March 31, 2009

EGM-09-003

MEMORANDUM TO: Eric J. Leeds, Director, Office of Nuclear Reactor Regulation
Brian W. Sheron, Director, Office of Nuclear Regulatory Research
Michael F. Weber, Director, Office of Nuclear Material Safety and Safeguards
Charles L. Miller, Director, Office of Federal and State Materials and Environmental Management Programs
Roy P. Zimmerman, Director, Office of Nuclear Security and Incident Response
Michael R. Johnson, Director, Office of New Reactors
Samuel J. Collins, Regional Administrator, Region I
Luis A. Reyes, Regional Administrator, Region II
Mark A. Satorius, Regional Administrator, Region III
Elmo E. Collins, Regional Administrator, Region IV

FROM: Cynthia A. Carpenter, Director
Office of Enforcement /RA/

SUBJECT: ENFORCEMENT GUIDANCE MEMORANDUM – DISPOSITIONING VIOLATIONS OF NRC REQUIREMENTS FOR INITIAL VALIDITY AND DRUG TESTS AT LICENSEE TESTING FACILITIES

Purpose:

The purpose of this Enforcement Guidance Memorandum (EGM) is to provide guidance for dispositioning violations of U.S. Nuclear Regulatory Commission (NRC) requirements for quality control (QC) specimens associated with performing initial drug and validity tests at licensee testing facilities (LTFs).

Background:

In August 2005, the NRC proposed changes to Title 10 of the *Code of Federal Regulations*, Part 26 (10 CFR Part 26), "Fitness for Duty Programs," in part, to improve the effectiveness and efficiency of fitness for duty programs, and enhance consistency with Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines). On March 31, 2008, the Commission issued the final rule (73 FR 16965). On March 31, 2009, the drug and alcohol provisions must be implemented.

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The NRC relies on HHS to establish the technical requirements for various drug testing activities and deviates from the HHS Guidelines only for considerations that are specific to the nuclear industry. One area in which 10 CFR Part 26 differs from the HHS Guidelines is that 10 CFR Part 26 permits licensees to establish an onsite LTF and perform initial drug and validity tests of urine specimens to detect substance abuse. Requirements for LTFs are contained in Subpart F, "Licensee Testing Facilities," of the final rule.

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 to conceal substance abuse, licensees are required to forward the specimen to an HHS-certified laboratory for supplemental testing. Requirements for specimen testing at HHS-certified laboratories are contained in 10 CFR Part 26, Subpart G, "Laboratories Certified by the HHS."

Discussion:

On March 13, 2009, the Nuclear Energy Institute (NEI) submitted to the NRC a request for enforcement discretion (ADAMS Accession No. ML090780477) regarding 10 CFR Part 26, Subpart F, Sections 26.137(d)(5) and 26.137(e)(6)(v). NEI stated that these two sections of the final rule, compared to the related text of the former (54 FR 24494; June 7, 1989, as amended) and proposed (73 FR 71858; November 25, 2008) rules, would cause licensees and other entities that operate LTFs to incur unnecessary burden and cost to meet the requirements of the final rule.

As described below, the staff reviewed NEI's request and found that the language in the subject requirements of the final rule does not accurately reflect the intended testing requirements for LTFs. The staff also found that these inaccuracies, if left uncorrected, would result in an unnecessary regulatory burden on licensees and other entities that operate LTFs. The incorrect (final rule) and intended requirements are provided below. Underlined sections are provided to illustrate substantive differences.

Incorrect Section 26.137(d)(5)		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.
	Intended	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.
Incorrect Section 26.137(e)(6)(v)		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.
	Intended	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” is used in Subpart G to refer 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 was 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 intended for initial drug and validity 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 collect specimens and to perform specimen testing. That practice is consistent with the former and proposed rules, and the intent of the final rule.

The language in Section 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 were not intended to 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 in order to evaluate the accuracy of licensee testing procedures and equipment. This flexibility is appropriate and consistent with the intent of the final rule.

Actions:

Immediate actions:

a. In accordance with the NRC Enforcement Policy, Section VII.B.6, “Violations Involving Special Circumstances,” the NRC will exercise enforcement discretion and not cite licensees for violations of 10 CFR 26.137(d)(5) and 10 CFR 26.137(e)(6)(v) if they choose to implement these requirements as described below:

Section 26.137(d)(5)	Each analytical run performed to conduct initial validity testing shall include at least one quality control sample that appears as a normal specimen to the licensee testing facility technicians.
Section 26.137(e)(6)(v)	At least one quality control sample that appears to be a normal specimen to the licensee testing facility technicians.

Licensees who elect to implement the requirements as written in the final rule would be in compliance and discretion would not be necessary.

b. When exercising enforcement discretion in accordance with this EGM, the following or similar language should be included in the text of the inspection report discussing the finding:

"A violation of 10 CFR 26.137(d)(5) (or 10 CFR 26.137(e)(6)(v)) was identified. Because the violation was identified during the discretion period in Enforcement Guidance Memorandum 09-003 (EGM-09-003) and because the licensee was implementing the requirements as described in the EGM, we are exercising enforcement discretion in accordance with Section VII.B.6, "Violations Involving Special Circumstances," of the NRC Enforcement Policy and are not issuing enforcement action for this violation."

c. The staff will issue a Regulatory Issue Summary to inform affected licensees and other entities of this EGM.

Long-term staff action:

a. The staff will coordinate with external stakeholders on future rulemaking to further evaluate the 10 CFR Part 26 rule and will, if necessary, propose rulemaking to the Commission.

b. This enforcement discretion will remain in place until staff has completed changes to the 10 CFR Part 26 rule to correct the language that is inconsistent with our intended regulatory positions in order for the industry to establish, implement, and maintain effective fitness for duty programs.

cc: R. W. Borchardt, EDO
V. Ordaz, AO
M. Virgilio, DEDMRT
B. Boger, NRR
D. Dorman, NMSS/FCSS
B. Mallet, DEDR
G. Tracy, NRO
SECY

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