



DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-5040

(Proposed New Regulatory Guide)

URINE SPECIMEN COLLECTION AND TEST RESULT REVIEW UNDER 10 CFR PART 26, “FITNESS FOR DUTY PROGRAMS”

A. INTRODUCTION

Purpose

This regulatory guide (RG) describes methods and procedures the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for certain nuclear facility applicants and licensees to demonstrate compliance with NRC regulations pertaining to the collection of urine specimens and the review of test results in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26, “Fitness for Duty Programs” (Ref. 1).

Applicability

This RG applies to all nuclear facilities subject to the regulatory requirements in 10 CFR 26.3, “Scope.”

Applicable Regulations

- The regulations at 10 CFR Part 26 establish, in part, requirements for specimen collection; drug and alcohol testing; policies, procedures, and other program elements; audits and corrective actions; quality assurance and verification; recordkeeping and reporting; evaluation of drug test results; determinations of fitness; and sanctions, inspections, violations, and penalties.

Related Guidance

- RG 5.84, “Fitness-For-Duty Programs at New Reactor Construction Sites” (Ref. 2), endorses the methods used to develop a fitness-for-duty (FFD) program at new reactor construction sites as described in the industry guidance document Nuclear Energy Institute (NEI) 06-06, “Fitness-for-Duty Guidance for New Nuclear Power Plant Constructions Sites,” Revision 6, issued April 2013 (Ref. 3). The guidance applies to licensees, applicants, and contractor/vendors who implement FFD programs.

This regulatory guide is being issued in draft form to involve the public in the development of regulatory guidance in this area. It has not received final staff review or approval and does not represent an NRC final staff position. Public comments are being solicited on this draft guide and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Comments may be submitted through the Federal rulemaking Web site, <http://www.regulations.gov>, by searching for Docket ID: NRC-2009-0225. Alternatively, comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments must be submitted by the date indicated in the Federal Register notice.

Electronic copies of this draft regulatory guide, previous versions of this guide, and other recently issued guides are available through the NRC’s public Web site under the Regulatory Guides document collection of the NRC Library at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/>. The draft regulatory guide is also available through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML16120A435. The regulatory analysis may be found in ADAMS under Accession No. ML16123A006.

- U.S. Department of Health and Human Services (HHS), “Mandatory Guidelines for Federal Workplace Drug Testing Programs” (HHS Guidelines) (Ref. 4).

Purpose of Regulatory Guides

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This regulatory guide contains and references information collections covered by 10 CFR Part 26 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), control number 3150-0146.

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 OMB control number.

B. DISCUSSION

Reason for Issuance

This RG describes methods that the NRC staff considers acceptable for complying with the urine specimen collection and test results review requirements in 10 CFR Part 26. The intent of this RG is to assist the licensees and other entities implementing 10 CFR Part 26 by describing processes and procedures that the NRC finds acceptable for the collection of urine specimens and test result reviews by the Medical Review Officer (MRO). The staff has issued this RG in conjunction with a revision of 10 CFR Part 26, which incorporates enhanced guidance from the HHS Guidelines.

Specifically, the RG provides guidance on (1) the monitoring of a donor during the 3-hour hydration process, (2) the optional use of mirrors to assist in conducting observed collections, and (3) the conduct of an additional review by the MRO for urine specimens with invalid test results due to high pH values (in the range of 9.0 to 9.5).

Background

The requirements in 10 CFR Part 26, in part, provide reasonable assurance that individuals subject to the 10 CFR Part 26 regulations are trustworthy and reliable, as demonstrated by the avoidance of substance abuse; are not under the influence of drugs or alcohol while performing their duties; and are not mentally or physically impaired from any other cause that would in any way adversely affect their ability to perform their duties safely and competently. The NRC uses the HHS Guidelines as part of its regulatory and technical basis for 10 CFR Part 26 because these guidelines are used by all Federal employee workplace drug testing programs, comparable Federal agency drug testing programs that test

civilians in safety- and security-sensitive positions (e.g., U.S. Department of Transportation), and the testing programs of many private companies. The HHS Guidelines also are vetted by independent organizations and the public and subjected to review by experts within the drug testing profession. Further, the HHS Guidelines are periodically updated to incorporate changes in specimen collection guidance, drug testing technology, laboratory procedures, and the panel of drugs to be tested. This RG provides guidance on matters addressed in 10 CFR Part 26 that are based on changes to the HHS Guidelines in 2008, in part, to enhance the collection and testing of urine specimens and standards for collectors and evaluations conducted by MROs.

Harmonization with International Standards

The International Atomic Energy Agency (IAEA) has established a series of safety guides and standards constituting a high level of safety for protecting people and the environment. IAEA guides present international good practices. IAEA Safety Guide No. NS-G-2.8, “Recruitment, Qualification and Training of Personnel for Nuclear Power Plants,” issued 2004 (Ref. 5), is pertinent to this RG. The safety guide states that “A programme to identify personnel with a tendency towards drug or alcohol abuse should be established. Personnel prone to drug or alcohol abuse should not be employed for safety related tasks.” This RG describes a method for implementing the NRC’s requirements for specific elements of such a program.

C. STAFF REGULATORY GUIDANCE

1. Monitoring a donor during the hydration process

A. General guidance

- (1) The NRC intends the term “monitoring” to mean that the collector or hydration monitor maintains visual (i.e., direct line of sight) and aural contact with the donor to ensure that the donor is adhering to the hydration process instructions and is not attempting to subvert the collection process.
- (2) The licensee has sole discretion on whether to only use qualified specimen collectors (10 CFR 26.85(a)) or to use hydration monitors (10 CFR 26.4(g)(6)) to observe a donor during the hydration process (10 CFR 26.109(b)(1)).
- (3) The hydration monitor shall receive instruction on the duties and responsibilities of this position, and acceptable donor behavior during the collection process.
- (4) A hydration monitor may watch more than one person in the hydration process; however, the FFD program manager should ensure that the hydration monitor is able to effectively perform hydration monitor duties and responsibilities for all donors.
- (5) A communication protocol should be established between the hydration monitor and the collector to facilitate the timely completion of a specimen collection.
- (6) If a collector transfers responsibility for monitoring a donor to a hydration monitor, the collector should verbally confirm that the hydration monitor does not have a personal relationship with the donor(s).

- (7) Upon transferring responsibility for monitoring the donor to the hydration monitor, the collector should enter the name of the hydration monitor on the Federal custody and control form (Federal CCF). The area used for hydration should have a working clock visible to the donor(s) and the collector or hydration monitor. The clock that is used should be synchronized with the clock that the collector uses to document the start of the 3-hour hydration process.
- (8) The Federal CCF should be controlled during the hydration process to protect privacy information and to prevent loss or unauthorized revision. "Control" means that the Federal CCF is under the direct observation of the collector or hydration monitor or within a locked drawer or cabinet with access controlled by the collector or hydration monitor.
- (9) Only the collector should print or type information onto the Federal CCF, unless a hydration monitor has responsibility for a donor during the hydration process (10 CFR 26.85(a)(1)).

B. Monitoring the donor during the hydration process

- (1) The donor shall be monitored throughout the hydration process (10 CFR 26.109(b)).
- (2) During the hydration process, the donor should not have access to personal belongings that were secured before he or she entered the privacy enclosure for the initial specimen collection attempt under 10 CFR 26.105(a) and 10 CFR 26.105(b), unless the items have been evaluated by the collector and have been identified as items that cannot be used to subvert the testing process (10 CFR 26.105, "Preparing for Urine Collection").
- (3) If during the hydration process, the collector or hydration monitor observes any action or behavior by the donor that may indicate an attempt to subvert the testing process, a description of the donor's conduct should be immediately documented on the Federal CCF (10 CFR 26.107(b)). If a hydration monitor observes the donor conduct, the hydration monitor shall then inform the collector of the observation. The hydration monitor should communicate this information to the collector while maintaining continuous monitoring of the donor.
- (4) The collector shall contact FFD program management to determine whether a directly observed collection should be performed (10 CFR 26.107(b)).
- (5) If the donor states an intention to leave or physically leaves the hydration area (i.e., collection site), the donor should not be prevented from leaving, but the collector or hydration monitor should inform the donor that leaving before the collection is completed will be considered a refusal to test (10 CFR 26.89(c)) and would result in the FFD sanction of the permanent denial of authorization, except for the following:
 - i. If the collection process has not been completed; and the collection is for a random test; and the donor is on shift to perform a duty or responsibility described in 10 CFR 26.4(a)(1)–(5) or designated to perform a duty or responsibility under 10 CFR 26.4(c) or 10 CFR 26.4(e)(1); and is specifically assigned or directed to respond to a plant transient, plant/site emergency, or security contingency response event, as described in the licensee's operating procedures, emergency plan, or security plan, respectively, the collector or hydration monitor should do the following:
 - a) Stop the hydration/collection process, unless the donor voluntarily elects to complete the specimen collection process.

- b) Allow the donor to respond to the plant transient, emergency, or security event.
 - c) Document the time the donor left the collection site and provide a short description of the occurrence on the Federal CCF.
 - d) Immediately inform FFD program management.
 - e) If the donor has provided a specimen of acceptable quantity (10 CFR 26.89(b)(2)), but the collection process has not been completed in accordance with 10 CFR 26.89(d), and if the individual is directed to respond to the event, the specimen should be discarded. The collector shall document on the Federal CCF that the specimen was discarded, unless characteristics of the specimen indicate that it may have been adulterated or tampered with (e.g., color, clarity, contaminants, precipitants, and smell), in which case, the specimen should be processed according to 10 CFR 26.109(b)(4).
 - f) Maintain the collector's copy of the Federal CCF in accordance with 10 CFR 26.715(b)(2).
 - g) If the specimen collection process was terminated and the specimen was discarded, initiate a new unannounced specimen collection at the earliest reasonable and practical opportunity.
- (6) Consistent with the sequence of requirements in 10 CFR 26.89(c) and other sections, the phrase "will be considered a refusal to test" means that (1) a collector, hydration monitor, or FFD program person has identified an occurrence indicative of a refusal to test, (2) the occurrence has been communicated to, and evaluated by, FFD program management, and (3) FFD program management makes the sole determination that a refusal to test had occurred.

C. Providing liquid for hydration

- (1) The donor is not allowed to bring liquid into the collection site and, therefore, is not allowed to consume his or her own liquid at the collection site (10 CFR 26.87(e)(3), 10 CFR 26.105(a), and 10 CFR 26.105(b)).
- (2) The licensee should make a known quantity of liquid available to the donor, not to exceed 40 ounces (10 CFR 26.109(b)). For example, five 8-ounce bottles of water could be made available to the donor. Providing a donor with an empty cup and access to a water fountain is not considered an acceptable way to provide a known quantity of liquid to the donor because the collector or hydration monitor would not be able to ensure that that the donor does not consume more than 40 ounces of liquid.

If the collector or hydration monitor observes the donor consuming fluid that was not assigned to him or her (e.g., drinking from a water fountain), the donor has failed to cooperate with the specimen collection process under 10 CFR 26.89(c).

- (3) The collector or hydration monitor should encourage, but cannot require, the donor to consume the liquid provided at a reasonable rate. A reasonable rate is about 8 ounces (237 milliliters (mL)) every 30 minutes; however, this rate is dependent on the donor. Therefore, the collector or hydration monitor should control the pace in which liquid is provided to the donor. However, if the donor requests more liquid than that provided and if the total liquid provided up to that point

is less than 40 ounces, the collector or hydration monitor should provide more liquid (such as another 8 ounces), as long as the total volume of consumed liquid and liquid to be provided does not exceed 40 ounces.

Note the following:

- (i) Two kidneys (in a healthy adult) produce about 1 to 2 quarts (946 to 1,892 mL) of urine per day or about 40 to 80 mL of urine per hour (Ref. 6). A normal bladder capacity is about 300 to 400 mL (Ref. 7).
 - (ii) Riebl and Davy (Ref. 8) state, “Typically, healthy individuals can maintain water balance through urination when excess fluid is consumed; hyperhydration is not commonly encountered.”
- (4) The collector or hydration monitor should not encourage or urge the donor to attempt to provide a specimen quickly or repeatedly during the hydration process. Requesting the donor to provide a specimen before he or she is ready to do so could result in the donor providing a specimen of inadequate volume. (See paragraph 1(D)(9)).

D. Providing a specimen during the hydration process

- (1) The collector or hydration monitor should coordinate to minimize the time a donor needs to wait to provide a specimen.
- (2) Any subsequent failed attempt to provide a specimen of sufficient volume (10 CFR 26.109(b)(3)) during the hydration process does not reset the clock that is measuring the 3-hour hydration period (i.e., the start of the 3-hour hydration process begins when the donor exits the room, stall, or private area and the collector determines that the initial specimen was of insufficient quantity).
- (3) If the hydration monitor is not qualified as a collector, the donor shall be transferred to a collector when the donor is ready to attempt to provide a specimen.
- (4) A donor may try to urinate as many times as necessary within the 3-hour hydration period.
- (5) If the collector has initiated another collection procedure, the collector may not take responsibility for the hydrating donor until that collection has been completed (10 CFR 26.89(d)).
- (6) If the donor’s attempt to provide a specimen of sufficient volume (10 CFR 26.109(b)(2)) is not successful and the collector wants the hydration monitor to resume responsibility for monitoring the donor during the 3-hour hydration period that has already been established, the donor should be directed to the hydration area, and the collector should make a statement transferring responsibility for monitoring the donor back to the hydration monitor.
- (7) At about 2 hours and 30 minutes and then at 2 hours and 45 minutes into the hydration period, the collector or hydration monitor should inform the donor when the 3-hour hydration period will lapse.
- (8) The hydration monitor should inform the collector about 2 hours and 45 minutes into the hydration period that the donor’s hydration period will end in 15 minutes so that the collector can be available to complete the collection process with the donor.

- (9) At 3 hours into the hydration period, the donor should be offered one last opportunity to provide a specimen.
- (10) If the donor was unable to provide a specimen of sufficient volume and the 3-hour hydration period has ended, the following actions apply:
- (i) The collector shall document on the Federal CCF that the donor failed to provide a specimen of sufficient volume and then shall notify the FFD program manager or the MRO of the failed collection attempt (10 CFR 26.109(b)(3)).
 - (ii) If, during the collection process, the donor provided a specimen that the collector had reason to believe was diluted, adulterated, substituted, or otherwise tampered with, the specimen should be sent to the HHS-certified laboratory for testing (10 CFR 26.109(b)(4)).

2. Using mirrors during specimen collections under direct observation (10 CFR 26.115, “Collecting a Urine Specimen under Direct Observation”)

Note the following:

- The preferred direct observation technique is to see the urine exit directly from the donor’s body into the specimen collection container without the use of a mirror; however, a directly observed collection can be conducted with the use of a mirror or mirrors to help ensure the effectiveness of the directly observed collection (10 CFR 26.115(f)(2)).
 - During urination, the observation of all sides of the donor’s body at the same time is not required. However, the collector or observer’s ability to view all sides must be immediate and unfettered to assess whether subversive paraphernalia are present (10 CFR 26.115(f)(1)).
 - The use of the word “mirror” or “mirrors” in this RG refers to those used for directly observed collections, not to the mirrors placed on walls or doors for vanity purposes.
- A. The licensee or entity should establish a procedure for the use of permanent mirrors or temporary mirrors (i.e., those needed based on a case-by-case determination). (See paragraphs 2(F) and 2(I).)
- B. The FFD program manager or an individual designated by the licensee (10 CFR 26.87, “Collection Sites”) has the authority to approve the positioning of any permanent mirror within the room, stall, or private area used to collect a urine specimen from a donor. The positioning of a mirror shall not infringe upon the privacy of a donor who is providing a specimen during a normal collection. (See paragraph 2(J) (10 CFR 26.87(b) and 10 CFR 26.107(a)(1).)
- C. A two-way mirror, hand-held mirror, or installation of a mirror within the bowl of a toilet or other urine collection apparatus exceeds the reasonable expected loss of privacy associated with a directly observed collection and should not be used.
- D. All mirrors should be sufficiently affixed or secured to a wall or structure to prevent injury to the occupants in the room, stall, or private area.

- E. The collector or observer for the assigned donor may incrementally adjust the position of a mirror for a particular donor or the particular collection area, or both.
- F. Unless all directly observed collections use a mirror(s), the collector or observer should determine whether the use of a mirror is necessary to conduct a directly observed collection for a particular individual (i.e., a case-by-case determination).
- G. The case-by-case determination for use of a mirror or mirrors is met if the collector or observer cannot do the following:
 - (1) Implement 10 CFR 26.115(f) by observing the urine exit directly from the donor's body into the collection cup/container (i.e., paragraph 2(J)) and by observing the area between the donor's waist and knees.
 - (2) Implement 10 CFR 26.107(b) and 10 CFR 26.115(f) to ensure that the donor is not attempting to subvert the testing process by observing all sides of the donor's body between the waist and knees (i.e., front, back, and sides).
- H. If a directly observed collection cannot be performed based on paragraph 2(G) or paragraph 2(H), or both, the collector or observer for that particular collection should timely inform the FFD program manager or MRO (10 CFR 26.115(b)) and the following should be considered:
 - (1) This situation could represent a rare occurrence in which the size and spatial relationship between the individual, urine collection area, and collector/observer do not facilitate an effective directly observed collection.
 - (2) The licensee should afford an accommodation above that considered for a directly observed collection. This accommodation, in part, implements the requirements of 10 CFR 26.31(d)(5)(i) and should be conducted with approval by the FFD program manager, as authorized by the MRO (10 CFR 26.31(d)(5)(i)).
- I. If the directly observed collection cannot be performed because the collector/observer cannot observe the urine exit directly from the donor's body into the collection cup/container (a funnel is part of the collection cup/container) because the individual requires the use of a urostomy bag (or other similar medical appliance), the following apply:
 - (1) This situation represents a medical condition, and an attached urostomy bag is an extension of the individual's urinary tract.
 - (2) The collector or hydration monitor shall observe the donor pour urine directly from the urostomy bag into the collection cup/container. For this situation, the temperature requirement in 10 CFR 26.111(a) would not apply because this accommodation implements the requirements of 10 CFR 26.31(d)(5)(i), as authorized by the MRO. The collector should document the temperature consideration and use of the urostomy bag on the Federal CCF.
- J. If the stall, room, or private area has a mirror installed and it is also used for normal collections (i.e., collections not under direct observation), the following applies:
 - (1) The mirror(s) shall be installed in such a way that the enclosure provides the same privacy as an enclosure without a mirror (10 CFR 26.87(b) and 10 CFR 26.107(a)(1)).

3. MRO consideration of time and temperature for urine specimens with invalid test results due to pH in the range of 9.0 to 9.5 (10 CFR 26.185(f)(3))

- A. If an MRO receives an invalid test result from the HHS-certified laboratory due to high pH (9.0 to 9.5) and if the MRO and laboratory agree that further testing would not be useful and that no technical explanation exists for the result, the MRO shall question the donor to determine whether the donor can provide an acceptable medical explanation for this test result (10 CFR 26.185(c)).
- (1) If the donor cannot provide such an explanation, the MRO shall consider whether elapsed time between the collection and testing of the specimen or exposure of the specimen to high temperatures during this elapsed time, or both, might have caused the high pH test result (10 CFR 26.185(f)(3)).
- B. To determine whether sufficient objective information exists to conclude that time or temperature, or both, might be the cause of high pH in a specimen with an invalid validity test result, the MRO or MRO staff (10 CFR 26.183(d)) should contact the licensee or other entity, collection site, transportation company, licensee testing facility, or HHS-certified laboratory to obtain information necessary to determine the time-temperature profile that the specimen was exposed to during the period between collection and the completion of the pH test.
- (1) The MRO is the only individual who may evaluate the information on elapsed time and temperature to assess a high pH test result (10 CFR 26.185(a)).
- (2) Personnel at collection sites (10 CFR 26.117(j)), licensee testing facilities (10 CFR 26.129(f)), and HHS-certified laboratories (10 CFR 26.159(h)) are required to take appropriate and prudent actions to minimize false negative results from specimen degradation, such as promptly inspecting, testing, or refrigerating specimens. As a result, personnel at these facilities could know of conditions, such as delays, high temperatures, or other information, useful to the MRO's evaluation and should communicate this information to the MRO.
- C. The MRO should consider test results from other specimens that were subject to the reasonably equivalent collection, transportation, storage, and temperature conditions if results from other such specimens are available. For example, if other specimens collected at the same collection site were transported to the HHS-certified laboratory in the same package or different packages but in the same transport vehicle, or in a different transport vehicle by the same company during reasonably equivalent weather/environmental conditions, and the specimens yielded invalid test results due to pH in the range of 9.0 to 9.5, the MRO could have sufficient objective evidence to conclude that donor action was not responsible for the invalid result.
- D. As described in the "Medical Review Officer Handbook" (Ref. 9), the MRO may use, but is not limited to, the following guidelines in evaluating elapsed time between specimen collection and pH testing for specimens with invalid test results due to pH (9.0 to 9.5):
- (1) For an elapsed time greater than 48 hours, consider cancelling the test and requiring a second unannounced collection (not observed) (10 CFR 26.185(f)(2)).
- (2) For an elapsed time between 24 and 48 hours, when the urine was transferred or stored at a temperature greater than 98 degrees Fahrenheit, consider cancelling the test and requiring a second unannounced collection (not observed) (10 CFR 26.185(f)(2)).

- (3) For an elapsed time less than 24 hours, consider cancelling the test and requiring a second unannounced collection under direct observation (10 CFR 26.185(f)(4)).
- E. The MRO may also use the guidance in the HHS “Medical Review Officer Manual for Federal Workplace Drug Testing Programs,” effective May 31, 2014, or later (Ref. 10).
- F. If the MRO concludes that an acceptable nonmedical explanation exists for an invalid test result due to high pH, the MRO should report a cancelled test result and direct the licensee or other entity to collect a second urine specimen from the donor as soon as reasonably practicable (10 CFR 26.185(f)(3)).
- G. The MRC shall document the information that he or she used in making a determination on pH (10 CFR 26.185(p)). The MRO should provide sufficient information to enable reconstruction of the situation(s) that resulted in the determination.

D. IMPLEMENTATION

The purpose of this section is to provide information on how licensees¹ may use this guide and information regarding the NRC’s plans for using this regulatory guide. In addition, it describes how the NRC staff complies with 10 CFR 50.109, “Backfitting,” and any applicable finality provisions in 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.”

Use by Licensees

Licensees may voluntarily² use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this regulatory guide may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.

Licensees may use the information in this regulatory guide for actions which do not require NRC review and approval such as changes to a facility design under 10 CFR 50.59, “Changes, Tests, and Experiments.” Licensees may use the information in this regulatory guide or applicable parts to resolve regulatory or inspection issues.

Use by NRC Staff

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this regulatory guide. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this regulatory guide, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this regulatory guide to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action that would require the use of this regulatory guide without further backfit consideration. Examples of such

1 In this section, “licensees” refers to licensees and other entities specified in 10 CFR 26.3 except those licensees and other entities in 10 CFR 26.3(c) that establish, implement, and maintain an FFD program under Subpart K, “FFD Programs for Construction,” of 10 CFR Part 26.

2 In this section, “voluntary” and “voluntarily” means that the licensee is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.

unplanned NRC regulatory actions include issuance of an order requiring the use of the regulatory guide, requests for information under 10 CFR 50.54(f) as to whether a licensee intends to commit to use of this regulatory guide, and generic communication, or promulgation of a rule requiring the use of this regulatory guide.

During regulatory discussions on plant specific operational issues, the staff may discuss with licensees various actions consistent with staff positions in this regulatory guide as one acceptable means of meeting the underlying NRC regulatory requirement. Such discussions would not ordinarily be considered backfitting even if prior versions of this regulatory guide are part of the licensing basis of the facility. However, unless this regulatory guide is part of the licensing basis for a facility, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this regulatory guide constitutes a violation.

If an existing licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this new or revised regulatory guide and (2) the specific subject matter of this regulatory guide is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 50.109(a)(1) or a violation of any of the issue finality provisions in 10 CFR Part 52.

Additionally, an existing applicant may be required to comply with new rules, orders, or guidance if 10 CFR 50.109(a)(3) applies.

If a licensee believes that the NRC is either using this regulatory guide or requesting or requiring the licensee to implement the methods or processes in this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with the guidance in NUREG-1409, "Backfitting Guidelines," (Ref. 11) and the NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 12).

REFERENCES³

1. *U.S. Code of Federal Regulations* (CFR), “Fitness for Duty Programs,” Part 26, Chapter 1, Title 10, “Energy.”
2. U.S. Nuclear Regulatory Commission (NRC), Regulatory Guide 5.84, “Fitness-For-Duty Programs at New Reactor Construction Sites,” Washington, DC.
3. Nuclear Energy Institute (NEI),⁴ Document 06-06, “Fitness-for-Duty Program Guidance for New Nuclear Power Plant Construction Sites,” Revision 6, Washington, DC, April 2013. (ADAMS Accession No. ML15083A412)
4. U.S. Department of Health and Human Services (HHS), “Substance Abuse and Mental Health Services Administration, Mandatory Guidelines for Federal Workplace Drug Testing Programs,” *Federal Register*, Vol. 73, pp. 71858–71907, Washington, DC, November 25, 2008.⁵
5. International Atomic Energy Agency (IAEA),⁶ Safety Guide No. NS-G-2.8, “Recruitment, Qualification and Training of Personnel for Nuclear Power Plants,” Vienna, Austria, 2004.
6. National Institutes of Health (NIH), National Institute of Diabetes and Digestive and Kidney Diseases, NIH Publication No. 14-3195, “The Kidneys and How They Work,” May 21, 2014. (Available at http://www.niddk.nih.gov/health-information/health-topics/Anatomy/kidneys-how-they-work/Documents/yourkidneys_508.pdf.)
7. Lukacz, E.S., and Sampsel, C., “A Healthy Bladder: A Consensus Statement,” *International Journal of Clinical Practice* 65(1):1026–1036, October 2011. (PubMed)
8. Riebl, S.K., and Davy, B.M., “The Hydration Equation: Update on Water Balance and Cognitive Performance,” *American College of Sports Medicine, Health and Fitness Journal* 17(6):21–28, November/December 2013. (PubMed)

3 Publicly available NRC published documents are available electronically through the NRC Library on the NRC’s public Web site at <http://www.nrc.gov/reading-rm/doc-collections/> and through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>. The documents can also be viewed online or printed for a fee in the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD. For problems with ADAMS, contact the PDR staff at 301-415-4737 or (800) 397-4209; fax (301) 415-3548; or e-mail pdr_resource@nrc.gov.

4 Copies of Nuclear Energy Institute (NEI) documents may be obtained through its Web site at <http://www.nei.org/> or by contacting the headquarters at Nuclear Energy Institute, 1201 F Street NW, Suite 1100, Washington DC 20004-1218; telephone 202-739-8000.

5 U.S. Department of Health and Human Services (HHS) guidelines are available online at <http://www.samhsa.gov/workplace/drug-testing#HHS>.

6 Copies of International Atomic Energy Agency (IAEA) documents may be obtained through its Web site at WWW.IAEA.Org/ or by writing the International Atomic Energy Agency, P.O. Box 100, Wagramer Strasse 5, A-1400 Vienna, Austria; telephone (+431) 2600-0; fax (+431) 2600-7; or e-mail at Official.Mail@IAEA.Org.

9. Shults, T.F., "Medical Review Officer Handbook," 10th Edition, Quadrangle Research, April 2014.⁷
10. HHS, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention, "Medical Review Officer Manual for Federal Workplace Drug Testing Programs," May 31, 2014. (Available at <http://www.samhsa.gov/sites/default/files/mro-manual.pdf>.)
11. NRC, NUREG-1409, "Backfitting Guidelines," Washington, DC. (ADAMS Accession No. ML032230247)
12. NRC, Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection," Washington, DC.

⁷ The Medical Review Officer Handbook is available for a fee from the American Association of Medical Review Officers (AAMRO), P.O. Box 12873, Research Triangle Park, NC, 27709; telephone (800) 489-1839; fax (919) 490-1010; or via its online store at <https://www.aamro.com/mro-store.aspx>.