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specimens, in making his or her determination, as long as those split specimens have been stored and tested under the procedures described in this part.

(d) *MRO staff*. Individuals who provide administrative support to the MRO may be employees of a licensee or other entity, employees of the MRO, or employees of an organization with whom a licensee or other entity contracts for MRO services. Employees of a licensee or other entity who serve MRO staff functions may also perform other duties for the licensee or other entity and need not be under the direction of the MRO while performing those other duties.

(1) Direction of MRO staff activities. MROs shall be directly responsible for all administrative, technical, and professional activities of individuals who are serving MRO staff functions while they are performing those functions, and those functions must be under the MRO's direction.

(i) The duties of MRO staff must be maintained independent from any other activity or interest of a licensee or other entity, in order to protect the integrity of the MRO function and donors' privacy.

(ii) An MRO's responsibilities for directing MRO staff must include, but are not limited to, ensuring that—

(A) The procedures being performed by MRO staff meet NRC regulations and HHS' and professional standards of practice;

(B) Records and other donor personal information are maintained confidential by MRO staff and are not released to other individuals or entities, except as permitted under this part;

(C) Data transmission is secure; and

(D) Drug test results are reported to the licensee's or other entity's designated reviewing official only as required by this part.

(iii) The MRO may not delegate any of his or her responsibilities for directing MRO staff to any other individual or entity, except another MRO.

(2) MRO staff responsibilities. MRO staff may perform routine administrative support functions, including receiving test results, reviewing negative test results, and scheduling interviews for the MRO.

(i) The staff under the direction of the MRO may receive, review, and report negative test results to the licensee's or other entity's designated representative.

(ii) The staff reviews of positive, adulterated, substituted, invalid, and, at the licensee's or other entity's discretion, dilute test results must be limited to reviewing the custody-and-control form to determine whether it contains any errors that may require corrective action and to ensure that it is consistent with the information on the MRO's copy. The staff may resolve errors in custody-and-control forms that require corrective action(s), but shall forward the custody-and-control forms to the MRO for review and approval of the resolution.

(iii) The staff may not conduct interviews with donors to discuss positive, adulterated, substituted, invalid, or dilute test results nor request medical information from a donor. Only the MRO may request and review medical information related to a positive, adulterated, substituted, or invalid test result or other matter from a donor.

(iv) Staff may not report nor discuss with any individuals other than the MRO and other MRO staff any positive, adulterated, substituted, invalid, or dilute test results received from the HHS-certified laboratory before those results have been reviewed and confirmed by the MRO. Any MRO staff discussions of confirmed positive, adulterated, substituted, invalid, or dilute test results must be limited to discussions only with the licensee's or other entity's FFD program personnel and may not reveal quantitative test results or any personal medical information about the donor that the MRO may have obtained in the course of reviewing confirmatory test results from the HHS-certified laboratory.

§ 26.185 Determining a fitness-for-duty policy violation.

(a) *MRO review required*. A positive, adulterated, substituted, dilute, or invalid drug test result does not automatically identify an individual as having used drugs in violation of the NRC's regulations, or the licensee's or other entity's FFD policy, or as having

attempted to subvert the testing process. An individual who has a detailed knowledge of possible alternate medical explanations is essential to the review of the results. The MRO shall review all positive, adulterated, substituted, and invalid test results from the HHS-certified laboratory to determine whether the donor has violated the FFD policy before reporting the results to the licensee's or other entity's designated representative.

(b) *Reporting of initial test results prohibited*. Neither the MRO nor MRO staff may report positive, adulterated, substituted, dilute, or invalid initial test results that are received from the HHS-certified laboratory to the licensee or other entity.

(c) *Discussion with the donor*. Before determining that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation and reporting it to the licensee or other entity, the MRO shall give the donor an opportunity to discuss the test result or other occurrence with the MRO, except as described in paragraph (d) of this section. After this discussion, if the MRO determines that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation, the MRO shall immediately notify the licensee's or other entity's designated representative.

(d) *Donor unavailability*. The MRO may determine that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation without having discussed the test result or other occurrence directly with the donor in the following three circumstances:

(1) The MRO has made and documented contact with the donor and the donor expressly declined the opportunity to discuss the test result or other occurrence that may constitute an FFD policy violation;

(2) A representative of the licensee or other entity, or an MRO staff member, has successfully made and documented contact with the donor and has instructed him or her to contact the MRO, and more than 1 business day has elapsed since the date on which the licensee's representative or MRO's staff member successfully contacted the donor; or

(3) The MRO, after making all reasonable efforts and documenting the dates and time of those efforts, has been unable to contact the donor. Reasonable efforts include, at a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the donor at the day and evening telephone numbers listed on the custody-and-control form.

(e) *Additional opportunity for discussion*. If the MRO determines that the donor has violated the FFD policy without having discussed the positive, adulterated, substituted, dilute, or invalid test result or other occurrence directly with the donor, the donor may, on subsequent notification of the MRO determination and within 30 days of that notification, present to the MRO information documenting the circumstances, including, but not limited to, serious illness or injury, which unavoidably prevented the donor from being contacted by the MRO or a representative of the licensee or other entity, or from contacting the MRO in a timely manner. On the basis of this information, the MRO may reopen the procedure for determining whether the donor's test result or other occurrence is an FFD policy violation and permit the individual to present information related to the issue. The MRO may modify the initial determination based on an evaluation of the information provided.

(f) *Review of invalid specimens*. (1) If the HHS-certified laboratory reports an invalid result, the MRO shall consult with the laboratory to determine whether additional testing by another HHS-certified laboratory may be useful in determining and reporting a positive or adulterated test result. If the MRO and the laboratory agree that further testing would be useful, the HHS-certified laboratory shall forward the specimen to a second laboratory for additional testing.

(2) If the MRO and the laboratory agree that further testing would not be useful and there is no technical explanation for the result, the MRO shall contact the donor and determine whether there is an acceptable medical explanation for the invalid result. If

there is an acceptable medical explanation, the MRO shall report to the licensee or other entity that the test result is not an FFD policy violation, but that a negative test result was not obtained. If the medical reason for the invalid result is, in the opinion of the MRO, a temporary condition, the licensee or other entity shall collect a second urine specimen from the donor as soon as reasonably practical and rely on the MRO's review of the test results from the second collection. The second specimen collected for the purposes of this paragraph may not be collected under direct observation. If the medical reason for the invalid result would similarly affect the testing of another urine specimen, the MRO may authorize an alternative method for drug testing. Licensees and other entities may not impose sanctions for an invalid test result due to a medical condition.

(3) If the MRO and the laboratory agree that further testing would not be useful and there is no legitimate technical or medical explanation for the invalid test result, the MRO shall require that a second collection take place as soon as practical under direct observation. The licensee or other entity shall rely on the MRO's review of the test results from the directly observed collection.

(g) *Review of dilute specimens.* (1) If the HHS-certified laboratory reports that a specimen is dilute and that drugs or drug metabolites were detected in the specimen at or above the cutoff levels specified in this part or the licensee's or other entity's more stringent cutoff levels, and the MRO determines that there is no legitimate medical explanation for the presence of the drugs or drug metabolites in the specimen, and a clinical examination, if required under paragraph (g)(4) of this section, has been conducted, the MRO shall determine that the drug test results are positive and that the donor has violated the FFD policy.

(2) If the licensee or other entity requires the HHS-certified laboratory to conduct the special analysis of dilute specimens permitted in § 26.163(a)(2), the results of the special analysis are positive, the MRO determines that there is no legitimate medical explanation for the presence of the drug(s) or drug metabolite(s) in the specimen, and a clinical examination, if required under paragraph (g)(4) of this section, has been conducted under paragraph (j) of this section, the MRO shall determine whether the positive and dilute specimen is a refusal to test. If the MRO does not have sufficient reason to believe that the positive and dilute specimen is a subversion attempt, he or she shall determine that the drug test results are positive and that the donor has violated the FFD policy. When determining whether the donor has diluted the specimen in a subversion attempt, the MRO shall also consider the following circumstances, if applicable:

(i) The donor has presented, at this or a previous collection, a urine specimen that the HHS-certified laboratory reported as being substituted, adulterated, or invalid to the MRO and the MRO determined that there is no adequate technical or medical explanation for the result;

(ii) The donor has presented a urine specimen of 30 mL or more that falls outside the required temperature range, even if a subsequent directly observed collection was performed; or

(iii) The collector observed conduct clearly and unequivocally indicating an attempt to dilute the specimen.

(3) If a dilute specimen was collected under direct observation, the MRO may require the laboratory to conduct confirmatory testing at the LOD for any drugs or drug metabolites, as long as each drug class is evaluated as required by § 26.31(d)(1)(ii).

(4) If the drugs detected in a dilute specimen are any opium, opiate, or opium derivative (e.g., morphine/codeine), or if the drugs or metabolites detected indicate the use of prescription or over-the-counter medications, before determining that the donor has violated the FFD policy under paragraph (a) of this section, the MRO or his/her designee, who shall also be a licensed physician with knowledge of the clinical signs of drug abuse, shall conduct the clinical examination for abuse of these substances that is required in paragraph (j) of this section. An evaluation for clinical evidence of abuse is not required if the laboratory confirms the presence of 6–AM (i.e., the presence

of this metabolite is proof of heroin use) in the dilute specimen.

(5) An MRO review is not required for specimens that the HHS-certified laboratory reports as negative and dilute. The licensee or other entity may not take any administrative actions or impose any sanctions on a donor who submits a negative and dilute specimen.

(h) *Review of substituted specimens.* (1) If the HHS-certified laboratory reports a specimen as substituted (i.e., the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200), the MRO shall contact the donor and offer the donor an opportunity to provide a legitimate medical explanation for the substituted result. The burden of proof resides solely with the donor, who must provide legitimate medical evidence within 5 business days that he or she produced the specimen for which the HHS-certified laboratory reported a substituted result. Any medical evidence must be submitted through a physician who is experienced and qualified in the medical issues involved, as verified by the MRO. Claims of excessive hydration, or claims based on unsubstantiated personal characteristics, including, but not limited to, race, gender, diet, and body weight, are not acceptable evidence without medical studies which demonstrate that the donor did produce the laboratory result.

(2) If the MRO determines that there is no legitimate medical explanation for the substituted test result, the MRO shall report to the licensee or other entity that the specimen was substituted.

(3) If the MRO determines that there is a legitimate medical explanation for the substituted test result and no drugs or drug metabolites were detected in the specimen, the MRO shall report to the licensee or other entity that no FFD policy violation has occurred.

(i) *Review of adulterated specimens.* (1) If the HHS-certified laboratory reports a specimen as adulterated with a specific substance, the MRO shall contact the donor and offer the donor an opportunity to provide a legitimate medical explanation for the adulterated result. The burden of proof resides solely with the donor, who must provide legitimate medical evidence within 5 business days that he or she produced the adulterated result. Any medical evidence must be submitted through a physician experienced and qualified in the medical issues involved, as verified by the MRO.

(2) If the MRO determines there is no legitimate medical explanation for the adulterated test result, the MRO shall report to the licensee or other entity that the specimen is adulterated.

(3) If the MRO determines that there is a legitimate medical explanation for the adulterated test result and no drugs or drug metabolites were detected in the specimen, the MRO shall report to the licensee or other entity that no FFD policy violation has occurred.

(j) *Review for opiates, prescription and over-the-counter medications.* (1) If the MRO determines that there is no legitimate medical explanation for a positive confirmatory test result for opiates and before the MRO determines that the test result is a violation of the FFD policy, the MRO or his/her designee, who shall also be a licensed physician with knowledge of the clinical signs of drug abuse, shall determine that there is clinical evidence, in addition to the positive confirmatory test result, that the donor has illegally used opium, an opiate, or an opium derivative (e.g., morphine/codeine). This requirement does not apply if the laboratory confirms the presence of 6-AM (i.e., the presence of this metabolite is proof of heroin use), or the morphine or codeine concentration is equal to or greater than 15,000 ng/mL and the donor does not present a legitimate medical explanation for the presence of morphine or codeine at or above this concentration. The MRO may not determine that the consumption of food products is a legitimate medical explanation for the presence of morphine or codeine at or above this concentration.

(2) If the MRO determines that there is no legitimate medical explanation for a positive confirmatory test result for drugs other than opiates that are commonly prescribed or included in over-the-counter preparations (e.g., benzodiazepines in the first case, barbiturates in the second) and are listed in the licensee's or other entity's panel

of substances to be tested, the MRO shall determine whether there is clinical evidence, in addition to the positive confirmatory test result, of abuse of any of these substances or their derivatives.

(3) If the MRO determines that the donor has used another individual's prescription medication, including a medication containing opiates, and no clinical evidence of drug abuse is found, the MRO shall report to the licensee or other entity that the donor has misused a prescription medication. If the MRO determines that the donor has used another individual's prescription medication and clinical evidence of drug abuse is found, the MRO shall report to the licensee that the donor has violated the FFD policy.

(4) In determining whether a legitimate medical explanation exists for a positive confirmatory test result for opiates or prescription or over-the-counter medications, the MRO may consider the use of a medication from a foreign country. The MRO shall exercise professional judgment consistently with the following principles:

(i) There can be a legitimate medical explanation only with respect to a drug that is obtained legally in a foreign country;

(ii) There can be a legitimate medical explanation only with respect to a drug that has a legitimate medical use. Use of a drug of abuse (e.g., heroin, PCP) or any other substance that cannot be viewed as having a legitimate medical use can never be the basis for a legitimate medical explanation, even if the drug is obtained legally in a foreign country; and

(iii) Use of the drug can form the basis of a legitimate medical explanation only if it is used consistently with its proper and intended medical purpose.

(5) The MRO may not consider consumption of food products, supplements, or other preparations containing substances that may result in a positive confirmatory drug test result, including, but not limited to supplements containing hemp products or coca leaf tea, as a legitimate medical explanation for the presence of drugs or drug metabolites in the urine specimen above the cutoff levels specified in § 26.163 or a licensee's or other entity's more stringent cutoff levels.

(6) The MRO may not consider the use of any drug contained in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 812] as a legitimate medical explanation for a positive confirmatory drug test result, even if the drug may be legally prescribed and used under State law.

(k) *Results consistent with legitimate drug use.* If the MRO determines that there is a legitimate medical explanation for a positive confirmatory drug test result, and that the use of a drug identified through testing was in the manner and at the dosage prescribed, and the results do not reflect a lack of reliability or trustworthiness, then the donor has not violated the licensee's or other entity's FFD policy. The MRO shall report to the licensee or other entity that no FFD policy violation has occurred. The MRO shall further evaluate the positive confirmatory test result and medical explanation to determine whether use of the drug and/or the medical condition poses a potential risk to public health and safety as a result of the individual being impaired while on duty. If the MRO determines that such a risk exists, he or she shall ensure that a determination of fitness is performed.

(l) *Retesting authorized.* Should the MRO question the accuracy or scientific validity of a positive, adulterated, substituted, or invalid test result, only the MRO is authorized to order retesting of an aliquot of the original specimen or the analysis of any split specimen (Bottle B) in order to determine whether the FFD policy has been violated. Retesting must be performed by a second HHS-certified laboratory. The MRO is also the only individual who may authorize a reanalysis of an aliquot of the original specimen or an analysis of any split specimen (Bottle B) in response to a request from the donor tested.

(m) *Result scientifically insufficient.* Based on the review of inspection and audit reports, quality control data, multiple specimens, and other pertinent results, the MRO may determine

that a positive, adulterated, substituted or invalid test result is scientifically insufficient for further action and may declare that a drug or validity test result is not an FFD policy violation, but that a negative test result was not obtained. In this situation, the MRO may request retesting of the original specimen before making this decision. The MRO is neither expected nor required to request such retesting, unless in the sole opinion of the MRO, such retesting is warranted. The MRO may request that the reanalysis be performed by the same laboratory, or that an aliquot of the original specimen be sent for reanalysis to another HHS-certified laboratory. The licensee testing facility and the HHS-certified laboratory shall assist in this review process, as requested by the MRO, by making available the individual(s) responsible for day-to-day management of the licensee testing facility or the HHS-certified laboratory, or other individuals who are forensic toxicologists or who have equivalent forensic experience in urine drug testing, to provide specific consultation as required by the MRO.

(n) *Evaluating results from a second laboratory*. After a second laboratory tests an aliquot of a single specimen or the split (Bottle B) specimen, the MRO shall take the following actions if the second laboratory reports the following results:

(1) If the second laboratory reconfirms any positive test results, the MRO may report an FFD policy violation to the licensee or other entity;

(2) If the second laboratory reconfirms any adulterated, substituted, or invalid validity test results, the MRO may report an FFD policy violation to the licensee or other entity;

(3) If the second laboratory does not reconfirm the positive test results, the MRO shall report that no FFD policy violation has occurred; or

(4) If the second laboratory does not reconfirm the adulterated, substituted, or invalid validity test results, the MRO shall report that no FFD policy violation has occurred.

(o) *Re-authorization after a first violation for a positive test result*. The MRO is responsible for reviewing drug test results from an individual whose authorization was terminated or denied for a first violation of the FFD policy involving a confirmed positive drug test result and who is being considered for re-authorization. In order to determine whether subsequent positive confirmatory drug test results represent new drug use or remaining metabolites from the drug use that initially resulted in the FFD policy violation, the MRO shall request from the HHS-certified laboratory, and the laboratory shall provide, quantitation of the test results and other information necessary to make the determination. If the drug for which the individual first tested positive was marijuana and the confirmatory assay for delta-9-tetrahydrocannabinol-9-carboxylic acid yields a positive result, the MRO shall determine whether the confirmatory test result indicates further marijuana use since the first positive test result, or whether the test result is consistent with the level of delta-9-tetrahydrocannabinol-9-carboxylic acid that would be expected if no further marijuana use had occurred. If the test result indicates that no further marijuana use has occurred since the first positive test result, then the MRO shall declare the drug test result as negative.

(p) *Time to complete MRO review*. The MRO shall complete his or her review of positive, adulterated, substituted, and invalid test results and, in instances when the MRO determines that there is no legitimate medical explanation for the test result(s), notify the licensee's or other entity's designated representative within 10 business days of an initial positive, adulterated, substituted, or invalid test result. The MRO shall notify the licensee or other entity of the results of his or her review in writing and in a manner designed to ensure the confidentiality of the information.

§ 26.187 Substance abuse expert.

(a) *Implementation*. By March 31, 2010, any SAEs on whom licensees and other entities rely to make determinations of fitness under this part shall meet the requirements of this section. An MRO who meets the requirements of this section may serve as both an MRO and as an SAE.