added to DG-1145 and SRP Sections 11.2 to 11.4.

C.I.11-9 All references to "site-specific cost benefit analysis, regardless of purpose or liquid effluent type, should be deleted. This includes any requirement to show that the proposed systems contain all items of reasonably demonstrated technology that, when added to the system in order of diminishing cost-benefit return, can for a favorable cost-benefit ratio affect reductions in dose to the population or comparing equipment to outdated technology. Additionally requires an isotopic analysis that pertains only to surface waters. 10 CFR50 provides for an alternative approach.

Response/ **Disposition**:

As worded, this item is not suggestive of "best available technology," presumably assumed by NEI to mean the NRC's adoption of an EPA nomenclature. The text in DG-1145 is consistent with the requirements of Appendix I, Section II.D to 10 CFR Part 50. Section II.D of Appendix I states: "... the applicant shall include in the radwaste system all items of reasonably demonstrated technology that, when added to the system sequentially and in order of diminishing cost-benefit return, can for a favorable cost-benefit ratio effect reductions in dose to the population reasonable expected to be within 50 miles of the reactor. "In this context, the description of the information contained in DG-1145 is consistent with applicable regulations and is in full agreement with the ALARA objectives of Appendix I to Part 50.No changes needed to DG-1145 and SRP sections.

C.I.11-10 The required information is basically equivalent in SRP 11.2 Draft Rev. 3, Section III.2.c & Section IV.3; SRP 11.3 Draft Rev 3, Section III.2.b & SectionIV.3, plus it's associated ETSB 11-5, Section B.1.b; SRP 11.4; DG-1145 Section C.I.11.3 and DG-1145 Section C.I.3.1. However, it conflicts with Regulatory Guide 8.8 Revision 3, 1978, Section C.2 on page 8.8-7. SRP 11.2 Draft Rev. 3 Section III.2.c states: "The system capability to process wastes at design basis fission product leakage levels, i.e., from 1% of the fuel producing power in a PWR or, in a BWR, consistent with a noble gas release rate of 3.7 MBq/sec per MWt (100 Ci/sec per MWt) measured after 30 minutes delay. "In conflict, Regulatory Guide 8.8 Revision 3 states: "Fission product source terms should be estimated using these bases: (1) an offgas rate of 100,000 Ci/sec after 30 minutes delay for BWRs and (2) 0.25% fuel cladding defects for PWRs."

Response/ Disposition:

A review of Regulatory Guide 8.8 (p.8.8-6 to 8.8-8) indicates that the stated source term parameters are for the purpose of designing radiation shielding in keeping doses to workers within Part 20 occupational dose limits and ALARA. The source term parameters stated in DG-1145 are for defining the operational basis to treat radioactive effluents, with sufficient capacity, and demonstrate compliance with the limits of 10 CFR Part 20, Appendix B, Table 2 for members of the public located in unrestricted areas. The source term parameters for BWR and PWR plants were not changed in DG-1145 and are consistent with the provisions of Regulatory Guide 1.70 and prior and revised sections of the Standard Review Plan. No changes needed to DG-1145 and SRP sections.

C.I.11-11 "Excessive" suggests an unplanned event or accident; the focus of the SAR is on "normal operation, including anticipated operational occurrences."

Staff agrees with NEI comment. Change "excessive" to "peak" for clarification.

C.I.11-12 RG 1.143 also applies to in-plant systems (i.e., not just mobile equipment).

Response/ Disposition:

Staff agrees with NEI comment. Add reference to RG 1.143 to C.I.11.2, C.I.11.3, and C.I.11.4. Staff found RG 1.143 was appropriately referenced in C.III.1 in Chapter 11.

C.I.11-13 With regard to plant interface, skid-mounted systems are mobile, and all mobile and skidmounted systems have the same plant interface (connection) considerations in terms of the SAR. Confusion arises when DG-1145 provides extensive discussion on mobile systems, then it separately addresses skid-mounted systems with the same requirements.

Response/ Disposition:

The staff agrees that "skid-mounted systems" are mobile systems. For consistency with ANSI/ANS 40.37-200x, changed "... skid-mounted waste processing equipment..." to read "... mobile waste processing equipment..." in discussion about mobile systems on page 10.

C.I.11-14 At most plants, the Liquid Radwaste System is always "in-service." Therefore, unlike many other systems, it cannot be taken out of service and tested. Monitoring of system performance and function on a daily/weekly basis meets the intent of this guidance.

Response/ Disposition:

Staff disagrees with comment. The discussion of inspection and testing provisions is consistent with Section 4.5 of RG 1.143.

C.I.11-15 A significant aspect of environmental contamination relates to groundwater contamination. EPRI has developed groundwater documents which capture the latest industry guidance, as well as industry lessons learned and technical references. These references will be very useful in responding to this requirement.

Response/ Disposition:

Staff agrees, a significant aspect of environmental contamination relates to recent ground water contamination events. However, since EPRI documents on this topic are released under strict license conditions and are not readily available to the public, they cannot be referenced here.

C.I.11-16 Some systems are not normally considered Radioactive Waste systems, e.g., PWR turbine drains and steam generator blowdown.

Response/ Disposition:

Staff disagrees with comment. The staff does not want to confine the discussion to systems listed in RG 1.143 since the systems listed there are not all inclusive. Note that PWR turbine drains and steam generator blowdown are included in RG 1.143. For clarification, the following was added "... and others as applicable." to the end of the sentence in DG-1145.

C.I.11-17 It is not clear why the NRC is pushing SI units, especially as a priority over USA units. Becquerels are routinely required and as more desirable than curies (or perhaps the NRC is requiring both); other passages in the SAR call for kg/yr and m3/yr. If the NRC is seeking an across-the-board change, then it should do so for all licensees and all regulatory requirements. It is not appropriate to seek such a change within a new DG.

Response/ Disposition:

The use of dual radiological units is consistent with 10 CFR Part 20.1005. This approach is also consistent with NCRP Report No. 82 - SI Units in Radiation Protection and Measurements. The Metric Conversion Act of 1975 and Executive Order 12770 require that each Federal agency use the metric system of measurements in its procurement, grants, and other business-related activities. Finally, the NRC has endorsed metrification in SECY 96-098 and in Fed. Reg. Vol. 61, No. 119, June 19, 1996. As a result, the use of dual units (SI and English (SAE)), is kept in DG-1145 for data presentation.

C.I.11-18 This is an operational consideration, requires specific knowledge of liquid waste processes and reactor water chemistry, and is not a regulatory consideration.

Response/ Disposition:

Staff partially agrees with comment. Sentence changed to read "Describe factors used in determining whether processed liquid wastes will be recycled for reuse or further treated or discharged to the environment as they relate to maintaining effluent releases ALARA." for clarification in DG-1145.

C.I.11-19 This section states that Regulatory Guide 1.109 should be used to calculate doses to members of the public, and then to compare the doses to 10CFR20 dose limits. The problem with this requirement is that RG 1.109 and 10CFR20 are based on different ICRP dose methodologies and can not be directly compared. Moreover, RG 1-109 is out of date. Federal Register Vol. 56, No.98, 5/21/91 which issued a revised 10CFR20, states that demonstrating compliance with the design objectives on 10CFR50, Appendix I, and the limits of 40CFR190 will demonstrate compliance with the 0.1 rem 10CFR20 dose limit.

Response/ Disposition:

The NRC is aware of the need to update the bases of 10 CFR Part 50 Appendix I dose objectives and several regulatory guides to be consistent with the dose methodology of Part 20 and current ICRP dosimetry concepts. The scientific bases for the current Appendix I dose objectives are outdated, as compared to current international standards. Also, there is a need to revise supporting computer codes and determine whether other documents (NUREGs) should be revised as well. Consistency between Part 20 and Part 50 (Appendix I) in using the same radiation dosimetry or dose assessment methodology would eliminate the existing dual regulatory requirements. The Commission is yet to decide on whether to retain ICRP-26 and ICRP-30, adopt the 1991 recommendations of ICRP-60, or yet consider upcoming ICRP recommendations - see SECY-04-0223, SECY-05-0117, and SECY-05-0202. The Commission will determine whether Part 20 needs to be revised, and, if so, it will define the scope of a revision to Part 20 and update the dosimetry concept of Appendix I dose objectives. A formal decision is expected by 2008.

C.I.11-20 RG 1.143 also applies to in-plant systems (i.e., not just to mobile or temporary equipment).

Response/ **Disposition**:

See response to comment C.I.11.12.

C.I.11-21 This paragraph requires inspection and testing provisions for periodic evaluation of operability and functional performance IAW RG 1.143, yet many operating plants have never committed to this guidance. Also, at most plants, the Gaseous Effluent System is always "in-service." Therefore, unlike many other systems, it cannot be taken out of service and tested. Monitoring of system performance and function on a daily/weekly basis meets the intent of this guidance.

Response/ Disposition:

See response to comment C.I.11.14.

C.I.11-22 Same comment as above for C.11.2.3 with regard to RG 1-109.

Response/ Disposition:

See response to comment C.I.11.19.

C.I.11-23 This section requires that, for gaseous radioactive releases, the licensee must "demonstrate compliance with regulations by comparing the calculated effluents with the concentration limits of 10 CFR Part 20, Appendix B, Table 2, Column 1". Showing compliance with the EC values in 10CFR20, App. B, Table 2 is currently being performed only for liquid effluents per NUREG-1301 and NUREG-1302. As stated in NUREG-1301, for gaseous effluents, site boundary dose limits provide reasonable assurance that the gaseous EC values in 10CFR20, App. B, Table 2 will not be exceeded.

Response/ Disposition:

For radioactive effluents, the approach for demonstrating compliance with the dose limits of 10 CFR Part 20.1301 is described in 10 CFR Part 20.1302. A licensee can demonstrate compliance with the annual dose limits by (a) confirming that doses to members of the public do not exceed the stated limits, or (b) by demonstrating that the annual average concentration at the site boundary does not exceed the effluent concentration limits of Table 2 to Appendix B to Part 20. Accordingly, the regulations provide two options which can be implemented by the licensee using the Offsite Dose Calculation Manual (ODCM) and guidance of NUREG-1301 or NUREG-1302. The objective of the ODCM is to describe the methodology and parameters used in controlling effluent discharge release rates and offsite effluent concentrations, and for calculating offsite doses resulting from gaseous and liquid releases. Accordingly, there is no need introduce further requirements beyond that stated in 10 CFR Part 20.1302 and guidance of NUREG-1301 or NUREG-1301 or NUREG-1302.

C.I.11-24 SI unit discussion again; should not be preferential

Response/ Disposition:

See response to comment C.I.11.17.

C.I.11-25 Mobile systems do not need to be skid-mounted

Response/ Disposition:

See response to comment C.I.11.13.

C.I.11-26 RG 1.143 also applies to in-plant systems (i.e., not just to mobile or temporary equipment).

Response/ **Disposition**:

See response to comment C.I.11.12.

C.I.11-27 As used in this paragraph, the word "cleaning" is unclear. Clarification is recommended. It is also recommended that the phrase "and ANSI 55.1" be added after "Regulatory Guide 1.143" along with an appropriate reference to ANSI 55.1 in Section C.I.11.6.

Response/ Disposition:

Text was changed by removing "cleaning" to read "radioactive decontamination" for clarity. Since ANSI 55.1 is already endorsed by reference in RG 1.143, there is no need to included here.

C.I.11-28 The intent of the paragraph is not clear, specifically in reference to the term "cleaning." Also add reference to ANSI 55.1.

Response/ Disposition:

See response to comment C.I.11.27.

C.I.11-29 This paragraph requires inspection and testing provisions for periodic evaluation of operability and functional performance IAW RG 1.143, yet many operating plants have never committed to this guidance. Also, at most plants, the Solid Radwaste System is always "in-service." Therefore, unlike many other systems, it cannot be taken out of service and tested. Monitoring of system performance and function on a daily/weekly basis meets the intent of this guidance.

Response/ Disposition:

See response to comment C.I.11.14.

C.I.11-30 Discussed previously; technologies may not be used and are not required.

Response/ Disposition:

See response to comment C.I.11.1.

C.I.11-31 This is vendor specific, would vary over the life of the plant, varies more often if mobile systems are used, and varies as often as annually if off site vendors used.

Response/ **Disposition**:

See response to comment C.I.11.5.

C.I.11-32 Clarification; resolution of SI confusion.

Response/ Disposition:

See response to comment C.I.11.17.

C.I.11-33 This business option was discussed previously as a General Comment in C.I.11.9

Response/ Disposition:

See response to comment C.I.11.9.

C.I.11-34 This is adequately addressed in Section C.I.11.3.

Response/ Disposition:

The staff partially agrees with comment. For clarification, moved number and size of tanks holding charcoals and their locations in plants to Section C.I.11.3 since it addresses gaseous wastes. However, charcoal is solid waste and, therefore, needs to remain in this section. In response to deleting units of kg/yr and m3/yr, see response to comment C.I.11.17.

C.I.11-35 Solidification may not be used and is not required. The process control program is an NRC requirement and will automatically address this information. A requirement for compliance with the PCP appears on the top of page 14, paragraph 2, and should suffice.

Response/ Disposition:

See response to comment C.I.11.5.

C.I.11-36 Solidification not required and may not be used; fraction of off site waste processed is addressed above as a business option and as not being appropriate in the SAR.

Response/ Disposition:

See response to comment C.I.11.5.

C.I.11-37 This is a solid waste section. Liquid wastes aren't processed by solid waste systems only wet wastes (resins, liquid filters, evaporator concentrates, membrane rejects) are processed.

Response/ Disposition:

Staff agrees with comment and recommendation. Text edited accordingly.

C.I.11-38 These shipping requirements are called out in the next section. They should not be stated in this paragraph. The Process Control Program only addressed disposal waste form issues and cannot demonstrate compliance with shipping regulations

Response/ Disposition:

Staff agrees with comment and recommendation. Text edited accordingly.

C.I.11-39 SECY 94-198 superseded GL 81-038.

Response/ **Disposition**:

It should be noted that NRC terminated SECY 94-198 and it never became effective. The 5-year restriction on LLW storage was rescinded by SECY 93-323, under an SRM issued on Feb. 1, 1994. Text edited and SECY 93-323 added to references.

C.I.11-40 This business option was discussed previously as a General Comment in C.I.11.9

Response/ Disposition:

See response to comment C.I.11.9.

C.I.11-41 Compaction and baling may not be used and is not required

Response/ Disposition:

Staff agrees with comment. Replaced "compaction and baling" with "processing, e.g., compaction operation" for clarity.

C.I.11-42 Clarification needed as to when applicable

Response/ Disposition:

Staff disagrees with comment. It should be noted that waste stability is one of several requirements of Part 61.56, and applicant must have a program that demonstrates compliance with all requirements of Part 61.56. No changes needed to DG-1145.

C.I.11-43 Flexibility is needed to preclude constant, non-valuable updates to SAR.

Response/ Disposition:

Staff agrees with comment and recommendation. Text will be edited accordingly in DG-1145.

C.I.11-44 Filling and handling are not methods to obtain loose contamination or measure radiation levels.

Response/ Disposition:

Staff partially agrees with comment. Text will be changed to read "Describe the method of filling and handling radwaste containers; and monitoring methods used to determine..." for clarification.

C.I.11-45 There is no 5 year limit for on-site storage. This former requirement of GL 81-038 was superseded by SECY 94-198, which specifically deleted the 5-year limit. SRP 11.4 contains outdated guidance on this topic.

Response/ Disposition:

Staff agrees with comment. Text will be edited to remove the time constraint (up to 5 years) for onsite LLW storage. See related response to comment C.I.11.39.

C.I.11-46 Paragraph is unclear. Moreover, it is not common in current SARs and should be considered for deletion or should be entirely rewritten.

Response/ Disposition:

Staff agrees with comment. The last sentence of revised paragraph was moved to the end of the previous paragraph. The rest of the remaining paragraph was edited using NEI suggested text, as edited by Staff.

C.I.11-47 Clarification; resolution of SI confusion.

Response/ **Disposition**:

See response to comment C.I.11.17.

C.I.11-48 P&IDs and process flow diagrams: Only one or the other should be required, based on the specific plant design.

Response/ Disposition:

See response to comment C.I.11.2.

C.I.11-49 Clarification; minimizes ambiguity and potential for expanded scope of analysis to "all possible anticipated events."

Response/ Disposition:

Staff disagrees with comment. The language is consistent with current NRC guidance, i.e., SRP 11.1-11.3 and 10 CFR 50, Appendix A, GDC 60 criterion. No changes needed to DG-1145.

C.I.11-50 This information applies to liquid wastes; it should not appear in the solid waste section.

Response/ Disposition:

Staff disagrees with comment. This section addresses effluents generated as a result of processing solid and wet waste. As a result, the applicant has to demonstrate that all incidental waste streams are handled and controlled for the purpose of meeting 10 CFR 20 and Appendix I to 10 CFR 50 requirements. No changes needed to DG-1145.

C.I.11-51 This information applies to liquid wastes; it should not appear in the solid waste section.

Response/ **Disposition**:

See response to comment C.I.11.50.

C.I.11-52 For clarification purposes. This section is for solid waste, and releases tends to be (1) generally applicable to liquid and gaseous effluents; and (2) focused on clearance (unrestricted release) rather than the extensive listing near the bottom of the same page.

Response/ Disposition:

Staff partially agrees with comment. Subsection title will be changed to include "effluent." However, other portions of the text will remain as is for consistency with 10 CFR 50, Appendix A, GDC 60 and 64 criteria.

C.I.11-53 (1) clarification; and (2) typo.

Response/ Disposition:

Staff agrees with comment and recommendation for clarification. Text will be edited accordingly.

C.I.11-54 Mention of liquid and gaseous waste not applicable to solid waste section.

Response/ Disposition:

See response to comment C.I.11.50.

C.I.11-55 The requirements in C. I.11.4.3 and C.III.11.4.3 should be identical at this point, but they are worded differently for some unclear reason. This leads to confusion by the user.

Response/ **Disposition**:

Staff agrees with comment and recommendation for clarification. The text in paragraphs C.I.11.4.3 and C.III.11.4.3 paragraph will edited for consistency.

C.I.11-56 A copy of the PCP is required, but this will not be available during the COLA phase. The PCP should NOT be required, as it is primarily an operational business decision which will likely change or only be known very near the time the plant is commissioned. This same concept applies to the ODCM. In addition, the PCP does not apply to transport.

Response/ Disposition:

The PCP is one of several documents describing operational programs that must be submitted for NRC approval. In the context of the guidance related to Chapter 11, the other documents include the ODCM, REMP, and the RETS/SREC. The documents describing the operational programs must be approved by the NRC before the receipt of fuel and fuel loading. It is the responsibility of the applicant to determine whether such documents will be made available to the NRC before fuel loading and in compliance with 10 CFR Part 50.120 in qualifying personnel to operate and maintain the plant within the stated time limit. Finally, nothing in the guidance prevents applicants from noting that at the time the application was submitted that the document will be submitted later. In its review, the staff will consider such a possibility during the acceptance review, make a determination as to the impact of the missing document on the conduct of its full technical review, and, if found acceptable, make it an RAI item tracked during the technical review process.

Regarding the deletion of DOT shipping regulations from the PCP, it should be noted that being an operational program, the PCP must identify the applicable regulations in its objectives and commit to demonstrate compliance with them. The description, classification, packaging, and shipping of radioactive wastes and materials must comply with Part 20, Part 71, Part 61, and U.S. DOT regulations, and waste acceptance criteria of the disposal site and waste processor, when used. However, it is recognized that compliance with some specific regulatory requirements identified in the PCP may be addressed in implementing procedures containing all necessary technical details. Conceptually, these observations also apply to the other operational programs, such as the ODCM.

C.I.11-57 Clarification.

Response/ Disposition:

Agreed with comment. Text will be reviewed and edited accordingly.

C.I.11-58 The information in EPRI report TR-101965 satisfies these guidance documents.

Regarding the deletion of DOT shipping regulations from the PCP, it should be noted that being an operational program, the PCP must identify the applicable regulations in its objectives and commit to demonstrate compliance with them. The description, classification, packaging, and shipping of radioactive wastes and materials must comply with Part 20, Part 71, Part 61, and U.S. DOT regulations, and waste acceptance criteria of the disposal site and waste processor, when used. However, it is recognized that compliance with specific regulatory requirements identified in the PCP are addressed in implementing procedures containing all necessary technical details. Conceptually, these observations also apply to the other operational programs, such as the ODCM.

C.I.11-59 This refers to the second paragraph from the bottom of the page. Regulatory Guide 1.109 is outdated.

Response/ Disposition:

See response to comment C.I.11.19.

C.I.11-60 General comment – review all references in the document and (1) ensure they appear in the References in C.12.6; (2) delete any References which are not used in the basic text; (3) delete any references which are out of date, superseded, etc.

Response/ Disposition:

The following will be added to the list of references in Section C.I.11.6: SECY 93-323, "Withdrawal of Proposed Rulemaking to Establish Procedures and Criteria for On-Site Storage of Low-Level Radioactive Waste After January 1, 1996;" ANSI/ANS 40.37-200x Draft, "Mobile Low-Level Radioactive Waste Processing Systems;" and "Regulatory Guide 1.11, Instrument Lines Penetrating Primary Containment."

C.I.11-61 References are addressed without specific revision numbers. It is critical that those developing and reviewing each document know which regulatory or other references applied. This is especially true for frequently or annually revised RGs and NUREGs, as well as for periodically revised ANSI standards and industry standards (including the EPRI URD).

Response/ Disposition:

It is the responsibility of applicants to provide information indicating its intent to comply with specific regulations, regulatory guides, standard review plan, generic issues, and generic communications. The application should include a listing of such documents and their respective dates and revisions. This aspect is addressed in Section C.1.1.9 (Conformance with Regulatory Criteria) of DG-1145 generically for all sections of an application. Accordingly, this aspect of DG-1145 guidance is not elaborated again here in the context of topics related to Sections 11.2 to 11.5 of Chapter 11. No changes needed to DG-1145.

C.I.11-62 Clarification and completeness of references routinely used by industry (e.g., NEI, EPRI or other guidance documents). Similarly, embedded references within other DG-1145 references should be included. For example, if a Regulatory Guide is referenced as the source of a requirement, but within the RG is an explicit related or controlling reference to an ANSI standard, then the ANSI standard is considered as an "embedded" standard" and should be referenced in DG-1145.

Updated in DG-1145 as noted in disposition of comments noted herein.

C.I.11-63 The conversion factors in RG 1.109 are outdated. Those contained in the Federal Guidance are based on more current guidance and models.

Response/ Disposition:

See response to comment C.I.11.19.

C.I.11-64 Regulatory Guide 1.110 is outdated

Response/ Disposition:

See response to comment C.I.11.19.

C.I.11-65 RG 1.113 has been incorporated into RG 1.143

Response/ Disposition:

See response to comment C.I.11.19.

C.I.11-66 GL-81-038 replaced by SECY 94-198.

Response/ Disposition:

See response to comment C.I.11.39.

C.I.11-67 Additional references

Response/ Disposition:

See responses to comments C.I.11.3, C.I.11.8, and C.I.11.62. Reference to ANSI/ANS 40.37-200x and Regulatory Guide 1.11 will be added to DG-1145.

C.I.11-68 Compliance with EPA 40CFR190 is required as part of section 11.2. Compliance with this standard has typically been part of the Offsite Dose Calculation Manual.

Response/ Disposition:

Text was retained, but qualified in each section and also in Section C.1.11.5 given that the subject addresses radioactive releases from all potential sources of effluents, liquid, gaseous, and radwaste.

C.I.11-69 Identification of the types of adsorbent media to be used is required. However, the detailed type of this media will be determined based upon performance and availability throughout the plant operation. Technology improvements should not be precluded from adoption by requiring excessive detail here.

Response/ Disposition:

Staff disagrees with the comment. As part of its review, the staff will evaluate the types and characteristics of filtration and adsorbent media proposed by the applicant to treat gaseous process and effluent streams, including removal efficiencies and decontamination factors, taking into account the expected physical, chemical, and radiological properties of gaseous process and effluent

streams. The objective of the review is to (a) determine whether performance of the selected media meets or exceeds that noted in NRC guidance (Regulatory Guide 1.140 and NUREG-0016 or NUREG-0017), standards committed to in DCs, industry standards, or topical reports; and (b) confirm compliance with Part 20 Appendix B effluent concentration limits and Part 50 Appendix I dose objectives. No changes needed to DG-1145.

C.I.12-1 Many of the requirements in this document appear to require details related to specific processes, equipment and procedures that may not be accurately defined at the COLA. For example the types of portable and in-plant radiation protection instrumentation, training, specific procedures, as well as discussion of routine survey frequencies, etc.

Response/ Disposition:

Staff does not accept comment. The level of detail described in the various sections of DG-1145 is generally consistent with the level of detail contained in the precursor document to DG-1145, i.e., Regulatory Guide 1.70. Descriptive details are included in DG-1145 as elaboration as to what the staff expects on specific technical or regulatory topics. This approach provides a clear understanding as to the level of details that should be included in licensee applications. The information presented in DG-1145 parallels that of the respective sections of the SRP. Industry has stated that there are details related to specific processes, equipment and procedures that may not be available at the time the COLA is submitted. Many of these areas are included as part of the operational radiation protection program. DG-1145 allows the COL applicant to implement the radiation protection program on a phased basis. This permits the COL applicant to provide information (which may not be available at the time the COLA is submitted) to the NRC prior to the start of four separate implementation milestones. The level of detail described in the various sections of DG-1145 is generally consistent with the level of detail contained in the precursor document to DG-1145, i.e., Regulatory Guide 1.70. Descriptive details are included in DG-1145 as elaboration as to what the staff expects on specific technical or regulatory topics. This approach provides a clear understanding as to the level of details that should be included in licensee applications. The information presented in DG-1145 parallels that of the respective sections of the SRP. Industry has stated that there are details related to specific processes, equipment and procedures that may not be available at the time the COLA is submitted. Many of these areas are included as part of the operational radiation protection program. DG-1145 allows the COL applicant to implement the radiation protection program on a phased basis. This permits the COL applicant to provide information (which may not be available at the time the COLA is submitted) to the NRC prior to the start of four separate implementation milestones. Nothing in the guidance prevents applicants from noting that at the time the application is being submitted that some specific information was not available and that the missing or incomplete technical information or design will be submitted at a later time. In its review, the staff will consider such a possibility during the acceptance review, make a determination as to the impact of the missing information on the conduct of its full technical review, and, if found acceptable, make it an RAI item to be issued and tracked during the technical review process. The COL applicant should identify any information listed in Section C.I.12 of DG1145 but not provided in the COL application and provide a detailed schedule for when this data will be provided to the NRC.

C.I.12-2 At the end of the first paragraph of this section: "These descriptions should be detailed in the SAR, including an indication of whether and, if so, how the plant will implement and follow the design consideration guidance provided in Section C.1 of Regulatory Guide 8.8, as well as other industry-developed design guidance that includes ALARA criteria. Conversely, if the plant will not follow such guidance, describe the specific alternative approaches to be used. "It is important to define the documents referred to in general

terms in the DG-1145. For example when it says "as well as other industry developed design guidance that includes ALARA criteria." This is open ended and dependent on the NRC reviewer can entail compliance with a multitude of various documents. This goes back to the idea of making sure that the COL applicants have all the documents and regulations they need to follow on hand so as to decrease the number of RAIs.

Response/ Disposition:

Staff accepts comment. This paragraph will be modified to remove reference to other industrydeveloped design guidance. Wording already says that applicants should use experience from past designs and operating plants and gives the applicant the option of specifying alternate approaches to RG 8.8

C.I.12-3 "Include a general discussion of the plant's approach to meeting the requirements by specifying the selected design concept and the supporting design bases and criteria. Demonstrate that the design concept is technically feasible and within the state-of-the-art, and that reasonable assurance exists that the requirements will be properly implemented prior to the issuance of operating licenses."

Response/ **Disposition**:

Staff agrees with comment. The third paragraph in section C.I.12.1.2 will be deleted since it has no added value.

C.I.12-4 First paragraph of this section requested information, such as "Describe the methods to be used to develop the detailed operational plans, procedures, and policies." This data may not be available during the design and construction phase. This information may not be available until the fueling begins.

Response/ **Disposition**:

Staff does not accept comment. See response to C.1.12.1The information described in this paragraph was identified as a COL Action Item during the staff review of the AP1000 DCD and is listed as COL Item 12.1-1 in Revision E of Draft NEI 04-01

C.I.12-5 Specify what kind and the detail of information is being asked for, i.e. what kind of isotopes at what dose ranges, what detail is meant by "location" of the source.

Response/ Disposition:

Staff does not accept comment. No change required. The level of details described in Section C.1.12.2.1 is generally consistent with the level of detail contained in Regulatory Guide 1.70

C.I.12-6 It is not clear how N-16 sources from BWR operation are contained sources.

Response/ Disposition:

Staff does not accept comment. No change required. C.1.12.2.1 requests that the sources of N-16 during operation, including the steam lines and turbine system, be described in the manner needed for input to the shield design calculation.

C.I.12-7 Instrument calibration methods and radiation sources used for calibration may change from the time of design and construction to the time of operation. If this information is provided at the apparent detailed level requested will a license change be required to use different methods and sources than reported?

Response/ **Disposition**:

Staff does not accept comment. No change required. Industry has stated that there are details related to specific processes, equipment and procedures that may not be available at the time the COLA is submitted. Many of these areas are included as part of the operational radiation protection program. DG-1145 allows the COL applicant to implement the radiation protection program on a phased basis. This permits the COL applicant to provide information (which may not be available at the time the COLA is submitted) to the NRC prior to the start of four separate implementation milestones. Information concerning instrumentation calibration is part of the operational radiation protection program which is covered under the implementation milestone which should be implemented prior to initial receipt of by-product, source, or special nuclear materials (excluding Exempt Quantities as described in 10 CFR 30.18). Since this information is not required to be included as part of the initial COL submittal, but at a date which is closer to the time of operation, this information should be known at this time. The COL applicant should identify any information listed in Section C.I.12 of DG1145 but not provided in the COL application and provide a detailed schedule for when this data will be provided to the NRC. See response to C.1.12.1

C.I.12-8 Revise this to provide separate requirements that are dependent on source origination (owner license, other license, etc.) and plant status.

Response/ **Disposition**:

Staff does not accept comment. No change required. The level of details described in Section C.1.12.2.1 is generally consistent with the level of detail contained in Regulatory Guide 1.70.

C.I.12-9 "Provide a listing of isotope, quantity, form, and use of all sources in this latter category that exceed 100 millicuries." Is this only for sealed sources? Is this for any non-reactor generated source in the plant. What is the regulatory basis for the 100 millicuries limit?

Response/ **Disposition**:

Staff does not accept comment. No change required. The 100 mCi limit is part of the NRC's licensing review criteria which was contained in Regulatory Guide 1.70. DG-1145 (and Regulatory Guide 1.70 before it) states that the applicant should provide a listing of all sources containing byproduct, source, and special nuclear material sources that may warrant shielding design consideration.

C.I.12-10 "This description should include those airborne sources that are created by leakage, opening formerly closed containers, storage of leaking fuel elements, and so forth."

Response/ Disposition:

Staff agrees with comment. In response to comment, Section C.1.12.2.2 will be revised.

C.I.12-11 The referenced sections refer to NUREG 0737. Since this NUREG was written significant regulatory work has been done that changes many of the requirements or allows for alternate ways to meet the intent of the guidance.

Staff does not accept comment. No change required. The portions of NUREG-0737 referenced in Chapter 12 have not changed.

C.I.12-12 "Also, include descriptions of methods for reducing the production, distribution, and retention of activation products through design, material selection, water chemistry, decontamination procedures, and so forth."

Response/ Disposition:

Staff does not accept comment. No change required. Without this information, the staff cannot complete its review and evaluation, and conclude, with reasonable assurance, that the proposed systems comply with acceptance criteria, that all design commitments will be fulfilled, and that the plant will be built and will operate in accordance with its design certification and NRC regulations. Nothing in the guidance, however, prevents applicants from noting, at the time the application is being submitted, that some specific information was not available and that the missing or incomplete technical information or design will be submitted at a later time. In its review, the staff will consider such a possibility during the acceptance review, make a determination as to the impact of the missing information on the conduct of its full technical review, and, if found acceptable, make it an RAI item to be issued and tracked during the technical review process.

C.I.12-13 This is a complex paragraph that asks for a significant volume of information. "Provide scaled layout and arrangement drawings of the facility. On these drawings, show the locations of all sources described in Section 12.2 of the SAR and identify those sources in a manner that can easily be related to tables containing the pertinent and necessary quantitative source parameters. Accurately locate positions, indicating the approximate size and shape of each source. On the layout drawings, provide the radiation zone designations, including zone boundaries for normal operations, refueling outages, and post-accident conditions (based on the applicable guidance in Regulatory Guides 1.3, 1.4, 1.7, and 1.183). Reference other chapters of the SAR, as appropriate. The layout drawings should show shield wall thicknesses; traffic patterns (including post-accident access routes to and from vital areas); and locations of controlled access areas (including locked

Response/ Disposition:

Staff does not accept comment. No change required. Most of the information requested in this paragraph was contained in the precursor document to DG-1145, i.e., Regulatory Guide 1.70 and is part of the NRC's licensing review criteria. Descriptive details are included in DG-1145 as elaboration as to what the staff expects on specific technical or regulatory topics. This approach provides a clear understanding as to the level of details that should be included in applications. The information presented in DG-1145 parallels that of the respective sections of the SRP. Most of the information described in this paragraph is already described in the various Design Control Documents either approved by or currently being reviewed by the NRC. With the exception of the description of some equipment and facilities which can be described as part of the operational radiation protection program (as described in C.III .12.5), this information should be described at the time of the COLA. See response to comment C.1.12.12.

C.I.12-13 (cont'd)

Response/ Disposition:

Staff does not accept comment. See above.

C.I.12-14 C.III.1 retains the section header "12.4 Dose Assessment", whereas C.I removes the 12.4 numbering completely. This creates a different sub-section numbering for the last section between C.III.1 and C.I

Response/ Disposition:

Agree with comment. The formatting of section C.I.12 in DG-1145 will be changed so that it is consistent with the formatting of section C.III.12 and Chapter 12 of the SRP.

C.I.12-15 Prior to initial loading of fuel in the reactor, the program described in this section will be fully implemented, with the exception of the organization, facilities, equipment, instrumentation, and procedures necessary for transferring, transporting or disposing of radioactive materials in accordance with 10 CFR Part 20, Subpart K, and applicable requirements in 10 CFR Part 71.

Response/ Disposition:

Agree with comment. Modifications will be made to this paragraph to more clearly define part of radiation protection program to be implemented.

C.I.12-16 "Identify the staffing levels, instrumentation and equipment, facilities, procedures, and training necessary to ensure radiation safety of workers and the public for each phase of implementation." This information will not be available until before the start of operation.

Response/ Disposition:

Staff does not accept comment. However, changes to be made to last paragraph for clarification. C.I.12.4(5) states that these parameters must be provided prior to implementation of each of the listed 4 milestones, not at the time of the COLA submission. By the time each of the 4 milestones is reached, the licensee should have all of this information available.

C.I.12-17 This section appears to address fixed and portable instrumentation and also facilities. Fixed instrumentation is addressed in 12.3.1 and 12.3.4. Facilities are addressed in sections 12.3.1 and in part in others.

Response/ **Disposition**:

Staff does not accept comment. However, a minor change was made to second paragraph in C.I.12.5.2 for clarification. In general, Sections C.I.12.3 and C.I.12.4(5) request different information regarding instrumentation, equipment, and facilities. While C.I.12.3.1 requests information regarding the design features of equipment and facilities to ensure that occupational radiation exposures are ALARA, C.I.12.4(5) specifically requests information concerning the selection criteria and types and numbers of portable instrumentation and laboratory equipment and airborne radioactivity monitoring systems while C.I.12.4(5) specifically requests information concerning the selection criteria and types and numbers of portable instrumentation and laboratory equipment and airborne radioactivity monitoring systems while C.I.12.4(5) specifically requests information concerning the selection criteria and types and numbers of portable instrumentation and laboratory equipment and instrumentation. In order to ensure that a COL applicant does not have to describe

plant facilities that may have been previously described in an applicable design control document, the first sentence of the facilities section of C.III.12.4(5).2 states, "This section of the SAR need not include facilities that were previously described and reviewed in an applicable design control document. In order to remove one possible source of confusion that may have prompted this industry comment, the words "and fixed" in item (1) in the second paragraph of C.I.12.5.2 will be deleted.

C.I.12-18 Current language is too restrictive and would require an SAR revision for every new instrument type, quantity, etc.

Response/ **Disposition**:

Staff accepts comment and accepts proposed industry wording change. It should be noted, however, that because the request for this information on portable monitors is contained in Section C.I.12.5 of DG-1145 and is part of the operational radiation protection program, the applicant is not required to provide details on portable monitor types, quantities, etc. (as described in Section C.I.12.5.2) until prior to implementation of milestone 1 (initial receipt of by-product, source, or special nuclear materials). At this time, the applicant should have a much better idea of the types, quantities, and characteristics of portable radiation detectors and monitors that will be required for the operational radiation protection program.

C.I.12-19 C.I.12-11 applies to non-DCD COLA only. There will be no DCD to refer to.

Response/ **Disposition**:

Staff accepts comment. First sentence under "Facilities" should be deleted in C.I.12.4.2 and should remain in C.III.12.4.2

C.I.12-20 Use of the term disposal in the last sentence of the first paragraph implies that it will be disposed at a licensed burial facility.

Response/ Disposition:

Staff accepts comment. The word "disposal" will be changed to "disposition".

C.I.12-21 IN 91-40 uses industry experience to update IE 80-10

Response/ **Disposition**:

Staff does not accept comment. No changes needed to DG-1145 and SRP sections. IE Bulletin 80-10 is already referenced in Chapter 11. IE 80-10 addresses the initial NRC concern and, in that context, the issues identified in it are still relevant. IN 91-40 is a follow-up reminder to licensees of the continuing possibility of unmonitored and uncontrolled releases of radioactive materials in light of the issuance of IE Bulletin 80-10 and therefore does not contain any new information.

C.I.12-22 The detailed procedures for refueling, etc., are not appropriate for inclusion in this section. This should address only the ALARA aspects.

Response/ **Disposition**:

Staff agrees with comment. Sentence will be changed as suggested.

C.I.12-23 Significant typo

Response/ Disposition:

Staff agrees with comment. "position control" will be changed to "positive control".

C.I.12-24 Add RG 1.140

Response/ Disposition:

Staff does not accept comment. Although Regulatory Guide 1.52 addresses the design, inspection, and testing of post-accident ESF atmosphere cleanup systems, this regulatory guide provides good practice guidance that can be used for atmosphere cleanup systems during normal operations as well. Release of radioactivity in normal operational occurrences is usually different only in quantity from some of the accident cases. Section C.I.12 and C.III.12 of DG-1145 are consistent with Chapter 12 of the SRP

C.I.12-25 Outdated.

Response/ Disposition:

Staff does not accept comment. Regulatory Guide 8.28 "Audible Alarm Dosimeters," has not been withdrawn. It is scheduled to be revised and updated in the 2008-2009 timeframe.

C.I.12-26 Sub-numbers are not correct (start with 49)

Response/ Disposition:

Agree with comment. The numbering will be corrected.

C.I.12-27 Many documents referenced in this guidance direct the user to other supporting documents. The guidance document reference list does not appear to list all of those cross referenced documents and therefore is an incomplete reference list.

Response/ **Disposition**:

Staff does not accept comment. Regulatory Guide users should be able to identify cross references as needed through the existing reference list.

C.I.12-28 It is stated in the first paragraph of this section that the intent of the section is to address those items "not addressed in Chapter 11 or described in Chapter 9", however the statement to that effect is not concise nor in the optimal location in that paragraph.

Response/ Disposition:

Staff agrees with comment. Paragraph will now read: "Section 12.3.3 of the SAR should describe any ventilation system personnel protective features that are not addressed in Chapter 11 or described in Chapter 9. Section 12.3.3 should include a description of those system aspects which relate to controlling the concentration of radioactivity in equipment cubicles, corridors, and operating areas normally occupied by operating personnel. By contrast, Chapter 11 of the SAR should describe those aspects of the design that relate to removing airborne radioactivity from equipment cubicles, corridors, and operating areas normally occupied by operating personnel and transporting it into the effluent control systems."

C.I.12-29 Bioassays is redundant. Monitoring bioassays is covered completely in the previous section of C.I.12.4.3 under the heading "Personnel Monitoring and Dose Control." See the 1st para, 2nd sentence.

Response/ Disposition:

Staff agrees with comment. The word "bioassays" will be deleted from section 12.4.3 (12.5.3) under sub heading "Respiratory Protection".

C.I.13-1 NRC should consider changing the required format for section 13.1 to include an appendix in which would be placed all the design and construction information currently required in subsection 13.1.1. This information becomes historical after construction/startup and is generally removed from site FSARs.

Response/ Disposition:

The NRC staff agrees that use of an Appendix would make it simpler for the applicant in the future to maintain the FSAR as a living document.

C.I.13-2 NRC should consider changing the required format for section 13.1 to include a table or appendix which would contain information which is site specific or different from a standard/generic FSAR section 13.1. Industry and NRC are currently attempting to make much of the FSAR generic.

Response/ Disposition:

The NRC staff agrees with the comment.

C.I.13-3 Items 13.1.1, d. and e. seem to be asking for the same information except that d. uses the adjective "general".

Response/ Disposition:

The NRC staff agrees with deletion of 13.1.1(4). The class of person in 13.1.1(e) is included in 13.1.1(d).

C.I.13-4 The section requests detail that does not impact public health and safety. Presentation of the numbers is highly variable considering contractor or utility experience and task duration. All requests for numbers of people should be eliminated.

Response/ Disposition:

The applicant needs to provide information relative to the projected size and organization of the staff. The staffing numbers and the organization provided in the application will be estimates. NRC will determine if the staff and organization estimates submitted are reasonable. The size and structure of the actual organization will be verified during construction.

C.I.13-5 This section requests detail that does not impact public health and safety. Organizational alignments do not add value to the descriptions and are not useful. For the industry to provide consistent descriptions in the SARs this section should only address responsibilities and qualifications. Numbers of people and organization design should not be included. Delete reference to Technical Support Organization from this section, too much of the information belongs in 13.1.2 relative to Operating Organization.

The NRC staff disagrees with the comment. This section requests information similar to the information required in SRP Sections 13.1.1 and 13.1.2. 13.1.1 and 13.1.2 - the requested information is sufficient to allow the NRC to determine if the applicant's corporate organization (offsite), technical support staff (offsite), and operating organization (onsite) can operate and maintain the plant safely. The size and structure of the actual organization will be verified during construction. See Comment C.I.13 for information related to including organizational information in an appendix.

C.I.13-6 Pre-Operational Responsibilities -- This item indicates that a description of the proposed plans for the development and implementation of staff training programs should be included and should be substantially accomplished before preoperational testing begins.

Response/ Disposition:

Delete section 13.1.1.1 (2), and renumber section 13.1.1.1 (3).

C.I.13-7 This section is too large because it includes Design, Construction and Operating Responsibilities. Organization alignment information is provided that does not impact public health and safety. As an example, delete the requirement for organization charts. Simplify the presentation of information and focus only on functions and qualifications.

Response/ Disposition:

The NRC staff disagrees with the comment. This section requests information similar to the information required in SRP Sections 13.1.1 and 13.1.2. 13.1.1 and 13.1.2 - the requested information is sufficient to allow the NRC to determine if the applicant's corporate organization (offsite), technical support staff (offsite), and operating organization (onsite) can operate and maintain the plant safely. The size and structure of the actual organization will be verified during construction.

C.I.13-8 It is not necessary to differentiate between an operating organization responsibility and support organization responsibility at the site. Pull site operational functions out of 13.1.1 and place in 13.1.2. Only address function and qualification. Remove organization charts and organization alignment descriptions. Only include a description of required functions and qualifications.

Response/ Disposition:

The NRC staff disagrees with the comment. This section requests information similar to the information required in SRP Sections 13.1.1 and 13.1.2. 13.1.1 and 13.1.2 - the requested information is sufficient to allow the NRC to determine if the applicant's corporate organization (offsite), technical support staff (offsite), and operating organization (onsite) can operate and maintain the plant safely. The size and structure of the actual organization will be verified during construction. See Comment 13.1 for information related to including organizational information in an appendix.

C.I.13-9 Plant Organization, first sentence-- This sentence requires 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 COL application since the details needed for the requested chart would not be known at the time the application was filed. The industry understanding of the discussion of this issue is

that the NRC 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. This comment was addressed in Appendix I of DG-1145 with the NRC documenting their concurrence with the comment. However, subsection 13.1.2.1 was not revised to reflect the adequacy of the alternate approach.

Response/ **Disposition**:

The NRC staff disagrees with the comment. This section requests information similar to the information required in SRP Sections 13.1.1 and 13.1.2. 13.1.1 and 13.1.2 - the requested information is sufficient to allow the NRC to determine if the applicant's corporate organization (offsite), technical support staff (offsite), and operating organization (onsite) can operate and maintain the plant safely. The size and structure of the actual organization will be verified during construction. See Comment 13.1 for information related to including organizational information in an appendix.

C.I.13-10 Change the title of 13.2 to Training Program

Response/ **Disposition**:

The NRC staff disagrees with the comment. NUREG-0800 section 13.2 is titled "Training."

C.I.13-11 Too much detail is being requested for submittal in the training program descriptions. None of this can be entered until the systematic approach to training is followed and materials are actually developed.

Response/ Disposition:

The NRC staff agrees with the comment about SAT process. These sections request information similar to the information required in SRP Sections 13.2.1 and 13.2.2. The applicant needs to provide sufficient information about the training programs to allow NRC to determine if the proposed training is reasonable. Training programs will be verified during construction.

C.I.13-12 The second sentence of the first paragraph refers to requalification programs as required in 10 CFR 50.54 (i)(I-1). This section of 50.54 states "Within three months after issuance of an operating license, the licensee shall have in effect an operator requalification program which must as a minimum, meet the requirements of § 55.59(c) of this chapter."

Response/ **Disposition**:

The NRC staff agrees with this comment. Add as third sentence, Within three (3) months after either the issuance of an operating license or the date the Commission makes the finding under §52.103(g) of this chapter for a combined operating license, as applicable, the licensee shall have in effect an operator requalification program.

C.I.13-13 First paragraph – at the end of this paragraph, reference is to Section 13.2.3. Following renumbering from initial draft, the correct reference is 13.2.2.

Response/ Disposition:

The NRC staff agrees with the comment.

C.I.13-14 These items specify that license applicants should identify the proposed training course durations in the COL application. The industry provided comments that they believed it was not possible to prescribe course durations prior to the systems approach to training as described in 10 CFR 55.4 and that predetermination of course durations is inconsistent with the systems approach to training and that the reference to training course durations should be removed from DG-1145. This comment was addressed in Appendix I of DG-1145 with the NRC documenting their concurrence with the comment. However, subsection 13.2.1.1 was not revised to delete the reference to training course durations. It is recommended that the references to proposed training course durations be removed from items (1), (3), and (6) of Subsection 13.2.1.1.

Response/ Disposition:

The NRC staff agrees with the comment. In section 13.2.1.1(1), add the following to the end of the first sentence "to be verified during construction." In section 13.2.1.1(3), add the following to the end of the first sentence "to be verified during construction." In section 13.2.1.1(6), add the following to the end of the sentence "to be verified during construction."

C.I.13-15 Too much descriptive detail is requested in this section. Schedules are not needed, it is enough to say that sufficient operators shall be licensed prior to fuel load. Items 1 -6 request too much description on what is required by 10CFR55. No need to add this level of detail. For items 1-10 too much detail is requested for 10CFR50.120 programs.

Response/ Disposition:

The NRC staff disagrees with the comment. These sections request information similar to the information required in SRP Sections 13.2.1 and 13.2.2. The applicant needs to provide sufficient information about the training programs to allow NRC to determine if the proposed training is reasonable. Training programs will be verified during construction.

C.I.13-16 For clarity, add additional level of numbering for this section: 13.2.1.1.1 for licensed plant staff, 13.2.1.1.2 for non-licensed plant staff

Response/ **Disposition**:

The NRC staff agrees with the comment. This change would make this section easier to understand.

C.I.13-17 These items specify that license applicants should provide the subject matter including a syllabus or course description for the proposed training courses in the COL application. The industry provided comments that they believed it was not possible to prescribe syllabi or similar detailed course descriptions prior to the systems approach to training as described in 10 CFR 55.4 and that predetermination of course content is inconsistent with the systems approach to training and that the reference to syllabi of equivalent course descriptions should be removed from DG-1145. This comment was addressed in Appendix I of DG-1145 with the NRC making no distinction between course topics and a syllabus.

Response/ **Disposition**:

The NRC staff agrees with the comment. In section 13.2.1.1 non-licensed plant staff (3), delete "syllabus or equivalent".

C.I.13-18 Licensed Plant Staff Item 4 identifies RG 1.149 along with several regulations and refers to all of them as "requirements." The NRC RG is only guidance, not a requirement.

Response/ Disposition:

The version on the web has the correction made.

C.I.13-19 Non-Licensed Plant Staff Item 2 indicates that the application should include "a commitment to meet the requirements of 10 CFR 50.120 at least 18 months before fuel load." There is no need to commit to a regulation. Regulations are already required to be met, with or without a commitment

Response/ Disposition:

The NRC staff agrees with the comment to delete "a commitment to meet the requirements of 10 CFR 50.120 at least 18 months before fuel load."

C.I.13-20 Text refers to development of a schedule including course durations for the licensed operator training program and each part of the training program for each functional group of employees. NRC concurred with the industry's comment that the predetermination of the course durations is inconsistent with the systems approach to training (SAT) as described in 10 CFR 55.4 and required in this section.

Response/ Disposition:

In 13.2.1.1, licensed plant staff (1), end the first sentence after "program", delete section remainder of the sentence. In Section 13.2.1.2, nonlicensed plant staff (3), delete the first sentence. In Section 13.2.1.2, nonlicensed plant staff (6), delete "the duration of the course (approximate number of weeks personnel are in full-time attendance), the organization teaching the course or supervising instruction."

C.I.13-21 Text specifies the development of program implementation timelines. The industry believes the level of detail requested in these FSAR section is beyond that necessary to support required COL findings. Consistent with SECY-05-0197, industry believes that timeline information should be supplied as part of program implementation materials separately from the FSAR.

Response/ **Disposition**:

The NRC staff does not agree with the comment. The applicant is to provide enough information for the NRC staff to determine if sufficient staff will be trained and qualified prior to fuel load.

C.I.13-22 Text specifies evaluation of training program effectiveness for all employees in accordance with SAT. Industry believes that the FSAR section 13.2 only includes specific training programs for personnel detailed in the section (e.g. licensed personnel and personnel covered by 10 CFR 55.120.)

Response/ Disposition:

The NRC staff agrees with the comment. In section C.I.13.2.1.1(9), after "for all employees," add "and personnel covered by 10 CFR 50.120."

C.I.13-23 First sentence requires that course length be identified. This information will not be known at the time of COL application

Response/ Disposition:

The NRC staff agrees with the comment.

C.I.13-24 This section discusses the training provided to all employees regarding physical security. This information will be included in section 13.6. Additional information will also be included in the Physical Security Plan, which is a separate document that will be developed post-COL application.

Response/ Disposition:

The NRC staff agrees with the comment. In Section 13.2.1.1, non-licensed plant staff, add "(to be verified during construction)"

C.I.13-25 First sentence refers to the inclusion of 10 CFR 55.31 (how to apply for a license) as needing to be described in the FSAR training program description. This is an administrative requirement that should not be included in the FSAR

Response/ Disposition:

The NRC staff does not agree with the comment. No change to DG-1145. 10 CFR 55.31 requires the licensed operator applicant to provide evidence of completion of five control manipulations. The facility applicant has to describe how the licensed operator applicant will complete these manipulations.

C.I.13-26 First sentence – subject matter, course description and durations will be developed using SAT post-COL application

Response/ Disposition:

The NRC staff agrees with the comment. In Section 13.2.1.1, non-licensed plant staff, add "(to be verified during construction)"

C.I.13-27 Reference is made to 10 CFR 55.31 (how to apply). This is not related to description of simulator capability and should be deleted.

Response/ Disposition:

The NRC staff does not agree with the comment. 10 CFR 55.31 requires the licensed operator applicant provide evidence of completion of five control manipulations. The facility applicant has to describe how the licensed operator applicant will complete these manipulations.

C.I.13-28 Paragraph requires the COL applicant to state how its program will meet regulatory requirements and guidance, including fidelity to the plant and control room. This information will be contained in plant administrative procedures that will be developed post-COL application.

Response/ Disposition:

The NRC staff agrees with the comment. In Section 13.2.1.1, "Non-licensed Plant Staff," add "(to be verified during construction)"

C.I.13-29 The fire protection program description will be included in FSAR section 9.5.1. The fire protection training program will be developed to meet the requirements of NFPA Standard 600. Training program information detailed in this section of DG-1145 will be developed post-COL application.

Response/ Disposition:

The NRC staff agrees with the comment. In Section 13.2.1.1, "Non-licensed Plant Staff," add "(to be verified during construction)"

C.I.13-30 This section discusses Emergency Plan training. Emergency Plan training will be included in the Emergency Plan, which is a separate document that will be developed post-COL application

Response/ Disposition:

The NRC staff agrees with the comment. In Section 13.2.1.1, "Non-licensed Plant Staff," add "(to be verified during construction)"

C.I.13-31 Paragraph requires the COL applicant to state how its program will meet regulatory requirements and guidance, including fidelity to the plant and control room. This information will be contained in plant administrative procedures that will be developed post-COL application.

Response/ **Disposition**:

The NRC staff agrees with the comment. In Section 13.2.1.1, "Licensed Plant Staff Training Program," Item 4, add "(to be verified during construction)."

C.I.13-32 These items specify that license applicants should identify the proposed training course durations in the COL application. The industry provided comments that they believed it was not possible to prescribe course durations prior to the systems approach to training as described in 10 CFR 55.4 and that predetermination of course durations is inconsistent with the systems approach to training and that the reference to training course durations should be removed from DG-1145. This comment was addressed in Appendix I of DG-1145 with the NRC documenting their concurrence with the comment. However, subsection 13.2.1.1 was not revised to delete the reference to training course durations.

Response/ Disposition:

The NRC staff agrees with the comment. In Section 13.2.1.1, "Non-licensed Plant Staff," add "(to be verified during construction)" after "the following elements:"

C.I.13-33 The first sentence of the section contains conflicting text.

Response/ Disposition:

The NRC staff agrees with the comment and will delete the last three words in the first sentence.
C.I.13-34 NUREG-0711, "Human Factors Engineering Program Review Model", should not be listed as a reference for this section. This NUREG is applicable to detailed development of training programs, but is not applicable to the high-level program description provided by FSAR 13.2.

Response/ **Disposition**:

The NRC staff disagrees with the comment. The COL submittal needs to provide enough information for the NRC staff to make an assessment of the training program. NUREG-0711 provides guidance related to what should be included in the training program description.

C.I.13-35 RG-1.134,"Medical Evaluation of Licensed Personnel at Nuclear Power Plants", should not be listed as a reference for this section. The information in this RG applies to the licensed operator training program, but not to the high-level program description.

Response/ Disposition:

The NRC staff agrees with the comment and will delete reference (13)

C.I.13-36 The emergency class definitions have been revised to include security events.

Response/ Disposition:

The Commission issued NRC BULLETIN 2005-02, "EMERGENCY PREPAREDNESS AND RESPONSE ACTIONS FOR SECURITY-BASED EVENTS" (BL-05-02), to collect information on the type of EP enhancements licensees had implemented to address the hostile action contingency. Licensees responded that the types of enhancement examples in BL-05-02 had been or would be implemented. Further, industry developed a guidance document which NRC endorsed in Regulatory Issue Summary 2006-12 Endorsement of Nuclear Energy Institute Guidance "Enhancements to Emergency Preparedness Programs for Hostile Action". However, implementation of these enhancements was voluntary and they have not been nor can they be inspected for compliance. It is acceptable to submit the revised classifications if the emergency plan is written to address BL-05-02 or RIS 2006-12.

C.I.13-37 This confirmation of agreement does not need to be a permanent part of the E-plan. Also, the letter showing offsite agency agreement is needed whether or not there are other reactors at the site.

Response/ Disposition:

The applicant should provide a form of confirmation of the agreement, such as a letter of agreement signed by State and local governmental authorities, with the application. This document could be included in the emergency plan or docketed separately.

C.I.13-38 This should be able to be provided by reference to other sections.

Response/ Disposition:

Add the sentence after the second paragraph on page C.I.13-11:"It is acceptable to satisfy this requirement by referencing the appropriate sections of the FSAR that address site characteristics."

C.I.13-39 Existing regulations do not require submittal of State and local emergency response procedures, just plans. (10 CFR 50.33(g))

The staff agrees that there is no requirement to submit state and local emergency response procedures with the application. The document must included the emergency plans which address the DHS/FEMA requirements.

C.I.13-40 It is permissible for the Emergency Plan to be a stand alone document.

Response/ Disposition:

This emergency plan may be a physically separate document referenced by Section 13.3 of the FSAR, and may incorporate by reference various State and local emergency plans or other relevant materials. The staff realizes that it is current common practice to maintain a separate, stand alone document for the licensees emergency response plan.

C.I.13-41 The requirement of 10CFR 73.71(a) should be addressed under security, not EP.

Response/ Disposition:

The staff agrees that there is no emergency preparedness requirement to report safeguards events. However the staff has proposed a change to the reporting requirements of 10CFR 73.71 to address the prompt notification requirement of the NRC for security-related events considered to pose an imminent or actual threat. The staff has verified that the reference is resident in Section C.I.13.6 Security of the DG-1145.

C.I.13-42 Explicitly state what type of documents must be addressed - GL, BL, Orders. This should not include IN's as these are not supposed to set new requirements.

Response/ **Disposition**:

The staff believes that the term generic communications apply to all the referenced documents described in the DG-1145 whether or not they required a specific response from the licensee. They are provided to establish a complete dossier of emergency preparedness operating experience to aid the applicant in developing an emergency plan that appropriately addresses the existing generic guidance. Where a specific response is required the applicant must appropriately address the required actions. These documents are posted to the NRC website under the heading of Generic Communications.

C.I.13-43 The EAL information should be in the stand alone Emergency Plan.

Response/ Disposition:

The FSAR should contain a general description of the emergency classification and action level scheme. The emergency plan submitted must address the requirements of 10CFR50.47(b)(4).

C.I.13-44 For security-related aspects of EP to be addressed, explicitly reference BL 2005-02 and RIS 2006-12, not just the 2002 orders.

Response/ Disposition:

The lack of specificity by staff for each Bulletin and Regulatory Information Summary issued subsequent to September 11, 2001 reflects the ongoing evaluation and rulemaking that may be in progress following publication of this document. Both references included in this comment are listed in Generic Communications.

C.I.13-45 10 CFR 2.390 gives the requirements for marking information to be withheld from public disclosure.

Response/ Disposition:

The staff agrees that 10CFR2.390 provides the requirements for marking information submitted to the NRC.

C.I.13-46 Refer to the table at it is labeled - Table C.II.2.B-1.

Response/ **Disposition**:

The staff agrees with the comment. It should be incorporated with the correct reference.

C.I.13-47 Section 7.1 states that the TSC and OSC may be combined. Section 7.1.6 states that the OSC be separate from the TSC.

Response/ **Disposition**:

The staff agrees that the TSC and OSC may be combined at a single location. 7.1.6 to be revised.

C.I.13-48 C.I.13.3.1 states: "The application should also include a table of contents and a cross reference to applicable regulatory requirements, guidance documents, generic communications, and other criteria that are used to develop the application and emergency plan." C.I.13.3.1 defines "generic communications" by directing the reader to C.I.13.3.4. The C.I.13.3.4 listing of generic communications includes not only generic letters and bulletins but also NRC IN, RIS, EPPOS, and CR documents. The C.I.13.3.1 use of the term "generic communications" appears to be inconsistent with requirements in proposed Part 52.79(a)(37) which limits this scope to bulletins and generic letters (which is specifically noted in Footnote 3 in C.I.13.3.1). Inclusion of documents beyond GL and bulletins is also inconsistent with C.I.1.9.4 which justifies "The significance of limiting this review to generic letters and bulletins is that these documents pertain to issues that were considered to have risen to a level of safety-significance such that they required responses and resolutions from nuclear operating plant licensees.

Response/ **Disposition**:

The staff agrees with the comment however, the staff believes that the term generic communications apply to all the referenced documents described in the DG-1145 whether or not they required a specific response from the licensee. They are provided to establish a complete dossier of emergency preparedness operating experience to aid the applicant in determining the appropriate guidance to address. These documents are posted to the NRC website under the heading of Generic Communications. As a minimum, the applicant should address the various generic letters and bulletins and Commission Orders that are in effect and applicable to emergency planning in support of an Operating License (see Generic Communications identified in Subsection 13.3.4, below). NRC staff wants applicants to be knowledgeable and use all applicable guidance.

C.I.13-48 Furthermore, 52.59(a)(37) and C.I.1.9.4 limits this scope to how the subject operating experience insight is incorporated into facility design. In public workshop discussions, this listing in C.I.13.3.4 was discussed; however, it remains unclear as to why emergency planning would be given different requirements in contrast with any other area that may involve operational aspects.

See response to comment C.I.13.48 above.

C.I.13-49 The first two paragraphs refer to two different documents for definition and discussion of the term "fully described". NRC should change the first reference from "SECY-05-0197" to "C.IV.4" and remove the second reference such that the third sentence in the second paragraph would read "Descriptions of operational programs, consistent with the definition of "fully described" as discussed in Section C.IV.4, should be provided..."

Response/ **Disposition**:

The NRC staff chooses to maintain the reference to SECY-05-0197 as the source for the definition of "fully described" in the context of operational programs.

C.I.13-50 Reference 23 is a proposed Reg. Guide revision that dates back to 1986 that has never been finalized.

Response/ Disposition:

Reference 23 should now reference Reg Guide 1.23 revision 1, March 2007.

C.I.13-51 Typo in document title for reference 104.

Response/ Disposition:

The staff agrees with the comment. Revise document title--ref is now 105

C.I.13-52 Reference 125 is a duplicate of 124

Response/ Disposition:

The staff agrees with the comment. Delete duplicate ref. Ref in question is now 126.

C.I.13-53 NRC should change the third sentence of the second paragraph and state that "Descriptions of operational programs ... should be provided in this the chapter of the FSAR or in other, applicable to the operational program sections of the FSAR.

Response/ Disposition:

The NRC staff agrees with the comment. The third sentence of the second paragraph will be changed as follows: "Descriptions of the operational programs in the attached table should be provided in the applicable sections of the FSAR."

C.I.13-54 FSAR section is incorrectly stated as 3.9.6. ISI is actually covered in two places.

Response/ Disposition:

The NRC staff agrees with the comment. The referenced SRP Sections will be changed to 5.2.4 and 6.6.

C.I.13-55 Implementation requirement listed could be clarified

The NRC staff agrees with the comment. The requirement will be as follows: "ASME XI 2004 IWA 2430(b)."

C.I.13-56 Based on ASME OM 2004, ISTA 3120(c)(1), the milestone shown is not correct

Response/ Disposition:

The NRC staff agrees with the comment. The milestone will be changed to: "After generator is online on nuclear heat."

C.I.13-57 The implementation milestone states 'Authorization for fuel load'. There is no compelling reason to tie implementation to an authorization

Response/ Disposition:

Since the regulations do not specify implementation milestones, "Milestone" will be changed to "None specified". Milestones proposed by the applicant are described in the applicable section(s) of the FSAR and incorporated as a license condition per SECY-05-0197.

C.I.13-58 The implementation requirement listed is not correct. 10 CFR 50.49(a) does not specify when the program is to be initiated.

Response/ Disposition:

The NRC staff agrees with the comment. The subject implementation requirement will be changed to "License condition."

C.I.13-59 The milestone is listed as 'None specified'

Response/ Disposition:

Since Regulations do not specify implementation milestones, "Milestone" is "None specified".

C.I.13-60 PST requirements are only covered in DG-1145 section 3.9.6

Response/ Disposition:

The NRC staff agrees with the comment. The subject section will be changed to: "3.9.6."

C.I.13-61 There is only one milestone listed. The FP program will be implemented in two phases: (1) Fuel receipt (for building storing new fuel and adjacent areas that could affect fuel storage area) (2) Fuel load (for remaining areas)

Response/ Disposition:

Since Regulations do not specify implementation milestones, "Milestone" will be changed to "None specified". Milestones proposed by the applicant are described in the applicable section(s) of the FSAR and incorporated as a license condition per SECY-05-0197.

C.I.13-62 Missing regulation

The subject regulation is as follows: "10 CFR 50.120(b)."

C.I.13-63 FSAR section indicated is not correct

Response/ Disposition:

The indicated FSAR (SRP) Sections have been changed to conform to the final FSAR (SRP) numbering system.

C.I.13-64 Milestone is not reasonable. States Ops training program to begin within 3 months after COL issuance. Should be tied to need for operators on-shift

Response/ Disposition:

Since Regulations do not specify implementation milestones, "Milestone" will be changed to "None specified". Milestones proposed by the applicant are described in the applicable section(s) of the FSAR and incorporated as a license condition per SECY-05-0197.

C.I.13-65 A capital I is used instead of a lower case i for 10 CFR 50.54(i)

Response/ Disposition:

The NRC staff agrees with the comment. The subject regulation will be changed to the following: "10 CFR 50.54(i-1)."

C.I.13-66 Implementation milestone states 'Within 3 months after authorization for fuel load'. There is no compelling reason to tie the implementation to an authorization

Response/ **Disposition**:

The NRC staff agrees with the comment. The subject milestone will be changed to: "Within 3 months after issuance of an operating license or the date the Commission makes the finding under 10 CFR 52.103(g)."

C.I.13-67 Implementation requirement is specified as 10 CFR 50.54(i-1). The time required by this CFR (within 3 months of issuance of plant operating license) can not be met under part 52.

Response/ **Disposition**:

Comment noted.

C.I.13-68 Implementation milestone states '...180 days prior to authorization for fuel load'. There is no compelling reason to tie the implementation to an authorization

Response/ **Disposition**:

Implementation is to conform to Regulations for Part 50 and Part 52 applicants.

C.I.13-69 Use of the words 'Program' and 'Plan' is not consistent with typical industry usage

Response/ **Disposition**:

The NRC staff chooses to use the term "Program".

C.I.13-70 17. Improve correspondence with other documents by listing the appropriate 'programs' from SECY-05-0197, as they are listed in C.IV.4

Response/ Disposition:

The NRC staff chooses to retain the existing structure.

C.I.13-71 Implementation milestone states 'Prior to fuel being on-site'. This could be simplified to be consistent with the rest of the table

Response/ Disposition:

SECY-05-0197 recommends that implementation of this operational program be addressed in a license condition and that the Regulations do not specify implementation milestones.

C.I.13-72 Implementation requirement quotes 10 CFR 50.54(a), but the regulation does not include any such specification.

Response/ Disposition:

A milestone of "30 days prior to scheduled date for the initial loading of fuel" is specified in proposed 10 CFR 50.54(a)(1).

C.I.13-73 Milestone states 'No later than 30 days prior to scheduled date for fuel load'. This is not consistent with the draft Final Part 52 Rule.

Response/ Disposition:

A milestone of "Fuel load authorization per 10 CFR 52.103(a)" is specified in proposed 10 CFR 50.65(a)(1).

C.I.13-74 Implementation requirement quotes 10 CFR 50.65, but the regulation does not include any such specification.

Response/ **Disposition**:

A milestone of "Fuel load authorization per 10 CFR 52.103(a)" is specified in proposed 10 CFR 50.65(a)(1).

C.I.13-75 Program title shown is cumbersome and does not match C.IV.4 wording or typical industry terminology

Response/ Disposition:

The term "Maintenance Rule" will be used.

C.I.13-76 Equivalent terms are used: fuel on-site, fuel receipt, receipt of fuel, etc

Response/ **Disposition**:

This terminology has been eliminated.

C.I.13-77 Section C.I.13.5.1 indicates that the FSAR should specifically indicate whether the "applicable portions" of Regulatory Guide 1.33 concerning plant procedures will be followed. As Regulatory Guide 1.33 is not directly applicable to the AP1000 design, and

this has been accepted by the Staff, the Staff should provide specific guidance as to which portions of Regulatory Guide 1.33 are applicable to the task delineated in Section C.I.13.5.1, or remove this wording altogether as indicated in the mark-up following.

Response/ Disposition:

Reference to RG 1.33 is clear. Applicants must either indicate whether the applicable portions of RG 1.33 concerning plant procedures will be followed or not. If RG 1.33 will not be followed, then an alternative acceptable to the staff must be described. DG-1145 guidance applies to and is developed for all vendors.

C.I.13-78 Plant-specific technical guidelines are also known a Emergency Response Guidelines (ERGs). This language should be included in DG-1145

Response/ Disposition:

Plant-specific technical guidelines are also known a Emergency Procedure Guidelines (EPGs). In addition, plant-specific technical guideline (P-STG) is a generic term, EPG and ERG are vendor specific terms. Using generic terminology minimizes future changes required as a result of new vendors.

C.I.13-79 Section 13.5.2.1(2) has incorrect information in parentheses.

Response/ Disposition:

Agree

C.I.13-80 Typographical error – delete the 'close' parentheses at end sentence.

Response/ **Disposition**:

Agree

C.I.13-81 NRC should consider removing requirement of the second sentence in section 13.5.2.1 to describe the "format" of procedures in the FSAR. Section 13.5 should be a generic section of the FSAR for all plants. Since applicants will/do not have the exact same format requirements for their procedures complying with this requirement would probably prevent the section from being generic. The format of procedures can be developed as part of the station procedure writer's guide. NRC agreed with this approach in response to Comment C.I.13.5.2.1-2.

Response/ **Disposition**:

Agree, in section 13.5.2.1, add the following to the end of the third sentence "to be verified during construction."

C.I.13-82 Similar to fire protection, flooding and HELB are common mode events that require a methodical operations strategy to manage the transient. Most plants have procedures that address these events.

Response/ **Disposition**:

Flooding and HELB procedures do not provide administrative controls with respect to procedures and do not define and provide controls for operational activities of the staff as described in

13.5.1.1. Flooding and HELB procedures will be included in 13.5.2.1(1)(c), off normal condition procedures and 13.5.2.1(1)(d), emergency operating procedures.

C.I.13-83 For completeness – maintenance would be a leading reason for having to refill and vent systems.

Response/ Disposition:

Agree, add "or maintenance" after the word "testing" in 13.5.2.1.(1)(a)

C.I.13-84 These are not specifically covered in the types of procedures already listed and typically make up a large percentage of plant procedures.

Response/ Disposition:

Agree, add "maintenance, surveillance, and periodic testing" to 13.5.2.1(1)(b).

C.I.13-85 The industry commented that the general content of each class of procedures should be available at the time the application is filed. However, the industry comment indicated that the format of procedures would be developed as part of the procedure writers' guide and would occur after the application was filed. This comment was addressed in Appendix I of DG-1145 with the NRC documenting their agreement with the comment and stating that detailed procedures would be verified during construction. However, DG-1145 was not revised to reflect this agreement.

Response/ Disposition:

See comment CI.13.81

C.I.13-86 The industry commented that the part of the organization responsible for maintaining procedures and the general content of procedures could be identified at the time of application. However, the industry comment indicated that the specific group(s) responsible for procedure maintenance and the format of procedures would be developed subsequent to the application filing. This comment was addressed in Appendix I of DG-1145 with the NRC documenting their agreement with the comment and stating that detailed procedures would be verified during construction. However, DG-1145 was not revised to reflect this agreement

Response/ Disposition:

Agree, in section 13.5.2.1 (1), add the following to the end of the second sentence "to be verified during construction."

C.I.13-87 Parts (5) and (6) appear to conflict. Part (5) allows an applicant to be consistent with one of the options in the commission's Policy statement on Engineering Expertise on Shift, however, part (6) specifically requires an applicant have an STA. Note that NUREG-0737 acknowledges that STA is an interim position until other control room staff has the requisite engineering expertise. In current plants, an STA is not specifically required. In the Policy statement< NRC states a preference for a combined SRO and STA position.</p>

Response/ Disposition:

Agree, delete the words "shift technical advisor" from part (6).

C.I.14-1 Section C.I.14.2.2 specifies that license applicants "should develop a training program for each fundamental group in the organization, with regard to the scheduled pre-operational and initial startup testing, to ensure that the necessary plant staff are ready for commencement of the test program."

Response/ Disposition:

A detailed description of the training program is not required. Applicants should provide a commitment to have a training program "in place" that includes training for individuals conducting pre-op and initial startup testing activities.

C.I.14-2 We appreciate the clarification that detailed procedures are not expected to be provided with the COLA. However, this section continues to seek description of "specific administrative controls that will be used to ensure that necessary prerequisites are satisfied for each major phase and for individual tests," and "methods that will be used to ensure retesting following [modifications or maintenance]." This language raises questions about the level of detail expected by the NRC staff.

Response/ **Disposition**:

Text should read "The COL applicant should describe the administrative controls that will govern the conduct of each major phase of the test program. This description should include the administrative controls that will be used to and ensure that necessary prerequisites are satisfied for each major phase and for individual tests. The COL applicant should also describe the methods to be followed in initiating plant modifications or maintenance that are determined to be necessary to conduct the test program. This description should include the methods that will be used to ensure and provisions for retesting following such modifications or maintenance."

C.I.14-3 The staff agreed with our earlier comment that post work testing and/or analysis may be as varied as the ITAAC themselves and thus is not practical to describe in the FSAR, however no change was made to the guidance. The guidance should be modified.

Response/ **Disposition**:

Ok with recommended wording: The description should also include methods and identify provisions to ensure that retesting that is required for modifications or maintenance remains in compliance with ITAAC commitments.

C.I.14-4 Appendix I says the last two sentence of Section 14.2.5 have been moved to 14.2.6. They have not.

Response/ Disposition:

Ok with recommended wording.

C.I.14-5 The NRC staff has acknowledged that COLAs need not contain procedure-level information. This section still calls for COLAs to "describe the procedures" that will guide initial fuel loading and initial criticality.

Response/ Disposition:

Ok with recommended wording: The COL applicant should describe its plans for initial fuel loading and initial criticality. . .

C.I.14-6 The fourth sentence states that each test required to be completed before initial fuel load or designed to satisfy the requirements for completing ITAAC should be identified, cross-referenced and provided with the COL application or be made available for audit during NRC COL application review. This sentence should be deleted. ITAAC completion info is not required to be included in COLAs or made available prior to COL issuance. Indeed, proposed new Section 52.99(a) requires licensees to submit within one year after COL issuance a schedule for completing ITAAC. The suggested cross reference may be part of such a submittal; this should be the subject of further industry-NRC discussion.

Response/ Disposition:

Ok with recommended wording.

C.I.14-7 The NRC staff agreed with our previous comment regarding the likelihood that approved startup test procedures may change in the last 60 days prior to their use, but no change was made to the guidance.

Response/ Disposition:

Okay with wording: Approved test procedures should be in a form suitable for review by regulatory inspectors at least 60 days prior to their intended use, or at least 60 days prior to fuel loading for fuel loading and startup test procedures. Licensees should provide timely notification to NRC of changes in approved test procedures that have been made available for NRC review.

C.I.15-1 The text in this section lists applicable USIs and GSIs which should be considered. The lists begins with the following USIs.USI-A-9 (ATWS)USI-A-47 (Safety Implications of Control Systems)USI-B-17 (Criteria for Safety-Related Operator Actions)USI-C-4 (Statistical Methods for ECCS Analysis)However, a review of the November 2005 version of NUREG-0933 indicates that the above USIs have all been resolved. Has the status of USIs and GSIs been modified for the purpose of COL applications?

Response/ Disposition:

The NRC staff agrees with the comment. The USI/GSI will have to be addressed within the COL submittal and should have resolution within the application that the new applicants will comply with the latest officially dispositioned agency positions.

C.I.15-2 Anticipated transients without scram (ATWS) should not be included in this section. This section groups and summarizes design-basis accidents into categories by the type of thermal-hydraulic fault or phenomena which initiates the event. A table in this section identifies the following initiating event categories.(1) increase in heat removal by the secondary system(2) decrease in heat removal by the secondary system(3) decreases in reactor coolant system flow rate (4) reactivity and power distribution anomalies(5) increase in reactor coolant inventory(6) decrease in reactor coolant inventory(7) radioactive release from a subsystem or component(8) anticipated transients without scram (ATWS)

Response/ Disposition:

The NRC staff agrees with the comment. Item (8) Anticipated Transients without Scram (ATWS) will be removed from the list. A paragraph will be added in this section of DG-1145 to discuss ATWS.

C.I.15-2 An anticipated transient is not a thermal-hydraulic fault type. Designating a transient as an anticipated transient identifies the frequency grouping which should be assigned. The frequency of occurrence is discussed later in Section C.I.15.2.Failure assumptions of the protection system used in the mitigation of a transient are not initiating event categories. Additionally the assumption of the inability of the protection system to generate a scram on demand requires a beyond design basis common mode failure of the protection system to occur. Similarly, Appendix A to Section C.I.15 included ATWS giving it the status of a design basis accident (DBA). ATWS is not a design basis accident and should not be included in this list

Response/ **Disposition**:

Staff agrees with this comment. A footnote will be added to Group 15.8, Anticipated Transients Without Scram, in Appendix A, to clearly state that ATWS events are beyond design basis events as follows: "Note a: ATWS events are beyond design basis events. See Section C.I.15.1 for a detailed discussion."

C.I.15-3 Text states that only safety related systems can be used and then in the next sentence identifies when non-safety related systems can be used. "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: ..."

Response/ Disposition:

Staff agrees with this editorial comment. DG-1145 revised to incorporate recommended wording.

C.I.15-4 Text states "The applicant should provide a discuss of how the definitions..."

Response/ Disposition:

Staff agrees with this editorial comment. DG-1145 revised to incorporate recommended wording.

C.I.16-1 C.I.16, fourth paragraph, third sentence, states "No bases are required for the TS sections related to TS usage rules (definitions, logical connectors, required action completion times, and surveillance requirement frequencies) and the TS section for design features." This listing should also include the section for Administrative Controls. Bases are not required for the Administrative Controls.

Response/ **Disposition**:

Agreed with the recommended wording. Reg. Guide will be revised.

C.I.17-1 The guidance should distinguish between the purpose of RAP and how it is accomplished

Response/ **Disposition**:

Revise sentence 5 in the last paragraph of Section C.I.17.4.2 as follows: The objective during this stage is to ensure that the reliability for the SSCs within the scope of the RAP is maintained during plant operations. Reliability assurance activities are integrated into existing operational programs (e.g., maintenance rule, surveillance testing, inservice inspection, inservice testing, and QA). Individual component . . .

C.I.17-2 See also comment for C.III.1.17.4.2. SECY 95-132 rejected the establishment of a separate PROGRAM called Operational Reliability Assurance Program (O-RAP). In the staff's SECY response (Att. 1, Item E,) the staff agreed that operational reliability assurance ACTIVITIES would be incorporated into existing programs. The staff further stated that the Maintenance Rule Program and the QA Program together with a limited-scope COL action item covering the gap were sufficient to meet the objectives of operational reliability assurance.

Response/ Disposition:

Section C.I.17.4.2 of DG-1145, as revised in the previous comment does, not require any new programs be established to implement reliability assurance activities during plant operations. The comment to limit the discussion for the objectives of the RAP to the Maintenance Rule and QA program is not incorporated. The staff believes that other existing programs can be used to implement reliability assurance activities. The comment to establish a COL action item that addresses operational and design errors nonsaftey-related SSCs is not incorporated because a COL action item is not applicable to Section C.1 of the draft regulatory guide. However, there are several methods that a COL applicant could use that would allow that an item be completed after the COL license has been issued. For operational programs, the guidance in Section C.IV.4 of this draft regulatory guide could be applied. COL applicants could also make the item a commitment, licensing condition, or ITAAC.

C.I.17-3 This is Part 1 guidance; the guidance should not presume a design certification. In addition, 10 CFR 52 uses the term design control document (DCD) for certified designs. The guidance in Part 1 should also allow for the situation in which a DCD has been submitted to the NRC for approval, but has not been approved.

Response/ Disposition:

C.I.17.4.3 is revised as follows. The RAP is implemented in several phases. The first phase implements the aspects of the program that apply to the reactor design process. The second phase is the site-specific phase, which introduces the plant's site-specific design information to the RAP process. A Tier 1 inspection, test, analysis, and acceptance criteria (ITAAC) is required for these phases. The COL applicant establishes the probabilistic, deterministic, and other methods to determine the SSCs under the scope of RAP and the ITAAC. The COL applicant is also responsible for describing how reliability assurance activities will be integrated into existing programs (e.g., maintenance rule, surveillance testing, in-service inspection, in-service testing, and QA).

C.I.17-4 Last sentence states "COL applicant is also responsible for implementing...

Response/ **Disposition**:

The comment is not incorporated. However, there are several methods that a COL applicant could use that would allow that an item to be completed after the COL license has been issued. For operational programs, the guidance in Section C.IV.4 of this draft regulatory guide could be applied. COL applicants could also make the item a commitment, licensing condition, or ITAAC.

C.I.17-5 These two bullets are overly broad. • The design and operational information used for plant reliability assurance activities.• Procurement, fabrication, installation, construction and testing requirements for risk-significant SSCs.

C.I.17.4.4 is revised as follows. 10 CFR 52.79(b) require that COL applicants 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. A COL applicant should address the following in Chapter 17 of the SAR in accordance with the provisions in SRP Section 17.4: A description of the RAP that includes: scope, purpose, and objectives. The deterministic or other methods used for evaluating, identifying and prioritizing SSCs, according to their degree of risk significance. (Probabilistic/PRA methods and results for evaluating, identifying and prioritizing SSCs should be addressed in Section C.I.19.) A prioritized list of SSCs designated as risk-significant based on deterministic or other methods. (A prioritized list of SSCs designated as risk-significant based o probabilistic/PRA methods should be addressed in Section C.1.19.) The quality controls for developing and implementing the RAP (continued in adjacent column)

C.I.17-6 The discussion of the second phase of the Program implementation (sentence 6) indicates that this 'site-specific' phase is the responsibility of the COL Applicant, and then identifies actions that are required. Some of these actions may not occur until after the COL is issued; therefore it is appropriate to identify that this phase is a COL applicant/holder responsibility. The COL Applicant should provide a description in the FSAR of the information identified in Section C.I.17.4.4.At the time of COLA, the SSC list will be essentially unchanged from the DCD SSC list; site-specific changes to the DCD SSC list will not be identified until later in the design implementation process.

Response/ Disposition:

This comment is not incorporated. However, there are several methods that a COL applicant could use that would allow that an item be completed after the COL license has been issued. For operational programs, the guidance in Section C.IV.4 of this draft regulatory guide could be applied. COL applicants could also make the item a commitment, licensing condition, or ITAAC.

C.I.17-7 These following bullet is a COL Holder action versus A COL Applicant action: • A prioritized list of site-specific SSCs designated as risk-significant. At the time of the COL Application, the list of SSCs will be (essentially) the same as the DCD list; site-specific SSCs cannot be developed until later as the site specific design elements are finalized and the EOPs are written, etc. At this time the Expert Panel will append the DCD list, and the site-specific list will form the basis for the M-Rule program

Response/ Disposition:

See response to previous comment, Comment No. C.I.17.6.

C.I.17-8 The guidance in this section references a new SRP 17.5 as the document that will contain the detailed QA program description to be included in COLA. Industry is currently working to provide input to the Staff on the content of the SRP. It is anticipated that industry comments will be resolved in that process.

Response/ **Disposition**:

Comment does not require change.

C.I.17-9 The COL application will provide required information to support NRC staff reasonable assurance findings. Applicants are not required to explain in the FSAR why other information is not known or estimate when the information will become available.

Consistent with SECY-05-0197, operational program descriptions will identify the milestone(s) by which the program or portions thereof will be implemented. More detailed schedule info about program implementation, including when additional program implementation documents will be available, will be provided to the NRC separately from the FSAR. Attachment 1 is a markup of the NRC draft guidance that includes Industry input.

Response/ **Disposition**:

Agreed. The draft guide will be revised accordingly. However, for an operational program to be fully described in accordance with SECY 05-197, the staff needs to know about applicant programmatic choices where there is latitude within the regulations and the guidance. Therefore, certain details about program elements related to implementation of 10 CFR 50.65 that should be known at the time of the COL application with be retained.

C.I.17-10 The COL application will provide required information to support NRC staff reasonable assurance findings. Delete guidance to provide info "to the extent that this information is known at the time of the COL application." Also, delete reference to "information on structures, systems, and components (SSCs)" and the subsequent detailed listing of SSC specific information since this will not be available at the time of the COL application. The scoping description in the COL application should only include a description of the scoping method consistent with NUMARC 93-01 and RG 1.160

Response/ Disposition:

Agreed. The draft guide will be revised accordingly. However, for an operational program to be fully described in accordance with SECY 05-197, the staff needs to know about applicant programmatic choices where there is latitude within the regulations and the guidance. Therefore, certain details about program elements related to implementation of 10 CFR 50.65 that should be known at the time of the COL application with be retained.

C.I.17-11 The description of program procedures for compliance with 10 CFR 50.65(a)(4) includes statements about information "known at the time of COL application" and repeats guidance in existing NUMARC and RG documents.

Response/ Disposition:

Agreed. However, for an operational program to be fully described in accordance with SECY 05-197, the staff needs to know about applicant programmatic choices where there is latitude within the regulations and the guidance. Therefore, certain details about program elements related to implementation of 10 CFR 50.65(a)(4) that should be known at the time of the COL application with be retained.

C.I.17-12 Consistent with SECY/SRM-94-084, there is no requirement to establish an "Operational RAP." As described in Section 17.4, RAP during the operational phase is accomplished through existing operational programs, including the MR. To avoid confusion and to be consistent with Commission guidance, DG-1145 should refer to "RAP during the operational phase," not to "ORAP."

Response/ Disposition:

Agreed. The paragraph in Section C.I.17.6 relating to the use of the Maintenance Rule Program in the implementation of the Reliability Assurance Program in the operational phase will be revised as

follows: "Describe how the Maintenance Rule Program (MRP) will be used in implementation of the Reliability Assurance Program (RAP) during the operational phase (See Section C.I.17.4). In conjunction with the Quality Assurance Program, the MRP is acceptable in implementing the RAP during the operational phase, provided the SSCs within MRP scope classified as high-safety-significant (HSS) encompass all the SSCs in the RAP scope, by monitoring the effectiveness of the underlying maintenance program (including surveillance programs) that form the foundation of the RAP during the operational phase.

C.I.18-1 Do not rephrase existing regulatory guidance.(NUREG-0711)

Response/ **Disposition**:

NRC policy is that DG-1145 should generally be stand-alone. However, where appropriate, DG-1145 can reference portions of other guidance such as NUREG-0800 and -0711. This referencing has been done in portions of the updated C.I.18.

C.I.18-2 At the July 2006 public workshop, several issues were discussed where the industry believes additional guidance is needed in both NUREG-0711 and SRP Chapter 18. NRC staff agreed with the industry comments in terms of there being issues that need further definition. Neither the industry re-draft of C.I.18 nor the 9/06 SRP draft addressed these issues. Thus, these issues remain open, and further priority interaction between NRC staff and stakeholders is necessary to ensure proper resolution. The issues include: what minimum inventory of fixed position and continuously available indicators and controls is appropriate? What technical and regulatory requirements are appropriate for qualified HSIs for accident mitigation, display evaluation, soft controls, computerized procedures, automation, etc? What criteria should be applied to assure appropriate teamwork between operating crew members and between automation and operators?

Response/ **Disposition**:

NRC agrees in general with this comment. Meetings, discussions, and work on these issues will proceed on a separate schedule from the resolution of comments to DG-1145.

C.I.18-2 What types of verification and validation (V&V) are appropriate for human factors
 (cont'd) features, and how should their scope and rigor be graded based on complexity and/or safety significance and/or other criteria? What criteria govern the use of a single HSI to interface with both safety and non-safety equipment to ensure that the HIS will not become a single point of failure that can disable the safety function entirely?

Response/ Disposition:

Question 1: The types of V&V to be applied to plant personnel tasks and related HSIs are described in some detail here in C.I.18.10 and in NUREG-0711, Element 11, V&V. The scope is partially defined by operational condition sampling which is addressed in C.I.18.10.2 and in NUREG-0711, Element 11.4.1. Additional wording on scope has been added to C.I.18.10 to clarify. The rigor or grading of this process is addressed in NUREG-0711 via the sampling process, which includes consideration of safety significance. Additional wording on utilization of risk importance has been added to C.I.18.10. Question 2: This is an I&C question/issue and should be addressed in Section C.I.7.

C.I.18-3 Enhancement language recommended to ensure Sections 7 and 18 are closely coordinated with respect to HSI

Agreed - added words per comment.

C.I.18-4 NRC staff has indicated during public interactions that additional research is being initiated on systems communications issues associated with "glass control rooms." In addition, ACRS noted in a November 21, 2005 letter to the EDO, "The (Digital I&C) research plan includes a program to investigate advanced nuclear power plant digital systems (Section 3.6), but this work has not begun. Due to the rapidly increasing interest in new reactors and the anticipated regulatory needs, this research should be given higher priority than it currently has." Industry is concerned that the research the staff considers necessary to support new plants may result in new design requirements.

Response/ Disposition:

Agreed - no revision to document recommended.

C.I.18-5 Disposition of Public Comments C.I.18-1 & -10 [11 elements completed by COL application]: Disposition, as shown in the 9/06 drafts of C.I.18 and C.III.1, resolves the issue.

Response/ Disposition:

Agreed. - C.II.2.9 revised.

C.I.18-6 Disposition of Public Comments C.I.18-2 & -11 [Inspection of implementation vs. review of submittals]: Disposition, as shown in the 9/06 draft of C.I.18, resolves part of the issue by reference to ITAAC.

Response/ **Disposition**:

Agreed. A reference to C.II.2.2.9 has been added to Section C.I.18, Submittals For Activities That Have Not Been Completed.

C.I.18-7 Industry Re-draft of C.I.18 (Attachment 1): Various marginal comments are included to explain or justify changes. Note that colors in the comments are a product of the track changes feature in MS Word, and are irrelevant to the contents of the comments.

Response/ Disposition:

Incorporated changes from NEI draft as appropriate. A brief response to marginal comments is included here. NEI 1 - Agreed and incorporated. NEI 2 - C.I.18 has been revised in a number of places to indicate what must be submitted, versus referenced and/or retained. NEI 3 - same answer as NEI 2. NEI 4 - same answer as NEI 2. NEI 5 - C.I.18 was revised to include "should" and "may" as appropriate. NEI 6 - same answer as NEI 5. NEI 7 Section on elements not complete was revised including some of NEI comments. NEI 8 - same as comment C.I.18.8 below. NEI 9 - Added the purpose/objective wording from NEI draft to the various subsections of C.I.18. NEI 10 - This recommendation if addressed will be done at the global DG-1145 level not just the C.I.18 level. NEI 11 - same as comment C.I.18.8 below. NEI 12 - same as comment C.I.18.9 below. NEI 13 - same as comment C.I.18.8 below. NEI 14 - Revised C.I.18 to allow this material to be referenced and kept for NRC audit.

C.I.18-8 Disposition of Public Comments C.I.18-3 & -12 [Restated review guidance]: As proposed in the Staff response, Industry re-drafted C.I.18 using citations to available Staff guidance.

The re-draft treats each PRM element in three parts: Purpose - Presents a brief description of the element based on similar summaries in SRP Ch.18. Contents - Presents citations to Staff review guidance with clarifications of submittal contents and levels-of-detail. Added Review Guidance - Presents technical guidance from the original draft that did not map well to existing Staff review guidance, and so could not be properly cited under Contents (such as the cases identified in Public Comment C.I.18-4). The re-draft aims to avoid disparity with the available Staff review guidance and to provide the practical clarifications sought by Industry in a clear and concise manner.

Response/ Disposition:

NRC has incorporated some of the recommendations from the re-drafted C.I.18. The overall format of each section of C.I.18 has been maintained to be similar to NUREG-0711 rather than adopting the new proposed format (Purpose, Contents, Added Review Guidance) by NEI.

C.I.18-9 Public Comment C.I.18-4 & -13 [Added review guidance]: The Staff response to C.I.18-4 noted that NUREG-0711 & NUREG-0800 give guidance for Staff reviews but not for Applicant submittals. This may be true, but from a technical standpoint, the Industry finds the available Staff review guidance to be equally suited to either role. However, it is understood from the 7/06 workshop that the Staff expects NUREG-0711 review guidance to be revised again soon. Thus, where C.I.18 text aims to anticipate such changes, this should be clearly indicated. The "Added Review Guidance" sections in the Industry redraft provide a controlled means to do so. These sections in the re-draft include the cases of added Staff review guidance noted in the prior C.I.18 draft, with corresponding comments by Industry

Response/ **Disposition**:

NUREGS -0800 and -0711 provide staff review guidance and criteria for the review of applicant submittals. Reg. Guide 1.70 previously provided licensee/applicant guidance. The purpose of DG-1145 is to provide guidance for the content of applicant submittals, analogously to RG 1.70. The staff does not agree that the staff review guidance is equally suitable for the role of licensee submittal guidance.

C.I.18-10 Disposition of Public Comment C.I.18-5 & C.I.18.7.2.4-1 [FSAR contents & level of detail]: The Industry re-draft (Att. 4) provides an implemented approach for identifying the necessary contents and the acceptable levels of technical detail in COL applicant submittals.

Response/ Disposition:

Public Comment C.I.18-5 addresses the level of detail in DG-1145, Section C.I.18.7.2.4. This section has been revised to allow this information to be referenced and held for NRC audit.

C.I.18-11 Public Comment C.I.18-6 & -14 [Minimum Inventory]: It was understood from the 7/06 workshop that the Staff acknowledged the need for additional guidance in this area, but it was not clear that the Industry re-draft of C.I.18 was expected to address it. Thus, no guidance was proposed by the re-draft in this area, and the issue remains open.

Response/ Disposition:

Additional discussions between NRC and industry on minimum inventory would be beneficial to develop additional or revised guidance.

C.I.18-12 Disposition of Public Comment C.I.18-7 [Should vs. May]: The final guide as issued will resolve this comment by default. It is understood that such wording in the final guide will be governed by regulatory conventions.

Response/ Disposition:

Agreed. NRC will follow standard regulatory practice in the use of shall, should, and may.

C.I.18-13 The issued guide should define the following terms with respect to Applicant review and inspection material, if such terms are used in C.I.18 text or key references: Application, On-the-docket, FSAR, Submittal, Reference, Retained-but-available (i.e. for audit/inspection), etc. In addition, the impact of referencing (i.e., from the FSAR or the submittal) on the status of a reference (i.e., on/off the docket) should be clear. These are generic issues which, if addressed elsewhere, may be incorporated in C.I.18 by reference.

Response/ **Disposition**:

This is a generic comment and is not Chapter 18 specific. NRC to address at the project level.

C.I.18-14 Disposition of Public Comment C.I.18-8 [Conflicts of interpretation]: By using citations, conflicts of interpretation with Staff review guidance are generally avoided in the Industry re-draft. However, some of the items in the "added review guidance" sections remain a potential source of conflict. Each of these should be reviewed and replaced by the appropriate citation, if possible.

Response/ **Disposition**:

Recommended wording similar to that in public comment C.I.18-8 has been added to the introduction material of C.I.18. Also, where appropriate, some detailed material was removed from C.I.18 and a reference made to NUREG-0711.

C.I.18-7 continued

Response/ Disposition:

NEI 15 - Agreed and revised C.I.18. NEI 16 - Disagree with premise in comment. However, revised C.I.18 to allow some of material to be retained and referenced. NEI 17 - This is a comment on NUREG-0711 not DG 1145. However, staff believes that the guidance as written agrees with comment. NEI 18 - This is a comment on NUREG-0711 not DG 1145. -0711 is not being revised at this time, but the comment is noted for the next revision of -0711. NEI 19 - Agreed. Revised C.I.18. NEI 20 Reference maintained in C.I.18 NEI 21 Agreed. Revised C.I.18. NEI 22 - Agreed that added work in the area of minimum inventory is warranted. NEI 23 - Agreed, revised C.I.18. NEI 24 - Agreed, citation to 10CFR is limited to once in this section.

C.I.19-2 Issue: 4th paragraph, last sentence reads "The information in Chapter 19 should enable the NRC to conclude that the applicant has performed sufficiently complete and scrutable analyses, and the results support the COL application and will maintain acceptable risk throughout the life of the plant." Comment: Chapter 19 does not include detailed technical information. This sentence is unnecessary and should be deleted.

Accept intent, though not exactly as recommended. The NRC staff agrees that the sentence is not clear and will clarify that the information in Chapter 19, when taken with the supplemental PRA information submitted with the COL application and the PRA information available at the applicant's office(s) for staff audit, will enable the NRC to make the conclusions cited.

C.I.19-3 Issue: Last paragraph, 1st sentence reads: "To support the NRC staff's timely review and assessment, the applicant should adhere to the recommended format and content for Chapter 19 provided herein." Background: DG-1145, Appendix I, Response to Public Comments on DG-1145," provided the following comment, response and disposition on this topic: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/ Disposition:

Reject. The NRC staff disagrees with this comment in the context of this section of the regulatory guide, but agrees with its intent for sections of the regulatory guide that address a COL application referencing a certified design. It should be noted that this part of RG 1.206 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."

C.I.19-3 Response: The NRC staff disagrees with this comment. It should be noted that this part of (cont'd) 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.Comment: Industry needs formal concurrence that changes to the format of Chapter 19 and the plant-specific PRA will not require an exemption.

Response/ Disposition:

see above

C.I.19-4 Issue: Last paragraph, 2nd sentence reads "Chapter 19 should reference the applicable analyses and evaluations, as well as provide a summary description of the supporting information, needed to demonstrate compliance with the above identified regulatory requirements and Commission policies. "Background: DG-1145, Appendix I, Response to Public Comments on DG-1145," provided the following comment, response and disposition on this topic: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.

Response/ Disposition:

Accept intent, though not exactly as recommended. The NRC staff agrees that not all potentially applicable supporting information needs to be referenced and that a summary description is acceptable for most of this information. However, the significant supporting information, including the plant-specific PRA model/version, should be referenced explicitly in this section and updated consistent with 10 CFR 50.71 requirements. Changes to the FSAR are governed by 10 CFR 50.71, which requires the licensee to submit: "...all changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submittal of the FSAR;..." In light of this requirement, the staff does not expect PRA updates to create unnecessary FSAR updates. Also, changes to supporting analyses and evaluations referenced in the FSAR, but not submitted for review, do not need to be addressed in FSAR updates unless they result in changes to licensing basis information in the FSAR that is required to be there by regulation.

C.I.19-4 Comment: Language noted continues to lack clarity. One of the main reasons to require a
(continued PRA report that is separate from Chapter 19 is so that the PRA can remain a living
) document. The PRA should be able to evolve without causing unnecessary FSAR updates unless the specific information contained in Chapter 19 itself is changed.

Response/ Disposition:

see above

C.I.19-5 Issue: 1st paragraph, 2nd sentence reads "This section should summarize the scope and process used to develop the plant-specific PRA. This summary should include a reference to the plant-specific PRA and associated analyses that are available for review or docketed separately." Comment: See comment on Section C.I.19 on references.

Response/ Disposition:

Accept intent, though not exactly as recommended. See immediately preceding comment (regarding Section C.I.19, last paragraph, second sentence)

C.I.19-6 Issue: 3rd sentence reads "If some internal events are screened out or incorporated into other evaluations (e.g., grouped events), this section should describe the

screening/bounding/grouping." Comment: This information is not relevant for Chapter 19. It is part of the PRA submittal per C.II.1. If grouping is described in Chapter 19 as an attribute of the design, then that grouping would need, unnecessarily, to be maintained. This could cause maintenance of more than one PRA model: one that is grouped as described in the FSAR and others that are grouped differently according to how they were used in various applications.

Response/ **Disposition**:

Reject. The NRC Staff disagrees with the comment. The description of how initiating events have been grouped is necessary so the staff can understand how all applicable initiating events are being treated.

C.I.19-7 Issue: Fourth bullet reads "Identify important assumptions (including PRA key assumptions3 and PRA-based insights4)" Footnote 4 reads ""PRA-based insights" are those insights identified during design certification that ensures assumptions made in the PRA will remain valid in the as-to-be-built, as-to-be-operated plant 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 intended to be consistent with its use in referring to the information provided in Table 19.59-29 in the AP-600 and AP-1000 Design Control Documents (DCDs)."Comment 1: "(including PRA key assumptions3 and PRA-based insights4)" is inconsistent with other subsections, for example, subsection 19.2.3.1.2Comment 2: An acceptable alternative to providing PRA-based insights in many subsections is to provide the insights in one section, for example in section C.I.19.2.5.Comment 3: Is it appropriate to reference the AP-600 or AP-1000 DCD in a regulatory guide?

Response/ Disposition:

Accept intent, though not exactly as recommended. Comment 1: All subsections specify that important assumptions should be provided. The first time this phrase is used it is parenthetically emphasized as including PRA key assumptions and PRA-based insights. The understanding that important assumptions includes PRA key assumptions and PRA-based insights should be inferred in all other places throughout this Chapter of the regulatory guide whenever the phrase is used. Comment 2: The staff prefers PRA-based insights be identified by initiating event category (internal events, specific external events, specific other modes) so that it can clearly be determined what PRA-based insights affect which category of events. If some insights are generically applicable to all events (e.g. plant-design features), then these could be identified in Section C.I.19.2.5, as proposed in the comment, and cross-referenced by the specific event discussions. Comment 3: References to the AP-600 DCD and the AP-1000 DCD specific tables are provided as examples to indicate the type and level of detail to include. As these DCDs are in 10 CFR Part 52 of the regulations, it is not inappropriate to cite them in the RG.

C.I.19-8 Issue: 3rd paragraph reads "If a specific feature is described and analyzed elsewhere in the FSAR, this section should provide the relevant cross-references. and need not be repeated in this section. Comment: Many of the topics included in the DG were addressed in other sections on the certified design DCDs. For example, Anticipated Transients without scram, Mid-Loop Operation, Station Blackout.. Add "and need not be repeated in this section." to the end of the sentence.

Accept intent, though not exactly as recommended. The phrase: "and such descriptions and/or analyses need not be repeated in this section" will be added at the end of the 3rd paragraph. Note that the intent of this sentence is to ensure the cross-reference is to the appropriate section of the FSAR that addresses a specific area, not to the certified design DCD (though the section referenced to may then reference the DCD and the applicant could include a reference to a DCD). It should be remembered that this portion of the guidance does not presume the existence of a DCD.

C.I.19-9 Issue: 1st paragraph, 2nd sentence reads "This description and analysis should specifically address the issues identified below, as well as other issues identified in SECY-90-016 and SECY-93-087, which the Commission approved in related staff requirement memoranda (SRMs), dated June 26, 1990, and July 21, 1993, respectively." Comment: Sentence should be clarified to include "as appropriate."

Response/ Disposition:

Accept intent, though not exactly as recommended. The NRC staff agrees with the comment. The phrase: "as appropriate" will be incorporated into the sentence.

C.I.19-10 Issue: 3rd paragraph reads "If a specific feature is described and analyzed elsewhere in the FSAR, this section should provide the relevant cross-references." Comment: For efficiency add "and need not be repeated in this section" to the end.

Response/ Disposition:

Accept intent, though not exactly as recommended. The phrase: "and such descriptions and/or analyses need not be repeated in this section" will be added at the end of the 3rd paragraph.

C.I.19-11 Issue: 2nd paragraph, 1st sentence reads "The NRC staff expects the plant-specific PRA to reasonably reflect the plant as it was constructed, in preparations for startup, and therefore, the plant-specific PRA should be upgraded prior to initial operations to incorporate those changes that were deferred (i.e., screened as not being significant) during the design, COL application, and construction phases, and to address findings during the PRA-related plant walkdowns. "Comments: For clarity replace "findings during" with "results of"

Response/ Disposition:

Accept intent, though not exactly as recommended. The phrase "findings during" will be replaced with the phrase "results (including findings and observations) of". The use of the parenthetical phrase is consistent with PRA peer review terminology and would be appropriate in the context of walkdowns.

C.I.19-12 Issue: Last paragraph, last sentence reads "For example, in addressing the frequency of scheduled maintenance updates following initial operations, the FSAR section may state "the plant-specific PRA will be updated to reflect plant, operational, experience (data), and PRA modeling changes, consistent with the NRC-endorsed standards appropriate for the uses and applications of the plant-specific PRA and the information available 6 months prior to the issuance of the maintenance update, which will be scheduled to occur every other fuel cycle, not to exceed 5 years." Comment 1: For consistency insert "reasonably" before "reflect." Comment 2: A more reasonable example for "6 months prior to the

issuance of the maintenance update " is "6 months prior to the start of the maintenance update "

Response/ Disposition:

Accept. The NRC staff agrees with the changes as recommended.

C.I.19-13 Large Release Frequency (LRF): The guidance introduces a new PRA metric, LRF for evaluating changes to the licensing basis during operations. The development of Reg. Guide 1.174 and the ASME Standard RA-Sb-2005, PRA Internal Events, which will be endorsed in Reg. Guide 1.200, has taken many years. In that period of development, the use of LRF as a metric for operational decision-making was evaluated. It was rejected in favor of core damage frequency and large early release frequency. To propose the LRF metric so shortly after it was rejected for use in operational assessments is disconcerting. A more precise and consistent definition of LRF would have to be developed for use in an operational setting compared with the definitions that were developed for design certifications. This would require substantial interaction with the PRA technical community before a common understanding could be reached on such a definition and how it would be applied. This would

Response/ Disposition:

Reject. The NRC staff disagrees with the comment. First, 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, 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. Finally, all four certified designs that have been approved by the NRC to date have addressed the LRF metric, without any identified definitional issue/problem. The only definitional difference between LRF and LERF is that the LRF addresses the frequency of all large releases, not just those that occur "early" (i.e., as the ASME PRA Standard defines early in this context as being before effective evacuation)

C.I.19-13 introduce uncertainty at a critical time in the new licensing process as applicants start on the final drafts of their applications that will be submitted next year. The guidance should use the same metrics that are used for existing plants for evaluating changes to the licensing basis in the operational phase: Large Early Release Frequency, which corresponds to early health effects, and Core Damage Frequency.

Response/ **Disposition**:

NOTE – The previous section C.II.1 was deleted from the regulatory guide as a result of changes in the requirements in 10 CFR Part 52. The staff has not addressed the comments provided on that previous section. The following items (C.II.2 and 3) using the NEI comment numbers now relate to RG 1.206 Sections C.II.1 and 2.

C.II.2-1 C.II.2.1 states "in a table provided in FSAR Section 14.3, COL applicants should cross-reference the important design information and parameters from these analyses to their treatment (i.e., inclusion or exclusion) in the ITAAC."

Response/ **Disposition**:

accept the comment

C.II.2-2 New nuclear power plants likely will be constructed through the use of modular construction techniques. Since construction modules may be constructed offsite, it may be appropriate for some ITAAC to be performed at the site of manufacturing of the construction modules rather than the reactor site.

Response/ Disposition:

disagree - although some components may be manufactured offsite, the as-built configuration will follow installation at the site. Inspections or tests performed at the vendor may be incorporated into ITAAC but would not be considered the final as-built condition to be used to close an ITAAC

C.II.2-3 The 10th paragraph says that ITAAC should not reference the COLA, while the 3d paragraph says ITAAC should reference the FSAR portion of the COLA.

Response/ Disposition:

Unable to find the referenced text in this section.

C.II.2-4 As indicated earlier in DG-1145, ITAAC should be reserved for "top-level design information" that pertains to the "principal performance characteristics and safety functions of the SSCs." A design feature may be site-specific and unique, and yet have little or no safety function. A design feature does not warrant greater consideration for inclusion in an ITAAC, merely because it is unique or site-specific.

Response/ Disposition:

no change - bullet is to consider, understood that not all new items are ITAAC - criteria is same in terms of developing ITAAC

C.II.2-5 As indicated earlier in DG-1145, ITAAC should be reserved for "top-level design information" that pertains to the "principal performance characteristics and safety functions of the SSCs." Not all resolutions of USIs/GSIs, NRC bulletins and generic letters, and operating experience rise to that level. For certain designs, the resolution of a particular generic issue may have little or no safety significance. Therefore, similar to other information, the determination which resolutions should be included in ITAAC should be based upon a graded approach, depending upon the significance of the resolution to safety.

Response/ Disposition:

no change - bullet is to consider, understood that not all items related to generic issues would be ITAAC - criteria is same in terms of developing ITAAC

С.П.2-6 Туро

Response/ Disposition:

no change - SSC maintained to capture systems and structures

C.II.2-7 New nuclear power plants likely will be constructed through the use of modular construction techniques. Since construction modules may be constructed offsite, it may be appropriate for some ITAAC to be performed at the site of manufacturing of the construction modules rather than the reactor site.

No change - see comment 2

C.II.2-8 The definition of Design Description includes an inaccurate description of Tier 1. Tier 1 is not intended to summarize the FSAR. Instead, as indicated in Section C.II.2.1 of DG-1145, Tier 1 is the "top-level design information" from the FSAR.

Response/ Disposition:

accept - delete definition for design description

C.II.2-9 The term "Design Description" is not needed and should be deleted. The use and definition of the two similar terms, Design Description and ITAAC Design Description, are confusing and problematic. "Design Description" is a term that is commonly used in both ITAAC and non-ITAAC contexts. It may be helpful to define the term "Tier 1 Design Description."

Response/ Disposition:

accept - delete definition for design description

C.II.2-9 (cont'd)

Response/ Disposition:

C.II.2-10 Clarify definition of Design Requirement/Commitment.

Response/ Disposition:

disagree - keep language "portion of detailed.." but deleted second sentence

C.II.2-11 As literally worded, the definition of "Exists" would require an SSC to satisfy all of the provisions in the FSAR (without regard to safety significance). The wording should be changed to indicate that the SSC must satisfy the Design Requirement/Commitment in the ITAAC, which will identify the "top-level design information" applicable to the SSC.

Response/ Disposition:

accept - deleted definition of exists

C.II.2-12 As literally worded, the definition of Functional Arrangement would require a system to satisfy all of the design descriptions in the FSAR (without regard to safety significance). The wording should be changed to indicate that the system must satisfy the Design Requirement/Commitment in the ITAAC, which will identify the "top-level design information" applicable to the system.

Response/ **Disposition**:

partially accept - changed definition to bedescribed in the ITAAC design description and as shown in the figures

C.II.2-13 The definition of ITAAC should more closely track the language in proposed 10 CFR 52.80.

Response/ Disposition:

accept - deleted definition of ITAAC

C.II.2-14 As literally worded, the definition of Physical Arrangement would require a structure to satisfy all of the design descriptions in the FSAR (without regard to safety significance). The wording should be changed to indicate that the structure must satisfy the Design Requirement/Commitment in the ITAAC, which will identify the "top-level design information" applicable to the structure.

Response/ **Disposition**:

partially accept - changed definition to bedescribed in the ITAAC design description and as shown in the figures

C.II.2-15 GDC 1 pertains to quality assurance (QA). As the NRC has long recognized, ITAAC are not needed or appropriate for the QA Additionally, with respect to codes and standards, not all codes and standards are sufficiently important to rise to the level of "top level design information." Therefore, it is not appropriate in general to have ITAAC that verify implementation of codes and standards in general.

Response/ **Disposition**:

Due to GDC 1, ITAAC should be established to verify that appropriate codes and standards are used in the design of safety-related structures, systems and components. Therefore, the "Codes and Standards" bullet (item) should be retained and not deleted. The bulleted items in Section C.II.2.2.2 in the 9/7/2006 draft were numbered (13) through (20). In the current draft supplied to this branch with the review comments, that listing has been corrected so that the bulleted items are now numbered (1) through (8) in that section. So the correction desired by NEI has been made. Consideration should be given to adding two items to the bulleted list in Section C.II.2.2.2 to make this list consistent with the SRP Section 14.3.2 Update. In the SRP Section 14.3.2 Update, this branch is proposing to add "site proximity missiles and externally generated missiles" and "aircraft hazards" to the list of top-level attributes to be verified by ITAAC. Because this section C.II.2.2.2 references SRP 14.3.2 in the title of the section, this update to the listing of design attributes would keep the two documents consistent with each other.

C.II.2-16 The 2nd bullet under the heading Pressure Boundary Integrity should be changed to be consistent with the ITAAC for the existing design certifications and clarifies the scope of the NDE to be performed under the ITAAC.

Response/ **Disposition**:

The insertion of the words "for welds" after NDE is not necessary. The second bullet under the heading Pressure Boundary Integrity explicitly requires NDE should be required to be performed in conjunction with Section III and V of ASME Code. However, NRC secondary branch (DCI) should verify the response.

C.II.2-17 Determining load combinations is a detailed design function and is not appropriate for inclusion in the ITAAC. Instead, ITAAC should focus on verification of the adequacy of

the as-built plant (which occurs through the other bullets under the heading Normal Loads, pertaining to as-built stress reconciliation reports).

Response/ Disposition:

Due to GDC 2, ITAAC should be established to verify that the normal and accident loads have been appropriately combined with the effects of natural phenomena. Therefore, the first bullet under the heading "Normal Loads" in Section C.II.2.2.2 should be retained and not deleted.

C.II.2-18 The 3d bullet under the heading Normal Loads should be changed to clarify that the ITAAC in question pertain to ASME stress reports, not all ASME reports.

Response/ Disposition:

Since other reports such as fabrication and data reports are pertained to ASME reports, the staff does not agree to modify the third bullet under the heading Normal Loads to refer to "ASME Code required stress reports".

C.II.2-19 Determining load combinations is a detailed design function and is not appropriate for inclusion in the ITAAC. Instead, ITAAC should focus on verification of the adequacy of the as-built plant (which occurs through the other bullets under the heading Seismic Loads pertaining to as-built stress reconciliation reports).

Response/ Disposition:

Due to GDC 2, ITAAC should be established to verify that the safety-related structures, systems, and components have been design to seismic loadings.. Therefore, the first bullet item under the heading "Seismic Loads" in Section C.II.2.2.2 should be retained.

C.II.2-20 This section contains numerous statements similar to "COL applicants should provide ITAAC to reconcile the as-built plant with the structural design basis." Reconciliation between as-built configuration and structural analysis is neither performed nor required unless there is a deviation from the design drawings used in the analysis. As-built configurations are checked against design drawings to verify compliance with the design basis. There is no regulatory basis for this requirement and it is not consistent with precedent (none of the existing certified designs have these ITAAC). This comment is also applicable to draft SRP Section 14.3.2.

Response/ Disposition:

While agreeing with the description of the reconciliation process, the staff does not see a need to revise the text. Reconciliation to the design drawings infers reconciliation to the supporting analysis - if no deviation is identified - design drawing and supporting analysis confirmed; if deviation exists, reconciliation would include validating or revising supporting analyses

C.II.2-21 The 4th bullet under the heading Seismic Loads, should be changed to clarify that the ITAAC in question pertain to ASME stress reports, not all ASME reports.

Response/ Disposition:

Since other reports such as fabrication and data reports are pertained to ASME reports, the staff reject to modify the fourth bullet under the heading Seismic Loads to refer to "ASME Code required stress reports".

C.II.2-22 Under the heading Seismic Loads, to the extent that the 6th bullet is intended to refer to safety-related buildings, the ITAAC is inappropriate because safety-related buildings are designed to withstand seismic events without collapse. To the extent that this bullet is intended to refer to non-safety-related buildings, the subject is addressed by the seventh bullet and is therefore redundant.

Response/ **Disposition**:

The sixth bullet under the Seismic Load will not be deleted. However, the staff has decided to revise the bullet to read "ITAAC should be developed to verify that, under seismic loads, the intended function of buildings containing components designed to prevent fission product leakage will not impair the safety related functions of any structures or equipment located adjacent to or within those buildings". Additionally, the seventh bullet under Seismic Loads will be revised to read "ITAAC should be developed, as needed, to verify that the failure of non-seismic category SSC will not impair the safety-related functions of any SSC located adjacent to or within the non-seismic building".

C.II.2-23 Determining load combinations is a detailed design function and is not appropriate for inclusion in the ITAAC. Instead, ITAAC should focus on verification of the adequacy of the as-built plant (which occurs through the other bullets under the heading related to the Suppression Pool pertaining to as-built stress reconciliation reports).

Response/ **Disposition**:

Due to GDC 4, ITAAC should be established to verify that the safety-related systems and structures have been designed to withstand suppression pool hydrodynamic loadings, which include safety relief valve discharge and loss-of-coolant accident loadings. Therefore, the first bullet item under the heading "Suppression Pool Hydrodynamics Loads (BWR only)" in section C.II.2.2.2 should be retained and not deleted.

C.II.2-24 The 4th bullet under the heading related to the Suppression Pool should be changed to clarify that the ITAAC in question pertain to ASME stress reports, not all ASME reports.

Response/ **Disposition**:

Since other reports such as fabrication and data reports pertain to ASME reports, the staff reject to modify the fourth bullet under the heading Suppression Pool to refer to "ASME Code required stress reports".

C.II.2-25 Determining load is a detailed design function and is not appropriate for inclusion in the ITAAC. Instead, ITAAC should focus on verification of the adequacy of the as-built plant (which occurs through the other bullets under the heading Flood, Wind, etc., pertaining to as-built stress reconciliation reports).

Response/ Disposition:

Due to GDC 2, ITAAC should be established to verify that the safety-related systems, and structures have been design to withstand the effects of natural phenomena other than those associated with seismic loadings. The effects include those associated with flood, wind, tornado, rain and snow.. Therefore, the first bullet item under the heading "Flood, Wind, Tornado, Rain, and Snow" in Section C.II.2.2.2 should be retained and not deleted.

C.II.2-26 The 3d bullet under the heading Pipe Break makes no sense as written. RPVs are not postulated to experience LOCAs. Perhaps the reference to RPVs should be to the "reactor coolant pressure boundary," or "reactor coolant system."

Response/ Disposition:

accept - changed to RCS

C.II.2-27 This topic of Codes and Standards is redundant of the bullets under the other headings and therefore should be deleted.

Response/ Disposition:

The topic of "Codes and Standards" with its own bulleted item in Section C.II.2.2.2 is necessary to explain (further develop) the listing of "Codes and Standards" in the bulleted list earlier in this Section. See the "Response to NEI comment C.II.2.15" above as to the need to retain the listing for "Codes and Standards" in this bulleted list in this Section.

C.II.2-28 This topic of As-Built Reconciliation is redundant of the bullets under the other headings and therefore should be deleted.

Response/ Disposition:

The as-built reconciliation topic provides summarized section for ITAAC development. Therefore, this section will not be deleted.

C.II.2-29 Consistent with the practice for the ITAAC for the existing design certifications, a single ITAAC may address the as-built stress reconciliation for all loads applicable to a system, rather than having a separate ITAAC for each load.

Response/ Disposition:

agree - text added

C.II.2-30 As a general rule, ITAAC are not intended to, and are not appropriate for, verification of classifications. Instead, ITAAC are intended to verify that the as-built plant has certain design features and functions.

Response/ **Disposition**:

The ITAAC should verify that the piping components and systems have been fabricated in accordance with the proper Code class requirements. Code classification is part of the initial design certification. The ITAAC merely confirms that fabricated components meets its classification. (P. Higgins, SPWB)

C.II.2-31 It will not always be possible to simulate design basis conditions in the plant. Therefore, in some cases, it will be necessary to perform an analysis that extrapolates the results of tests at actual conditions to determine whether the MOVs will be able to perform their functions at design basis conditions.

Modify the last bullet of this section to indicate that the capability of installed pumps, valves, and dynamic restraints at design basis conditions should be verified by in-situ testing and functional design and qualification records. (T. Scarbrough, CPTB)

C.II.2-32 This section requires as-built analyses to be performed. See above comment on C.II.2.2.2, Section 14.3.2 concerning as-built reconciliation. As-built reconciliation is performed by confirmation that the as-built configuration conforms to the design drawings. Structural analyses are only revised if necessary to reconcile deviations that are identified. If the design uses LBB methods there should be an ITAAC developed to require that a report exists and concludes that the material properties in the certified material test reports are consistent with the material properties assumed in the LBB analysis.

Response/ Disposition:

ITAAC should be developed to require the existence of a report, which documents the results of an as-built reconciliation confirming that the piping systems have been built in accordance with the ASME Code Certified stress report. (P. Higgins, SPWB)

C.II.2-33 As a general rule, ITAAC are not intended to, and are not appropriate for, verification of classifications. Instead, ITAAC are intended to verify that the as-built plant has certain design features and functions.

Response/ Disposition:

The NRC staff does not agree. The ITAAC are intended not only to verify that the as-built plant has certain design features and functions, but also to verify that the as-built features, structures, systems, and components meet the seismic and ASME code classification. Therefore, Item #2 should be retained. (P. Higgins, SPWB)

C.II.2-34 Item # 9 under the last bullet is too vague to be meaningful. Not all numeric performance values need to be verified. Instead, only the "top-level" performance values need to be verified.

Response/ Disposition:

The NRC staff agrees that Tier 1 information should include top level design features and performance standards. Rather than deleting Item #9 as recommended, the last bullet will be revised for clarification as the following: "ITAAC should be developed to verify the top level design aspects of reactor systems listed below:" (P. Higgins, SPWB)

C.II.2-35 Some of the topics listed do not relate to the as-built plant, but instead pertain to the licensing analyses that will be reviewed and approved by the NRC in the COL proceeding (e.g., "identification of design basis events;" "minimum criteria for manual initiation and control of protective actions"; "single failure criterion"). Such topics are not appropriate subjects for ITAAC, as indicated by Attachment A.II.10 of DG-1145.Some of the topics listed pertain more to operation than the design of the as-built plant (e.g., "repair"; "control of access"). Such topics are not appropriate subjects for ITAAC.

ITAAC for instrumentation and controls should address design and performance requirements. Compliance with 10 CFR 50.55a(h) and the General Design Criteria of Appendix A to 10 CFR Part 50 are the top level design and performance requirements.

C.II.2-35 Much of the information listed in this paragraph is not "top-level information" and/or not "principal performance characteristics and safety functions of the SSCs" (e.g., capability for test and calibration"; maintenance bypasses"). Therefore, in accordance with the principles in Section C.II.1 of DG-1145, such topics are not appropriate for ITAAC. Furthermore, the information requested in this section is not necessary for ITAAC as evidenced by the ITAAC for the existing design certifications (which are by definition adequate for COL).

Response/ Disposition:

ITAAC for instrumentation and controls should address design and performance requirements. Compliance with 10 CFR 50.55a(h) and the General Design Criteria of Appendix A to 10 CFR Part 50 are the top level design and performance requirements.

C.II.2-36 This paragraph merely lists the relevant GDC and provides no useful information regarding the content of the ITAAC that are needed to verify the GDC. In this regard, the ITAAC for the existing design certification are not developed or structured on a GDC-by-GDC basis. Instead, they were developed and structured on a system-by-system basis. DG-1145 should reflect such a structure.

Response/ Disposition:

ITAAC for instrumentation and controls should address design and performance requirements. Compliance with 10 CFR 50.55a(h) and the General Design Criteria of Appendix A to 10 CFR Part 50 are the top level design and performance requirements.

C.II.2-37 As indicated in SECY-05-197 and the associated Staff Requirements Memorandum, ITAAC are not appropriate for operational programs.

Response/ Disposition:

ITAAC for instrumentation and controls should address design and performance requirements. Compliance with 10 CFR 50.55a(h) and the General Design Criteria of Appendix A to 10 CFR Part 50 are the top level design and performance requirements.

C.II.2-38 Most non-safety-related systems either have no safety function or minor safety functions. Therefore, it would be inappropriate to require ITAAC related to the electrical power for such systems. Instead, such ITAAC should be limited to those non-safety-related systems that have significant safety functions.

Response/ **Disposition**:

The NRC staff agrees with the comment.

C.II.2-39 As a general rule, ITAAC are not intended to, and are not appropriate for, verification of classifications. Instead, ITAAC are intended to verify that the as-built plant has certain design features and functions.

The NRC staff does not fully agree with the comment. In some instances, design classification is closely related to the safety function of the system. The text of the last bullet should the changed to read, "Commensurate with the importance of the design attribute to safety, ITAAC should be developed to verify the following design attributes for plant systems.".

C.II.2-40 Item 10 is too vague to be meaningful. Not all numeric performance values need to be verified. Instead, only the "top-level" performance values need to be verified.

Response/ Disposition:

The NRC staff agrees with the comment in that only higher level numeric performance values need to be specified. Therefore, the text of the last bullet should be changed to read, "Commensurate with the importance of the design attribute to safety, ITAAC should be developed to verify the following design attributes for plant systems."

C.II.2-41 Some of the discussion in this section specifies ITAAC for as-built reconciliation with analyses. As noted in the comments above, the as-built reconciliation is not performed with analyses, it is performed with the design drawings.

Response/ Disposition:

The NRC staff disagrees with the comment. During design certification, all important aspects of analyses have not typically been translated into analyses. Therefore, the ITAAC must verify all important attributes of the design analysis are satisfied by the as-built configuration.

C.II.2-42 Equipment leakage is a relatively minor detail that is not appropriate for ITAAC (which pertain to "top-level information"). In this regard, the ITAAC for the existing design certifications do not in general address equipment leakage characteristics (except for a few significant leakage issues, such as integrated containment leakage).

Response/ Disposition:

Agree with NEI comment. Delete fourth bullet item as redundant. The applicant will have this detailed information to complete ITAAC called for in second bullet.

C.II.2-43 The ITAAC for the existing design certification do not require that radiation protection equipment be environmental qualified (except as necessary to satisfy 10 CFR 50.49).

Response/ Disposition:

Partially agree. Revise fifth item to read; "ITAAC should be developed to verify the operability of radiation detection and monitoring equipment consistent with the requirements of 10 CFR 50.49(b)(3), and guidance in Regulatory Guide 1.97, Revision 2."

C.II.2-44 The application will describe the liquid and gaseous radwaste systems and will evaluate offsite releases to verify that the limits in Part 190 are met. The ITAAC should not be focused on reverification of compliance with Part 190. Instead, the ITAAC should be focused on verification of the important design features and functions of the liquid and gaseous radwaste that were the basis for the analyses in the application.

Agree with comment. ITAAC to be added to section C.II.2.2.7 of DG-1145.

C.II.2-45 The ITAAC should focus on the important design features and performance characteristics relied upon in the accident evaluations. ITAAC should not be established to re-verify analytical assumptions such as delay times.

Response/ Disposition:

Disagree with comment and recommendation. However, consistent with the recent revision to SRP 14.3.8, this item (the last bullet under C.II.2.2.8) should be deleted from the ITAAC list as outside the scope of CH. 12, "Radiation Protection", safety review. This is a Design Basis consequence Analysis (DBA) issue not a Radiation Protection issue. Verification of ESF system performance, consistent with DBA assumptions, should be covered in the ITAAC associated with each ESF system, structure, and component.

C.II.2-46 The ITAAC for the existing design certification, and the generic emergency ITAAC accepted by the NRC in Section C.I.13 of DG-1145, do not address HFE for the TSC or EOF. Such information does not rise to "top-level information."

Response/ Disposition:

The NRC staff disagrees with the comment. The bullets should not be deleted. If it is carried as an ITAAC, because it could not be completed prior to COL issuance, it is an HFE-ITAAC.

C.II.2-47 The ITAAC for the existing design certifications provide for a CILRT rather than individual valve leakage tests. Limiting the ITAAC to the CILRT is appropriate, because safety is ensure if the integrated leakage is acceptable.

Response/ **Disposition**:

The NRC staff does not agree with the comment. Valve leak rate test are required by regulation and should remain part of the ITAAC.

C.II.2-48 The ITAAC for the existing design certifications only require NDE for ASME welds, not NDE for all ASME components.

Response/ Disposition:

The NRC staff does not agree. In ITAAC #2 of Table C.II.2-1, it is not appropriate to change the word "components" to "welds", because in addition to welds, NDE is also required for components such as studs, bolts, and inner surface radius.

C.II.2-49 The ITAAC should focus on the results of type tests for equipment qualification, not whether there may be EQ documentation problems. In this regard, the ITAAC for the existing design certifications do not contain requirements to verify that the EQ documentation satisfies all of the requirements in 10 CFR 50.49.

Response/ **Disposition**:

The NRC staff does not agree with the comment.

C.II.2-50 Accessibility is not "top-level design information" that pertains to the "principal performance characteristics and safety functions of the SSCs." The ITAAC for the existing design certifications do not in general address accessibility.

Response/ Disposition:

The NRC staff does not agree, the referenced section that pertains to accessibility should not be deleted. Accessibility is one of the essential component design requirements to perform ISI and IST. This accessibility requirement may not fully addressed in the design certification documents, because at this early stage detailed designs of the components may not be available. However, if is not too late to discuss and implement this accessibility requirement during the final design stage of the components and, therefore, it is prudent to include this requirement in ITAAC for verification.

C.II.2-51 The ITAAC for the existing design certifications provide for a CILRT rather than individual valve leakage tests. Such provisions are appropriate, because safety is assured if the integrated leakage is acceptable.

Response/ Disposition:

preliminary - ITAAC to be maintained for CIV leak tests and not only on IRLT

C.II.2-52 In general, this Attachment would require extremely detailed design information to be included in the ITAAC, without regard to its safety significance. For example, there is no basis for including "cabinet layout and wiring" in the ITAAC - - inclusion of such information in the ITAAC would be entirely inconsistent with the ITAAC for other types of systems, which do not contain such details. Similarly, much of the information sought by this Attachment (e.g., single failure analysis) will need to be included in the application and approved by the NRC - - there is no reason (and it would be inconsistent with the entire purpose of ITAAC, which is focused on as-built SSCs) to reverify that design analysis as part of ITAAC.

Response/ **Disposition**:

The NRC staff does not agree; the Attachment A on I&C System should not be deleted. DG Section C.II.2: Attachment A on I&C System specify the COL application to address the compliance with 10 CFR 50.55a(h), "Criteria for Protection Systems for Nuclear Generating Stations." 10 CFR 50.55a(h) requires protection systems to meet the requirements of IEEE Std 603-1991. Appropriate ITAAC acceptance criteria to verify the COL applicant's commitment in compliance with REGULATION is the top-level information for ITAAC.

C.II.2-52 In general, this attachment does nothing more than repeat the requirements of IEEE 603,
 (cont'd) the GDC, and SRP. The attachment does not distinguish between design information that needs to be reviewed and approved as part of the application, and as-built attributes that should be verified by ITAAC. Furthermore, this attachment makes no attempt to distinguish between top-level information on the principal performance characteristics and safety functions that are appropriate for verification by ITAAC, and detailed design information that is not appropriate for ITAAC. As a result, this attachment is not consistent with the principles that the NRC has established for development of ITAAC, and provides incorrect guidance for ITAAC. As a result, this attachment (in its current form and substance) should be deleted in its entirety.

see above

C.II.2-53 Item C seeks submittal of the Software Test Plan. There is no regulatory basis for this requirement. The Software Test Plan is not mentioned in BTP-14.

Response/ Disposition:

The NRC staff does not agree. Regulatory Guide 1.170, "Software Test Documentation for Digital Computer Software used in Safety Systems of Nuclear Power Plants", endorse the requirements contained in IEEE Std. 826-1983, "IEEE Standard for Software Test Documentation". The updated BTP 7-14 has included the software test plan.

C.II.2-54 Not all recommendations in Regulatory Guides warrant treatment in ITAAC. For example, some recommendations simply call for analyses to be included in an application, but do not pertain to performance characteristics or safety functions. In other cases, the Regulatory Guides contain recommendations that pertain to detailed design information that does not rise to the level of "top-level information." Therefore, only those recommendations in Regulatory Guides that represent top-level information on the principal performance characteristics and safety functions should be included in the ITAAC.

Response/ Disposition:

The NRC staff partially agrees with the comment. The sentence should read, "Regulatory Guides (RGs) which have specific recommendations (all of the RG recommendations may not need Tier 1 treatment). Here may be an area that Tier 1 treatment captures the design aspect addressed by the RG."

C.II.2-55 Not all new design features warrant treatment in ITAAC. For example, some new design features may be non-safety-related and have no significant safety function. Therefore, only those new design features that represent top-level information on the principal performance characteristics and safety functions should be included in the ITAAC.

Response/ **Disposition**:

The NRC staff agrees with the comment. The sentence should read, "New features in the design (all of the new features may not need Tier 1 treatment). For example, on the ABWR this includes the main generator breaker for back feed purposes; and the potential for harmonics introduced by the new RIPs, MFW pump speed controllers and its potential effects on the Class 1E equipment.

C.II.2-56 Most of the dimensions requested by this paragraph are not critical to safety and should not be embedded in the ITAAC. In general, a licensee should be able to change these dimensions, without seeking prior NRC approval. However, if the dimensions are in the ITAAC, they cannot be changed without NRC approval. In this regard, the NRC certified the ABWR design, without requiring that the dimensions be verified by ITAAC (as provided in the footnote to ABWR Tier 1, Section 2.15.10). Although such information was required for the ITAAC for the AP1000, we recommend that the NRC reconsider that position and only require ITAAC for those key dimensions that cannot change without significant implications for safety. In this regard, we believe that it is appropriate to specify a wall thickness for protection against external floods as provided in paragraph II.3 of the Attachment, and are not recommending any change to that provision.
disagree - ITAAC for dimensions to remain for structures

C.II.2-57 Sentence 2 of paragraph 4 states that COLAs "must" include physical security ITAAC, in the same way that COLAs "must" include EP ITAAC. However, EP ITAAC are unique in the way they are called out in the regulation as required.

Response/ Disposition:

Disagree that wording needs to changed. ITAAC to be developed for physical security

C.II.3-1 In Pubic Comment C.II.3-1 and C.II.3-4, the Staff indicates that Reg. Guide 4.2 provides an acceptable approach for COL applicant ER work. However, as recognized by the Staff, Reg. Guide 4.2 is dated; it does not address a number of topics covered in NUREG-1555. [See also related comment and Staff response to Comment C.III.3-3. The Staff notes in this response it's consideration of using the ESRP as a format for its EIS. However, the industry question here deals with the expected format of the COLA ER.]

Response/ Disposition:

C.II.3-2 Both Public Comments C.II.3-5 and 7 pertain to the SAMDA evaluation provided in a design certification and finality of the resulting NRC's EA. The issue of referencing a design still undergoing NRC review is also raised in the comments. In response to C.II.3-5, the Staff indicates that a response will be provided via the final rulemaking. In response to C.II.3-7, the Staff described a number of actions needed by the SAMA evaluation that go beyond SAMDA and DCD scope. The Staff stated no revision to the Guide was required. Depending on the level of detail in provided in the rulemaking and accompanying comments, the final complete guidance on this subject may not be clear or fully responsive to this comment

Response/ Disposition:

C.III.1. C.III.1.x and Section 1.x of the "second half" of C.III.1 have the significant potential to become confused because of the format of DG1145.

Response/ Disposition:

Staff does not agree with comment at this time. Based on the effort required to implement this change, the staff should consider incorporating this comment into the next revision of RG 1.206.

C.III.1 - General – Because C.III.1 pulls much information from the C.I sections, each comment on the C.I sections should also be checked against the corresponding C.III section, and vice versa.

Response/ Disposition:

Staff agrees with this comment. No specific change to DG-145 as a result of this comment.

C.III.1-3 Section C.III.1 introductory material, in general, does not mention the specific guidance regarding incorporation of the rule and the DCD in the COLA. A reference to C.IV.2 is recommended, as a matter of completeness.

Staff agrees with this comment. DG-1145 revised to include statement similar to the recommended wording in C.III.1.10

C.III.1-4 Guidance refers to the need to identify net electrical output. Of what value is this information, and to what extent is it considered binding as part of the FSAR? The net electrical output will be influenced by many factors such as house loads that may not be known at the time of application.

Response/ Disposition:

Staff agrees with this comment. DG-1145 revised to identify net electrical output in Section 1.1.4 as approximate and for information only. Info is non-binding as facility is licensed to thermal power level.

C.III.1-5 The phrase "whether the plant is co-located with existing operating nuclear power plants" should be clarified as the parameters of interest. Does it apply to a new unit outside the protected area for the existing facility? Outside the exclusion area boundary? Does the unit's status matter in the definition of "operating"?

Response/ **Disposition**:

Staff agrees with this comment. DG-1145 has been revised to include the recommended wording, except it specifies exclusion area boundary only as it defines a larger area of owner control. Protected area was considered too limiting and discussions with industry have informed the staff that existing protected areas would have to be enlarged to encompass new nuclear units.

C.III.1-6 (1) "guides" is plural but DG-1145 is the only guide indicated (2) should indicated conformance with DG-1145 ensures/obviates need to address RG-1.70(3) "DG-1145" should be replaced with RG number when available

Response/ Disposition:

Staff agrees with this comment; however, staff does not believe that a discussion of obviation of Reg Guide 1.70 is necessary. DG-1145 revised to incorporate recommended wording.

C.III.1-7 Ambiguous reference to SRP conformance

Response/ **Disposition**:

Staff agrees with this comment. DG-1145 revised to reflect "application submittal date" instead of "docket date".

C.III.1-8 C.I.1.4 call the NSSS vendor "the reactor designer." On the other hand, C.III.1.1.4 call the NSSS vendor "the certified plant designer."

Response/ Disposition:

Staff agrees. However, DG-1145 revised to refer to "reactor/facility designer(s)" in both C.I.1 and C.III.1, Section 1.1.4

C.III.1-9 In several cases within 1.9, reference is made to the timing of conformance (e.g., Reg Guides or SRP in place 6 months before docket date). In some cases, the requirement is

ambiguous (i.e., "6 months before application"). Consistent with prior discussions and comments, it is expected that, either through changes to guidance and regulations, as applicable, or as a matter of practice, the standard applied here will be six months prior to the application date, as the applicant has no control over when the application is docketed.

Response/ Disposition:

Staff agrees with this comment and recognizes that the applicant "submits" and the staff "dockets" an application. Section C.III.1 of DG-1145 has been revised throughout to refer to guidance "in effect 6 months before the submittal date of the COL application" or equivalent language.

C.III.1-10 The first sub-heading ("COL Applicants That Reference a Certified Design") is redundant to the entire C.III.1 section, and is unnecessary. Coupled with the first two sentences of the following paragraph, it unnecessarily confuses the context of the balance of the section. This comment also applies to 1.9.2, 1.9.3, and 1.9.4.

Response/ Disposition:

Staff partially agrees with this comment: (1) sub-heading redundancies were intended to provide clarity and there is no change to these sub-headings, (2) first two sentences in 1.9.1 - 1.9.4 have been deleted to provide additional clarity.

C.III.1-11 The latter half of the first paragraph under the subheading "COL Application Timing" is not completely accurate, and is somewhat redundant to information in the same paragraph, and while it attempts to clarify by example, it is not worth the confusion created. If a design was certified in December 2005, the obligation to "six-month" conformance would not be keyed off of the Dec 2005 date, but rather on the date of submittal or docketing of the original application. This comment also applies to 1.9.2, 1.9.3, and 1.9.4.

Response/ **Disposition**:

Staff agrees with this comment. Section 1.9.2, 1.9.3, and 1.9.4 of DG-1145, Section C.III.1 have been revised as recommended and to provide additional clarity.

C.III.1-12 The third paragraph in this section (that begins, "There may be cases where a certified design addresses SRP conformance...") seems inconsistent with the regulation. It states, in part, "where the SRPs applicable to the certified design have been revised/updated, the COL applicant may address conformance with the version of the SRP evaluated in the certified design even though a later revision of the SRP is in effect." This seems correct, i.e., allowable, but the paragraph goes on to say, "However, it is expected that the COL applicant, in this situation, will identify and justify a deviation or exception from conformance with the SRP in effect 6 months before the docket date of the COL application." The discussion is in the context of "design-related issues for which the COL applicant's operationally-related issues/programs are dependent (e.g., fire protection)," but this scenario is not well explained, nor is there any justification presented as to why design finality of a certified design should not be weighted more heavily than the operational programs that might be related to those approved design elements.

Response/ **Disposition**:

Staff does not agree with this comment. The statement applies to SRPs used to evaluate the operational programs. Since operational programs were not evaluated as part of a certified design and must be evaluated as part of the COL application, the guidance recognizes that the revision

level of SRPs may be different between the certified design and COL application. There is no departure from design finality by this guidance. The guidance suggests that applicants may evaluate their operational programs in accordance with the same SRP revision level that was used for the certified design. The reason for this is because the operational programs have some design dependence and therefore should be evaluated using the same SRP basis as the design. While evaluating the operational programs against the SRP revisions referenced in the certified design, the applicant should identify and justify deviations to any SRP revisions relevant to the operational programs and the designs upon which they are dependent that were issued after those referenced in the certified design. No change to DG-1145.

C.III.1-12 The Staff needs to clarify the regulatory basis for requiring justification of conformance (cont'd) with the SRP that was in effect at the time the DCD was docketed.

Response/ **Disposition**:

There is no change to design finality.

C.III.1 discussion of FSAR 1.9.1 states "a COL applicant should address conformance with Regulatory Guides in effect 6 months before the docket date of the COL application for the site-specific portions of the facility design which are not included in the certified design. In addition, the COL applicant should address conformance with Regulatory Guides in effect 6 months before the docket date of the COL application insofar as they pertain to operational aspects of the facility." Does this guidance indicate that the only regulatory guides that need to be addressed are those that address "facility design" or "operational aspects of the facility? For example, Division 2 is for Research and Test Reactors; so, can we eliminate Division 2 assessments since they don't address design or operation of commercial power reactors?

Response/ Disposition:

Staff agrees with this comment. Section 1.9.1 has been revised to include a list of Reg Guide divisions for conformance evaluation by the applicant

C.III.1-14 Comment # C.I.1.18 on Section C.I.1.9.3 is applicable as well to C.III.1, Section 1.9.3. 1. C.I.1.9.3 mentions a listing of generic issues in C.IV.8. Section C.IV.8 no longer contains a listing of generic issues.2. C.I.1.9.3 indicates: "Those issues that remain open and are technically relevant to the COL applicant's design should be addressed in the application. Remaining "open" is not clear in that the cited proposed Part 52.79(a)(20) is understood to require COLAs to "include" the resolutions for those issues that, in fact, have NRC approved resolutions. "Open," therefore, does seem to apply. The Staff should restrict issues to those for which acceptable resolutions have been proposed.

Response/ Disposition:

Staff does not agree with this comment. The guidance in this section has been revised to refer to Section C.IV.8. Guidance in that section will request applicant to address all GSIs listed in NUREG-0933 that are identified as being applicable to future reactors.

C.III.1-15 The first sentence on the "international operating experience" section significantly overstates the regulatory requirement. DG1145 says "Applicants for certified design and applicants for a combined license are required to address comparable international operating experience," while the proposed regulation makes it clear that use of international

experience is an alternative to use of domestic experience. Further, COL applicants will, in most cases, have no ability to discern the extent to which international experience is factored into the design, and international regulations and guidance may have no relevance to those in the US.

Response/ Disposition:

Staff agrees with this comment. This section has been revised to indicate that use of international operating experience is an alternative for non-US based designs. Based on the availability of international operating experience information through INPO and WANO, staff does not believe that applicants will not be able to access this information.

C.III.1-16 Typo: Population density criteria is incorrectly stated as 500 persons/km2. C.I.2.1.3.6 correctly presents this as 500 persons / mi2.

Response/ Disposition:

Staff agrees. Change to recommended wording.

C.III.1-17 Footnote 7, page C.III.1-27, pertains to changes from the referenced DCD. However, it is not clear as to the relevance of Footnote 7 to the referenced text which does not speak to changes from the DCD.

Response/ Disposition:

Staff agrees - delete it.

C.III.1-18 What are major Seismic Category I structures?

Response/ Disposition:

The staff agrees with the comment that the word "major" should be deleted.

C.III.1-19 What is the definition of Seismic Category II? Based on the text, it implies SSCs that meet Regulatory Guide 1.29 Position C.2 requirements are classified as Seismic Category II.

Response/ **Disposition**:

See the staff's response to Comment C.I.3.3. [The staff agrees with the comment that the definition of Seismic Category II structures, systems and components (SSCs) should be provided. The definition is: "Seismic Category II applies to plant SSCs which perform no safety-related function, and the continued function of which is not required. However, these SSCs should be designed so that the SSE does not cause unacceptable failure of or interaction with Seismic category I items." Note that the term "Seismic Category II" has been widely used in the design of advanced reactors (ABWR, AP600, AP1000, ESBWR, etc.).]

С.ПП.1-20 Туро.

Response/ Disposition:

Agree. Replace ASMC with ASME

C.III.1-21 Currently, this section only addresses BWR reactor internals - PWR reactor internals need to be addressed as well.

Agree. The text will be revised to address the internals of the PWR

C.III.1-22 Please clarify if it will be acceptable to reference the EPRI Water Chemistry guidelines for the new plants, or will an applicant need to cut-and-paste much of the background information from those documents into the SAR? The last sentence in each item implies that incorporation by reference is acceptable, but there appears to be the opportunity for a lot of redundancy and downstream revision of the SAR every time those guidelines are updated.

Response/ **Disposition**:

The staff agrees with this comment. Add the following text to this section. The EPRI Water Chemistry guidelines can be referenced to support the plant-specific program. However, full description and discussion of the plant-specific water coolant chemistry control program and its compatibility with the RCPB materials should be provided.

C.III.1-23 Section C.I.5.2.4.1, "ISI and IST Programs": This section provides a list of 9 items to be provided in the COLA to allow the Staff to make a reasonable assurance finding. Some of the 9 items will not be available at the time the COLA is submitted. For example, items 11(1), 12(2), 17(7) and 18(8) would not be complete at COLA. Item 1 can be completed for major components of the RCPB. For item 2, it is not expected that all remote access equipment would be identified several years before the examinations. Also, items 17(7) and 18(8), code exemptions and relief requests will not be developed at the time the application is submitted. The list should be modified to recognize that all such items that have been identified may not be included in the application.

Response/ **Disposition**:

Staff agrees with this comment. Remove the last paragraph in C.I.5.2.4.1 (staring with Applicants may submit a general description....) and replace with the following text: "Because the ISI and IST are operational programs, as discussed in SECY-05-0197, the programs and their implementation milestones should be fully described and reference any applicable standards. 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 for a reasonable assurance finding of acceptability."

C.III.1-24 The numbering of the 9 items listed in this section start with 11, instead of 1.

Response/ **Disposition**:

The staff agrees with this comment. Remove the first digit of the item numbers. Items numbers (11) through (19) will become (1) through (9).

C.III.1-25 Please clarify the requirement to discuss the procedures used to meet Code requirements in the second sentence of this bullet. Procedures will not be developed by the time of COL application. Also, it does not seem to be advisable to submit detailed procedures which require a FSAR update if a change to the procedure is performed. We believe that a discussion of the methods and techniques used to meet Section XI Code requirements provides sufficient information to enable the staff to make a reasonable assurance finding regarding the acceptability of the inservice inspection program.

The staff disagrees with this comment and therefore, the words of "and procedures" should not be deleted. Add the following text to the end of this section. "Detailed procedures for performing the examinations need not be provided because such information may not available at the time of COL application. However, the applicants should make a commitment to provide sufficient information to demonstrate that the procedures to be used for examinations will meet the Code requirements. Such information should be provided to the staff at a pre-determined time agreed upon by the both parties. The applicant may need to work with the NRC staff during the review to agree on an appropriate method (e.g., ITAAC, license condition, FSAR update) to ensure that the as-built plant is consistent with the design reviewed during the licensing process."

C.III.1-26 The industry does not have "exemptions" from Code requirements, but rather has Relief Requests and alternatives per 10 CFR 50.55a. The industry also works to Code Cases, as specified in Regulatory Guide 1.147. Please clarify if our understanding is correct and this item can be deleted. If this requirement is addressing components that are exempt from the inspection requirements of Section XI as defined in Section XI (usually based on size), please clarify and elaborate that this is the intent of this item.

Response/ Disposition:

The staff agrees with this comment and provides the following clarification. Replace the words after "Code Exemptions" with the following to clarify the intent of this item: "Identify any components that are exempted from the ASME Code Section XI examination requirements."

C.III.1-27 Lead-in info of section C.III.1- Ch. 6 states "The applicants should state its intentions with regard to its adoption of risk informed categorization and treatment of structures, systems and components in accordance with 10 CFR 50.69." Generally, this should be done once in Section 3.2, not in the various sections of the FSAR discussing the SSCs. [Duplicate of comment on C.I.6.]

Response/ Disposition:

The staff agrees with this comment and address the use of §50.69 in Section 3.2 of the FSAR as proposed.

C.III.1-28 Lead-in info of section C.III.1- Ch. 6 states "Generic DCDs typically address the equipment, the material used to manufacture the components in the ESF system. If applicable, this information may be incorporated by reference." Workshop discussions have led the Industry to believe that the Staff interprets Part 52 to require that the COLA include the DCD information, not "incorporate by reference." [Duplicate of comment on C.I.6.2]

Response/ Disposition:

The staff agrees with the comment and the RG revised to delete statement .

C.III.1-29 The section labeled "General" duplicates C.I.6. It should be written to identify what is necessary beyond the referenced DCD consistent with the intent of C.III.1.

Response/ Disposition:

The staff disagrees and do not have much to expand specific guidance. However, the duplicate portion as in C.I.6 can be omitted.

C.III.1-30 The section labeled "General" states "The General Design Criteria (GDC) 1, 4, 14, 31, 35, 41 and Appendix B of 10 CFR Part 50, and 10 CFR Part 50, §50.55a, require that certain systems be provided to serve as engineered safety features (ESFs) systems." This statement is not consistent with similar statement in C.I.6.

Response/ Disposition:

The staff agrees with the comment and the statement will be made consistent with the as in C.I.6 (typo Appendix "A".

C.III.1-31 According to RG 1.82 Rev.3, the design of the adverse effects, such as debris, chemicals from buffering agents and debris effects generated from the use of unqualified coatings (which may not adhere to the surface) should be considered. In general, this information should be provided at the COL stage for COL applicants that reference a certified design.

Response/ Disposition:

The staff agrees with the comment and the proposed words will be added.

C.III.1.6.2.7 states "COL applicant that reference a certified design do not need to include additional information" while there is no correspond section in C.I.6.2. There should be consistency within these sections.

Response/ Disposition:

The staff agrees and will add the section in C.I.6.2.

C.III.1-33 C.I.6.6.6 requests "Describe the method to be used in evaluating examination results for Class 3 components and, until publication of IWD-3000, indicate the extent to which these methods are consistent with requirements in Article IWA-3000 of Section XI." This guidance should be updated to reflect that IWD-3000 has now been published. [Duplicate of comment on C.I.6.]

Response/ **Disposition**:

Staff agrees (see disposition comments in C.I.6.25). The IWD-3000 publication will be updated.

C.III.1-34 This section states: "Identify all instrumentation, control, and supporting systems that are not addressed in the design control document of the referenced certified design or other parts of the COL application." per C.I.1.7.1.1: "The application document should list all instrumentation, control, and supporting systems that are safety related, including alarm communication, and display instrumentation."

Response/ Disposition:

Non-safety-related I&C typically addressed in other parts of DCD (i.e., Chapters 6, 8, 9) C.I.7.1.1 more interested in safety-related I&C.

C.III.1-35 5th sentence has the phrase "accepting the" repeated twice in the sentence.

Response/ Disposition:

The guide will be revised.

C.III.1-36 This section describes additional information to be provided by a COL applicant referencing a certified design. The second and third bullets of this information require the following additional information: Describe operational program to maintain spent fuel decay heat load within spent fuel pool cooling system heat removal capacity during refueling, including analytical methods used to calculate decay heat generation and heat removal capacity. With respect to neutron absorber material, provide pool cleanliness requirements for normal operations in the design bases for the cooling and cleanup system for the spent fuel facilities. This information does not appear to be required in the corresponding section of DG-1145, C.I.9. Additionally, the operational program described is not identified as an operational program required by regulation, as addressed in Section C.I.13.4 and C.IV.3 of DG-1145. These requirements appear to be inappropriate.

Response/ Disposition:

Operating procedures for spent fuel cooling are part of the required quality assurance program. Replace text with "If a bounding design basis analysis for spent fuel pool cooling was not established in the design certification, describe operational procedures and analytical methods that will be used to maintain spent fuel decay heat load within spent fuel pool cooling system heat removal capacity during refueling." (S.Jones)

C.III.1-37 This section describes additional information to be provided by a COL applicant referencing a certified design. The additional information required is:• Describe the operational program governing fuel handling, including procedures and administrative controls. This information does not appear to be required in the corresponding section of DG-1145, C.I.9. Additionally, the operational program described is not identified as an operational program required by regulation, as addressed in Section C.I.13.4 and C.IV.3 of DG-1145. This requirement appears to be inappropriate.

Response/ Disposition:

Operating procedures for fuel handling are a part of the required quality assurance program. Information on fuel handling procedures is specified as necessary information in Section C.I.9 of DG-1145. Replace bullet with "Describe the operational procedures governing fuel handling, including administrative controls." (S.Jones)

C.III.1-38 This section describes additional information to be provided by a COL applicant referencing a certified design. The second and third paragraphs of the section requires the following additional information: Describe the operational program governing heavy load handling, including: A listing of all heavy loads and heavy load handling equipment outside the bounds of loads described in the certified design, and the associated heavy load attributes.• Heavy load handling safe load paths and routing plans including descriptions of automatic and manual interlocks and safety devices and procedures to assure safe load path compliance.• Heavy load handling equipment maintenance manuals and procedures. • Heavy load handling equipment inspection and test plans.• Heavy load personnel qualifications, training, and control programs.• OA programs to monitor, implement, and assure compliance to heavy load handling operations. For heavy loads outside the bounds of loads described in the certified design that are handled by non-single-failureproof handling systems, provide a safety evaluation demonstrating the consequences of potential load drops are acceptable with respect to releases of radiation through mechanical damage to fuel, maintenance of an acceptable margin to criticality, prevention of damage that could uncover fuel, and prevention of damage that alone could cause a loss of an essential safety function. This information does not appear to be required in the

corresponding section of DG-1145, C.I.9. Additionally, the operational program described is not identified as an operational program required by regulation, as addressed in Section C.I.13.4 and C.IV.3 of DG-1145. These requirements appear to be inappropriate.

Response/ Disposition:

The staff disagrees with comment. The specified information is part of the information requested by GL 81-07 as part of the resolution of safety issue A-36. Therefore, although the program is not required by rule, the applicant must address the content. (S.Jones)

C.III.1-39 Although the same design bases information is described, the list is worded differently between this section and the corresponding section in C.I.9. Specifically, the fifth bullet of the list reads as follows: The ability of essential components to withstand design loadings, provisions for inspection of essential structures and subsystems

Response/ **Disposition**:

Staff agrees. DG-1145 corrected to split 5th bullet into two for consistency with C.I.9.2.5.1.

C.III.1-40 The reference to RG 1.29 for this section is incorrect. RG 1.29 deals with seismic classification. The reference instead should be to RG 1.27, Ultimate Heat Sink for Nuclear Power Plants.

Response/ Disposition:

Staff agrees. DG-1145 corrected to reference RG 1.27.

C.III.1-41 The first sentence of the third paragraph of this section states, "Describe how the final size of the drywell sump is determined."

Response/ **Disposition**:

Staff agrees. DG-1145 corrected by deleting sentence.

C.III.1-42 The 10th bullet of the information required to be submitted in the second paragraph of the section reads as follows:(10) Fire PRA peer review results - these should include all high-level Facts and Observations and their resolution, or plan and schedule for resolution if at a future date, as documented by an "independent" peer review (i.e., one performed according to an approved fire PRA standard by a group independent from the applicant) A similar comment, C.I.9.5.1.3-1, was addressed by NRC in Appendix I to DG-1145, wherein the reference to "fire PRA" was removed and reference made to PRA requirements in Section C.I.19 and C.II.1. The same revision should be made in this section.

Response/ Disposition:

Staff concurs. The suggested change will be incorporated. (B. Radlinski)

C.III.1-43 Change the word "addition" to "edition."

Response/ **Disposition**:

Staff concurs. The suggested change will be incorporated. (B. Radlinski)

C.III.1-44 This section should be revised to address the fact that the design certification identifies the codes and standards applicable to the certified design.

Response/ Disposition:

Staff concurs. The suggested change will be incorporated. (B. Radlinski)

C.III.1-45 5th bullet states "Heavy" instead of "Heavy."

Response/ **Disposition**:

Staff agrees. DG-1145 corrected.

C.III.1-46 Section 9.4.5 is followed by Section 9.5.1. Section 9.4.5 should be followed by "9.5 Other Auxiliary Systems."

Response/ Disposition:

Staff agrees. DG-1145 revised to include Section 9.5, Other Auxiliary Systems. (Staff concurs. E. Forrest)

C.III.1-47 Numerous sections like 9.3.1, 9.3.3, 9.5.4, 9.5.5 should give credit to the noted items already having been addressed in the DCD. These sections do not do so as presently written.

Response/ Disposition:

Staff agrees. DG-1145 revised to expand statement to "Typically included as part of the referenced certified design, and if so, COL applicants do not need to include additional information." in Sections 9.3.1 - 9.3.5, 9.4.4, and 9.5.2 - 9.5.8 (Staff concurs w/recommended language. *Note: Language already incorporated into document by Eric for 9.3.1, 9.3.3, 9.5.4, 9.5.5.) (D. Shum)

C.III.1-48 Section states, "If not contained in the DCD, discuss how the environmental conditions, operational parameters, design features, fabrication, material properties, and maintenance are managed and considered to mitigate the following potential degradation mechanisms in the turbine rotor and buckets/blades: pitting, stress corrosion cracking, corrosion fatigue, low-cycle fatigue, erosion, and erosion-corrosion." If not contained in the DCD," is not an appropriate criterion for requiring COLA info. Rather, COLAs will contain information required by the regulations that is sufficient to support NRC safety reviews and findings, and need not provide additional detail about the approved standard design. Moreover, the requested information is not practical or necessary to provide at time of COLA.

Response/ Disposition:

The staff agrees with most of the recommended wording with the following modification. The fifth bullet in Section C.III.1.10.2.3 will be revised to read: "Provide a general description and/or reference to applicable standards on how design, environmental conditions, procurement, fabrication, maintenance and operations will be conducted so as to mitigate the following potential degradation mechanisms in the turbine rotor and buckets/blades: pitting, stress corrosion cracking, corrosion fatigue, low-cycle fatigue, erosion, and erosion-corrosion. The COL applicant should submit the information describing design features, fabrication methods, and material properties to the staff at a pre-determined time agreed upon by the both parties. The applicant may need to work with the NRC staff during the review to agree on an appropriate method (e.g., ITAAC,

license condition, FSAR update) to ensure that the as-built plant is consistent with the design reviewed during the licensing process."

C.III.1-49 Section states, "Describe the turbine rotor inservice test and inspection program. In this description, include inspection frequency, scope (components/areas to be inspected), inspection method for each component, acceptance criteria, disposition of reportable indications, and corrective actions. Provide the technical basis for the inspection frequency."

Response/ Disposition:

The staff agrees with the comment with the following revision to Section C.III.1.10.2.3. The first bullet of Section C.III.1.10.2.3 will be revised to state, "Describe the turbine rotor inservice test and inspection program. In this description, include inspection frequency, scope (components/areas to be inspected), inspection method for each component, acceptance criteria, disposition of reportable indications, and corrective actions. Provide the technical basis for the inspection frequency. It is acceptable for the COL applicant to submit a general description and reference any applicable standards regarding in-service inspection of the turbine rotor. However, the COL applicant should provide a schedule for submitting the finalized in-service inspection procedures and acceptance criteria. The applicant may need to work with the NRC staff during the review to agree on an appropriate method (e.g., ITAAC, license condition, FSAR update) to ensure that the as-built plant is consistent with the design reviewed during the licensing process."

C.III.1-50 Section states, "Develop flow-accelerated corrosion (FAC) monitoring program for carbon steel portions of the steam and power conversion system that contain water or wet steam." It is not necessary or practical to develop an FAC program at the time of COLA.

Response/ Disposition:

Staff agrees with this comment. Replace the first bullet item in C.III.10.3.6 with the following text, "Provide a general description and/or reference to applicable standards for developing a flow-accelerated corrosion (FAC) monitoring program for carbon steel portions of the steam and power conversion system that contain water or wet steam."

C.III.1-51 For non-code components, provide plant-specific materials property data such as chemistry, yield strength, fracture toughness data (KIC.), Charpy V-notch energy, nil-ductility temperature, fracture appearance transition temperature. Identify appropriate ITAAC to verify the expected material properties including manufacturer/fabricator, and heat number(s).

Response/ **Disposition**:

The staff agrees with the conclusion reached in the "Recommended Wording" section but a revision to DG-1145 on "non-code components" is not justified due to this conclusion. Clarification is not required.

C.III.1-52 Section states, "For non-code components, provide expected plant-specific materials property data such as chemistry, yield strength, fracture toughness data (KIC.), Charpy V-notch energy, nil-ductility temperature, fracture appearance transition temperature. Identify appropriate ITAAC to verify the expected material properties including manufacturer/fabricator, and heat number(s)." Per past practice for design certification and Section C.II.2, ITAAC are not established to verify material properties of non-code

components in the steam and feedwater systems. Rather, NRC may verify actual material properties through normal design implementation inspections.

Response/ Disposition:

The staff agrees with the recommended wording. Delete the sentence, "Identify appropriate ITAAC to verify the expected material properties including manufacturer/fabricator, and heat number(s)." from the last bullet of C.III.10.3.6.

C.III.1-53 Section states, "Discuss design and operational procedures for avoidance of steam binding on the AFW pumps" Design provisions will be described in the referenced DCD, as appropriate. Operational procedures will not be available at time of COLA so they cannot be discussed.

Response/ Disposition:

The staff agrees with this comment. Revise C.III.1.10.4.9 fourth bullet text with the following: "Discuss operational provisions for avoidance of steam binding on the AFW pumps."

C.III.1-54 Section states, "Describe the inspection and testing procedures to verify that the system is capable of automatically initiating auxiliary feedwater flow upon receipt of a system actuation signal.

Response/ **Disposition**:

The staff agrees with this comment. Revise C.III.1.10.4.9 fifth bullet text to the following: "Describe the inspection and testing to verify that the system is capable of automatically initiating auxiliary feedwater flow upon receipt of a system actuation signal."

C.III.1-55 Section states, "Describe the inspection and testing procedures to be performed to verify that the system satisfies the recommendations of Regulatory Guide 1.62 with respect to the system capability to manually initiate protective action by the auxiliary feedwater system.

Response/ **Disposition**:

The staff agrees with this comment. Revise C.III.1.10.4.9 sixth bullet text to the following: "Describe the inspection and testing to be performed to verify that the system satisfies the recommendations of Regulatory Guide 1.62 with respect to the system capability to manually initiate protective action by the auxiliary feedwater system."

C.III.1-56 Section states, "Describe the inspection and testing procedures to be performed to verify that essential portions of the AFWS are isolable from non-essential portions, so that system performance is not impaired in the event of a failure of a non-essential component.

Response/ **Disposition**:

The staff agrees with this comment. Revise C.III.1.10.4.9 seventh bullet text to the following: "Describe the inspection and testing to be performed to verify that essential portions of the AFWS are isolable from non-essential portions, so that system performance is not impaired in the event of a failure of a non-essential component."

C.III.1-57 Section states, "Describe the design features of the turbine rotor, shaft, couplings, and buckets/blades if these features were not described in the DCD. Provide drawings. Identify

the manufacturer and model number. Discuss fabrication methods." Describe ... if these features were not described in the DCD," is not an appropriate criterion for requiring COLA info. Design features of the turbine rotor, etc., will be described in the DCD as appropriate. COLAs will contain information required by the regulations that is sufficient to support NRC safety reviews and findings, and need not provide additional detail about the approved standard design. Moreover, manufacturer and model number are not practical or necessary to provide at time of COLA.

Response/ Disposition:

The staff does not agree with the first sentence in the Recommended Wording because the design certifications that the staff has reviewed (e.g., ESBWR or AP1000) do not contain design information for the turbine rotor, shaft, couplings, and buckets/blades. In addition, there are no industry codes and standards (such as ASME or ASTM) that are applicable to the turbine design. Turbine design information is usually proprietary. The staff may review the representative information regarding the turbine design. However, the staff cannot develop a safety findings without plant-specific turbine information. The staff understands that the plant-specific turbine information may not be available at the time of COL application. However, the staff expects that the plant-specific information should be available for staff review at a pre-determined time agreed upon by the both parties. The staff proposes to revise the third paragraph (bullet) in Section C.III.10.2.3 as follows: "Describe and provide drawings of the design features of the turbine rotor, shaft, couplings, and buckets/blades. Identify the manufacturer and model number. Discuss fabrication methods of the rotors. If the plant-specific information are unavailable at the time of the COL application, the representative information may be submit for staff review as part of the COL application. The plant-specific information should be submitted for staff review at a predetermined time agreed upon by the both parties. The applicant may need to work with the NRC staff during the review to agree on an appropriate method (e.g., ITAAC, license condition, FSAR update) to ensure that the as-built plant is consistent with the design reviewed during the licensing process."

C.III.1-58 Section states, "For BWRs, if an alternate leakage path is chosen, provide detailed drawings that show the MSIV alternate leakage path lines including the condenser, all applicable connections to the system and their seismic classification."

Response/ Disposition:

The requested rewording is not approved by the staff. DG-1145 text not to be changed. The following text from the SRP 3.2.2 review procedures applies to the MSIV alternate leakage path: "The information supplied in the application identifying fluid systems important to safety is reviewed for completeness, and the quality group classification, ASME Code and code class, and quality assurance requirements of each individual major component are checked for compliance with the above criteria. The various modes of system operation are checked to assure that the assigned NRC quality groups are acceptable. The piping and instrumentation diagrams are reviewed to assure that the applicant has delineated in detail the system quality group classification boundaries for systems important to safety. Each individual line on a diagram is checked to assure the accuracy of the assigned quality group classification, including branch lines such as vent lines, drain lines, fill lines, test lines, and sample lines..."

C.III.1-59 Section states, "When cast austenitic stainless steel materials are used, discuss what measures have been taken to ensure that these materials can be adequately inspected by volumetric methods as required in the inservice inspection program."

The staff agrees with this comment. Revise the third bullet of C.III.1.10.3.6 to: "When cast austenitic stainless steel materials are used, discuss what component configuration and access provisions have been made to ensure that these materials can be adequately inspected by volumetric methods as required in the inservice inspection program." In addition add the following statements to the third bullet: "Also discuss the effectiveness of using UT for the volumetric examination of such components. If UT has not been determined to be effective, discuss what other volumetric examination method will be used for inservice inspection."

C.III.1-60 This section makes reference to RG 1.123 which has been withdrawn.

Response/ Disposition:

Staff agrees with this comment. Revise C.III.1.10.4.3 second bullet text to the following: "Describe quality assurance criteria for the design, construction, and operational phases of the turbine gland sealing systems and demonstrate consistency with the guidance of Regulatory Guides 1.33.

C.III.1-61 Bullets one and four make reference to reactor water chemistry.

Response/ Disposition:

The staff agrees with the comment. The information has been rearranged to identify requirements that are specific to either direct cycle or indirect cycle plants. In order to keep the language more general, the terms "PWR" and "BWR" are not used. Revise all of C.III.1.10.4.6 text to the following: • Provide an analysis of the demineralizer capacity and anticipated impurity levels.• Describe condensate purity requirements, the basis for those requirements, and performance monitoring for impurity levels.• Demonstrate the compatibility of the materials of construction with service conditions and reactor water chemistry (direct cycle plants) or secondary water chemistry (indirect cycle plants). • For indirect cycle plants, describe the contribution of impurity levels from the secondary system to the primary coolant activity level.

C.III.1-62 Section 10.3 is followed by Section 10.3.6. It appears that Section 10.3 should be followed by "10.3.5 Water Chemistry (PWR only)."

Response/ Disposition:

The staff agrees with this comment however, the current SRPs do not include a Section 10.3.5 but if a DG-1145 Section 10.3.5 exists, we do not object to listing it after Section 10.3 and before Section 10.3.6. Note however that SBPB is not cognizant of SRP Section 10.3.5.

C.III.1-63 The objective and primary benefit of mobile systems is flexibility in terms of selection and replacement. Outage equipment (e.g., laundry processing system) may change with every outage, thereby requiring an SAR change. Outdated or defective equipment should allow replacement with an entirely different system without pursuing an SAR change. The objective of the SAR should be to identify what minimum operating characteristics will apply, ALARA objectives and minimum ALARA design features (as applicable), minimum instrumentation (monitoring) requirements, and minimum controls for governing critical or safety operation and termination functions. Minimum waste processing rates should only be required for liquid and gaseous effluent systems.

Response/ Disposition:

Staff disagrees with this comment. No change will be made to text.

C.III.1-64 Consistency.

Response/ Disposition:

Staff agrees with comment. However we are changing "SAR" to "FSAR" for consistency.

C.III.1-65 Current language is too prescriptive and would require an SAR revision for every new instrument type, quantity, etc.

Response/ **Disposition**:

Staff agrees with comment. This is the same comment as C.I.12.18. See response to C.I.12.18.

C.III.1-66 Provide a description of any additional contained radiation sources not identified in Section 12.2.1 of the DCD for the referenced plant design, including radiation sources used for instrument calibration or radiography.

Response/ Disposition:

Staff does not accept comment. The reference to describing additional contained radiation sources not identified in Section 12.2.1 of the DCD for the referenced plant design applies not only to sources that may be used for instrument calibration or radiography, but to all contained radiation sources not previously identified in the DCD. Nothing in the guidance prevents applicants from noting, at the time the application is being submitted, that some specific information was not available and that the missing or incomplete technical information or design will be submitted at a later time. In its review, the staff will consider such a possibility during the acceptance review, make a determination as to the impact of the missing information on the conduct of its full technical review, and, if found acceptable, make it an RAI item to be issued and tracked during the technical review process.

C.III.12.3.4 contains the two following items1. "Describe the use of portable instruments, and the associated training and procedures, to accurately determine the airborne iodine concentration in areas within the facility where plant personnel may be present during an accident, in accordance with the requirements of 10 CFR 50.4(f)(2)(xxvi) and criteria in Item III.D.3.3 of NUREG-0737"2. "Address the use of portable instruments, and the associated training and procedures, to accurately determine the airborne iodine concentration in areas within the facility where plant personnel may be present during an accident."

Response/ Disposition:

Staff agrees with comment. The second passage (beginning with "Address the use of portable instruments...") is a subset of the first passage. This second passage in C.III.12.3.4 will be deleted.

C.III.1-68 C.III.1.12.5.3, Radioactive Material Control, para

Response/ Disposition:

Staff agrees with comment. "position control" will be changed to "positive control".

C.III.1-69 Numerous changes that were made to C.I.13 during the various iterations of 5/1 to 6/30 to 9/1 were not carried over to C.III.1, Chapter 13.Examples include:1. The requirement for inclusion of resumes in the FSAR were removed in C.I.13.1, 9/01 version but not in C.III.1, Chap 13.1.2. The last sentence of the first paragraph of section 13.2.1.1(1) in

C.I.13 was changed from "The program should distinguish between classroom, on-the-job, and simulator training,..." to "The program should distinguish between formal instruction, on-the-job, and simulator training,...". This same change was not made in C.III.1, Chapter 13.

Response/ Disposition:

Agree. Make C.III section consistent with C.I

C.III.1-70 A "References" section was not included in section C.III.1-13 as is in section 13.1.4 of C.I.13

Response/ Disposition:

Agree, add the reference section

C.III.1-71 1st sentence has the phrase "provide the" repeated twice in the sentence.

Response/ Disposition:

Version on the web has the correction made

C.III.1-72 The emergency class definitions have been revised to include security events.

Response/ Disposition:

The Commission issued NRC BULLETIN 2005-02, "EMERGENCY PREPAREDNESS AND RESPONSE ACTIONS FOR SECURITY-BASED EVENTS" (BL-05-02), to collect information on the type of EP enhancements licensees had implemented to address the hostile action contingency. Licensees responded that the types of enhancement examples in BL-05-02 had been or would be implemented. Further, industry developed a guidance document which NRC endorsed in Regulatory Issue Summary 2006-12 Endorsement of Nuclear Energy Institute Guidance "Enhancements to Emergency Preparedness Programs for Hostile Action". However, implementation of these enhancements was voluntary and they have not been nor can they be inspected for compliance. It is acceptable to submit the revised classifications if the emergency plan is written to address BL-05-02 or RIS 2006-12.

C.III.1-73 This confirmation of agreement does not need to be a permanent part of the E-plan. Also, the letter showing offsite agency agreement is needed whether or not there are other reactors at the site.

Response/ Disposition:

The applicant should provide a form of confirmation of the agreement, such as a letter of agreement signed by State and local governmental authorities, with the application. This document could be included in the emergency plan or docketed separately.

C.III.1-74 This should be able to be provided by reference to other sections.

Response/ **Disposition**:

Add the sentence after the second paragraph on page C.I.13-11:"It is acceptable to satisfy this requirement by referencing the appropriate sections of the SAR that address site characteristics."

C.III.1-75 Existing regulations do not require submittal of State and local emergency response procedures, just plans. (10 CFR 50.33(g))

Response/ Disposition:

The staff agrees that there is no requirement to submit state and local emergency response procedures with the application. The document must included the emergency plans which address the DHS requirements.

C.III.1-76 It is permissible for the Emergency Plan to be a stand alone document.

Response/ **Disposition**:

This emergency plan may be a physically separate document referenced by Section 13.3 of the SAR, and may incorporate by reference various State and local emergency plans or other relevant materials. The staff realizes that it is current common practice to maintain a separate, stand alone document for the licensees emergency response plan.

C.III.1-77 The requirement of 10CFR 73.71(a) should be addressed under security, not EP.

Response/ **Disposition**:

The staff agrees that there is no emergency preparedness requirement to report safeguards events. However the staff has proposed a change to the reporting requirements of 10CFR 73.71 to address the prompt notification requirement of the NRC for security-related events considered to pose an imminent or actual threat. The staff has verified that the reference is resident in Section C.I.13.6 Security of the DG-1145.

C.III.1-78 Explicitly state what type of documents must be addressed - GL, BL, Orders. This should not include IN's as these are not supposed to set new requirements.

Response/ **Disposition**:

The staff believes that the term generic communications apply to all the referenced documents described in the DG-1145 whether or not they required a specific response from the licensee. They are provided to establish a complete dossier of emergency preparedness operating experience to aid the applicant in developing an emergency plan that appropriately addresses generic guidance. Where a specific response is required the applicant must appropriately address the required actions. These documents are posted to the NRC website under the heading of Generic Communications.

C.III.1-79 The EAL information should be in the stand alone Emergency Plan.

Response/ Disposition:

The FSAR should contain a general description of the emergency classification and action level scheme. The emergency plan submitted must address the requirements of 10CFR50.47(b)(4).

C.III.1-80 For security-related aspects of EP to be addressed, explicitly reference BL 2005-02 and RIS 2006-12, not just the 2002 orders.

The lack of specificity by staff for each Bulletin and Regulatory Information Summary issued subsequent to September 11, 2001 reflects the ongoing evaluation and rulemaking that may be in progress following publication of this document. Both references included in this comment are listed in Generic Communications.

C.III.1-81 10 CFR 2.390 gives the requirements for marking information to be withheld from public disclosure.

Response/ Disposition:

The staff agrees that 10CFR2.390 provides the requirements for marking information submitted to the NRC.

C.III.1-82 This should be covered under Security, not EP.

Response/ Disposition:

The staff agrees that this item (10) should be covered under Security, not EP.

C.III.1-83 Item (2), 1st sentence states "The FSAR or other submittal should describe the applicant's program for developing operating procedures (A.1-5 above)." It is not clear what "A.1-5 above" is referring to in the document.

Response/ Disposition:

Numbering changed to reflect new numbering of section

C.III.1-84 Item (3) 1st sentence states "The FSAR or other submittal ... should describe the applicant's program for developing EOPs (A.4 above) ..." It is not clear what "A.4 above" is referring to in the document.

Response/ Disposition:

Numbering changed to reflect new numbering of section

C.III.1 Chapter 16.2, second paragraph, states "The format and content of the technical specifications and bases for a COL or design certification should be based on approved certified designs listed as appendices to 10 CFR Part 52 (e.g., Appendix A to Part 52, "Design Certification Rule for the U.S. Advanced Boiling Water Reactor," Appendix D to Part 52, "Design Certification Rule for the AP1000," etc.), or the following STS NUREGs developed for Part 50 licensees..." Reference to "design certification" or "design certification" also occurs in other paragraphs of this section. It is not clear why the "or design certification" is addressed in this section that is intended to address a COL application that is referencing a certified design.

Response/ Disposition:

Deleted all instances of phrase "or design certification" in Section C.III.1.16.

C.III.1 Chapter 16.2, second and third paragraphs, implies that the use of STS and incorporation of TSTF Travelers is an option for the COL application that is referencing a certified design. This is misleading, in that an applicant might be led to believe that this is an acceptable alternative without following the change requirements of Section VIII.C of the applicable design certification rule.

Response/ **Disposition**:

The following paragraph has been added to 16.2: "In developing site-specific technical specifications for a COL application that references a certified design, the applicant may consider incorporating, where appropriate, NRC approved TSTF travelers suitably modified as necessary to account for any site-specific differences, such as in design. The COL applicant may propose deviations from the certified generic technical specifications, which derive from the adoption of approved TSTF travelers, either concurrently wit the COL application through a separately submitted exemption request, or following COL issuance using the license amendment process.

C.III.1 section 16.2, last paragraph, states, in part, "Certain plant-specific information may need to be provided with the COL or design certification application to demonstrate compliance with 10 CFR 50.36. This information may include but should not be limited to: ... Manuals, reports, and program documents identified in the technical specifications administrative controls section." This guidance is not consistent with C.I.16 which states "Manuals, reports, and program documents identified in the administrative controls section of the TS or applicable governing regulations, are considered to be neither part of the FSAR, nor part of the TS or the associated bases. These documents (such as the Offsite Dose Calculation Manual and Core Operating Limits Report) are to be prepared and submitted to the NRC as required by the associated TS administrative control requirements and any applicable governing regulations."

Response/ **Disposition**:

Modified last paragraph to be consistent with C.I16

C.III.1-88 The second paragraph of this section provides a recommendation (i.e., "should") to base the plant-specific TS on the Generic TS rather than reflecting the regulatory requirement to comply with the applicable Design Certification Rule Section III.B or to invoke the change mechanism under Section VIII.C.

Response/ Disposition:

Revised first sentence to state: The format and content of the technical specifications and bases for a COL referencing a certified design must be based on one of the approved certified designs listed as appendices to 10 CFR Part 52 (e.g., Appendix A to Part 52, "Design Certification Rule for the U.S. Advanced Boiling Water Reactor," Appendix D to Part 52, "Design Certification Rule for the AP1000," etc.).

C.III.1-89 The first bullet in the list contained in the fourth paragraph should be separated into two topics: the first and second sentences are associated with completing COL Information Items based on a certified design which may have an impact on the generic Technical Specifications, and require changing in accordance with Section VIII.C of the applicable design certification rule. The third sentence deals with Technical Specifications derived from the STS NUREG documents, which can only be invoked by an applicant referencing a certified design by application of VIII.C of the applicable design certification rule.

Removed bullet format. Divided first bullet into two paragraphs and removed from second new paragraph the reference to STS NUREGs for topical reports recognizing that the generic TS for the certified design should list them in the references in the TS bases; of course deviations at the COL stage would require an exemption per Appendix Section VIII.C.4.

C.III.1-90 This section identifies NUREG 1431 Revision 3.1 as the basis for review. However, section C.I.16 documents the use of the current revision to NUREG 1431 without identifying a revision number.

Response/ Disposition:

Removed reference to specific version of NUREGs.

C.III.1-91 This sections states that the applicant should consider incorporating the NRC approved TSTF Travelers where appropriate. Section C.I.16 does not discuss the consideration of these TSTF Travelers.

Response/ Disposition:

Added discussion of TSTF adoption and STS change process to C.I.16.

C.III.1-92 The recommendation associated with the TSTF Travelers is vague and requires clarification. Specifically, the issue remains unbounded with regard to when the NRC TSTF Traveler reviews will be completed. If these reviews are on going then up until the issuance of the documents by the applicant the NRC could be issuing approvals of these Travelers. In addition, the expectations of their use is vague. Will the applicant be required to document why they choose not to consider some as well as why they choose others.

Response/ Disposition:

C.III.1, Section 16.2 discussions regarding TSTF adoption has been clarified to indicate it is optional, and how to adopt either with the COL application or after the COL is issued.

C.III.1-93 The terminology between C.I and C.III is different. C.III assigns the terms "D-RAP and O-RAP for the two stages; C.I does not. For clarity and to conform to SRM/SECY-95-132, the term O-RAP should not be used, because there will not be a separate 'program' during stage two as the RAP elements will be in existing operational programs.

Response/ Disposition:

C.III.1.17.4.2 is revised as follows. The RAP applies to those plant structures, systems and components (SSCs) that are identified as being risk-significant (or significant contributors to plant safety), as determined by using a combination of probabilistic, deterministic, or other methods of analysis, including information obtained from sources such as plant- and site-specific probabilistic risk assessment (PRA), nuclear plant operating experience, relevant component failure data bases, and expert panels. The purposes of the RAP are to provide reasonable assurance that (1) a reactor is designed, constructed, and operated in manner that is consistent with the assumptions and risk insights for these risk-significant SSCs, (2) the risk-significant SSCs do not degrade to an unacceptable level during plant operations, (3) the frequency of transients that challenge SSCs is minimized, and (4) these SSCs function reliably when challenged. (continued in adjacent column)

C.III.1-94 Same comment as above regarding a DCD: The terminology between C.I and C.III is different. C.III assigns the terms "D-RAP and O-RAP for the two stages; C.I does not. For clarity, the D-RAP and O-RAP terms should not be used, because there will not be a separate 'program' during stage two as the RAP elements will be in existing operational programs:

Response/ Disposition:

Section C.III.1.17.4.3 is revised as follows. The RAP is implemented in several phases. The first phase implements the aspects of the program that apply to the design process. During this phase, risk-significant SSCs are identified for inclusion in the program by using probabilistic, deterministic, and other methods. The design certification document addresses this phase. The design certification document also addresses a Tier 1 inspection, test, analysis, and acceptance criteria (ITAAC) requirement for RAP. The second phase is the site-specific phase, which introduces the plant's site-specific design information to the RAP process. The COL applicant performs this phase. At this phase, the RAP is modified or appended based on considerations specific to the site. The COL applicant establishes the probabilistic, deterministic, and other methods to determine and maintain the site-specific list of SSCs under the scope of RAP. (continued in adjacent column)

C.III.1-95 In SECY 95-132, The Commission specifically disapproved the staff's proposal that an operational reliability assurance program (O-RAP) be continued for the life of the plant. SECY 95-132 states the following in the cover letter: "On Item E (reliability assurance program), the SRM approved a design reliability assurance program (D-RAP) subject to resolution of the recommendation by the Office of the General Counsel (OGC) to implement the D-RAP using the inspections, tests, analyses, and acceptance criteria (ITAAC) process. The SRM disapproved the staff's proposal that an operational reliability assurance program (O-RAP) be continued for the life of the combined license (COL). In response to the instructions of the SRM, the staff modified SECY-94-084 to: 1) revise the statement of purpose of the reliability assurance program; 2) require the use of the maintenance rule methodology for performance monitoring so that industry design reliability assumptions are not translated into new regulatory requirements; 3) require the D-RAP to be verified using the ITAAC process; 4) remove

Response/ Disposition:

C.III.1.17.4.2 is revised as follows. The RAP applies to those plant structures, systems and components (SSCs) that are identified as being risk-significant (or significant contributors to plant safety), as determined by using a combination of probabilistic, deterministic, or other methods of analysis, including information obtained from sources such as plant- and site-specific probabilistic risk assessment (PRA), nuclear plant operating experience, relevant component failure data bases, and expert panels. The purposes of the RAP are to provide reasonable assurance that (1) a reactor is designed, constructed, and operated in manner that is consistent with the assumptions and risk insights for these risk-significant SSCs, (2) the risk-significant SSCs do not degrade to an unacceptable level during plant operations, (3) the frequency of transients that challenge SSCs is minimized, and (4) these SSCs function reliably when challenged. (continued in adjacent column)

C.III.1-95 the requirement that a separate O-RAP exist for the life of the plant; and 5) incorporate the objective of the O-RAP into existing programs. These clarifications are reflected in the revised text of SECY-94-084 in Attachment 2."

C.III.1-96 Same comment as above: The terminology between C.I and C.III is different. C.III assigns the terms "D-RAP and O-RAP for the two stages; C.I does not. For clarity, the D-RAP and O-RAP terms should not be used, because there will not be a separate 'program' during stage two as the RAP elements will be in existing operational programs.

Response/ Disposition:

See Response to Comment No. C.III.1.94

C.III.1-97 Regarding 2nd bullet in list: the list of SSCs may not be complete for inclusion in the COLA since the detailed design will not be completed.

Response/ Disposition:

This comment is not incorporated. However, there are several methods that a COL applicant could use that would allow that an item be completed after the COL license has been issued. COL applicants could also make the item a commitment, licensing condition, or ITAAC.

C.III.1-98 The Commission directed that there would not be a separate program called O-RAP

Response/ Disposition:

Section C.III.1.17.4.4 is revised as follows. CFR 52.79(b) require that COL applicants 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. A COL applicant should address the following in Chapter 17 of the SAR in accordance with the provisions in SRP Section 17.4: A description of the RAP that includes: scope, purpose, and objectives. The deterministic or other methods used for evaluating, identifying and prioritizing site-specific SSCs, according to their degree of risk significance. (Probabilistic/PRA methods and results for evaluating, identifying and prioritizing site-specific SSCs should be addressed in Section C.III.1.19.) . A prioritized list of site-specific SSCs designated as risk-significant based on deterministic or methods. (A prioritized list of site-specific SSCs designated as risk-significant based on probabilistic/PRA methods should be addressed in Section C.III.1.19.) The quality controls for developing and implementing the RAP (continued in adjacent column)

C.III.1-99 The terminology between C.I and C.III is different. C.III assigns the terms "D-RAP and O-RAP for the two stages; C.I does not. For clarity, the D-RAP and O-RAP terms should not be used, because there will not be a separate 'program' during stage two as the RAP elements will be in existing operational programs:

Response/ Disposition:

See responses to previous comments.

C.III.1-100 This list should be identical to C.I.17.4.4; the same comments for C.I 17.4.4 above apply.

Response/ Disposition:

Comment incorporated.

C.III.1-101 Issue: Paragraph 4 says "The COL applicant should include updated risk insights, identify all differences between the updated risk insights and the certified design risk insights,

indicate which differences are important, and explain why the important differences have occurred (e.g., due to design changes, changes in PRA assumptions, or changes to PRA methodology). In this context, the "differences in risk insights" includes changes (either detrimental or beneficial) to the significant16 cutsets relative to sequences, significant cutsets relative to core damage frequency (CDF), significant cutsets relative to large release frequency (LRF), significant accident sequences, significant accident progression sequences, significant basic events, significant contributors, and significant containment challenges. The phrase "difference in risk insights" also includes any changes to the PRA-based insights.17 When identifying important differences between the plant-specific risk insights and the certified design risk insights, applicants should consider both quantitative changes (e.g., changes in risk metrics) and qualitative changes (e.g., revised or additional accident sequences)."

Response/ Disposition:

Accept intent, but not exactly as recommended. The NRC staff agrees that there are inconsistencies between the 4th and 7th paragraphs of this section regarding the information to be provided in the COL application. While paragraphs 4 through 6 discuss differences that should be addressed by the COL applicant, paragraph 7 states that only the "important differences" need to be included in the COL application and that the submittal should follow Section C.II.1, which does not address differences. These paragraphs will be clarified to be more explicit regarding what the NRC expects applicants to do regarding the identification and evaluation of differences from the certified design PRA and what information needs to be provided in the COL application. This clarification will also address the role of bounding analyses and what needs to be addressed at the COL stage, in which site-specific information is available, versus the information used during the design approval stage in which there is no specific site identified (but bounding or typical site parameters are used).

C.III.1-101 (cont'd)

Response/ **Disposition**:

see above

C.III.1-102 Issue: Section 19.1, para. 2, 1st sentence says "Applicants referencing a certified design can meet this requirement by updating and upgrading, as appropriate, the certified design..." Updating is the proper term to describe supplementation of the design PRA to consider site- and plant-specific information. The term "upgrading" is not necessary and should be deleted because it could be interpreted to imply more extensive changes to the PRA, which are not required for COLA.

Response/ **Disposition**:

Reject. The NRC staff disagrees with the comment to eliminate the word "upgrading" from the subject sentence. The staff's basis for rejection is two-fold: to avoid potential mis-interpretation and to gain consistency with the ASME PRA Standard (ASME RA-Sb-2005), as endorsed by RG 1.200. In the context of proposed final rule for Part 52, the word "upgrade" is used to encompass what the ASME PRA Standard defines as both "PRA maintenance" and "PRA upgrade." To avoid any confusion or the interpretation that it is not necessary to address changes in methodologies, etc., the RG uses both words "update" and "upgrade." There may be instances, especially many years after a design is certified, in which the methods used in the certified design PRA are no longer

the preferred method and other methods are used (e.g., human error analysis, data update methods, new approaches to quantification or truncation, or new treatment of common cause failure). In addition, if a significant change in scope or capability occurs, for example, when enhancing the PRA-based seismic margins analysis performed during certification with the site-specific seismicity to create the plant-specific seismic PRA during COL. In these cases, consistent with the ASME PRA Standard definitions, the use of new methodologies or significant changes in scope or capability would constitute a PRA upgrade.

C.III.1-103 Issue: Section 19.1 5th paragraph last sentence reads "In addition, the certified design PRA should be updated and upgraded, as appropriate, prior to initial fuel load to reflect all changes in plant design and operational programs so that it reflects the as-built, as-to-be-operated plant." Comment: For consistency replace "all" with "relevant", and insert "reasonably" before "reflects"

Response/ Disposition:

Accept intent, but not exactly as recommended. The NRC staff agrees that the use of the word "all" may be mis-interpreted in this sentence to include plant changes that are not reflected in the PRA model. However, the context of this paragraph is addressing the fact that some changes that do impact the PRA model and may impact risk insights may not have been incorporated into the plant-specific PRA model since the applicant may have determined these differences were not "important" and screened them from needing to be addressed in the COL application plant-specific PRA. The intent of the last sentence of this paragraph is to ensure that these less important differences that have an impact on the PRA risk insight are eventually incorporated into the plant-specific PRA prior to initial fuel load. The staff agrees that, consistent with prevailing ASME PRA Standards, the PRA needs to "reasonably" reflect the as-built, as-to-be-operated plant and will incorporate this aspect of the recommended wording change.

C.III.1-104 Issue: Section 19.1 6th paragraph 1st sentence reads "The applicant should adhere to the guidance provided in Section C.II.1 of this guide for the plant-specific PRA, including the format and content identified in Appendix B to Section C.II.1 of this guide." Comment: Please see previous comments on changes to format of Section 19 from the format used in the certified design PRA.

Response/ Disposition:

Accept. The staff agrees with the comment and recommended wording, which will be incorporated immediately following the subject sentence.

C.III.1-105 Issue: Section 19.1 Footnote 17 reads "Section 19.2 last sentence reads "The usage of this phrase is intended to be consistent with its use in referring to the information provided in Table 19.59-29 in the AP600 and AP1000 Design Control Documents (DCDs)." Comment: Please see previous comments.

Response/ Disposition:

Accept. The staff has determined that in this context, in which the reference is used as an example of the type and level of detail of information provided, it is acceptable to reference these documents.

C.III.1-106 Issue: Section 19.2 2nd sentence reads "To support the NRC staff's timely review and assessment, the applicant should adhere to the recommended format and content identified inspection C.I.19.Comment: Please see previous comments

Accept. The staff agrees with the comment and recommended wording, which will be incorporated immediately following the subject sentence.

C.III.2 discussion of FSAR 1.9.2 states "ESPs have already provided information addressing conformance with the applicable sections of the SRP that were in effect 6 months before the docket date of the ESP application." This is not a true statement. Part 52 did not (prior to the proposed revision) require that the ESPs address SRP conformance. Indeed, the SRPs were not even used – the application was evaluated against RS-002 by the NRC. For these cases, would a statement such as "Alternate approach utilized. The ESP addressed this section and was evaluated against RS-002 rather than the SRP" be considered to fulfill the 50.34(h) conformance assessment?

Response/ Disposition:

Accept - revised text to address conditions prior to Part 52 rule changes

C.III.2-2 The 1st paragraph of this section states: "The specific information that the applicant should provide has been copied from the corresponding section in Part I and pasted into this section of the guide." However, this is not an accurate statement for Chapters 3 through Chapters 19 which refers the reader back to CIII.1

Response/ **Disposition**:

Accept - revised text to not say copied from Part 1

C.III.2-3 First paragraph states: "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. For topics related to approval of a specific site in an ESP, the guide will state that the COL applicant does not need to include additional information."

Response/ Disposition:

Agree with the recommended wording.

C.III.2-4 The second paragraph in this section states: "Depending on the technology, some design topics may not have been reviewed during the design certification. COL applicants will need to provide this information only if it was not covered in the design certification." However, it is difficult for an applicant to determine what design topics were reviewed by the NRC and what were not reviewed for a specific Certified Design. A topic may have been reviewed by the staff but not addressed/discussed in the DCD or FSER. Or the design topic criteria may have changed between the time of certification and COL application. Requiring the applicant to address new design topics is inconsistent with design finality associated with a Certified Design.

Response/ Disposition:

Agree with the comment.

C.III.2-5 With regard to the pilot ESP applications, COL information items were not specifically identified. COL action items were generated as a result of the NRC review and are listed in the ESP FSER. Section C.III.2.4 mentions COL action or information items in the ESP.

However, permits associated with the pilot ESP applications have not been made available (draft or final).

Response/ Disposition:

Staff disagrees. COL information and action items are identified as a result of the NRC review and are listed on the Safety Evaluation Report. These items are different from site to site and from case to case, so that it is not feasible to make a standard temperate or source(s).

C.III.2-6 This section contains the statement: "The NRC recommends that the COL application facilitate this review wherever possible." It is not clear what the NRC expects from the COL applicant in this area.

Response/ Disposition:

Agree - revised text to be more specific

C.III.2-7 For consistency add the words " and the ESP" after "... is consistent with the certified design".

Response/ Disposition:

Agree - revised text to be more specific

C.III.2-8 1. Section C.III.2.9 (first paragraph) references Part 52 but does not provide a specific cite. In general, any reference to the regulation should include a specific, clear cite.2. In addition, C.III.2.9 (second paragraph) cites 10 CFR 52.93. 3. In that 52.93 addresses both exemptions and variances, the specific cite should be provided in C.III.2.9.

Response/ Disposition:

Agree - revised text to include cite

C.III.2-9 The second paragraph of C.III.2.9 indicates that if site characteristics do not fall within the site parameters specified in the design certification that the application should request an exemption or departure, as appropriate per Part 52.93. However, it is possible that should an actual site characteristic not fall within site parameters postulated in the design certification, a possible approach could be to request a variance from the ESP, as permitted by 52.79(b). This should be noted in C.III.2.9. This would depend of which parameter is involved, possible differences in methods, etc.

Response/ Disposition:

Agree - added text

C.III.2-10 Section C.III.2.10 does not mention referencing the ESP, consistent with the purpose of C.III.2.

Response/ **Disposition**:

agree - incorporated changes

C.III.2-11 Generally speaking, DG-1145 guidance and Part 52 provide little specific guidance regarding the administrative aspects of how a reference ESP is treated in the COL

application. Per the comment on C.IV.2, it is recommended that C.IV.2 be revised to address the administrative aspects of referencing an ESP in the COLA. It is recommended that C.III.2.10 include a statement that provides a reference to C.IV.2.

Response/ Disposition:

agree - incorporated changes

C.III.2-12 C.III.2.11 provides a reminder of the requirements of 10 CFR 52.6 without offering additional guidance. However, given that regulations and related criteria vary from safety, to environmental, to emergency preparedness areas, guidance that would cover each area must be addressed separately. For example, as noted in Section 6.4 of NEI 04-01 (Draft Rev. E), no review or collection of data associated with reviewed and final provisions of an ESP SSAR is considered appropriate. However, if the COL applicant referencing that ESP became aware of significant changes, the provisions of 10 CFR 52.6 would be applied. It is recommended that the Staff consult Section 6.4 and consider incorporating appropriate elements of that guidance into DG-1145, Section C.III.2.11.

Response/ Disposition:

generally agree with comment but changes not made with this revision of RG. Will consider in future revision.

C.III.2-13 1st paragraph refers to 10CFR 52.6. This is a proposed rule change. "COL applicants that reference a DC and/or an ESP are not required to revise the information included in the DC or 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."

Response/ **Disposition**:

timing of issuance of RG to follow rulemaking and so while good comment for DG, not accepted for RG

C.III.2-14 This section states: "The requirements for further technical information are included as part of the referenced certified design. The COL applicant that references a certified design and early site permit should identify any requirements for further technical information in their application for the portions of the facility that are not certified, including an estimated schedule for providing the additional technical information that may be necessary for issuance of a combined license." Per C.1, 1.5 this section is for applicants not referencing a certified design. However, since C.III is for applicants referencing a certified design, it is not clear what additional information would be appropriate for this section

Response/ **Disposition**:

C.III.2-15 Two new sentences were added to the second to last paragraph of this section. The newly added sentences read:" In addition, COL applicants referencing an ESP should include information in the application that is sufficient to demonstrate compliance with any ESP permit conditions. Tabulated cross-references to this information should be provided in this section." However, at the time an applicant submits a COL application, it is possible

that the ESP would not have been issued by the NRC and therefore permit conditions would not have been identified.

Response/ Disposition:

No change - expect preapplication discussions to address special circumstances and determine, for example, whether COLA should reflect expected ESP items

C.III.2-16 C.III.2.9 references C.III.2, Section 1.8.C.III.2.9 mentions the possible need for an exemption or departure should site characters not fall within site parameters specified in the design certification, citing § 52.93. However, Section 1.8 does not discuss the situation in which § 52.93 is applied. Section 1.8 should be revised to address not only the exemption process provided in § 52.93(a) but also to recognize that a variance from the ESP [per § 52.93(b)] may be an appropriate remedy, depending on the situation.

Response/ Disposition:

generally agree and revised text to highlight variance. Additional discussion regarding departure/exemption not added since it is discussed in other sections (C.III.2.6-8)

C.III.2-17 Throughout this section, the phrase "....6 months before the docket dates of the COL application" is used to refer to the need to reconcile regulatory guides, standard review plans, generic issues and operational experience. However, the docket date cannot be determined by the COL applicant.

Response/ Disposition:

agree - revised to reflect rule change

C.III.2-18 Throughout this section, the terms "deviation or variance" is used when determining when an applicant needs to evaluate conformance with regulatory guides, standard review plans, generic issues and operational experience. However, the lead-in sentences were all recently revised to use the term "departures". This occurs in many paragraphs throughout Section 1.9. For example:" For a COL application that includes departures from the certified design, these departures should be evaluated for conformance with the Regulatory Guides in effect 6 months before the docket date of the COL application, unless the deviation or variance is included in a Topical Report."

Response/ Disposition:

agree - revised text

C.III.2-19 C.III.1 discussion of FSAR 1.9.1 states: "a COL applicant should address conformance with Regulatory Guides in effect 6 months before the docket date of the COL application for the site-specific portions of the facility design which are not included in the certified design. In addition, the COL applicant should address conformance with Regulatory Guides in effect 6 months before the docket date of the COL application insofar as they pertain to operational aspects of the facility." Does this guidance indicate that the only regulatory guides that need to be addressed are those that address "facility design" or "operational aspects of the facility? For example, Division 2 is for Research and Test Reactors; so, can we eliminate Division 2 assessments since they don't address design or operation of commercial power reactors?

agree - added types of RGs

C.III.2-20 Section 1.9.2 currently states: "Applicants for an ESP also have a requirement in proposed 10 CFR 52.17(a)(1)(xiii) to provide an evaluation of the site against applicable sections of the Standard Review Plan (SRP) revision in effect 6 months before the docket date of the early site permit application. ESPs have already provided information addressing conformance with the applicable sections of the SRP that were in effect 6 months before the docket date of the ESP application." Since this proposed requirement is new, not all prior "pilot" ESP applicants provided a review against SRPs. In addition, the "pilot" ESPs were reviewed against RS-002. The guidance should be clarified to address the special licensing case of ESPs reviewed prior to the proposed rulemaking.

Response/ Disposition:

agree - added text

C.III.2-21 Comment # C.I.1.18 on Section C.I.1.9.3 is applicable as well to C.III.2, Section 1.9.3. 1. C.I.1.9.3 mentions a listing of generic issues in C.IV.8. Section C.IV.8 no longer contains a listing of generic issues.2. C.I.1.9.3 indicates: "Those issues that remain open and are technically relevant to the COL applicant's design should be addressed in the application. Remaining "open" is not clear in that the cited proposed Part 52.79(a)(20) is understood to require COLAs to "include" the resolutions for those issues that, in fact, have NRC approved resolutions. "Open," therefore, does seem to apply. The Staff should restrict issues to those for which acceptable resolutions have been proposed.3. In general, C.IV.8 guidance defines the broader scope of the generic issue review via the discussion and use of NUREG-0933, App. B. Guidance on scope should be provided in C.IV.8 (except for specific reductions in scope associated with referencing a DCD. This guidance should remain in C.III.1/2.

Response/ Disposition:

n/a - revised section to remove discussion

C.III.2-22 The last sentence of the last paragraph of this subsection states:".....to ensure the health and safety of the public is protected." For consistency with C.III.1, delete the words "is protected".

Response/ Disposition:

n/a - revised section to remove discussion

C.III.2-23 Second to last paragraph, last sentence contains a typo. Sentence currently reads: "Applicants for design certification and combined license are responsible for procuring and international operating experience information."

Response/ Disposition:

n/a - revised section to remove discussion

C.III.2-24 The section indicates that additional information need not be provided. However, as noted in C.I.2.2.2.2, a description of hazardous materials stored onsite should be provided. Accident categories considered include explosions of onsite stored materials

(C.I.2.2.2.1(1)).In that onsite hazardous material inventories may not have be known at the time of ESP application, this information would likely be required for the COL application. Section C.III.2, Section 2.2.2 should be revised to recognize this possibility.

Response/ Disposition:

Agree with the wording. Change text.

C.III.2-25 In that onsite hazardous material storage may not have been reviewed at the ESP stage, such onsite storage would be discussed and evaluated as necessary in the COLA. This would include evaluation for explosive impacts (C.I.2.2.3.1) as well as toxicity limits for control room habitability.

Response/ Disposition:

C.III.2-26 Correct typo in last sentence:" Identify and justify and deviations from the guidance provided in Regulatory Guide 1.23."

Response/ Disposition:

Staff agrees to recommended wording.

C.III.2-27 Cooling water canal and reservoir design information may likely be provided in the ESP if the ESP is referring to a specific technology. Therefore, this section should be begin with the words "If not provided in the ESP....".This will make this section consistent with Section 2.3.3 and 2.2.4.In addition, similar lead-in wording should be added to the following sections which may likely have included the subject information in the ESP. These sections are: 2.4.7, 2.4.10, 2.4.12, 2.4.14

Response/ Disposition:

Agree with the revised wording.

C.III.2-28 This section currently reads:" For an ESP with a permit condition precluding accidental liquid releases, provide information on how the DC complies with the permit condition." However, at the time of COLA submittal the ESP permit may not have been issued by the NRC and therefore permit conditions would not have been identified.

Response/ Disposition:

Agree with the revised wording.

C.III.2-29 This section uses the phrase "If not included in the ESP", while previous sections use the phrase "If not provided in the ESP" Also, the ESP may not have been issued by the NRC at the time of COLA submittal, therefore, "ESP" should be changed to :"ESP application"

Response/ Disposition:

Agree with the revised wording.

C.III.2.30 C.III.2, Chapter 6 refers the reader to C.III.1, Chapter 6. C.III.1, Chapter 6 requires no additional information for a COLA referencing a certified design. However, for the COLA referencing an ESP, onsite chemical storage may not have been reviewed during the ESP stage. Therefore, in additional to demonstrating that the control room dispersion

coefficients postulated in the certified design bound that established for the design at the selected site, the impact of hazardous materials stored onsite must also be evaluated in the COLA application. In addition, for new facilities proposed to be co-located onsite with existing facilities, the other units' hazardous materials must be considered in terms of control room habitability.

Response/ Disposition:

The staff agrees with the dispositioner's comment. But, the second part will need some more research to disposition and will be done later.

C.III.2-31 Information regarding details on Emergency Planning (Section 13.3) may have been included in the ESP application. Therefore, the COL applicant may not need to repeat this information in the COLA.

Response/ Disposition:

No change. The staff agrees with the statement, however, guidance already exists in RG 1.206. Section C.III.2, Information Needed for a Combined License Application Referencing a Certified Design and an Early Site Permit, as an introduction to C.III.2, provides guidance on additional information that may be provided by the applicant. If Design Certification or ESP approval topics are complete additional information may not be needed. However, this section cautions the applicant to exercise due diligence in providing proper and sufficient information for the staff to make it's determination. (RG 1.206, Page C.III.2-1) EHR

C.III.3-1 Industry comments regarding ESP environmental finality were provided to the NRC in the NEI letter dated 5/16/06 (as part of the Part 52 rulemaking process). As noted in C.III.3, guidance regarding ESP finality will be provided following the final Part 52 rulemaking. As discussed with the Staff on several occasions (e.g., ESBWR DCWG-NRC mtg of 7/14/06), applicants developing COLAs that reference an ESP are proceeding at risk in preparing ER material, given the lack of industry-NRC agreement on COLA ER content requirements (and related supporting review processes). In addition to comments raised in the NEI 5/16/06 letter, the industry understands from DG-1145 workshop discussions as well as the 7/14/06 NRC-ESBWR DCWG meeting, that there is a lack of clarity and agreement regarding the expected level of design detail in the COLA ER, particularly in the case of an ESP using the PPE approach. Separate comments on Section C.III.3 are provided on this subject.

Response/ **Disposition**:

C.III.3-2 In addition to comments raised in the NEI 5/16/06 letter, the industry understands from DG-1145 workshop discussions as well as the 7/14/06 NRC-ESBWR DCWG meeting, that there is a lack of clarity and agreement regarding the expected level of design detail in the COLA ER, particularly in the case of an ESP using the PPE approach. It is recognized that C.III.3 can not be updated until the Part 52 rule is finalized. However, it is not clear if the rulemaking will address the required level of design detail in the COLA ER. C.III.3 should be revised to include guidance on the expected level of design detail in the COLA ER. It is also noted that while this issue of design detail has been discussed with the Staff primarily in the context of a COLA referencing an ESP, this issue likely applies more broadly to non-ESP COLAs. For example, even in the case where no ESP was referenced, the level of design detail to satisfy all aspects of NUREG-1155 may not be

available at the time of COLA submittal due to limitations in the amount of design engineering and equipment procurement

- C.III.3-2 specification work completed. While NUREG-1155 has been updated to reference Part 52
- (cont'd) provisions, it generally does not recognize nor account for differences between Part 50 and Part 52 in the approach to COL application preparation, decision to procure and construct, timing of such decisions, and the wide variance in what engineering detail may be available at various stages of this process. Overall, even with no ESP, a COL applicant may not have the level of detail expected by NUREG-1155. Therefore, the issue regarding expected level of design detail in a COLA ER impacts guidance provided in Section C.II.3 as well.

Response/ **Disposition**:

C.III.3-3 C.IV.2.2 addresses the referencing of a design certification rule; however, neither C.IV.2 nor C.II.3 provides guidance on the referencing of and use of the ESP ER and/or FEIS. For that matter, it is recognized that neither the current nor proposed Part 52 provides requirements specifically address the incorporation or treatment otherwise of the ESP ER and/or FEIS. For the COLA referencing an ESP, the associated COLA ER must provide the information required by 10 CFR 51.50(c)(1). This includes (1) a demonstration that facility design falls within the site characteristics and design parameters established in the ESP, (2) issues deferred from the ESP, and (3) new and significant information. To the extent necessary, the COLA ER would reference, that is, cite the ESP ER and/or EIS, as needed, as a basis for COLA ER statements. The ESP ER and/or EIS is not required to be incorporated either by reference or by full integration unless helpful to understand context or support clarity.

Response/ Disposition:

C.III.3 should be clarified to address the administrative and licensing treatment of the ESP
(cont'd) ER and EIS in the COLA Regimen that C.II.3 address COLA ER format, it is recommended that C.II.3 be referenced to C.III.3 in regard to the appropriate administrative treatment of the ESP ER/EIS in the COLA ER.

Response/ Disposition:

C.III.5-1 The last bullet states "designing the communications path to be broadcast only from the protection system to the control system". There is no precedent or regulatory basis for this approach. This comment also applies to Section C.1.7, C.I.7.B-2, Item (3).

Response/ Disposition:

No Change - disagree with comment since bullets preceded by "previously accepted approaches have included"

C.III.5-2 Paragraph 3 of this section states: "compliance with DAC, including those intended to be verified early in the construction process, can be the subject of a hearing just prior to operation. This is another reason for the COL applicant to submit, early in its application, the detailed design information..." It is not clear how submitting this information early in the process will impact the likelihood of a hearing.

Agree - eliminated paragraph on hearings. Maintain emphasis that early resolution of DAC is recommended approach

C.III.6-1 COL Applications Referencing a Design Certification Application Under Review, page CIII.6-2, first paragraph, third sentence To clarify which applicant (DC or COL) is referred to in this sentence; recommend that "design certification" be added in front of "applicant."

Response/ Disposition:

agree - text revised

C.III.6-2 Early Site Permit, second paragraph, third sentence This sentence should be revised to also provide the same guidance with respect to applicable Topical Reports, the Environmental Report, and the Site Redress Plan

Response/ Disposition:

agree - text revised

C.III.6-3 Since 10 CFR 52 has been issued as a final rule, it is recommended that this sentence be clarified. The applicant's need this guidance as soon as possible. The COLA ERs are being written now

Response/ Disposition:

discussions of Environmental Reports moved to C.II.3

C.III.7-1 Sentence 2 of paragraph 3 states that COLAs "must" include physical security ITAAC, in the same way that COLAs "must" include EP ITAAC. However, EP ITAAC are unique in the way they are called out in the regulation as required.

Response/ **Disposition**:

Staff does not agree. Staff believes that ITAAC for security design features are necessary to verify that the facility has been constructed in accordance with the license.

C.III.7-2 Clarify first paragraph for consistency with 3d paragraph in this section

Response/ Disposition:

Staff agrees with this comment. DG-1145 has been revised to incorporate recommended wording.

C.III.7-3 Clarification

Response/ **Disposition**:

Staff agrees with this comment. DG-1145 has been revised to incorporate recommended wording in Sections C.III.7.5 with slight variations.

C.III.7.4 C.III.7.3 states "The complete set of COL-ITAAC will be incorporated into the COL as a license condition to be satisfied prior to fuel load. As such, a COL holder may request a change in one or more of the EP-ITAAC, except those provided in the referenced certified

design, via the license amendment process applicable to Part 52." C.III.7.4 makes a similar statement for SP-ITAAC.

Response/ Disposition:

Staff agrees with this comment. DG-1145 has been revised to incorporate recommended wording in Sections C.III.7.3 and C.III.7.4 with the exception of reference to "Section 52.63(b)(1)". Staff believes that including reference to "Section 52.63(b)(1)" may unnecessarily confuse the issue.

C.IV.1-1 This section is entitled "Acceptance Review Checklist," but needs clarification as to its scope and intent. The introductory section includes the following passage: "The staffs [sic] intent in using these checklists is to ensure that the application submitted for review is complete. The acceptance review focuses on whether there is sufficient information for the staff to perform a complete review. That is, acceptance review confirms that there is no missing information and there are no applicable regulatory requirements that have not been addressed. Upon docketing, the staff will perform a review of the application to determine the adequacy of the information submitted to resolve all safety issues. Sufficient information in the context of acceptance review is not interchangeable with adequate and acceptable information necessary for the staff to make a reasonable assurance finding. Therefore, the staff assumes that completing its review of the application may necessitate requests for additional information."

Response/ Disposition:

No change to reflect the comment. Although point taken, responsibility for providing application meeting all regulatory requirements remains with licensee - see introduction

C.IV.1-1 This is a useful clarification in response to prior comments on earlier drafts of the checklist (i.e., regarding whether the acceptance review was focused on being able to begin the review or complete the review). However, recent experience indicates that the Staff may require information beyond that indicated in this checklist before an application will be accepted (i.e., requiring, as a condition of acceptance, submittal of information that might previously have been the subject of post-acceptance RAIs). Accordingly, then, this might be thought of not as an "acceptance checklist," because meeting the requirements in the regulation and this checklist does not appear to ensure acceptance. Rather, one could view this as a "rejection checklist," i.e., the criteria in this checklist represent a necessary, but not sufficient, set of criteria for acceptance of the application. If this is accurate, then the Staff should so clarify; further, the Staff is urged to clarify what is required in order for an application to be accepted.

Response/ **Disposition**:

No change to reflect the comment. Although point taken, responsibility for providing application meeting all regulatory requirements remains with licensee - see introduction

C.IV.2-1 C.IV.2.2 states: "... The COL applicant must include the generic DCD in the application. Included in the application means that the actual document is provided with the application." The DCR (e.g., App. D in §IV.A.2a and 3) are read to understand that the application must include the plant specific DCD. However, Section IV.B states: "An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference ("IBR") and comply with the requirements of this appendix, including Tier 1, Tier 2." This is understood to mean that the plant specific DCD may "include" the generic DCD by the IBR method. Further, the current §52.79(b) explicitly states: "The final safety analysis report and other required information may incorporate by reference the final safety analysis report for a certified standard design." Thus, IBR is clearly allowed in the subject regulations. If this is an accurate understanding, the Staff should clarify this in C.IV.2.

Response/ Disposition:

Accepted - revised section to address incorporation by reference

C.IV.2-2 As noted in Comment #C.IV.2.1, the regulations (specifically the DCR, IV.A.2.a and D) are understood to mean that the generic DCD is not required by regulation to be physically included in the application. However, it is fully recognized that the Staff and public must have convenient access to the current and complete generic DCD that is referenced in the COL application.

Response/ Disposition:

Accepted - actions underway with vendors and applicants to ensure reference documents available in ADAMS

- C.IV.2-2 The COL application will clearly identify the version of the generic DCD that is
- (cont'd) referenced. In the case of a certified design (by final rule), the COL application would reference the version cited in the rule. For a design in some phase of Staff review, the COL application would unambiguously cite the version of the design application currently before the Staff at the time of the COL application submittal. Given current electronic media capabilities, it is reasonable that a complete, current and checked version of the reference DCD could be available through ADAMS. In this manner, the generic DCD could be readily available to the Staff and public, on demand, similar to other documents so filed. This would preclude the need and value of physically including the referenced generic DCD with the application. While physically including the generic DCD with the application is certainly feasible, this seems to be a fully unnecessary step and adds unwarranted complexity to the already sizeable electronic submittal of the COL application itself.

Response/ Disposition:

see above

C.IV.2-3 C.IV.2.2 discusses the referencing of a design certification rule; however, C.IV.2 (in general) provides no guidance on the expected format and treatment for referencing an ESP. In addition, it is noted that Part 52 (current or proposed) does not specifically address the incorporation method for the ESP application information. The proposed 10 CFR 52.79(b) provides that COLA's referencing an ESP need not repeat information and analyses submitted to the Commission in connection with the ESP. However, in Part 52, there is no analog to the DCR appendix, which provides specific requirements regarding the incorporation of the generic DCD. Moreover, as noted in recent DG-1145 workshops, the some Staff expressed the expectation that the ESP material should be included in the application package. While the industry agrees, there is no requirement or guidance on this topic.

Accepted - added mention of ESP

C.IV.2-4 As discussed in a separate comment on C.IV.2.2, the industry interprets Part 52 and DCR to allow incorporation by reference and consider statements accompanying the AP1000 rulemaking (SECY-05-0227) to be inconsistent with DCR IV.A.2a, IV.A.3, and 52.79(b). Since SECY-05-0227, there has been confusion regarding Staff interpretations of these Part 52 regulations and allowable methods for administratively handling the reference DCD in the COLA. With the publishing of C.IV.2.2, the Staff indicated a preference for full integration of the generic DCD as an effective means to facilitate staff review. It is recognized that full integration may well be appropriate and beneficial in cases for which contextual clarity would be preserved for the reviewer. However, this circumstance is considered to be rare. Full integration will demand that the applicant and Staff take steps to confirm (or even reconfirm) that the generic DCD is faithfully reproduced in the COLA FSAR. For those DCDs subject to revisions (which to varying degrees could apply to EPR, ESBWR, and AP1000 designs), the full integration represents a number of administrative challenges. Collectively, it is possible that the Staff's stated preference may be ill advised and create an unnecessary burden for applicants and the Staff leading to, on net, a less efficient review.

Response/ Disposition:

Accepted - incorporation by reference is acceptable approach

C.IV.2-5 C.IV.2.2, in the 2nd paragraph, states: "For certain DCRs, the COL applicant must include the plant-specific DCD in its application. This means that the COL applicant should include a copy of the generic DCD (updated to include all revision pages)..." This language implies that the DCRs differ in requirements on this point. Each DCR IV.A for the four current design certification appendices contain the same language in IV.A.2.a, namely, that a plant-specific DCD must be included in the COL application referencing that DCD. The meaning of this statement in C.IV.2.2 is, therefore, unclear and/or perhaps not consistent with the Part 52 DCRs.

Response/ Disposition:

Accepted - revised text

C.IV.2-6 C.IV.2.2, 3rd paragraph states: "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 information extracted from the generic DCD from the plant-specific departures and exemptions to the DCD that the NRC will review in the COL application." Information provided in the COLA FSAR, as noted by the Staff, may originate in the referenced DCD. While not noted, information in FSAR Chapter 2 may originate as well from a referenced ESP. In addition, "new COLA information" may be presented for a variety of reasons (to address COL information items, replacement of conceptual design information, identify departures, et. al.). Thus, the need and importance of clearly identifying and distinguishing the source and purpose of information in the COLA FSAR is important regardless of whether the referenced DCD is incorporated by reference or fully integrated into the COLA FSAR. It is recommended that C.IV.2.2 be clarified on this point.

Accepted - revised text

C.IV.2-7 A COL application will comprise several submittals for a variety of reasons (some documents comprising the application will be safeguard, some proprietary, etc.). Each submittal would contain a cover letter identifying the documents and files included and their relationship to the COL application. Each submittal may also contain multiple documents and multiple CD ROMs. During the course of the review, there will likely be revisions of several of the documents which comprise the application. Clarification is needed as to the staff's definition of "document." For example, a document could be all the files submitted with a single cover letter, it could be all files contained on a single CDROM, or it could be all files comprising a stand-alone previously-paper document like an FSAR or an Environmental Report.

Response/ Disposition:

Accepted - added discussion on submission and reference documents

C.IV.2-8 "Each page should include a change indicator (e.g., a bold vertical line at the margin adjacent to the portion that has been changed) and a page change identification including either the date of change, revision, or both." The application will contain pictures and drawings for which the use of vertical line revision bars may not be practical.

Response/ **Disposition**:

Accepted - added text

C.IV.3-1 Industry Comment IV.3-4 sought confirmation that the replacement of conceptual design information did not constitute a departure (under the provisions of Design Cert. Rule VIII.B). The Staff response concurred but offered no change to DG-1145. Section C.IV.3.3.2 should be clarified to list those elements of "new COLA information" that do not constitute a departure from the certified design. The following are considered not to constitute a departure: (1) information added to address COL information items (DCD or ESP generated); (2) replacement of conceptual design information; (3) application specific information.

Response/ **Disposition**:

Agree - text changed to clarify that resolution of CDI is not a departure

C.IV.3-2 If a departure only affects the bases and not the technical specifications themselves, the departure should be evaluated under the 50.59-like change process (similar to the process for licensed plants, in which changes to the bases are evaluated under 10 CFR 50.59).

Response/ **Disposition**:

No change - bases changes described in C.IV.3.3.3 and SOC for DCR as being VIII.C

C.IV.3-3 When Section VIII.B.5 of the design certification rules was developed, it was recognized that the 50.59-like change process was not appropriate for PRA-information. Therefore, while the NRC needs to be informed of changes in the PRA information in Chapter 19 through periodic FSAR updates, such changes are not subject to the change process in Section VIII.B.5 and do not require NRC approval.

Change deferred pending future discussions on change processes for post COL (NEI-06-01)

C.IV.3-4 Clarification should be added to DG-1145 to avoid any misconception that the NRC can change the generic TS based upon the existence of operating experience alone, without complying with Section VIII.C.3 of the design certification rules.

Response/ Disposition:

accept - added text

C.IV.3-5 C.IV.3.1, second paragraph states "When a COL is issued in this scenario, the 10 CFR Parts 2, 50, and 52 change processes apply to the entire FSAR. These include, but are not limited to:" and includes within the listing "10 CFR 52.63 Finality of standard design certifications." It is not really clear how or why the change processes in 52.63 would apply to a custom design.

Response/ Disposition:

accept - deleted text

C.IV.3-6 Section C.IV.3.1, second paragraph states "When a COL is issued in this scenario, the change processes established in 10 CFR Parts 2, 50, and 52 apply to the entire final safety analysis report (FSAR). These include, but are not limited to, the following regulations:" The list does not include 50.90-92 which is a major change process applicable for making changes to an approved, issued COL.

Response/ **Disposition**:

agree - added text

C.IV.3-7 C.IV.3.3.2 indicates that departures from DCD Tier 2 information may occur in five ways. All five of the listed items specifically refer to "Appendix A" which is specific to ABWRs. This listing should be worded more generically, or it should be identified as an example. This specific reference to Appendix A continues in much of the text of this section.

Response/ Disposition:

agree - revised text

C.IV.3.3.2, second paragraph indicates that departures from DCD Tier 2 information may occur in five ways. Item (4) of the list indicates "The licensee may request NRC approval for proposed departures that do not meet the requirements in Appendix A to Part 52, paragraph VIII.B.5 (71 FR 12914), as provided in paragraph VIII.B.5.d." Additionally, B.5.e indicates that "a departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix." However, B.5.a begins with "an applicant or licensee..." It is clear from B.5.d that a licensee would request a license amendment. What process does an applicant use under B.5 for a departure from Tier 2 information that requires NRC approval? Is this simply a request to depart without having to request an exemption?

agree - added explanation of process

C.IV.3-9 C.IV.3.3.2, second paragraph indicates that departures from DCD Tier 2 information may occur in five ways. Item (5) of the list indicates "The licensee may request NRC approval for a departure from Tier 2* information under Appendix A to Part 52, paragraph VIII.B.6 (71 FR 12914)." B.6.d indicates that "departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix." However, B.6.a begins with "an applicant…" It is clear from B.6.b that a licensee would request a license amendment. What process does an applicant use under B.6 for a departure from Tier 2* information that requires NRC approval? Is this simply a request to depart without having to request an exemption?

Response/ **Disposition**:

agree - added explanation of process

C.IV.3-10 C.IV.3.3.2 provides a confusing mixture of information related to the ABWR (references to part 52, Appendix A) and the AP1000 (locations of severe accident information). This guidance information should be provided on a more generic basis.

Response/ Disposition:

agree -revised text

C.IV.3-11 C.IV.3.3.3 discusses the change processes for operational requirements as though the Section VIII processes are still "proposed." These are in the phrases "with its own change process in proposed paragraph VIII.C," then "The key to using the change processes proposed in Section VIII," and finally "Generic changes made under proposed paragraph VIII.C.1...." The word "proposed" should be removed from each of these phrases.

Response/ **Disposition**:

agree - revised text

C.IV.3-12 C.IV.3.3.3, second paragraph discusses the change processes for operational requirements and indicates "The determination of whether the generic TS and other operational requirements were completely reviewed and approved in the design certification rulemaking is based upon the extent to which an NRC safety conclusion in the FSER is being modified or changed." However, the acceptable extent to which an NRC safety conclusion might be modified or changed is not identified. Is there some change that is acceptable? If so, what criterion is used to determine if the change is acceptable or requires NRC review and approval?

Response/ **Disposition**:

no change - will require additional discussion and reviews to determine consistency of staff FSERs

C.IV.3-13 C.IV.3.3.3 states "If it cannot be determined that the TS or operational requirement was comprehensively reviewed and finalized in the design certification rulemaking, then there is no backfit restriction under 10 CFR 50.109..." However, the level of review to be considered "comprehensive" is not identified. All TS items were reviewed but many

simply state that they are consistent with the improved Standard Technical Specifications and are acceptable. Is this considered a "comprehensive" review?

Response/ Disposition:

no change - will require additional discussion and reviews to determine consistency of staff FSERs

C.IV.3-14 C.IV.3.3.3, third paragraph states "Some generic TS and investment protection short-term availability controls contain values in brackets []. The brackets are placeholders indicating that the NRC's review is not complete, and represent a requirement that the applicant for a combined license referencing the AP1000 DCR must replace the values in brackets with final plant-specific values." The generic TS in the AP1000 DCD have a COL Information Item that requires the information in the brackets to be replaced with plant specific information. However, some certified design DCDs contain no such COL Information Item for the short-term availability controls. The COL Information Item is generally to provide a procedure. Further, there is no compelling reason to replace the bracketed generic information in the short-term availability controls.

Response/ Disposition:

agree - added connection to COL Information item

C.IV.3-14 The required procedure can be written with the plant specific information without any change to the short-term availability controls section containing the bracketed material. Additionally, leaving the bracketed material would remove the need to revise the FSAR Section each time there was a minor plant specific change to the material such as position titles. Would it be acceptable to leave the bracketed material in the short term availability controls section of the DCD as bracketed generic information?

Response/ Disposition:

see above

C.IV.3-15 C.IV.3.3.3, last paragraph (and the DC rule, VIII.C.6) indicates that "the generic TS will have no further effect on the plant-specific TS after the issuance of a license that references this appendix." However, there is no such statement with regard to the "other operational requirements." Additionally, VIII.C.4 does not identify how a licensee can change the "other operational requirements," as it addresses only "applicants." Is the licensee bound to the exemption process in VIII.C.4 for changes that affect "other operational requirements" as described in the DCD for the life of the plant? If so, how does the licensee determine the full scope of the "other operational requirements" should be under the 50.59 process.

Response/ Disposition:

agree - added text to address post COL process for other operational requirements

C.IV.4-1 Table has 3 columns, does not match Table 13.4.x.

The NRC staff agrees with the comment. The table headings and example have been changed to conform to the table in Section 13.4.

C.IV.4-2 Section C.IV.4.3 of DG-1145 discusses implementation of Operational Programs. Two examples are discussed with respect to delineating license conditions, one involving Fire Protection and another involving physical security. It is not clear from the writing of Section C.IV.4.3 whether these are examples of how all implementation license conditions should be addressed, whether these are exceptions or whether these are requirements for how the license conditions for the two programs discussed must be delineated based on recent regulatory changes. This needs to be clarified.

Response/ Disposition:

In SECY-05-0197, "Review of Operational Programs in a Combined License Application and Generic Emergency Planning Inspections, Tests, Analyses, and Acceptance Criteria," dated October 28, 2005, the NRC staff recommended implementation milestones for Security and Fire Protection operational programs be included as license conditions for COLs. In addition, SECY-05-0197 recommended that implementation milestones for operational programs be included as conditions in COLs where such implementation milestones are not specified in the Regulations; DG-1145 will be updated to reflect this requirement. In addition, SECY-05-0197 recommends that a COL license condition be included to require licensees to inform the NRC regarding a schedule to support planning for the conduct of NRC inspection of Operational Programs; DG-1145 will be updated to also reflect this requirement.

C.IV.5-1 Page C.IV.5-2, insert a new second paragraph as follows:" If the applicant is a Federal agency, including a corporate agency and instrumentality of the Federal Government, the application should contain the following:• the agency's enabling legislation• the location of the agency's headquarters• the name and address of the head of the agency, including, if applicable, that of each director and principal officer of the agency"

Response/ Disposition:

agree - added text for federal agency

C.IV.6-1 Remove the requirement to specifically list in the transmittal letter the activities that the applicant is requesting to perform since it is already specified in 10 CFR 50.10.

Response/ Disposition:

deleted section on LWA pending issuance of final rule

C.IV.6-2 If the redress plan is expected to be provided in the ER, format guidance is needed. Specifically, the guidance needs to indicate where in the ER the SRP is expected to be placed.

Response/ Disposition:

agree - added reference to NUREG-1555

C.IV.6-3 Determine a better model for site redress plans. Suggest one of the ESP's currently under review

Added additional reference

C.IV.6-4 Need additional supporting information as to why LWA-2 activities are not appropriate for inclusion at ESP stage.

Response/ Disposition:

deleted section on LWA pending issuance of final rule

C.IV.7-1 C.IV.7.1.2 states: "Pre-application activities that support a COL application referencing an early site permit (ESP) should focus on the following topics:• potential deviations from the ESP" The term "deviations" should be "variances" as indicated in the response to Comment C.IV.3-3.

Response/ **Disposition**:

agree - revised text

C.IV.7-2 C.IV.7.1.3 lists the following for pre-application discussion topic "• analysis needed to support offsite power analysis with RTO" What does the staff have in mind here?

Response/ Disposition:

clarified wording

C.IV.7-3 C.IV.7.2 identifies Staff activities. This is inconsistent with the rest of the DG and with the intent of the DG. This guidance should be for the applicant (SRPs provide Staff guidance) to identify what the NRC needs/wants from the applicant in the pre application phase to support the environmental review. Response to previous comment C.IV.7.2-1 indicated that the comment would be considered but also indicated "no change" to the DG.

Response/ Disposition:

Agree - revised text

C.IV.7-4 C.IV.7.2 lists pre-application activities that support the environmental review. The NRC recently indicated (during a pre-application meeting with Southern re Vogtle ESP application) the potential for a "five-step environmental review." The context, timing, and scope of this five-step process needs to be clarified. NRC clarification requested.

Response/ Disposition:

agree - revised text

C.IV.8-1 C.IV.8 is apparently missing section number and title: C.IV.8.1 "Generic Issues"

Response/ **Disposition**:

accept - revised text

C.IV.8-2 The cited proposed regulation limits review of generic issues to those that are resolved and applicable to design. C.IV.8's guidance regarding the use of App. B, NUREG-0933 is not clear. The vast majority of issues listed in the current App. B are coded "I" or "Note 3(a)".

These notes are understood to mean that the issues have acceptable technical resolutions and that those resolutions have been incorporated into regulations or other regulatory guidance. Such issues, so coded, do not need to be addressed further under "Generic Issues." In general, for a COLA referencing a certified design, the COL applicant should address those generic issues listed in App. B (in effect 6 months...) that are technically relevant to the site-specific portions of design. In addition, the applicant must address those actions identified in the referenced DCD that are assigned to the applicant and relate to generic issues. Per the proposed regulation, the generic issue review is limited to those that are resolved. The introduction of App. B is read to understand that "Note 3(a)" and "I" issues are resolved and

Response/ Disposition:

accept - revised text

C.IV.8-2 addressed in other regulations or guidance. "Note 6" applies to future plants but represents recommendations and not requirements. Overall, the use of App. B is unclear and the guidance of C.IV.8 does not resolve this. The Staff is requested to review App. B and provide explicit guidance (in C.IV.8 or other appropriate locations in DG-1145) as to how App. B's listing is to used, particularly for a COL applicant referencing a certified design.

Response/ Disposition:

see above

C.IV.8-3 See Comment C.IV.8.2. C.IV.8 indicates that applicants should address those issues (in App. B, NUREG-0933) for which there is no entry or "TBD" in the future plants effective date. It is not clear that these are resolved generic issues which is the basic scope of the proposed Part 2.79(a)(20). The Staff should delete or explain what issues so coded should be addressed in the COL application.

Response/ **Disposition**:

accept - revised text

C.IV.8-4 The Staff has provided a very helpful (preliminary) review of NRC generic letters and bulletins to "determine whether they have been superseded by other NRC generic communications." This explanation of the review is found in C.I.1.9.4. Given that the actual review results are provided in C.IV.8, this particular explanation of the review should also be provided in C.IV.8.

Response/ **Disposition**:

superseded by rule change

C.IV.8-5 The use of the Staff's review in C.IV.8 of generic letters and bulletins (GL/B) is not fully clear. Section C.IV.8 defines of the various "exclusion codes" applied as "screening criteria" in the Staff's review. The implication is that any GL/B given an exclusion code is screened out and need not be considered further by the COL applicant. C.IV.8 should be revised to clarify the use of this table.

superseded by rule change

C.IV.8-6 The Staff has provided a very helpful (preliminary) review of NRC generic letters and bulletins to "determine whether they have been superseded by other NRC generic communications." This explanation of the review is found in C.I.1.9.4. Given that the actual review results are provided in C.IV.8, this particular explanation of the review should also be provided in C.IV.8

Response/ Disposition:

superseded by rule change

C.IV.8-7 The use of the Staff's review in C.IV.8 of generic letters and bulletins (GL/B) is not fully clear. Section C.IV.8 defines of the various "exclusion codes" applied as "screening criteria" in the Staff's review. The implication is that any GL/B given an exclusion code is screened out and need not be considered further by the COL applicant. C.IV.8 should be revised to clarify the use of this table.

Response/ Disposition:

superseded by rule change