

Comments/Suggestions Regarding NEI 04-01

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1	1-3	C		General Comment: All Pages - Interpretations of NRC rules and regulations is the domain of the NRC. If the authors intend to provide clarity in the guidance to combine license (COL) applicants, then they should not introduce alternative language. If there is no intent to change meaning, then the specific language and the specific citation should be included in the guidance as quotes and references to the Code of Federal Regulations (CFR).

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4.3.9.7	4.3.9.7-2	C	85	The implementation of the design of the plant-specific safety instrumentation and control (I&C) systems is covered by the Chapter 7 DAC/ITAAC [design acceptance criteria/inspection, test, analysis, and acceptance criteria] of the safety evaluation for the certified design. The use of DAC enables the staff to arrive at a safety determination regarding a specific aspect of the overall plant design. By designating the DAC in the design certification rule, the Commission will establish the criteria which the staff will utilize to confirm that the as-built plant conforms to the design certification. The determination that the DAC have been satisfied will be made throughout the design implementation and construction process, as part of the ITAAC program.

The NRC staff intends to perform inspections that will audit the satisfactory completion of ITAAC requirements, including the DAC. In accordance with Section 52.99, "At appropriate intervals during construction, the NRC staff shall publish in the Federal Register notices of the successful completion of inspections, tests, and analyses."

The staff will use a two-part approach for the review of advanced I&Cs. The first part will involve a detailed, functional review at the block diagram level, to ensure appropriate implementation of NRC requirements related to postulated single failures, common-mode failures, appropriate signal isolation, and other aspects of NRC review. This review will establish the detailed functional requirements for the I&C systems.

The second part of the review will address the implementation of digital control systems to meet the functional system requirements. This will rely upon a formal process with phased ITAAC for design development. The ITAAC will all be specified in the design certification rule but could be satisfied at various points in time. An early ITAAC would address the procedures to be used by the COL holder to implement an acceptable design process for digital control systems. Acceptance criteria for the various phases of the design program would be specified, such that the NRC could objectively inspect and determine whether the licensee's procedure met the ITAAC criteria. As the design is subsequently developed and implemented, subsequent ITAAC would be used to verify key steps in the development process that have been satisfactorily accomplished. Because design detail is not available in this review area, and several design implementation methods would be acceptable to the staff, the ITAAC requirements and acceptance criteria in the design certification would have sufficient flexibility to be applied to the specific final design. The applicants and the NRC will establish agreed upon review points in the design development process to verify that the implementation is proceeding in accordance with the design certification.

The review guidance provided in SRP Chapter 7, Rev. 4, 1997, will be used by the staff in review of the of the I&C system design, installation, and operation. Of particular note is the guidance in Appendix 7-A, Branch Technical Position 14 - "Guidance on Software Reviews for Digital Computer-Based I&C Systems" which applies to the plant-specific software application. The review will be done at every life-cycle stage of the I&C system software and hardware

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				<p>development process.</p> <p>Additional guidance based on the lessons learned by using the guidance of SRP Chapter 7 in the review of computer-based I&C system design implementation at Temelin (Czech Republic, Westinghouse Eagle system) and the Lungmen Project (Taiwan, twin GE ABWRs), and guidance on Cyber Security will be part of the review. The lessons learned are included in the BTP-14 revision that was transmitted to NEI by letter dated March 16, 2005. The cyber security implementation guidance is provided in NRC Regulatory Guide (RG) 1.152, Revision 2, which is in the process of being issued. (Note: The draft version of this RG is DG-1130 and is available on the NRC website.)</p>

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4.6.1	4.6.1-1	C	254	Paragraph 2 including bullets: An early site permit (ESP) proceeding includes the preparation of an environmental impact statement (EIS) addressing the environmental impacts of reactor construction and operation. The environmental issues resolved in that EIS are sufficient to take the action on the ESP and, absent new and significant information, are expected to be sufficient to be considered resolved at the COL stage. Insofar as the actual design selected may contain new information or environmental changes may occur during the intervening years, the NRC staff will determine whether the new information is significant.
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The COL environmental report (ER) must contain the information specified in 10 CFR 51.45, 51.51, and 51.52, as modified in the following. For the base case, the COL ER need not contain information or analyses submitted to the Commission in connection with the ESP, but must contain, in addition to the information and analyses otherwise required, (1) information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the ESP; (2) information to resolve any other significant environmental issue not considered in the ESP proceeding, either for the site or design; and (3) any new and significant information on the site or design to the extent that it differs from, or is in addition to, that discussed in the ESP EIS. If the base case also references a design certification, then the COL ER may incorporate by reference any environmental assessment (EA) previously prepared by the NRC staff that relates to the certified design; if the EA is referenced, then the COL ER must contain information to demonstrate that the site falls within the site characteristics analyzed in the EA.

The NRC is required pursuant to 10 CFR 51.70(b) to independently evaluate and be responsible for the reliability of all information used in the draft EIS, including an EIS prepared for a COL. In carrying out its responsibilities under 10 CFR 51.70(b), the staff will (1) determine if the information submitted for the ESP application being relied on in the COL application is still reliable and (2) will look for any new information that may affect the assumptions, analysis, or conclusions reached in the ESP EIS.

In accordance with 10 CFR 51.45, the ER should contain sufficient data to aid the Commission in its development of an independent analysis. Therefore, the ER should contain new and significant information on the site or design only to the extent that it differs from, or is in addition to, that discussed in the ESP EIS. The NRC will take the "hard look" that is fundamentally necessary under the National Environmental Policy Act (NEPA) before granting any authorization for the construction and operation of a nuclear power plant. This "hard look" will be detailed and sufficient to establish a clear record on which to base a decision.

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4.6.2	4.6.2-1	C	255	Paragraph 1: NEI-04-01 suggests that the COL applicant consider the ESP EIS as the primary source for issues deferred to the COL to supplement the ESP ER. The ESP EIS is a starting point, but the COL applicant should focus on (1) the actual design selected and whether it may contain new information and (2) whether environmental changes may have occurred during the intervening years. In the end, the NRC staff will determine whether the new information is significant.

In the base case, the ESP will have been issued based on the NRC ESP EIS, not the ESP ER. Since the ESP and the COL are not connected actions, the applicant should provide the environmental information in a COL ER to aid the Commission in its development of an independent analysis.

NEI-04-01 suggests a theory, purported as fact, that would preclude consideration of “need for power.” Albeit there is Congressional interest in energy legislation that may preclude the NRC from performing this analysis, it is not law and it is not consistent with NRC rules and regulations. This issue was fully vetted as part of the NRC’s denial of NEI’s petition for rulemaking on the matter (see 68 FR 55905). At this time, the benefits assessment need not be considered with an ESP application; if it was not considered as part of the ESP under the base case, then it is required as part of the COL application.

Finally, NEI-04-01 must focus its guidance on the requirements for COL applicants, not for the NRC staff; the guidance should only refer to the techniques available to develop the COL ER. The COL applicant can take advantage of earlier environmental analyses by using concepts such as “incorporation by reference” provided that it can demonstrate the relevance and currency of such information to meet current regulatory requirements. The “tiering” principle is for governmental agencies’ use. The NRC does not require the assistance of the COL applicant to narrow the scope of the NRC’s COL review until the scoping process begins; the NRC review will be guided by its review standards and standard review plans.

Complete text: For the base case, the COL applicant should focus on (1) the actual design selected and whether it may contain new information and (2) whether environmental changes may have occurred during the intervening years. In the end, the NRC staff will determine whether the new information is significant. The COL ER need not contain information or analyses submitted to the Commission in connection with the ESP, but must contain, in addition to the information and analyses otherwise required, (1) information to demonstrate that the design of the facility falls within the parameters specified in the early site permit, (2) information to demonstrate that the site falls within the site characteristics specified in the early site permit, and (3) information on any other significant environmental issue not resolved in a previous proceeding on the site or design, such as the assessment of the benefits (for example, need for power) of the proposed action if it had not been considered in the ESP EIS. (Notes: the NRC does not supplant the general role of State governments in assessing “need for power,” however,

under NEPA, the NRC recognizes that the granting of authority for construction and operation of a nuclear power plant would result in environmental disturbance and that there should be a purpose and need for such an action that would result in some public good. The NRC's decision will be informed by analyses performed by State governments, if such analyses exist; it is not apparent that all States perform detailed analyses. (see 68 FR 55905) The NRC is aware of interest to advance legislation to remove NRC from the process, but that is speculative at this time.) If the COL application references a design certification, then the COL ER may incorporate by reference any environmental assessment (EA) previously prepared by the NRC staff that relates to the certified design (emphasis added); if the design certification is referenced, then the COL ER must contain information to demonstrate that the site characteristics fall within the site parameters analyzed in the EA.

For disclosure purposes, the NRC intends that the draft COL EIS will bring forward the Commission's earlier conclusions from the ESP EIS and articulate the activities undertaken by the NRC staff to ensure that an issue that was resolved can remain resolved. If there is new and significant information on a previously resolved issue, then the staff will limit its inquiry to determine whether such information changes the Commission's earlier conclusion. If there is no new and significant information on an issue resolved at the ESP stage, then the staff will tier off of the ESP EIS and disclose the NRC conclusion.

Finally, NEI-04-01 guidance should focus on the requirements for COL applicants, in lieu of the equivalent RG 1.70 and R.G. 4.2 dealing with the standard format and content for safety analysis and environmental reports. For ERs, the guidance should refer to the techniques available to the applicant, such as "incorporation by reference" provided that the applicant can demonstrate the relevance and currency of such information to meet current regulatory requirements. The NRC's environmental review will be guided by review standards, such as RS-002 for ESPs, and review plans, such as NUREG-1555. Furthermore, just as applicants have to comply with NRC rules and regulations, the NRC staff must comply with its own rules and regulations; however, requirements on the applicants do not apply to the staff and requirements of the staff do not apply to applicants. The guidance needs to recognize the difference rather than blend them together.

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4.6.3	4.6.3-1	C	256	NEI 04-01 suggests that the COL applicant provide a conclusion that the final design is bounded by the ESP EIS parameters, if the design falls within the specified parameters. Certainly, the COL applicant must determine whether the final design is within the ESP EIS parameters, but the representation of that determination and the demonstration that leads to the applicant's conclusion is still subject to NRC review and assessment, particularly with respect to new information. Paragraph 1: For the base case, the NRC prepares an EIS that resolves numerous issues within certain bounding conditions. These issues are candidates for issue preclusion at the COL stage. A COL application must also demonstrate that the design of the facility falls within parameters specified in the ESP. In addition, the application should indicate whether the site is in compliance with the terms of the ESP. The information supporting a conclusion that the site is in compliance with the ESP should be maintained in an auditable form by the applicant. While the NRC is ultimately responsible for completing any required NEPA review, for example, to ensure that the conclusions for a resolved ESP environmental issue remain valid for a COL action, the COL applicant must identify whether there is new and significant information on such an issue. A COL applicant should have a reasonable process to ensure it becomes aware of new and significant information that may have a bearing on the earlier NRC conclusion, and should document the results of this process in an auditable form for issues for which the COL applicant does not identify any new and significant information.

In the context of the base case, the staff defines "new" in the phrase "new and significant information" as any information that was not contained or referenced in the ESP application or the ESP EIS. This new information may include (but is not limited to) specific design information that was not contained in the application, especially where the design interacts with the environment, or information that was in the ESP application, but has changed by the time of the COL application. Such new information may or may not be significant. The ESP EIS is starting point, but the COL applicant should focus on (1) the actual design selected and whether it may contain new information and (2) whether environmental changes may have occurred during the intervening years. In the end, the NRC staff will determine whether the new information is significant.

Pursuant to 10 CFR 51.70(b), the NRC is required to independently evaluate and be responsible for the reliability of all information used in the EIS, including an EIS prepared for a COL. In carrying out its responsibilities under 10 CFR 51.70(b), the staff may (1) inquire into the continued validity of information disclosed in an EIS for an ESP that is referenced in a COL application and (2) look for any new information that may affect the assumptions, analysis, or conclusions reached in the ESP EIS. As part of its COL environmental inquiry, the NRC staff will conduct a scoping process, communicate with governmental agencies, and conduct environmental audits so that the NRC can develop a record adequate to disclose the environmental impacts of the proposed licensing action.

For disclosure purposes, the COL EIS brings forward the Commission's earlier conclusions from

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				<p>the ESP EIS and would articulate the activities undertaken by the NRC staff to ensure that an issue that was resolved can remain resolved. If there is new and significant information on a previously resolved issue, then the staff will limit its inquiry to determine whether such information changes the Commission's earlier conclusion. Environmental matters subject to litigation in a COL proceeding mainly include (1) those issues that were not considered in the previous proceeding on the site or the design, (2) those issues for which there is new and significant information, and (3) those issues subject to the change or waiver process in 10 CFR Part 52.</p> <p>To establish a basis for the record of decision, the NRC staff will independently evaluate and be responsible for the reliability of all information upon which it relies. The NRC expects that the COL applicant will provide such information to the NRC as may be useful in aiding the Commission in complying with its responsibilities under the NEPA. Absent the COL applicant providing such information, the NRC will undertake the effort that is necessary to discharge its responsibilities.</p>
4.6.4	4.6.4-1	C	256	<p>The NRC staff looks forward to the guidance for these issues. Based on the experience gained to date, the NEI 04-01 authors should specifically address the requirements in 10 CFR 51.51 and 51.52 in the context of the necessary detail for light-water reactor (LWR) designs, which may be in substantial compliance with the parameters specified, and for other-than-LWR reactors, which, by the nature of the reactor design, do not meet the entry conditions to rely upon the analyses contained therein.</p>
4.6.5	4.6.5-3	C	256	<p>If the base case also references a standard design certification or manufacturing license), then the COL ER may incorporate by reference any EA previously prepared by the NRC staff that relates to the design certification (or manufacturing license). If the EA is referenced, then the COL ER must contain information to demonstrate that the site characteristics fall within the site parameters considered in the environmental assessment. Other than the EA associated with the design certification rulemaking, the standard design certification EA is limited to the severe accident mitigation design alternatives (SAMDA) evaluation. The SAMDA EA considered surrogate demographic information and atmospheric dilution information; the COL applicant must demonstrate that there are no unique characteristics of the site that fall outside the bounds of the earlier analyses.</p> <p>If the base case references a standard design certification and make changes to the design or requests exemptions from one or more elements of the design certification, then these actions may have some influence on the SAMDA or the severe accident risk analyses. Furthermore, an ESP may have only provided resolution on the severe accident risk analysis for one type of reactor design (for example, an LWR), but not another. Finally, SAMAs are broader than SAMDAs in that they consider factors other than the design, for example, training and operating procedures; these SAMAs are not generally considered in the design certification reviews and may not have been considered in the ESP reviews, consequently, it should be considered as new information and subject to the review of new and significant information.</p>

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4.6.6	4.6.6-1	C	257	The NRC staff looks forward to the guidance for this issue. Based on the discussions to date, the NEI 04-01 authors should specifically address the requirements of 10 CFR 50.36b in the context of the conditions that may be applied to licenses to protect the environment. For these purposes, the ESP is considered to be a license and an adequate environmental protection plan (EPP) would be necessary to undertake any authorized activities such as those pursuant to 10 CFR 52.25. The issuance of a COL will authorize construction and operation activities for one or more units. These activities are fundamentally different from those authorized, if any, under an ESP. Consequently, the ESP and the COL are expected to identify the obligations of the permit or license holder in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirements for the protection of the nonaquatic environment. In addition, the NRC staff will remain cognizant of other conditions and monitoring requirements that may be imposed on the permit or license holder in the environmental area by other agencies, for example, a State agency regarding the aquatic environment. The NRC still has obligations under statutes other than NEPA, for example, the Endangered Species Act, where the permit or license holder is expected to identify and report environmental concerns to the NRC so that the NRC can fulfill its responsibilities.
4.7	4.7-1	C	258	For the base case where the ESP did not authorize work pursuant to 10 CFR 52.25 or authorized only a subset of the range of work activities, and the COL applicant wishes to perform activities not previously considered, then the COL application must contain a redress plan pursuant to 10 CFR 52.79(a)(3). These are the circumstances where a redress plan is necessary for a COL applicant and the discussion should be put in that context to avoid confusion. The work activities already authorized by the NRC may involve infrastructure issues that (1) should be subject to NRC inspection, (2) could have unintended consequences at other operating nuclear power plants, or (3) could require other approvals, such as a State permit; as a result, the permit or license holder will be required to notify the NRC and the operator of any nearby nuclear power plant in advance of undertaking an authorized activity.

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6.4.1	6.4.1-2	C	273	<p>NEI-04-01 suggests an alternate framework predicated on a theory of connected actions, i.e., that the COL is an extension of the ESP. NEI was encouraged to articulate the bases for its position and it was provided in a letter dated February 10, 2005. This was the topic of several meetings with the staff and a response to NEI was issued on July 6, 2005. The ESP and the COL are separate major Federal actions under NEPA; a Federal action is taken with the issuance of an ESP and a separate Federal action is taken with the issuance of a COL. From an environmental perspective, the NRC's action is based on the NRC final EIS; there may very well be differences between the ESP applicant's ER and the NRC's final ESP EIS. The NRC will prepare an EIS for every COL application. The COL applicant will provide a COL ER.</p> <p>The staff considered the narrowly framed argument that there should be no re-review in a COL proceeding of environmental issues that were evaluated in issuing an ESP referenced in the COL application, the base case. A portion of the underlying bases for industry's view is not consistent with the NRC's regulations and the applicable case law interpreting the National Environment Policy Act of 1969, as amended (NEPA). In particular, inasmuch as an ESP and a COL are major Federal actions, an environmental assessment (EA) is not a sufficient environmental inquiry on which to base an action on an ESP or COL application. Accordingly, pursuant to 10 CFR 51.20, both actions require the preparation of an environmental impact statement (EIS).</p> <p>The Part 52 framework does provide for previously resolved issues. Under NEPA, the COL environmental review is informed by the EIS prepared at the ESP stage and the NRC staff intends to use tiering and incorporation-by-reference whenever it is appropriate to do so. The staff agrees that a COL applicant must address any other significant environmental issue not considered in any previous proceeding, such as those issues deferred from the ESP stage to the COL stage (e.g., the benefits assessment). The initial burden to assess newly identified information and those issues that were deferred to the COL application falls to the applicant.</p> <p>For the base case, the COL ER need not contain information or analyses submitted to the Commission in ESP ER, but must contain, in addition to the environmental information and analyses otherwise required: (1) information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit; (2) information to resolve any other significant environmental issue not considered in the early site permit proceeding, either for the site or design; and (3) any new and significant information on the site or design to the extent that it differs from, or is in addition to, that discussed in the ESP EIS. The information supporting a conclusion that the site is in compliance with the ESP should be maintained in an auditable form by the applicant. The applicant is expected to have a reasonable process for identifying any new and significant information regarding the NRC's conclusions in the ESP EIS. The staff defines "new" in the phrase "new and significant information" as any information that was not contained or referenced in the ESP application or the ESP EIS. This new information may include (but is not limited to) specific design information that was not contained in the application, especially where the design interacts with the</p>

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				<p>environment, or information that was in the ESP application, but has changed by the time of the COL application. Such new information may or may not be significant.</p> <p>If the base case also references a standard design certification or manufacturing license), then the COL ER may incorporate by reference any EA previously prepared by the NRC staff that relates to the design certification (or manufacturing license). If the EA is referenced, then the COL ER must contain information to demonstrate that the site characteristics fall within the site parameters considered in the environmental assessment.</p> <p>In summary, the environmental review process established in 10 CFR Part 51 and the body of other regulatory guidance (i.e., regulatory guides, standard review plans, review standards, and office instructions) is consistent across the types of actions taken by the NRC for power reactors. The NRC staff expects that a COL applicant will comply with the certified design regulation, if a standard design certification is referenced, and the other applicable NRC regulations at the time of the COL application, the terms and conditions of the ESP, and other Federal, State, tribal, and local statutes and regulations, licenses and permits. To establish a basis for the record of decision, the NRC staff will independently evaluate and be responsible for the reliability of all information upon which it relies. The NRC expects that the COL applicant will provide such information to the NRC as may be useful in aiding the Commission in complying with its responsibilities under the NEPA. Absent the COL applicant providing such information, the NRC will undertake the effort that is necessary to discharge its responsibilities.</p>

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- S - Suggested change to improve guidance.**
 - C - Comment NRC Staff believes needed to make guidance reflective of NRC regulations and guidance.**