

PROPOSED RULE PROVISIONS THAT DIFFER FROM HHS GUIDELINES

Introduction

The Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines) (1988, as amended in 1994, 1998, and 2004) establish requirements and standards for drug testing by Federal agencies. The purpose of the HHS Guidelines is to ensure that Federal agencies' urine drug test results are accurate, reliable, and legally defensible. The HHS Guidelines address the collection, laboratory analysis, medical review, and reporting of specimens tested under HHS requirements. The HHS Guidelines are generally recognized as the national standard in this area.

Part 26 includes requirements for drug testing as part of a broader set of requirements for fitness-for-duty (FFD) programs. Most NRC licensees are private-sector employers and, therefore, are not subject to the HHS Guidelines. Historically, however, Part 26 has incorporated many of the provisions of the HHS Guidelines. The proposed revisions to Part 26 generally incorporate the requirements in the most recent revision of the HHS Guidelines, which was published in the *Federal Register* on April 13, 2004 (69 FR 19644).

The proposed Part 26 would supplement, adapt, or update the Guidelines in two areas. First, this proposed rule would supplement and adapt some provisions in the HHS Guidelines to address the unique circumstances of the NRC and its licensees. Second, the proposed rule would incorporate a limited set of revisions to HHS-recommended practices for conducting drug testing that have not yet been published by HHS as a final rule. This attachment discusses these differences in more detail.

Adaptations of Provisions in the HHS Guidelines to NRC's and Licensees' Circumstances

To address the unique circumstances of NRC and its licensees, certain drug testing provisions in the HHS Guidelines would be modified for inclusion in proposed Part 26. The most significant differences between the drug-testing provisions of proposed Part 26 and the HHS Guidelines derive from decisions the Commission made when Part 26 was first published. These differences include:

- Permission for NRC licensees to operate licensee testing facilities at which initial drug tests are performed (at §26.24(d)(1) of the current rule and §26.31(d)(3)(ii) of the proposed rule);
- Permission for NRC licensees to test for any illegal drug or any other substances that an individual is suspected of having abused when testing for cause (at Section 2.1(b) of Appendix A to the current Part 26 and §26.31(d)(1)(ii) of the proposed rule);
- Permission for NRC licensees to establish more stringent cutoff levels for drugs and drug metabolites than those required in the HHS Guidelines (at §26.24(b) of the current rule and §26.31(d)(iii) of the proposed rule);

- A requirement for licensees to test for all five of the drugs and drug metabolites for which testing is permitted under the HHS Guidelines (i.e., the HHS panel) (at Section 2.1(a) of Appendix A to the current Part 26 and §26.31(d)(1) of the proposed rule); and
- Requirements related to ensuring the honesty and integrity of FFD program personnel (at Section 2.3 of Appendix A to the current Part 26 and proposed §26.31(b)(1)).

In addition, proposed Part 26 would incorporate different or more detailed procedural requirements in some areas than the HHS Guidelines.

- C Proposed Part 26 would define a procedure for assuring that NRC licensees' drug testing is scientifically sound and legally defensible when the licensee tests for drugs or drug metabolites that are not included in the HHS panel. Proposed §26.31(d)(1) would require a qualified forensic toxicologist to review and certify the assays and cutoff levels that a licensee will use when testing for any drugs or drug metabolites not included in the HHS panel. The HHS Guidelines require Federal agencies to submit written petitions to test for additional drugs to the Secretary for review and approval. The alternative procedure in proposed Part 26 is necessary because NRC licensees do not have access to the HHS review process.
- C Proposed §26.31(d)(3)(iii)(B) would require NRC licensees to apply the FFD program's cutoff levels uniformly to all types of tests (e.g., pre-access, random, for cause) and equally to all individuals tested. The HHS Guidelines do not include a similar requirement. The proposed requirement would respond to implementation issues that have arisen since Part 26 was first published and would protect the due process rights of individuals who are subject to the rule.
- C Proposed §26.31(d)(5) would permit the Medical Review Officer (MRO) to authorize alternative specimen collection and evaluation procedures for rare circumstances in which it would be difficult or hazardous to the donor to collect breath, oral fluids, or urine specimens. These circumstances would include, but would not be limited to, required post-event testing when an individual has been seriously injured. The HHS Guidelines do not include a similar provision. This provision would protect the health of individuals who are subject to Part 26 and would be adapted from the Department of Transportation (DOT) Procedures for Transportation Workplace Drug and Alcohol Testing, effective August 1, 2001 (49 CFR Part 40, 65 FR 79462), in response to stakeholder requests.
- C In response to stakeholder requests, proposed §26.87(d) would provide more detailed requirements for collection site security than the HHS Guidelines. The HHS Guidelines require a collection site to be secure, but do not specify the implementation details desired by stakeholders. Proposed Part 26 would not permit unauthorized personnel to have access to a collection site and would permit use of locked doors, alarms, or visual monitoring of the collection site when it is not occupied, or other means, as acceptable security physical measures to control access. Proposed Part 26 would also require posting a sign to indicate access is permitted only for authorized personnel when a site is not solely dedicated to collecting specimens.
- C In response to stakeholder requests, proposed Part 26 would permit colors other than blue to be used in toilet tanks or any other source of standing water in an area that is used for

urine specimen collections. The HHS Guidelines only permit the color blue to be used. Also in response to stakeholder requests, proposed §26.87(e) would provide more detailed instructions to collectors for ensuring that no potential adulterants are available at the collection site. The HHS Guidelines do not provide similarly detailed instructions.

- C Proposed §26.87(f) would provide more detailed requirements than the HHS Guidelines for collection of urine specimens in the unusual circumstance when a designated collection site is inaccessible. These provisions would be adapted from DOT's Procedures in response to stakeholder requests.
- C Proposed Part 26 would provide more detailed requirements than the HHS Guidelines for the actions a collector would take if an individual selected for testing fails to appear at the appointed time. The HHS Guidelines direct the collector to "contact the appropriate authority to obtain guidance on the action to be taken." Proposed §26.89(a) would direct the collector to contact FFD program management and would define the steps that FFD program management would take in these circumstances.
- C Proposed §26.89(b) would provide more detailed requirements than the HHS Guidelines for identifying a donor, and would require that specimens be collected even if the donor does not present the required photo-identification. The proposed requirements would provide greater assurance that the individual who appears for testing is the correct donor, that FFD program management is informed of any donor-identity problems, and that the collection is not unnecessarily delayed or cancelled, if the lack of identification is easily explained and resolved.
- C Proposed §26.89(e) would prohibit any delay in medical treatment that could result from collecting specimens for drug and alcohol testing if an individual has been injured and is subject to post-event testing. The HHS Guidelines do not include a similar provision. This provision would protect the health of individuals who are subject to Part 26 and would be added in response to stakeholder requests.
- C In response to stakeholder requests, proposed §26.103(b) would require the donor to permit the collector to examine the contents of the donor's pockets prior to urine specimen collection. The HHS Guidelines require the collector to make the examination and imply, but do not clearly state, that the donor must permit the examination to occur. The current Part 26 requirement is consistent with the HHS provision. Stakeholders requested this clarification because some donors have used this loophole in the current Part 26 to disrupt the collection process.
- C Proposed §26.105(a)(3) would permit the collector to set a reasonable limit on the time within which a donor must provide a urine specimen. Neither the HHS Guidelines nor the current Part 26 includes a similar provision. Stakeholders requested this clarification because some donors have used this gap in the current Part 26 to disrupt the collection process. This provision would be adapted from the DOT's Procedures.
- C Proposed §26.105(b) would provide more detail on the actions a collector would take if a donor exhibits any conduct that clearly indicates an attempt to tamper with a urine specimen. The related provisions in the HHS Guidelines and in the current Section 2.4(g)(9) in Appendix A to Part 26 require the collector to note the unusual behavior on the specimen

custody-and-control form and in the permanent record book. In response to stakeholder requests, proposed §26.105(b) would further direct the collector to contact FFD program management to determine whether a directly observed collection should be performed.

- C Proposed §26.105(c) would require the collector to inspect the cubicle or stall in which the donor provides a urine specimen for evidence of a subversion attempt, which would increase the likelihood that a subversion attempt will be detected. The HHS Guidelines do not include such a provision.
- C Proposed §26.107 would provide more detailed requirements than the HHS Guidelines related to the quantity of urine that donors would provide for drug testing. The additional requirements would support related provisions in the proposed rule, which would permit licensees to perform initial tests at licensee testing facilities and to test for drugs and drug metabolites that are not included in the HHS panel.
- C Proposed §26.113 would provide more detailed procedures than the HHS Guidelines for collecting a urine specimen under direct observation. The procedures would be adapted from the DOT Procedures to increase consistency among Part 26 programs in how directly observed collections are performed as well as consistency between how collections are performed under Part 26 and the DOT's Procedures. Proposed Part 26 would permit licensees to accept drug test results from collections that are performed in accordance with DOT Procedures in some cases and would retain the permission in the current rule for licensees to accept drug test results from other licensee FFD programs.
- C Proposed §26.167(f) would require licensees to submit blind performance test specimens to HHS-certified laboratories at a lower rate than the HHS Guidelines require for Federal agencies. This difference from the HHS Guidelines would reduce the performance-testing burden on NRC licensees and, because of the very large number of blind performance test specimens that are submitted by Federal agencies, would not adversely affect the effectiveness of the HHS' laboratory performance-testing requirements.
- C Proposed §26.169(a) would require HHS-certified laboratories to report drug test results to the licensee's MRO within 5 business days of receiving the specimen. The HHS Guidelines require the laboratories to report drug test results to the Federal agencies' MROs "within an average of 5 working days." The difference is necessary to support related requirements in Subpart C of proposed Part 26.
- C Proposed §26.169(k) would decrease the frequency with which HHS-certified laboratories must submit summary reports of drug test results to NRC licensees from monthly (in the current Section 2.7(g) of Appendix A) to annually. The HHS Guidelines require the laboratories to submit these reports to Federal agencies semiannually. FFD program experience indicates that neither a monthly nor a semiannual summary report is necessary. Proposed Part 26 would reduce the required frequency for submitting these reports to a frequency consistent with the NRC's need for the information but would not prohibit licensees from obtaining the reports more frequently if they wish.
- C In response to implementation issues that have arisen since Part 26 was first published, proposed §26.183(d) would specify requirements related to persons who serve as MRO staff. These provisions would be adapted from the DOT's Procedures to assure the

independence and confidentiality of the MRO review function, including those tasks that MRO staff are permitted to perform under the proposed rule. The HHS Guidelines require MRO staff to be under the direct personal supervision of the MRO. Because the MRO is required to be independent, the HHS Guidelines do not include specifics to ensure the staff's independence. Stakeholders requested proposed Part 26 not require MRO staff to be under the direct personal supervision of the MRO and permit staff to be employees of the licensee or other entity subject to Part 26. Accordingly, proposed Part 26 would permit MRO staff to be employees of the licensee or other entity, but would incorporate detailed provisions specifying which tasks the MRO staff may perform, require the MRO to direct the MRO staff's duties, and specify many other of the interactions between the MRO and MRO staff to ensure independence of the MRO staff.

- C In response to implementation questions and stakeholder requests, proposed Part 26 would provide more detailed requirements than the HHS Guidelines related to the MRO's contact with a donor who has had a non-negative drug test result that was confirmed by an HHS-certified laboratory, at proposed §26.185(c)–(e). The HHS Guidelines require the MRO to contact the donor as part of the drug test review process. Proposed §26.185(c)–(e) would specify procedures for contacting the donor and the actions the MRO would take in several circumstances. The proposed provisions would be adapted from the DOT's Procedures.
- C Proposed Part 26 would permit the MRO to request drug testing at the assay's limit of detection for dilute specimens at proposed §26.185(g). Under the HHS Guidelines, a specimen is considered "dilute" if the specimen's creatinine concentration falls between 2–20 milligrams per deciliter. Submitting a dilute specimen would not be a violation of the FFD policy and no sanctions would be imposed on the donor under the proposed rule because there are many legitimate reasons that a donor may provide a dilute specimen. However, some donors who provide dilute specimens may also have consumed large amounts of liquids in order to decrease the concentrations of drugs or drug metabolites in their urine specimen below the FFD program's cutoff levels. Therefore, the proposed rule would authorize the MRO to request the HHS-certified laboratory to test at the assay's limit of detection to determine whether a urine specimen contains drugs or drug metabolites in order to determine whether the individual has violated the FFD policy.
- C Proposed §26.185(j) would provide more detailed requirements for the MRO's review of non-negative test results for opiates and over-the-counter and prescription medications than the HHS Guidelines and the current Section 2.9(d) of Appendix A to Part 26. Proposed Part 26 would add requirements for the MRO's review of non-negative test results from the consumption of supplements or preparations containing ingredients such as hemp oil or coca leaf tea, use of another person's prescription medications, and use of a drug that was legally obtained in a foreign country. The more detailed requirements would be added in response to implementation issues that have arisen since Part 26 was first published. The requirements related to supplements or preparations containing ingredients such as hemp oil or coca leaf tea would incorporate the Federal policy in this matter that was published by the Department of Transportation, with the concurrence of the Departments of Justice and Health and Human Services and the Office of National Drug Control Policy.
- C Proposed §26.185(o) would provide requirements for several steps in the MRO's review of return-to-duty drug test results. The HHS Guidelines do not include a similar provision. The

proposed requirements respond to implementation issues that have arisen since Part 26 was first published.

- C The HHS Guidelines require Federal agencies to use the Federal specimen custody-and-control form to transmit specimens to HHS-certified laboratories for testing. Proposed Part 26 would not require NRC licensees to use this form because the HHS Guidelines prohibit private-sector employers from using the Federal form. NRC licensees would be able to use their own form.

Updated Provisions

At the same time that the HHS published updated requirements for urine specimen validity testing, HHS also published a Notice of Proposed Revisions to the Guidelines (69 FR 19673; April 13, 2004). Among other changes to the Guidelines, the HHS proposed permitting Federal agencies to use non-instrumented validity testing devices to perform validity screening tests of urine specimens. Proposed Part 26 would incorporate the related provisions from these proposed revisions to the HHS Guidelines and permit licensee testing facilities to rely on such devices to conduct validity screening tests, at proposed §26.131(a). This permission would be added in response to stakeholder concerns that instrumented validity screening testing, as currently required in the HHS Guidelines, would be too costly. In addition, proposed Part 26 would require licensee testing facilities to conduct the performance testing of these devices that the HHS Guidelines would require, at proposed §26.137(b), until the proposed HHS Guidelines have been published as a final rule in the Federal Register and the HHS publishes a list of acceptable devices. Such performance testing is necessary to ensure that the devices produce accurate and legally defensible results.

Attachment 3

Attachment 4