

August 16, 2007

Mr. Russell J. Bell, Director
New Plant Licensing
Nuclear Generation Division
Nuclear Energy Institute
1776 I Street, NW, Suite 400
Washington, DC 20006-3708

Dear Mr. Bell:

I am responding to your letter dated July 16, 2007, and to related comments from a public meeting held on August 9, 2007, concerning the nuclear industry's proposed approach to satisfy the requirement in 10 CFR 52.79(a)(44) that a combined license (COL) applicant describe its 10 CFR Part 26 Fitness for Duty (FFD) program in the COL application's Final Safety Analysis Report (FSAR).

You propose in your letter that COL applicants use the following language in Section 13.7 of a COL application's FSAR:

A Fitness for Duty (FFD) program is implemented and maintained to meet the requirements contained in 10 CFR Part 26. The FFD program complies with the FFD requirements contained in 10 CFR Part 26 at the new plant construction site during both the construction and operating phases of the nuclear unit. This program will be implemented at the new plant construction site prior to construction of safety- and security-related structures, systems, and components.

You state that a COL applicant's description of its FFD program can be very brief because the current Part 26 "contains uniquely prescriptive FFD requirements for both the construction and operational phases." You also remark that the new Part 26 "will be even more prescriptive, at least for the operational phase."

First, as the NRC staff noted at the August 9 public meeting: the new Part 26 is not yet in effect, and COL applicants are not required to address it until it goes into effect. Nevertheless, the NRC agrees that the new Part 26 for the reactor's operating phase will be very prescriptive and concludes that FSAR Section 13.7 language stating the applicant's commitment to implement an FFD program that will comply with the new Part 26 for the reactor's operating phase would satisfy the 10 CFR 52.79(a)(44) requirement.

For an applicant's FFD program for construction under the new Part 26, the description requirement could be met by a reference to NEI 06-06, Rev. 1, "Fitness for Duty Program Guidance for New Nuclear Power Plant Construction Sites;" a reference to a regulatory guide if the NRC develops one; or a full description of the program. The Commission explained in SRM-SECY-04-0032, dated May 14, 2004, that a program is

considered “fully described” when “the program is clearly and sufficiently described in terms of the scope and level of detail to allow a reasonable assurance finding of acceptability. Required programs should always be described at a functional level and at an increased level of detail where implementation choices could materially and negatively affect the program effectiveness and acceptability.”

If an applicant references NEI 06-06 while that document is being reviewed by the Commission for endorsement, then the applicant should indicate that NEI 06-06 is under review by the Commission and reference the NRC’s Agencywide Documents Access and Management System (ADAMS) accession number of NEI 06-06. All applicants referencing a generic document such as NEI 06-06 should provide, as appropriate, additional site-specific information. Near-term applicants also need to be aware of the risks of using NEI 06-06. They should ensure that NEI 06-06 provides a full program description because they will be relying on an industry document that has not been reviewed yet by the NRC. Essentially, such applicants will be in the same position as an applicant using its own program description. Also, if the NRC does not endorse NEI 06-06, applications will have to be amended to provide the full description of the applicant’s FFD program for construction. If NEI 06-06 is endorsed by the NRC and the endorsed version differs from the version referenced in the COL application, applicants will need to amend their applications to reflect the revised document. In addition, if the NRC endorses NEI 06-06, the NRC will need to write a safety evaluation on the FFD program description provided in the COL application before issuing a license.

Regarding the current Part 26, the NRC has determined that the proposed language for FSAR Section 13.7 would not meet the requirement of 10 CFR 52.79(a)(44) under the current Part 26 because the current Part 26 is not as prescriptive as the new Part 26 is expected to be. Applicants could meet the requirements of 10 CFR 52.79(a)(44) for the current Part 26 with a full description of: (1) an existing FFD program at the same site as the proposed reactor(s); (2) an existing FFD program used by a licensee within the same corporate family as the applicant; or (3) the following 10 points:

- (1) How the FFD program personnel responsibilities will be assigned by the licensee and implemented within the licensee’s organizational units;
- (2) The estimated number of persons to be assigned to implement the FFD program;
- (3) The general educational and experience requirements for positions or classes of positions necessary to implement the FFD program;
- (4) FFD program equipment maintenance and calibration procedures;
- (5) Quality assurance procedures for operations and maintenance of FFD program equipment;
- (6) Training of supervisors, escorts, and FFD program personnel;
- (7) Random drug and alcohol testing rates;
- (8) The drugs the licensee will test for and the cutoff level for each of these drugs;
- (9) The alcohol testing cutoff level; and
- (10) Procedures for establishing which substances the licensee will test for, other than the substances required by 10 CFR Part 26

A fourth option for meeting the requirements of 10 CFR 52.79(a)(44) for the current Part 26 exists. Compliance with the provisions of the December 2006 version of the new Part 26 (ADAMS Accession No. ML062550263) would satisfy most requirements in the current Part 26. Thus, an applicant could submit the text of the new Part 26, minus the

few provisions that conflict with the current Part 26 (e.g., the use of oral fluids for initial alcohol testing), and describe how the applicant would meet those provisions of the current rule that would not be satisfied by compliance with the new rule.

Notwithstanding the option chosen by the applicant, the program description must include implementation milestones (e.g., the FFD program for the reactor's operational phase will be implemented before the receipt of special nuclear material in the form of fuel assemblies).

To comply with the current Part 26 requirements for an entity performing NRC-authorized construction, this entity must comply with the current Part 26 requirements for an operating licensee. Therefore, an applicant's FFD program description under the current Part 26 should be the same for a reactor's construction and operating phases.

During the August 9, 2007, public meeting, the industry asked whether a COL applicant could request an exemption from the requirement of 10 CFR 52.79(a)(44) to describe the applicant's FFD program under the current Part 26. The NRC's response is that the NRC would have to consider any exemption request and the basis for the request in accordance with the applicable standards in the NRC's regulations.

One commenter at the public meeting mentioned that the NRC had previously informed the industry that COL applicants could seek exemptions from the requirement to fully describe FFD programs under the current Part 26. The NRC believes that in past public meetings, stakeholders and NRC staff discussed the possibility of an applicant seeking an exemption from the current Part 26 while requesting NRC authority to conduct certain activities under a limited work authorization pursuant to the current 10 CFR 50.10(e). The NRC is not aware of any previous public discussions concerning COL applicants seeking exemptions from the current Part 26.

The NRC looks forward to continuing to work with the industry and stakeholders to further develop guidance for COL applicants.

Sincerely,

/RA/

William D. Reckley, Branch Chief
Guidance, Rulemaking and Advanced
Reactor Branch
Division of New Reactor Licensing
Office of New Reactors

cc: see attached list

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