

(Westinghouse) Discuss 10CFR part 52 Renewal Requirements and Expectations

- 1. 10 CFR part 52.55(a) establishes the duration of a certification to be 15 years and provides a provision for renewal in § 52.57, however, there is no provision for "recertification."**

Staff Response

The staff addressed many issues related to a design certification (DC) that was not submitted for timely renewal in a letter to Westinghouse, dated May 19, 2014, “AP600 Reactor Design Certification—Non-Acceptance of Exemption Request Regarding the Period for Submitting an Application for Renewal and Duration,” (Agencywide Documents Access and Management System [ADAMS] Accession No. ML14094A549). Where applicable, this response repeats what was stated in that letter.

As noted by Westinghouse, there are no regulatory provisions for “recertification” and therefore the use of the term could be misunderstood. Therefore, for the sake of clarity, the staff will instead use the phrase “a new DC application related to a previously certified design,” where “previously certified design” refers to a DC rule that has expired and for which a DC renewal application either was not timely submitted or, if timely submitted, was denied.

How are certifications which exceed their validity date and seeking recertification to be addressed?

Staff Response

A new DC application related to a previously certified design is treated as a new design certification application. The staff explained one possible approach for such an application in the May 19, 2014 letter, depending on the supplemental information provided by the applicant:

The staff review of a new DC application related to a previous certified design can focus on areas in which either the design or regulations have changed or where the staff has identified new information. To support a focused review by the staff, the applicant could describe in detail the differences between the original DC and a new DC application. Where the design or regulations have not changed or where the staff has not identified new information, the staff could verify that previous reviews remain applicable. This would allow the applicant and staff resources to be focused on areas with safety and regulatory significance.

For a new DC application related to a previously certified design that “regulations that have changed” it should be noted that this should include new or revised regulations (including applicable orders), new or revised guidance (SRPs, ISGs, RGs, etc.), new operating experience (GLs, BLs, GSIs, Fukushima, etc.).

In regulatory review space, does it differ from renewal?

Staff Response

A new DC application and a renewal DC application are subject to different regulations. It is possible that the staff could conduct a focused review of a new DC application related to a

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previously certified design, depending on the supplemental information provided by the applicant, as discussed in the answer to the second part of this question.

2. Does a renewal under Part 52.57 impact a COL Applicant or Holder who references the existing certified design in the license application (or license)? Is it necessary for a COL Applicant or Holder to "true up" to the "renewed design" or does the design as referenced in the COLA (COL Application) or License remain valid as is?

a. Does 10 CFR 52.63(a)(3) apply to renewals and any changes made during the renewal process such that a COL Applicant or Holder would need to revise their application or license to reflect the "renewed certification"?

Staff Response

As explained below, changes made during the DC renewal review would not automatically be imposed on COL applicants or holders referencing the originally certified design. However, if the applicable criteria in 10 CFR 52.63(a)(1) or (a)(4) are satisfied, the NRC may take independent action to impose changes on plants referencing the originally certified design.

The staff addressed many issues related to DC renewal applications in the “Advanced Boiling Water Reactor Design Certification Renewal Applications: Draft NRC Staff Views on Application Content and Draft Staff Review Guidelines” Revision 3, dated December 1, 2010, (ADAMS Accession No. ML103140050) hereafter called “ABWR Renewal Review Guidelines.” While the ABWR Renewal Review Guidelines were specifically developed for the ABWR renewal, they address a number of topics that can be applied to renewals in general.

As explained in the ABWR Renewal Review Guidelines, changes made during the DC renewal review are governed by 10 CFR 52.59 instead of the issue finality provisions in 10 CFR 52.63. Nothing in 10 CFR 52.59 requires that changes made during DC renewal be imposed on plants referencing the originally certified design. Although there is an auto-update provision in 10 CFR 52.63(a)(3), this provision, by its terms, applies only to a “modification” made under 10 CFR 52.63(a)(1). As stated above, changes during the DC renewal review are subject to 10 CFR 52.59, not 10 CFR 52.63.

Nonetheless, the NRC intends to implement design certification renewal and 10 CFR 52.59 with consideration of the policies underlying 10 CFR 52.63(a). Thus, “modifications” necessary for adequate protection or compliance – absent technically acceptable action under 10 CFR 52.63(a)(4) or (b)(1) – will ordinarily be imposed on plants referencing the originally certified design.

3. How does the Staff reconcile the requirements of § 52.57 and § 52.59?

a. § 52.57 states: "An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application; and

b. § 52.59 states: "(a) The Commission shall issue a rule granting the renewal if the design, either as originally certified or as modified during the rulemaking on the renewal, complies with the Atomic Energy Act and the Commission's regulations applicable and in effect at the time the certification was issued."

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Specifically, should § 52.57 be viewed in the context of § 52.59? Does "bringing up to date" mean modifying the application only where necessary to account for those updates necessary to address changes that would be required under § 52.63 or Part 50.109 but the regulations applicable at the time of the original certification are still controlling as stated in § 52.59?

Staff Response

The difference between 10 CFR 52.57 and 10 CFR 52.59 was set forth in the staff's understanding of the ABWR Renewal Review Guidelines." As discussed in that document, 10 CFR 52.57 establishes the requirements applicable to the *content of the application for renewal*, and is being applied by the staff to require the correction of known errors, typos, and defects and to reflect the need for a wide range of information to allow the NRC to determine if changes can be imposed under 10 CFR 52.59 as part of the renewal. By contrast, 10 CFR 52.59 establishes the criteria governing NRC approval of a renewal application, and (as stated above in the NRC staff's response to question 2) includes the applicable issue finality/backfitting restriction applicable to the NRC's renewal decision and action.

The ABWR Renewal Review Guidelines' discussion of 10 CFR 52.57 and 52.59, as they relate to the contents and review of a DC renewal application, is as follows:

Updated ABWR Design Control Document

The ABWR DC Renewal application should contain a separate ABWR DCD representing the DCD for the applicable period of renewal of the ABWR design. The content of the ABWR renewal DCD should comply with the guidelines below under *Content of Renewal DCD*.

Content of Renewal DCD

The entire ABWR DCD (i.e., the version of the ABWR DCD last approved for incorporation by reference) must be updated under 10 CFR 52.57(a) to include corrections of errors, typos, and defects (as defined in 10 CFR Part 21), which are known by the ABWR DC Renewal applicant. The ABWR DCD must also reflect any design changes (defined below.) In addition, the ABWR DCD must be updated to include the information necessary to demonstrate the technical qualification of the applicant, if different from the original applicant. Finally, the ABWR DCD must be submitted to the NRC in accordance with the current requirements for electronic document submittal in 10 CFR 52.3 and the filing requirements in 10 CFR 2.811 through 10 CFR 2.819.

For clarity, the staff considers design changes to be in three categories and accordingly refers to these three categories distinctly. The staff considers the following three categories of changes included in the ABWR DC Renewal application: *modifications, renewal backfits, and amendments*.

Modifications to the certified design are considered to be those changes that are necessitated by the requirement to update the application in accordance with § 52.57(a) [e.g., to correct known errors and defects] and § 52.59(a). Modifications must comply with the Atomic Energy Act (AEA) and the Commissions regulations applicable and in effect at the time the certification was originally issued with the

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exception of those changes proposed by the DC Renewal applicant to comply with 10 CFR 50.150, as required by § 52.59(a).

Renewal backfits to the certified design are considered to be those changes that are necessary to comply with additional requirements imposed by the NRC through application of the criteria in § 52.59(b). The NRC staff is responsible for justifying renewal backfits under this provision. However, to gain insight as to whether a change needs to be made under this criterion, additional information is being requested from the applicant pursuant to the updating requirement in 10 CFR 52.57(a) (see Additional Application Information below.)

Amendments to the certified design are considered to be those changes proposed by the DC Renewal applicant in accordance with § 52.59(c). Amendments must comply with the AEA and the Commissions regulations applicable and in effect at the time of renewal. ABWR DC Renewal applications that include amendments to the certified design are not required to address the criteria in 10 CFR 52.63, but in accordance with § 52.59(c), if the amendment request entails such an extensive change to the certified design that an essentially new standard design is being proposed, a new DC application must be submitted.

The staff intends to review the DC renewal application for the ABWR certified design to ensure that it includes updates to all topical reports, sensitive unclassified non-safeguards information (including proprietary information), and safeguards information that were incorporated by reference into the original DC. The updates must include corrections of errors, typos, and defects (as defined in 10 CFR Part 21) which are known by the ABWR DC Renewal applicant. To the extent that information incorporated by reference into the ABWR DCD contains design information that would ordinarily be placed in the DCD but for its protected status, the staff should ensure that this information has been updated to reflect any design amendments sought by applicants under 10 CFR 52.59(c), as well as any modifications to the design that the ABWR DC Renewal applicant proposes to include to meet the renewal criteria in 10 CFR 52.59(a). Additions, deletions, and any necessary changes to these referenced materials should be clearly identified.

Additional Application Information

Pursuant to the updating requirement in 10 CFR 52.57(a), the staff intends to also review the DC renewal application to ensure that it includes additional information that addresses the items below and that this additional information is submitted in addition to the updated ABWR DCD:

- i. any new and relevant information regarding the ABWR DC Renewal applicant, including, but not limited to the information required by 10 CFR 52.46;
- ii. whether there is material new information with respect to technical resolutions to high and medium priority unresolved safety issues (USIs) and generic safety issues (GSIs) addressed in the original ABWR DCR, and if the ABWR DC Renewal applicant is proposing any change to the design as a result of the material new information;

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- iii. whether there are new USIs and GSIs created/identified since the ABWR design was certified and whether the applicant is proposing any change to the design as a result of any new USI and GSI, and if no changes are proposed, the bases for the renewal applicant's determination that no change to the design is necessary;
- iv. whether there are new generic letters and bulletins issued after the ABWR design was certified and whether the applicant is proposing any changes to the design as a result of any new generic letter and bulletin, and if no changes are proposed, the bases for the applicant's determination that no change to the design is necessary;
- v. whether there is any relevant domestic and international operating experience that has been documented since the ABWR design was certified and whether the applicant is proposing any changes to the design as a result of this new information, and if no changes are proposed, the bases for the renewal applicant's determination that no change to the design is necessary.

The staff will review the additional information discussed above that is provided by the applicant to determine whether any other NRC requirements should be imposed on the certified design based on application of the renewal criteria in § 52.59(b). These criteria include: adequate protection, compliance with the regulations in effect at the time of the original certification, and cost-justified significant increase in overall protection of the public health and safety or common defense and security. The NRC staff will go through a process for determining whether imposing additional requirements on the ABWR certified design is justified, and will prepare appropriate documentation to support such a determination. For approved backfits, the NRC staff will advise the applicant of the options for resolving the issue, which include the following: (i) the applicant may submit the necessary changes to comply with the additional requirements; (ii) the NRC will recommend denial of the application unless the additional requirements are met; or (iii) the applicant may withdraw the application.

4. What standard review plans (SRPs) would be used to support a renewal, particularly in light of § 52.59?

Staff Response

The version of the SRP that is used depends on the applicable regulations governing the review. Those portions of the application subject to the regulations in effect at the time the original certification was issued would be reviewed using SRP section revisions in effect on that date. Those portions of the application subject to the regulations in effect at the time of renewal, for example amendments made to the design certification in accordance with 10 CFR 52.59(c), would be reviewed using SRP section revisions in effect on the renewal date.

This might be alternatively explained using the three categories of changes discussed in the previous response. *Modifications* are subject to the regulations in effect at the time the original certification was issued and thus would be reviewed using SRP section revisions in effect on that date. *Amendments* are subject to the regulations in effect at the time of renewal and would be reviewed using SRP section revisions in effect on the renewal date. Proposed *renewal backfits* would be reviewed under the criteria in 10 CFR 52.59(b), but information in current or former SRP revisions, and any other relevant information, may be used to inform the NRC

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staff's evaluation under 10 CFR 52.59(b). While information in the SRP may be used to inform 10 CFR 52.59(b) evaluations, the mere fact that the SRP has changed would not, by itself, be sufficient to satisfy the 10 CFR 52.59(b) criteria.

a. Demonstrating compliance to the latest SRP can be a costly exercise without benefits. Does the Staff impose any cost/benefit evaluation to the requirements of a certification or renewal before implementing or requiring changes to the previously certified design?

Staff Response

As discussed in the response to the first part of this question, the amount of the design subject to the latest SRP is largely dependent on the applicant, i.e., how many amendments the applicant chooses to make in accordance with 10 CFR 52.59(c). Section 52.59(b) identifies three criteria where the Commission may impose other requirements; only the changes imposed under 52.59(b)(3) are subject to a cost/benefit evaluation. The use of current or former SRP revisions to inform the NRC staff's evaluation under 10 CFR 52.59(b) is described in the response to the first part of this question.

5. What is the staff's current position regarding the uses of "Branches" and "Options" as described or defined by SECY 2010-0142 and FRN dated Dec 16th, 2011 (NRC-2010-0134)?

Staff Response

The staff proposed the use of "Branches" and "Options" in SECY-10-0142, "Proposed Rule: U.S. Advanced Boiling Water Reactor Aircraft Impact Design Certification Amendment (RIN 3150-AI84)," dated October 27, 2010. SECY-11-0106, "Final Rule: U.S. Advanced Boiling-Water Reactor Aircraft Impact Design Certification Amendment (RIN 3150-AI84)," dated August 4, 2011 identifies that major changes were made in the final rule in response to public comments. Therefore, the staff position regarding the uses of "Branches" and "Options" is contained in SECY-11-0106, and the associated staff requirements memorandum (SRM), dated November 1, 2011. The staff position in SECY-11-0106 was elaborated on in the *Federal Register* notice (FRN) for an amendment to the ABWR design certification that was published in the Federal register on December 16, 2011 (76 FR 78096). The FRN in Table 1, "Differences in Regulatory Treatment of Alternatives for Addressing Multiple Design Certification Suppliers" under Regulatory Feature "Summary Description of Alternative" describes "Branches" and "Options" as follows:

- One Rule with Multiple Branches: Each supplier's certified design would be contained in a single design certification rule (a single appendix to 10 CFR Part 52).
Each supplier's design is a complete design and presented as an alternative or "branch" within the rule.
- One Rule with Options: The original applicant's certified design would be contained in a single design certification rule (a single appendix to 10 CFR Part 52). An "option" represents an alternative to the specified portion(s) of the original applicant's certified design. The supplier of the option would be providing only the portion(s) of the certified design contained within the option.

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A COL referencing a design with options would obtain the total design from two (or more) suppliers: i) the main portion of the design from the original applicant (unless the COL applicant demonstrated that another entity was qualified to supply the design) and ii) the selected design option from the applicable supplier of the option.

SECY-11-0106 further elaborates on “Branches” and “Options” by stating, in part:

[T]he NRC will regard the “branches” alternative as the default for all renewals of design certifications and for major design certification amendments. Under the “options” approach, applicants seeking amendments to already certified designs must be found to be qualified to supply the limited scope of the revisions they seek. If the staff receives other limited-scope design certification amendments (similar in scope to the STPNOCA amendment request), it will consider whether the “branches” approach or the “options” approach offers the most effective and efficient regulatory option at that time based on the scope of the amendment and the specific circumstances associated with the particular application.

Table 1 in the FRN, which addresses differences in regulatory treatment of alternatives for addressing multiple design certification suppliers, provides a comparison of the “branches” and “options” alternatives for many regulatory features:

- Summary Description of Alternative
- DCD
- Identification of Applicant in Rule
- Technical Content of Application for Amendment
- Technical Content of Application for Renewal
- Submission of SUNSI (including proprietary information), and SGI (if applicable)
- Nature and Scope of NRC Safety Review – Amendment
- Nature and Scope of NRC Safety Review – Renewal
- Nature and Scope of NRC Technical Qualifications Review – Initial Supplier Approval
- Nature and Scope of NRC Technical Qualifications Review – Amendment
- Nature and Scope of NRC Technical Qualifications Review – Renewal
- Scope of Comments in Proposed Rule FRN – New Rule or Initial Approval of Branch or Option
- Scope of Comments in Proposed Rule FRN – Amendment
- Scope of Comments in Proposed Rule FRN – Renewal
- Part 21 Applicability
- Supplier Recordkeeping Responsibilities
- Mode of Referencing by COL applicant.

a. To what extent can "Branches" and "Options" be considered to accommodate variations or modifications from the primary design?

WEC Clarification: To better address the diversified needs of the Industry, and its market, consideration should be given to approving a basic design concept and allowing variations on the design as identified by the vendor and as necessary to meet industry needs. If a substantial portion of a basic design remains applicable then variations should be considered for approval as a branch or option without a complete review of previously reviewed and approved material. This approach

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would benefit from the "one issue/one review" philosophy and allow the regulator to focus on what is different.

Staff Response

The “Branches” and “Options” approaches discussed in SECY-11-0106 addresses an alternative designs or portions of a design provided by alternative suppliers, SECY-11-0106 does not consider “variations” in the design proposed by the original supplier. In addition, the “Options” approach is a limited-scope design certification amendment that would be incorporated into a “Branch” at a renewal. The staff did not consider an “Option” to be eligible for renewal, as discussed in Table 1 in the aforementioned FRN (76 FR 78096). The draft FRN was also attached to SECY-11-0106.

- Table 1, Item “Technical Content of Application for Renewal,” states under Alternative 3 in part, “(Supplier of option may not renew the DCR option. …”
- Table 1, Items “Technical Content of Application for Renewal,” “Nature and Scope of NRC Safety Review – Renewal,” and “Scope of Comments in Proposed Rule FRN – Renewal” states under Alternative 3 in part, “N/A (Supplier of option would not be allowed to renew the option)
- Table 1, Item “Nature and Scope of NRC Technical Qualifications Review – Renewal” states under Alternative 3 in part, “(supplier of option would not be allowed to renew the option unless it was incorporated into a wholesale renewal of the design certification)”

Since SECY-11-0106 does not consider “variations” in the design proposed by the original supplier, it will require additional discussion among the staff and possibly engagement of the Commission. It would help for Westinghouse or industry to clarify what specific types of design alternatives are being considered.

SECY-11-0106 describes the nature and scope of the NRC safety review for an amendment as a verification that: i) the portion of design being amended meets current applicable NRC requirements, and ii) the proposed change does not affect previous conclusions in other design areas. This is consistent with the "one issue/one review" philosophy.

6. Is there guidance regarding the number or kind of technical changes which can be made via an "amendment" or "renewal" to a "Certified Design" before the changes constitute a "new design"? For example, we believe that while there are discrete departures and amendments to the current construction projects, these are clearly still AP1000's and do not either individually or in total constitute a new design.

Staff Response

There is no guidance regarding the number or kind of technical changes which can be made via an "amendment" or "renewal" to a "Certified Design" before the changes constitute a "new design" under 10 CFR 52.59(c). One consideration the staff has discussed is, if the same facility were being licensed under Part 50, would a new construction permit be needed for the facility.

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7. What is the NRC doing to improve the Part 52 process?

- a. Current work is underway to revise R.G. 1.206 addressing COLAs. Will it be modified to more explicitly address design certifications?

Staff Response

The current staff approach regarding RG 1.206 is to expand the discussion on safety analysis report content expectations and to move this discussion to the appendices, including adding an appendix for standard design certifications:

- Appendix A – Combined License FSAR
- Appendix B – Early Site Permit SSAR
- Appendix C – Standard Design Certification FSAR
- Appendix D – Combined License FSAR for application referencing Standard Design Certification and/or Early Site Permit.

- b. Has NRC considered providing a regulatory guide to address renewals? We believe the first-of-a-kind issues raised by a design certification renewal potentially coincident with plants operating, plants under construction, and applications under review merits standalone guidance.

Staff Response

The staff is considering the development of a regulatory guide to address renewals though no specific plans have been developed. As noted above, the ABWR Renewal Review Guidelines, while specifically developed for the ABWR renewal, may in part be applied to DC renewals in general.

- How does the NRC reconcile the different expectations for design renewals & recertification with COLA & License requirements referencing different version of the same design? (ITAAC, Tier 2* and ISG-11 process)

WEC Clarification: A consistent set of regulatory requirements should be applied to design applicants, design certifications, COL licenses and Operating plants. If an issue warrants NRC prior review and approval before implementation then it should be equally applied. (ex; Tier 2* is one clear example where there appears to be inconsistent requirement for regulatory review). Use of existing regulatory tools like Part 21, Part 50 Section 50.59, Part 52 Section 52.63 and Section 8 of the Appendix in Part 52 provides adequate control and protection. In addition unless the regulation changes or a new safety issues are identified the NRC Safety Evaluation Reports should remain valid from initial certification through operations

Staff Response

The question in the bullet is not clear while the clarification does not appear to be related to DC renewals. We recommend that Westinghouse/industry focus on DC renewal issues at the meeting.

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The staff does have some ongoing initiatives with industry to clarify the implementation of 10 CFR Part 52. This includes the clarification of the Tier 2* designation and the development of standardized ITAAC. When these initiatives have resolved the key concerns, it would be useful to interact on the considerations for DC renewal. While staff can discuss the general implementation of these types of changes in a DC renewal application, the staff considers a detailed discussion of the initiatives to be outside the scope of a meeting on DC renewal.

8. What level of review should be expected for design features and analyses which remain unchanged from the original certification (whether the design certification is "currently valid" or beyond its original "validity date")?

Staff Response

Regarding a timely application for a renewal see the quotation of the ABWR Renewal Review Guidelines in the response to question 3.

Regarding a new DC application related to a previously certified design, see the response to question 1.

a. To support "renewal" or a "recertification" is it correct to assume the staff review would focus on the changes and any safety issues identified since the original certification?

Staff Response

See above response.

b. Would design changes being imposed by the Staff on a certified design undergoing renewal or recertification be limited to those which would be mandated on an operating plant via the "back-fit rule" (§50.109) or under Part 52.63 "Finality"?

Staff Response

Regarding a timely application for a renewal, the staff would apply the criteria in 10 CFR 52.59(b).

Regarding a new DC application related to a previously certified design, 10 CFR 50.109, 52.59(b), and 52.63 are not applicable. As with any new design certification review, the applicable criteria are in 10 CFR 52.54.