WordPerfect Document Compare Summary

Original document: P:\RG 1.206 draft\C.IV.2.wpd
Revised document: @PFDesktop\:MyComputer\C:\ADAMS\Cache\ML0625000060.wpd
Deletions are shown with the following attributes and color:
~~Strikeout~~, Blue RGB(0,0,255).
Deleted text is shown as full text.
Insertions are shown with the following attributes and color:
Double Underline, Redline, Red RGB(255,0,0).

The document was marked with 107 Deletions, 101 Insertions, 0 Moves.

C.IV.2. Submittal Guidance for Combined Licenses ~~(COLs)~~

The purpose of this section is to provide ~~summarized~~ information to combined license (COL) applicants ~~who reference a design certification rule (DCR) as well as on the existing~~on methods of submitting COL applications. COL applicants should also refer to U.S. Nuclear Regulatory Commission (NRC) guidance for submitting electronic documentation. The ~~information on electronic submissions discussed in this section supplements~~NRC will update the electronic submission guidance found on ~~the NRC's~~its public Web site ~~at http://www.nrc.gov/site-help/eie/ guid-elec-submission.pdf~~as appropriate to reflect new conventions and best practices for the electronic submittal of COL applications.

C.IV.2.1 *Background*

~~The NRC staff is issuing this guidance to provide additional information on the procedures that an applicant should follow to submit documentation necessary for the licensing process. This section includes guidance on referencing a certified design in the COL application as well as a brief description of the documentation needed in a COL application if a DCR is not referenced (See Figure C.IV.2.1-1), if a DCR is referenced (See Figure C.IV.2.1-2), and if a DCR and an early site permit (ESP) are referenced (See Figure C.IV.2.1-3). This section also addresses electronic submissions of license applications, related documentation, and submission of subsequent revisions.~~

In accordance with the provisions of Title 10, ~~Part~~Section 52.3, of the *Code of Federal Regulations* ~~(10 CFR Part 52),~~(10 CFR 52.3), all correspondence, reports, applications, and other written communications from an applicant, licensee, or holder of a standard design approval ~~(person) shall submit licensing documentation to the NRC by mail or electronically, where applicable~~to the NRC concerning regulations, individual license conditions, or the terms and conditions of an early site permit (ESP) or standard design approval must be sent either by mail to the NRC's Document Control Desk or, where practicable, by electronic submission (e.g., CD-ROM). Table C.IV.2.2-1 ~~depicts the documents required by regulation and their respective addressees.~~summarizes the distribution requirements for specific correspondence, given in 10 CFR 52.3(b).

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Table C.IV.2.2-1. Submission of Documentation per 10 CFR 52.3

Type of Submission	Addressees and Copies (CD-ROM or paper)	Regulation(s)
Application for amendments of permits and licenses~~;~~, reports~~;~~, and other communications	NRC~~'s~~ Document Control Desk (if on paper, signed original) 1 copy to the appropriate ~~R~~regional ~~O~~office 1 copy to the ~~R~~resident ~~I~~inspector, if applicable~~52~~ (to be provided under oath or affirmation)	10 CFR 52.3(b)(1) 10 CFR 50.30
Application~~s~~ and amendment~~s~~ to application~~s~~	NRC~~'s~~ Document Control Desk (if on paper, signed original) 1 copy to the appropriate ~~R~~regional ~~O~~office 1 copy to the ~~R~~resident ~~I~~inspector, if applicable~~52~~ (to be provided under oath or affirmation)	10 CFR 52.3(b)(2) 10 CFR 50.30
Acceptance review application	NRC~~'s~~ Document Control Desk (if on paper, signed original) 1 copy to the appropriate ~~R~~regional ~~O~~office	~~52~~10 CFR 52.3(b)(3)
Security plan and related submissions	NRC~~'s~~ Document Control Desk (if on paper, signed original) 1 copy to the appropriate ~~R~~regional ~~O~~office	~~52~~10 CFR 52.3(b)(4)

Type of Submission	Addressees and Copies (CD-ROM or paper)	Regulation(s)
Emergency plan and related submissions	NRC's Document Control Desk (if on paper, signed original) 1 copy to the appropriate Rregional Ooffice 1 copy to the Rresident Iinspector, if applicable	52 10 CFR 52.3(b)(5)
Updated FSAR	NRC's Document Control Desk (if on paper, signed original) 1 copy to the appropriate Rregional Ooffice 1 copy to the Rresident Iinspector, if applicable	52 10 CFR 52.3(b)(6)
Quality assurance-related submissions	NRC's Document Control Desk (if on paper, signed original) 1 copy to the appropriate Rregional Ooffice 1 copy to the Resident Inspector, if applicable	52 10 CFR 52.3(b)(7) [50 10 CFR 50.54(a)(3) or 50 10 CFR 50.55(f)(3)]
Certification of permanent cessation of operations	NRC's Document Control Desk (Submission must beto be provided under oath or affirmation)	52 10 CFR 52.3(b)(8)
Certification of permanent fuel removal	NRC's Document Control Desk (Submission must beto be provided under oath or affirmation)	52 10 CFR 52.3(b)(9)

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C.IV.2.2 *Referencing a Design Certification Rule*

The or Early Site Permit

In accordance with the applicable design certification rule (DCR), the COL applicant must include the plant-specific design control document (DCD) in its application. The plant-specific DCD, as defined in the design certification rules which are set forth in the appendices to 10 CFR Part 52Section II.C of the DCRs, is a combination of the generic DCD and the plant--specific departures and exemptions from the generic DCD. 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. For example, when a COL applicant is required to include the DCD for the certified design that it references in its application, the NRC expects that the COL applicant provide a copy of this DCD with its COL application upon submittal.

For certain DCRs, the COL applicant must includeHowever, in accordance with 10 CFR 52.79(d), the plant-specific DCD in its application. This means that the COLmay incorporate the generic DCD by reference.[1] To facilitate staff review and support features such as hyperlinks between electronic files, the applicant should include a copy of the generic DCD (updated to include all revision

[1] The statements of consideration for the design certification rules issued before the date of this regulatory guide may have precluded incorporation by reference of the generic DCD because of NRC concerns about the availability of controlled copies of the generic DCD. If the entirety of the generic DCD, updated to reflect the revision certified by the NRC, is provided to the NRC and is subsequently made available in ADAMS, the NRC will work with applicants planning to reference those DCDs to support incorporation by reference.

~~pages), the plant-specific departures and exemptions from the generic DCD, as well as the plant-specific information, siting information, and operational programs in the FSAR of~~identify the actual generic DCD (complete and current to the revision referenced in the COL application) as a reference document when an electronic medium is used for the COL application. ~~COL applicants should not expect the NRC to use the generic DCD submitted to support the design certification review in their~~When an application includes hyperlinks to the DCD and other reference documents, these files should be the files within the NRC electronic recordkeeping system, the Agencywide Documents Access and Management System (ADAMS). Likewise, a COL application may incorporate by reference documents related to an ESP, and the electronic applications may include hyperlinks to the ESP references in ADAMS.

The NRC recommends that COL applicants facilitate NRC review of COL applications. ~~One acceptable method to facilitate NRC review is to~~For example, the applicant may integrate the generic DCD into the final safety analysis report (FSAR) included in the COL application. ~~While this is not the only~~This can be accomplished by inserting actual portions of the generic DCD into the FSAR or, if using electronic submittals, by providing hyperlinks from the COL application to the appropriate section of generic DCD. While an applicant may use other means to include the generic DCD in the COL application, ~~it~~this method will provide the NRC technical reviewer with a complete description of the area of review in ~~context with the complete discussion on the subject. If a COL applicant does integrate~~the COL application and ready access to the related discussions in the generic DCD. Regardless of the incorporation approach selected for referencing the generic DCD in~~to~~ the FSAR ~~submitted with the COL application~~, the ~~applicant is~~agency strongly ~~encouraged~~encourages the applicant to clearly distinguish information ~~extracted~~quoted directly from the generic DCD from the plant-specific departures and exemptions to the DCD that the NRC will review in the COL application. In addition, site~~-~~-specific information and operational programs should also be distinguished from the generic DCD. ~~While integration of the generic DCD into the FSAR of~~Applicants are encouraged to clearly identify the information provided in the application, including the FSAR, in terms of its role in addressing COL information items, proposing departures or variances, replacing conceptual design information, and supplementing information provided in a DCD or ESP. Likewise, the agency encourages applicants to clearly identify information that is specific to the subject application and information that is referencing or will be referenced by another COL application (e.g., reference or standard information).

The staff anticipates that, as described in 10 CFR 52.55(c), some COL applications will reference a design for which a design certification application has been docketed but not granted. Such COL applications may use the above guidance to incorporate by reference the DCD under review by the NRC and clearly indicate relevant departures, COL information items, and other information correlating the application to the proposed design. The NRC staff, design certification applicant, and COL applicant will need to closely coordinate their activities related to the reviews of the proposed design and COL applications. In some cases, it may be appropriate for a COL applicant to submit a revision of major COL documents (e.g., the FSAR) to reflect intermediate revisions to the DCD. The COL applicant should at least submit a letter following each revision of the referenced DCD to supplement the COL application and acknowledge the related activities in the design review. In all cases, the COL applicant should submit a revision to its application, including the FSAR and other affected documents, upon the completion of the NRC's review and certification of the referenced design.

The agency expects some COL applications to reference DCRs for which an amendment to the applicable design certification has been requested but not yet granted by the NRC. There are three options available to COL applicants in such cases and the decision on which option to choose will depend on the specific circumstances related to the DCR and COL applications.

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- The COL applications may be prepared based on the expected outcome of the rulemaking related to the proposed changes to the DCD under review by the NRC. This approach is similar to the above approach for cases involving a new design certification application.

- The COL applications may be prepared independent from the petition to revise the DCR. The outcome of the rulemaking could then be addressed by an amendment to the COL application or as otherwise required by the provisions of change processes related to maintaining the relationship between generic and plant-specific DCDs.

- COL applications may include within the identified departures from the existing DCR those changes related to the requested amendment to the DCR. The report regarding departures from the certified design may refer to the request for an amendment to the certified design. In this way, the COL application may present some challenges to the applicant, the NRC believes that the review of the FSAR included in the COL application will be more efficient. In addition, for requirements on submittingthen incorporate by reference the DCD under review by the NRC. Within the FSAR and other parts of the application, the COL applicant may correlate the proposed departures, COL information items, and other information to the NRC regarding updates to a DCD that has been referenced in aversion of DCD under review by the NRC.

As mentioned above, there are several ways to handle the coordination of activities related to the reviews of the DCD and COL application,applications. The COL applicants are directed to Section X.B.3 of the appendix to 10 CFR 52 that is applicable toapplicant should submit a revision to its application, including the FSAR and other affected documents, upon the NRC issuing a decision on the request to amend the referenced certified designdesign certification.

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C.IV.2.3 ***Electronic Submissions***

Effective January 1, 2004 (Volume 68, page 58792, of the *Federal Register* (68 FR 58792)), the NRC amended its rules regarding electronic submissions in order to implement the Government Paperwork Elimination Act (GPEA). As stated in this final rule, entitled "Electronic Maintenance and Submission of Information" (e-rule),Information," the NRC issued specific guidance on acceptable procedures for electronic submissions. SinceBecause electronic technology is evolving, the staff laid out specific guidance in a document that can be updated as necessary to reflect new technology and experience. This guidance, entitled "Appendix A: United States Nuclear Regulatory Commission (NRC) Guidance for Electronic Submissions to the Commission" (Appendix A) (from now on referred to hereafter as "thethe Guidance Document"), which is posted on the NRC's public Web site at http://www.nrc.gov/site-help/eie/guid-elec-submission.pdf, superscedes previous information for electronic submissions under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and the proposed 10 CFR Part 52. Forms used to submit information electronically are available on the NRC's public Web site at http://www.nrc.gov/site-help/eie.html. The purpose of this section is to address file format, file size, submission of revised information, submission using CD-ROM, and submission of portable document file (PDF) documents, which specific guidance information is included in the e-rule issued in 68 FR 58792. The applicant or licensee should refer to the e-rule when submitting information electronically.

For persons applying for a COL for nuclear power plants, the proposed .

10 CFR 52.3 addresses electronic submissions in a general manner~~. The applicant can submit documentation via Electronic Information Exchange, e-mail, or CD-ROM and these submissions should be in a manner that allows the NRC staff to receive, read, authenticate, distribute, and archive the information. The documentation should be submitted in a manner that allows the NRC to process and retrieve the submission one page at a time~~ for COL applicants. The NRC Guidance Document specifically addresses COL applications and describes an acceptable protocol to provide new or revised documents, reference documents available in ADAMS, and a companion file to describe the content of the CD-ROM or DVD. COL applicants should use the process described in the Guidance Document ~~to the final e-rule~~ when submitting documents to the NRC in electronic format.

~~**C.IV.2.3.1 File Format**~~

~~The applicant should submit documents using the file format guidelines provided in the Guidance Document. The NRC has standardized the use of Portable Document Format (PDF) files to store official agency records. The NRC staff performs a review before accepting electronic submissions to verify that the files conform to the published guidance.~~

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~~**C.IV.2.3.2 File Size**~~

~~The Guidance Document to the e-rule summarizes size limitations for submitting electronic files. These limitations primarily relate to the end user's ability to access or download files from the NRC's Agencywide Documents Access and Management System (ADAMS) or the Internet.~~

C.IV.2.~~3.3~~4 ***Submission of Revised or Additional Information***

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During the licensing process, the ~~NRC~~applicant may ~~receive~~submit various revisions of COL applications, or portions thereof, as the review progresses. The Guidance Document ~~to the e-rule~~ provides information regarding the process to submit changes to electronic documents. ~~If the applicant elects to submit changes, each document (including all of the electronic files and electronic objects that comprise the document) should be submitted in its entirety, preferably on a CD-ROM~~For electronic submittals, applicants submit a complete revised document (e.g., a FSAR) even if it has only revised portions of the document. If the revised document includes hyperlinks to other documents within the COL application and those documents are not being revised (e.g., revised FSAR with hyperlinks to same generic DCD), the referenced documents may be identified as reference documents on the CD-ROM or DVD and are not be entered as new records into ADAMS (even if the CD-ROM or DVD includes the reference documents). The updated version of a document should include a list of changes ~~to~~from the previous version. 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.~~

~~**C.IV.2.3.4 Submission Using CD-ROM**~~

~~Electronic submittals on CD-ROM are acceptable to the NRC staff. The Guidance Document provides instructions for CD-ROM submissions to the NRC. The files on the CD-ROM must not be locked or password protected. The applicant may submit the COL FSAR, design control document (DCD), and site SAR (SSAR) as separate PDF files on the same CD-ROM.~~

~~**C.IV.2.3.5 Submission of PDF Documents**~~

~~In order to decrease the possibility of rejection of an application, or related documentation, when it is submitted electronically, the applicant should open the PDF document and verify that the PDF document meets NRC's submission requirements. The applicant may use the verification process delineated in http://www.nrc.gov/site-help/eie/pdf-doc-submittal-checklist.pdf.~~

~~C.IV.2.4 *References*~~

~~*Federal Register*, "Electronic Maintenance Submission of Information; Final Rule" (e-rule), 68 FR 58792, October 10, 2003, available on the NRC's public Web site at http://www.nrc.gov/site-help/eie/10cfr1.pdf.~~

~~*Federal Register*, "Licenses, Certifications, and Approvals for Nuclear Power Plants; Proposed Rules," 71 FR 12782, March 13, 2006. U.S. Nuclear Regulatory Commission, "Electronic Submittals — Electronic Information Exchange," Washington, DC, available on the NRC's public Web site at http://www.nrc.gov/site-help/eie.html.~~

~~U.S. Nuclear Regulatory Commission, "Appendix A: United States Nuclear Regulatory Commission (NRC) Guidance for Electronic Submissions to the Commission" Washington, DC, available on the NRC's public Web site at http://www.nrc.gov/site-help/ eie/guid-elec-submission.pdf.~~

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~~Figure C.IV.2.1-1. Information Requirements~~ number, or both. Alternative means may be acceptable when designating changes to drawings and pictures.

In addition to the initial COL application and the revision of major parts of the application such as the FSAR, the licensing process will likely involve general correspondence, responses to requests for additional information, and other submittals. The agency expects that the supplemental submittals will involve a combination of electronic information exchange, additional CDs or DVDs, and paper correspondence. Applicants should follow established requirements and practices to ensure that these various submittals are addressed in accordance with 10 CFR 52.3 and include the docket number and subject, and that copies are provided to the NRC project manager. The agency has adopted the specific requirements for ~~an Application Referencing Neither a Design Certification Rule nor an Early Site Permit Figure C.IV.2.1-2. Information Requirements for an Application Referencing a Design Certification Rule Figure C.IV.2.1-3. Information Requirements for an Application Referencing a Design Certification Rule and an Early Site Permit~~ submitting documents directly related to the hearing process given in 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders."

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