POLICY ISSUE
(Information)

August 20, 1990 SECY-90-295

For: The Commissioners

From: James M. Taylor
Executive Director for Operations

Subject: PROPOSED RULE PUBLISHED BY THE HEALTH CARE FINANCING ADMINISTRATION OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) AND ITS POSSIBLE EFFECT ON 10 CFR PART 26

Purpose: To inform the Commission of the possible effect on 10 CFR Part 26 "Fitness-for-Duty Programs" of a rule proposed by the Health Care Financing Administration of HHS and actions the staff is performing to avoid unnecessary conflicts and redundancy between the proposed rule and NRC regulations.

Discussion: On May 21, 1990, the Health Care Financing Administration of the Department of Health and Human Services published a proposed rule (42 CFR Part 405 et al.) that would require all laboratories that examine human specimens to meet certain performance requirements and be certified by HHS. To obtain HHS certification, laboratories would be required to specify certain quality standards and controls, personnel qualifications, and other measures. These measures are separate and distinct from those contained in HHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs." Laboratories used by NRC licensees for drug testing are presently adhering to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" and are certified by the National Institute on Drug Abuse (NIDA) of HHS.

The rule, as proposed, would not apply to any component or function of a laboratory that has been certified by NIDA for the performance of forensic urine drug testing. However, according to the proposed rule, components or functions of laboratories that are not certified by NIDA would not be exempt. Therefore, NIDA-certified laboratories performing drug testing for NRC licensees that test for drugs that are not included in the NIDA program and that use lower cutoff levels than those specified by NIDA would have those portions of their laboratories performing such functions subject to certification by the Health Care Financing Administration.

Contact:
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DESIGNATED ORIGINAL

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Because NRC licensees conducting onsite preliminary screening tests are not required to be certified by NIDA, their laboratories would be subject to the certification requirements in the proposed rule.

If adopted as proposed, the rule would impose additional regulatory requirements on NRC licensees. This additional burden could have a chilling effect on NRC licensees' use of onsite screening, testing for additional drugs, and use of lower cutoff levels. Also, the rule could require an amendment to 10 CFR Part 26 to add additional criteria for onsite testing laboratories.

The staff has contacted HHS and discussed the possible effect of the rule on NRC licensees and the areas where the rule may conflict or be redundant with NRC regulations. To avoid conflicts and redundant regulations and in recognition of the rigorous programs established by NRC regulations, the staff's position is that the HHS rule should not apply to NRC licensees conducting preliminary urine screening tests for drugs and breath analyses for alcohol under the provisions of 10 CFR Part 26. In addition, we will note the effect of a second certification of NIDA-certified laboratories when these laboratories perform testing for additional drugs or at lower cutoff levels. We plan to formally document our concerns and position on the HHS rule in a letter (draft enclosed) to the Administrator, Health Care Financing Administration.

We will keep the Commission informed of the status of the subject HHS rulemaking and the effects, if any, of the rulemaking on the NRC's fitness-for-duty programs.

James M. Taylor
Executive Director
for Operations

Enclosure:
Draft Letter to HHS
w/o enclosure

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UNITED STATES
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WASHINGTON, D. C. 20555

DRAFT

Dr. Gail Wilensky
Administrator
Health Care Financing Administration
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Dr. Wilensky:

It has come to our attention that a Health Care Financing Administration proposed rule (42 CFR Part 405 et al.) published in the Federal Register on May 21, 1990 (55 FR 20896) may have a significant effect on NRC licensees and NRC regulations. That rule sets forth certain quality control measures adopted from the HHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs" to ensure that test results are accurate, and that individual rights are properly protected.

On June 7, 1989, the Commission published in the Federal Register (54 FR 24468) a final rule (Part 26 of Title 10 of the Code of Federal Regulations (10 CFR) and Appendix A) that required licensees authorized to construct or operate nuclear power reactors to implement a fitness-for-duty program.

Section 26.24(d) of 10 CFR permits NRC licensees to conduct initial screening tests of an aliquot before forwarding presumptive positive specimens to a laboratory certified by the Department of Health and Human Services (HHS). The HHS-certified laboratories must subject all submitted specimens to initial screening, and all specimens screened as presumptively positive must be subject to confirmation testing. Section 26.24 of 10 CFR requires NRC licensees to test for alcohol using breath analysis devices meeting certain evidential standards. The NRC's rule and its Appendix specify that the licensee's staff possess the necessary training and skills for the tasks assigned, that their qualifications are documented, and that adequate quality controls are implemented.

Section 2.6 of Appendix A to 10 CFR Part 26 requires that any licensee testing facility shall have an individual responsible for the day-to-day operations and to supervise the testing technicians. That individual is required to have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she must have training and experience in the theory and practice of the procedures used in the licensee's testing facility, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; and proper remedial actions to be taken in response to detecting aberrant test or quality control results.

DRAFT

Appendix A to 10 CFR Part 26 is NRC's adaptation of the HHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (53 FR 11970). Many of the quality control measures, including proficiency testing, applicable to HHS-certified laboratories also apply to NRC licensee testing facilities.

Further quality controls are achieved through annual audits conducted by each licensee. As required by 10 CFR 26.80, these audits must focus on the effectiveness of the program and be conducted by objective individuals qualified in the subject(s) being audited. In addition, the NRC has initiated an inspection program that will further ensure that the required quality controls are being implemented.

We conclude that there is no risk of producing erroneous test results that could harm any patient because of an NRC licensee conducting tests for alcohol or initial screening tests of an aliquot. In the rigorous sample screening procedure required by NRC regulations, the urine specimen must be forwarded to an HHS-certified laboratory for further screening and confirmation testing, and the results evaluated by a Medical Review Officer before any action is taken with the individual. Further, we consider that the testing done by NRC licensees is sufficiently simple and accurate that the likelihood of erroneous results are negligible, and that the overall testing process ensures accurate results.

It appears that the intent of the proposed 42 CFR 493.3 is to not apply the rule to certain components or functions of a laboratory whose forensic functions are governed by regulations adopted by the NRC. However, the proposed rule suggests that the drug screening laboratories operated by NRC licensees are certified by the National Institute on Drug Abuse (NIDA). That suggestion is not correct. While the proposed rule exempts any component or function of a laboratory that is certified by NIDA for the performance of forensic drug testing, components or functions of those laboratories not certified by NIDA are not exempt. Many of the NIDA-certified laboratories that perform the drug testing for NRC licensees test for drugs not included in the NIDA programs and use lower cutoff levels than those specified by NIDA. These laboratories would appear to be subject to certification by both NIDA and the Health Care Financing Administration, which seems to place an unnecessary burden on both HHS and the laboratory.

To clarify the intent of 42 CFR 493.3 concerning the applicability of the proposed rule, and because the current testing process required by 10 CFR Part 26 ensures that false positive results are not obtained, we recommend that 42 CFR Parts 405 et al. specifically exempt entities licensed by the U.S. Nuclear Regulatory Commission that are conducting urine screening tests for drugs and breath analyses for alcohol under the provisions of 10 CFR Part 26. We also recommend that you consider approaches to allow for laboratories conducting drug testing for NRC licensees to only be subject to certification by NIDA.

A copy of 10 CFR Part 26 is enclosed for your information. We would be pleased to meet with you or your staff to discuss this matter further. If you or your staff would like to meet, please contact me at (301) 492-1270 or Phillip F. McKee at (301) 492-0933. A copy of this letter is being provided for consideration in your rulemaking proceedings.

Sincerely,

Thomas E. Murley, Director
Office of Nuclear Reactor Regulation

Enclosures:
FFD Rule (54 FR 24468)
Copy of Ltr. for Rulemaking
Consideration

cc:
Health Care Financing Administration
Department of Health and Human Services
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