

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
OFFICE OF NEW REACTORS
WASHINGTON, DC 20555-0001

May 24, 2010

**NRC REGULATORY ISSUE SUMMARY 2010-05
APPLICABILITY OF 10 CFR PART 21 REQUIREMENTS TO APPLICANTS FOR
STANDARD DESIGN CERTIFICATIONS**

ADDRESSEES

All holders of and applicants for an early site permit, combined operating license (COL), manufacturing license, and standard design approval; and applicants for a standard design certification under the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to clarify the agency's regulatory position regarding the applicability of 10 CFR Part 21 requirements to standard design certification or design certification rule (DCR) applicants (hereafter referred to as DCR applicants) before and after the DCR is issued by the NRC. This RIS requires no action or written response on the part of addressees.

BACKGROUND INFORMATION

The regulations in 10 CFR Part 21 establish procedures and requirements for implementation of Section 206 of the Energy Reorganization Act (ERA) of 1974, as amended. Section 206 applies to any individual or responsible officer of a firm "constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated" by the NRC.

The statements of consideration that accompanied the final rule for 10 CFR Part 52 (3150-AG24), published in the *Federal Register* on August 28, 2007 (72 FR 49352), clarified the applicability of various requirements to each of the licensing processes in 10 CFR Part 52, including how Section 206 reporting requirements and, therefore, the provisions of 10 CFR Part 21, should be extended to early site permits, standard design certifications, and combined licenses. As indicated in the statements of consideration for the 2007 conforming changes to 10 CFR Part 52 Final Rule; the NRC's reporting requirements in 10 CFR Part 21, as applicable to Part 52 licensing and approval processes, are consistent with three key principles as described below.

The first principle ensures that the regulatory requirements of Section 206 of the ERA extend throughout the entire "regulatory life" of a standard design certification. The NRC considers "regulatory life" as the period of time in which a standard design certification needs to meet the

regulations in effect. This period begins when an application is docketed and ends at the later of: (1) the termination or expiration of the standard design certification; or (2) the termination or expiration of the last license, directly or indirectly, referencing the standard design certification. Section 206 of the ERA applies whenever necessary to support effective NRC decision-making and regulatory oversight of the referencing licenses and regulatory approvals.

The second principle ensures that the NRC, its licensees, and license applicants receive information on defects or failures to comply at the time when the information would be most useful to: (1) the NRC in carrying out its regulatory responsibilities, and (2) the licensee or applicant when engaging in activities regulated by the NRC. Under the 10 CFR Part 52 licensing process, the NRC requires immediate reporting throughout the period of pendency of an application, be it for a license or a standard design certification. This reporting obligation must be extended to contractors and subcontractors supporting an application with services that are basic components (i.e., safety-related) and could be relied upon in the siting, design, and construction of a nuclear power plant. However, the NRC considers that DCR applicants may delay the reporting of a defect or failure to comply if there is no immediate consequence or regulatory interest in prompt reporting. For those Part 52 processes (e.g., early site permits, design approvals, and design certifications) which do not authorize continuing activities required to be licensed under the Atomic Energy Act or the ERA, but are intended solely to provide early identification and resolution of issues in subsequent licensing or regulatory approvals, the reporting of defects or failures to comply associated with substantial safety hazards may be delayed until the time that the Part 52 process is first referenced. After referencing, the DCR applicant must make the necessary notifications to the NRC as well as provide the necessary corrections to the final design.

The third principle ensures that entities conducting activities under 10 CFR Part 52 accurately fulfill their reporting obligation in a timely manner with the development and implementation of procedures and practices. This principle is consistent with the current requirements in 10 CFR Part 21 in that licensees, license applicants, and other entities seeking a design certification must have contractual provisions with their contractors, subcontractors, consultants, and other suppliers which notify them that they are subject to the NRC's regulatory requirements on reporting and the development and implementation of reporting procedures.

SUMMARY OF ISSUES

Based on questions raised by applicants for combined licenses and design certifications, the NRC staff developed this RIS to clarify the NRC's position on how and when a DCR applicant notifies the NRC of a defect or failure to comply in order to meet the notification requirements established in 10 CFR Part 21.

Issue 1: Under 10 CFR Part 21, when does a DCR applicant have to notify the NRC of "Part 21 defects or failures to comply" on information provided in a COL application that referenced the DCR applicant's certified design?

The DCR applicant has a current obligation under 10 CFR Part 21 to report to the NRC any identified defect or failure to comply within its scope of supply that could create a substantial safety hazard. This obligation exists even if the COL applicant did not actually contract with the DCR applicant to provide further design and engineering for the standard design certification. As stated in the second key principle of reporting under Section 206 of the ERA, the reporting obligation of a DCR applicant under 10 CFR Part 21 continues until the termination or expiration

of the standard design certification; or until the termination or expiration of the last license referencing the DCR applicant's design certification.

Issue 2: If a DCR applicant states that it addressed all potential 10 CFR Part 21 defects in a recent revision of the Design Control Document (DCD) or in a COL application that references the DCD, does it also have to make a specific 10 CFR Part 21 notification to the NRC, or can it assert that the NRC has been adequately informed about the defects?

A DCD revision by itself does not satisfy the reporting requirements of Part 21. 10 CFR 21.21(d)(3) and 10 CFR 21.21(d)(4) set forth the form and content of the required notification. Consistent with the second principle of reporting under Section 206 of the ERA, if the referenced revision to the DCD or COL application did not include the information required by 10 CFR Part 21, then the reporting requirement has not been satisfied.

Issue 3: If issues identified in a standard design certification rise to the level of a 10 CFR Part 21 notification, does the DCR applicant have to notify a COL applicant or holder referencing that design certification in addition to the NRC, even though the DCR applicant no longer has a contract with the COL applicant?

The DCR applicant is required to notify a COL applicant or holder only if (1) the DCR applicant either has or had a contract with the referencing COL applicant/holder and (2) the DCR applicant has identified a deviation or failure to comply with its design certification and it does not have the capability to determine if it is a defect or failure to comply as defined in 10 CFR Part 21. If the DCR applicant is unable to determine whether the deviation is a defect or failure to comply, then it must inform the COL applicant or holder referencing the design certification of the identified deviation or failure to comply in accordance with § 21.21(b). This is consistent with the third principle. The notification must be provided within five working days of this determination so that the affected entities may evaluate the deviation or failure to comply.

However, if the DCR applicant has determined that the deviation constitutes a defect or failure to comply, then the applicant need only report the defect or failure to comply to the NRC under § 21.21(d). The DCR applicant should consider whether notification to purchasers (even if there is no longer a contract in effect with the purchasers) needs to be part of the corrective action that the supplier is required to describe in the notification to the NRC under 10 CFR 21.21(d)(4)(vii) and 10 CFR 21.21(d)(4)(viii).

Issue 4: Does the COL applicant or holder have to notify the DCR applicant of any deviation, defect, or failure to comply that it finds even if there is no contract between the COL applicant and the DCR applicant?

No. The COL applicant does not have a duty under 10 CFR Part 21 or 10 CFR 50.55(e) to notify the DCR applicant of any deviation, defect, or failure to comply that the COL applicant finds in the certified or approved standard design. In this circumstance, the COL applicant is not supplying a basic component to the DCR applicant. Consistent with the third principle, the COL applicant's only duty under Part 21 or 10 CFR 50.55(e) is to notify the NRC of the defect or failure to comply.

BACKFIT DISCUSSION

This RIS provides regulatory clarification on information collection and reporting requirements in 10 CFR Part 21. Information collection and reporting requirements are not subject to the

provisions of the Backfit Rule, 10 CFR Part 50.109 or comparable backfitting requirements in 10 CFR Part 52. In addition, this RIS does not present a new or different staff position about the implementation of 10 CFR Part 21, "Reporting of Defects and Noncompliance," within the definition of "backfitting" in either the Backfit Rule or comparable provisions in Part 52. The staff positions for this RIS are either taken from, or represent the logical extension of, the discussion of Part 21 obligations for design certification applicants presented in the statement of considerations that accompanied the final rule (3150-AG24) for Part 52 (72 FR 49352; August 28, 2007).

This RIS requires no action or written response by addressees. Any action that addressees take to implement changes to their 10 CFR Part 21 programs in accordance with the clarifications in this RIS is strictly voluntary, and therefore does not constitute backfitting. For these reasons, the Backfit Rule does not apply and a backfit analysis is not required for issuance of this RIS.

FEDERAL REGISTER NOTIFICATION

Although this RIS is informational and does not represent a departure from current regulatory requirements, a notice of opportunity for public comment on this RIS was published in the *Federal Register* (75 FR 14212) dated March 24, 2010. There were no public comments in response to the *Federal Register* posting.

CONGRESSIONAL REVIEW ACT

This RIS is a rule as designated in the Congressional Review Act (5 U.S.C. §§ 801–808). The Office of Management and Budget (OMB) has determined this is not a major rule.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing information collection requirements were approved by the OMB, control numbers 3150-0035, 3150-0011 and 3150-0151.

PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

CONTACT

Please direct any questions about this matter to the technical contacts listed below.

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Note: NRC generic communications may be found on the NRC public Web site,
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