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

Sept XX, 2009

NRC REGULATORY ISSUE SUMMARY 2009-08
PROCESS FOR TEST CONTROLS ASSOCIATED WITH PERFORMING INITIAL VALIDITY TESTS AND DRUG TESTS DESCRIBED IN 10 CFR PART 26, SUBPART F

ADDRESSEES

All holders of operating licenses for nuclear power reactors under the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

All holders of nuclear power plant construction permits and early site permits with a limited work authorization (LWA) and applicants for nuclear power plant construction permits that have an LWA under the provisions of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

All holders of a combined license (COL) for a nuclear power plant under the provisions of 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," and applicants for a COL that have an LWA.

All licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material under the provisions of 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

All holders of a certificate of compliance or an approved compliance plan under the provisions of 10 CFR Part 76, "Certification of Gaseous Diffusion Plants," if the holder engages in activities involving formula quantities of strategic special nuclear material.

All contractors and vendors (C/Vs) who implement fitness-for-duty (FFD) programs or program elements to the extent that the licensees and other entities listed above rely on those C/V FFD programs or program elements to comply with 10 CFR Part 26, "Fitness For Duty Programs."

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this Regulatory Issue Summary (RIS) to inform stakeholders that the NRC has issued an Enforcement Guidance Memorandum (EGM) dispositioning violations of certain NRC requirements for initial validity tests and drug tests. This RIS requires no action or written response on the part of an addressee.

BACKGROUND INFORMATION

In August 2005, the NRC proposed amendments to 10 CFR Part 26, in part, to improve the effectiveness and efficiency of FFD programs and enhance consistency with U.S. Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines). The NRC requires licensees and other entities that are subject to 10 CFR Part 26 to use only HHS-certified laboratories to perform certain types of drug testing. On March 31, 2008, the Commission issued a final rule amending Part 26 (73 FR 16966). Licensees and other entities were required to implement all provisions of the rule by March 31, 2009, except for Subpart I, "Managing Fatigue," which must be implemented no later than October 1, 2009.

The NRC utilizes HHS established technical requirements for various drug testing activities and has only deviated from the HHS Guidelines for considerations that are specific to the nuclear industry. For example, unlike the HHS Guidelines, 10 CFR Part 26 allows the establishment of onsite licensee testing facilities (LTFs) for the conduct of initial drug and validity tests of urine specimens to detect whether certain individuals may have engaged in substance abuse. Subpart F, "Licensee Testing Facilities," of 10 CFR Part 26 includes the requirements for LTFs. If the results of initial drug and validity tests at an LTF indicate that an individual may have engaged in substance abuse or attempted to tamper with his or her specimen in an effort to conceal substance abuse, licensees are required to submit the individual's specimen to an HHS-certified laboratory for supplemental testing. Requirements for testing these specimens at the HHS-certified laboratories are contained in Part 26, Subpart G, "Laboratories Certified by the Department of Health and Human Services."

SUMMARY OF ISSUE

On February 24, 2009, the NRC conducted a public meeting (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML090420577 and ML090771060) with industry representatives and members of the public to discuss issues related to 10 CFR Part 26 and the HHS Guidelines. On March 13, 2009, the Nuclear Energy Institute (NEI), on behalf of the nuclear power industry, requested enforcement discretion (ADAMS Accession No. ML090780477) for 10 CFR 26.137(d)(5) and 10 CFR 26.137(e)(6)(v). NEI stated, in part, that these two requirements of the final rule, compared to the related text of the former (54 FR 24494; June 7, 1989, as amended) and proposed (70 FR 50442; August 25, 2005) rules, would cause licensees and other entities that operate LTFs to incur unnecessary burden and cost to meet the requirements of the final rule.

The NRC reviewed the NEI request and found that the language in the subject requirements does not accurately reflect the testing requirements necessary for LTFs and as described in the former and proposed rules. The NRC also found that these inaccuracies, if left uncorrected, would result in an unnecessary regulatory burden on licensees and other entities that operate LTFs. The NRC issued EGM-09-003, dated March 31, 2009, to grant enforcement discretion for the affected requirements. The NRC conducted public meetings on February 24, and June 24, 2009, to discuss these requirements with the public. The summaries of these meetings can be viewed at the NRC's Agencywide Documents Access and Management System (ADAMS)

utilizing accession number ML090771060 and ML091910511, respectively. The NRC will also continue its interaction with the public and industry to evaluate 10 CFR Part 26 requirements.

Evaluation of Issue

When responding to public comments on the August 2005, proposed amendments to 10 CFR Part 26, the NRC inadvertently transposed quality control (QC) requirements that are appropriate for HHS-certified laboratories, as specified in Subpart G of the final rule, into Subpart F regulations applicable to LTFs. As described in EGM-09-003, the incorrect language in the final rule and the correct requirements are provided below. The underlined sections are provided to illustrate substantive differences. NRC evaluation of these differences follows.

10 CFR 26.137(d)(5)

Incorrect Each analytical run performed to conduct initial validity testing shall include at least one quality control sample that appears to be a donor specimen to the laboratory analysts.

Correct Each analytical run performed to conduct initial validity testing shall include at least one quality control sample that appears to be a normal specimen to the licensee testing facility technicians.

10 CFR 26.137(e)(6)(v)

Incorrect At least one positive control, certified to be positive by an HHS-certified laboratory, that appears to be a donor specimen to the laboratory analysts.

Correct At least one quality control sample that appears to be a normal specimen to the licensee testing facility technicians.

Use of the term “laboratory analysts” in Subpart F, rather than “licensee testing facility technicians,” is inconsistent with the terminology used throughout the remainder of the rule (e.g., Subpart G). The position description “laboratory analysts” used in Subpart G refers to HHS-certified laboratory analysts who must be trained and qualified to perform more sophisticated and complex confirmatory tests than those performed at LTFs. By using the term “laboratory analyst” in Subpart F, rather than “licensee testing facility technician,” the rule inadvertently imposes unnecessary and unduly burdensome training and qualification requirements on licensees.

Use of the phrase “donor specimen,” rather than “normal specimen,” is inconsistent with the intent of the rule. If the specimen were required to be a “donor specimen,” licensees would then be required to assign the roles of specimen collector and LTF technician to different persons, which is not required for initial validity and drug tests performed at LTFs. If left uncorrected, the final rule would represent an unnecessary cost and burden on licensees because procedure changes would be necessary and an additional trained and qualified person would be required to implement these tests. The majority of LTFs utilize a single LTF technician to perform specimen testing. That practice is consistent with the former and proposed rules and the intent of the final rule.

The language in 10 CFR 26.137(e)(6)(v) will prevent licensees from using the same QC sample to test both the accuracy of testing and implementation of custody-and-control procedures. The former and proposed rules did not require a specimen that "appears to be a normal specimen" to be certified by an HHS-certified laboratory to be a positive QC sample (i.e., a sample that contains drugs or drug metabolites at a concentration that exceeds the applicable cutoff levels for initial drug tests in 10 CFR Part 26). Requirements for positive QC samples are addressed in other provisions of this same section of the rule. Furthermore, the former and proposed rules permitted this sample to be negative or to have positive characteristics to evaluate the accuracy of licensee testing procedures and equipment. This flexibility is appropriate and consistent with the intent of the final rule.

EGM-09-003 provides enforcement discretion for licensee compliance with 10 CFR 26.137(d)(5) and 10 CFR 26.137(e)(6)(v). As detailed in the EGM, licensees shall continue to meet the requirements of the former rule for the subject initial drug and validity testing requirements as described in Sections 2.7 and 2.8 of Appendix A of the former rule. Licensees may elect to voluntarily comply with the final rule.

BACKFIT DISCUSSION

This RIS is being issued to inform stakeholders that the NRC has issued an EGM dispositioning violations of certain 10 CFR Part 26 requirements for initial drug and validity tests performed at LTFs. The NRC is not imposing or requiring any new positions on licensees. The RIS does not require licensees to change or modify procedures or processes. Any action on the part of addressees in response to the information in this RIS is strictly voluntary. Therefore, pursuant to 10 CFR 50.109, "Backfitting," the backfit rule does not apply and a backfit analysis is not required.

FEDERAL REGISTER NOTIFICATION

The NRC did not publish a notice of opportunity for public comment on this RIS in the *Federal Register* because this RIS is informational. Furthermore, although this RIS refers to a departure from regulatory requirements detailed in an EGM, it does not impose new or more stringent requirements.

On February 24, 2009, the NRC conducted a public meeting (ADAMS Accession Nos. ML090420577 and ML090771060) and met with industry representatives and members of the public to discuss issues related to 10 CFR Part 26 and the HHS Guidelines. The NRC intends to continue working with industry representatives, members of the public, and other stakeholders in its consideration of proposed rulemaking related to these matters.

CONGRESSIONAL REVIEW ACT

The RIS is not a rule as designated by the Congressional Review Act (5 U.S.C. 801-808) and therefore is not subject to the Act.

PAPERWORK REDUCTION ACT

This RIS does not contain information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

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 U.S. Office of Management and Budget clearance number.

CONTACTS

Please direct any questions about this matter to the technical contact listed below or to the appropriate NRC project manager.

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Note: NRC generic communications may be found on the NRC public Web site, http://www.nrc.gov, under Electronic Reading Room/Document Collections.