

(b) Audits must focus on the effectiveness of the program and be conducted by individuals qualified in the subject(s) being audited, and independent of both fitness-for-duty program management and personnel directly responsible for implementation of the fitness-for-duty program.

(c) The result of the audit, along with recommendations, if any, must be documented and reported to senior corporate and site management. The resolution of the audit findings and corrective actions must be documented. These documents must be retained for three years. NRC Guidelines require licensee audits of HHS-certified laboratories as described in appendix A.

ENFORCEMENT

§ 26.90 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974; or

(3) Any regulation or order issued under these Acts.

(b) A court order may be obtained for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act of 1954, for violations of—

(1) Section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act;

(2) Section 206 of the Energy Reorganization Act of 1974;

(3) Any rule, regulation, or order issued under these Sections;

(4) Any term, condition, or limitation of any license issued under these Sections; or

(5) Any provisions for which a license may be revoked under section 186 of the Atomic Energy Act of 1954.

[54 FR 24494, June 7, 1989, as amended at 57 FR 55072, Nov. 24, 1992]

§ 26.91 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 26 are issued

under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 26 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 26.1, 26.2, 26.3, 26.4, 26.6, 26.8, 26.90, and 26.91.

[57 FR 55072, Nov. 24, 1992]

APPENDIX A TO PART 26—GUIDELINES FOR DRUG AND ALCOHOL TESTING PROGRAMS

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SUBPART A—GENERAL

1.1 Applicability

(1) These guidelines apply to licensees authorized to operate nuclear power reactors and licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM).

(2) Licensees may set more stringent cut-off levels than specified herein or test for substances other than specified herein and shall inform the Commission of such deviation within 60 days of implementing such change. Licensees may not deviate from the provisions of these guidelines without the written approval of the Commission.

(3) Only laboratories which are HHS-certified are authorized to perform urine drug testing for NRC licensees, vendors, and licensee contractors.

1.2 Definitions

For the purposes of this part, the following definitions apply:

“Aliquot.” A portion of a specimen used for testing.

“BAC.” Blood alcohol concentration (BAC), which can be measured directly from blood or derived from a measure of the concentration of alcohol in a breath specimen, is a measure of the mass of alcohol in a volume of blood such that an individual with 100 mg of alcohol per 100 ml of blood has a BAC of 0.10 percent.

“Commission.” The U.S. Nuclear Regulatory Commission or its duly authorized representatives.

“Chain-of-custody.” Procedures to account for the integrity of each specimen by tracking its handling and storage from the point of specimen collection to final disposition of the specimen.

“Collection site.” A place designated by the licensee where individuals present themselves for the purpose of providing a specimen of their urine, breath, and/or blood to be analyzed for the presence of drugs or alcohol.

“Collection site person.” A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the specimen(s) provided by those individuals. A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required herein. In any case where: (a) a collection is observed or (b) collection is monitored by nonmedical personnel, the collection site person must be a person of the same gender as the donor.

“Confirmatory test.” A second analytical procedure to identify the presence of a specific drug or drug metabolite which is independent of the initial screening test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (At this time gas chromatography/mass spectrometry [GC/MS] is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, phencyclidine). For determining blood alcohol levels, a “confirmatory test” means a second test using another breath alcohol analysis device. Further confirmation upon demand will be by gas chromatography analysis of blood.

“Confirmed positive test.” The result of a confirmatory test that has established the presence of drugs, drug metabolites, or alcohol in a specimen at or above the cut-off level, and that has been deemed positive by the Medical Review Officer (MRO) after evaluation. A “confirmed positive test” for alcohol can also be obtained as a result of a confirmation of blood alcohol levels with a second breath analysis without MRO evaluation.

“HHS-certified laboratory.” A urine and blood testing laboratory that maintains cer-

tification to perform drug testing under the Department of Health and Human Services (HHS) “Mandatory Guidelines for Federal Workplace Drug Testing Programs” (53 FR 11970).

“Illegal drugs.” Those drugs included in Schedules I through V of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

“Initial or screening test.” An immunoassay screen for drugs or drug metabolites to eliminate “negative” urine specimens from further consideration or the first breathalyzer test for alcohol.

“Licensee’s testing facility.” A drug testing facility operated by the licensee or one of its vendors or contractors to perform the initial testing of urine samples and to perform initial breath tests for alcohol. Such a testing facility is optional and not required to maintain HHS certification under this part.

“Medical Review Officer.” A licensed physician responsible for receiving laboratory results generated by an employer’s drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual’s positive test result together with his or her medical history and any other relevant biomedical information.

“Permanent record book.” A permanently bound book in which identifying data on each specimen collected at a collection site are permanently recorded in the sequence of collection.

“Reason to believe.” Reason to believe that a particular individual may alter or substitute the urine specimen.

“Split sample.” A portion of a urine specimen that may be stored by the licensee to be tested in the event of appeal.

SUBPART B—SCIENTIFIC AND TECHNICAL REQUIREMENTS

2.1 The Substances

(a) Licensees shall, as a minimum, test for marijuana, cocaine, opiates, amphetamines, phencyclidine, and alcohol for pre-access, for-cause, random, and follow-up tests.

(b) Licensees may test for any illegal drugs during a for-cause test, or analysis of any specimen suspected of being adulterated or diluted through hydration or other means.

(c) Licensees shall establish rigorous testing procedures that are consistent with the intent of these guidelines for any other drugs not specified in these guidelines for which testing is authorized under 10 CFR 26, so that the appropriateness of the use of these substances can be evaluated by the Medical Review Officer to ensure that individuals granted unescorted access are fit for maintaining access to and for performing duties in protected areas.

(d) Specimens collected under NRC regulations requiring compliance with this part may only be designated or approved for testing as described in this part and shall not be used to conduct any other analysis or test without the permission of the tested individual.

(e) This section does not prohibit procedures reasonably incident to analysis of a specimen for controlled substances (e.g., determination of pH on tests for specific gravity, creatinine concentration, or presence of adulterants).

2.2 General Administration of Testing

The licensee testing facilities and HHS-certified laboratories described in this part shall develop and maintain clear and well-documented procedures for collection, shipment, and accession of urine and blood specimens under this part. Such procedures shall include, as a minimum, the following:

(a) Use of a chain-of-custody form. The original shall accompany the specimen to the HHS-certified laboratory. A copy shall accompany any split sample. The form shall be a permanent record on which is retained identity data (or codes) on the employee and information on the specimen collection process and transfers of custody of the specimen.

(b) Use of a tamperevident sealing system designed in a manner such that the specimen container top can be sealed against undetected opening, the container can be identified with a unique identifying number identical to that appearing on the chain-of-custody form, and space has been provided to initial the container affirming its identity. For purposes of clarity, this requirement assumes use of a system made up of one or more pre-printed labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(c) Use of a shipping container in which one or more specimens and associated paperwork may be transferred and which can be sealed and initialed to prevent undetected tampering.

(d) Written procedures, instructions, and training shall be provided as follows:

(1) Licensee collection site procedures and training of collection site personnel shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the individual tested, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(2) A non-medical collection site person shall receive training in compliance with this appendix and shall demonstrate proficiency in the application of this appendix prior to serving as a collection site person. A medical professional, technologist, or technician licensed or otherwise approved to prac-

tice in the jurisdiction in which collection occurs may serve as a collection site person if that person is provided the instructions described in 2.2(3) and performs collections in accordance with those instructions.

(3) Collection site persons shall be provided with detailed, clearly-illustrated, written instructions on the collection of specimens in compliance with this part. Individuals subject to testing shall also be provided standard written instructions setting forth their responsibilities.

(4) The option to provide a blood specimen for confirmatory analysis following a positive breath test shall be specified in the written instructions provided to individuals tested. The instructions shall also state that failure to request a confirmatory blood test indicates that the individual accepts the breath test results.

2.3 Preventing Subversion of Testing

Licensees shall carefully select and monitor persons responsible for administering the testing program (e.g., collection site persons, laboratory technicians, specimen couriers, and those selecting and notifying personnel to be tested), based upon the highest standards for honesty and integrity, and shall implement measures to ensure that these standards are maintained. As a minimum, these measures shall ensure that the integrity of such persons is not compromised or subject to efforts to compromise due to personal relationships with any individuals subject to testing.

As a minimum:

(1) Supervisors, co-workers, and relatives of the individual being tested shall not perform any collection, assessment, or evaluation procedures.

(2) Appropriate background checks and psychological evaluations shall be completed prior to assignment of any tasks associated with the administration of the program, and shall be conducted at least once every three years.

(3) Persons responsible for administering the testing program shall be subjected to a behavioral observation program designed to assure that they continue to meet the highest standards for honesty and integrity.

2.4 Specimen Collection Procedures

(a) "Designation of Collection Site." Each drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine or blood specimens to a drug testing laboratory. A properly equipped mobile facility that meets the requirements of this part is an acceptable collection site.

(b) "Collection Site Person." A collection site person shall have successfully completed training to carry out this function. In any case where the collection of urine is observed, the collection site person must be a person of the same gender as the donor. Persons drawing blood shall be qualified to perform that task.

(c) "Security." The purpose of this paragraph is to prevent unauthorized access which could compromise the integrity of the collection process or the specimen. Security procedures shall provide for the designated collection site to be secure. If a collection site facility cannot be dedicated solely to drug and alcohol testing, the portion of the facility used for testing shall be secured during that testing.

(1) A facility normally used for other purposes, such as a public rest room or hospital examining room, may be secured by visual inspection to ensure other persons are not present, and that undetected access (e.g., through a rear door not in the view of the collection site person) is impossible. Security during collection may be maintained by effective restriction of access to collection materials and specimens. In the case of a public rest room, the facility must be posted against access during the entire collection procedure to avoid embarrassment to the individual or distraction of the collection site person.

(2) If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed container is transferred for shipment, the following minimum procedures shall apply: The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in a mailer or secured for shipment. The mailer shall be immediately mailed, maintained in secure storage, or remain until mailed under the personal control of the collection site person. These minimum procedures shall apply to the mailing of specimens to licensee testing facilities from collection sites (except where co-located) as well as to the mailing of specimens to HHS-certified laboratories. As an option, licensees may ship several specimens via courier in a locked or sealed shipping container.

(d) "Chain-of-Custody." Licensee chain-of-custody forms shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine and blood specimens from one authorized individual or place to another shall always be accomplished through chain-of-custody procedures. Every effort shall be made to minimize the number of persons handling the specimens.

(e) "Access to Authorized Personnel Only." No unauthorized personnel shall be permitted in any part of the designated collection site where specimens are collected or

stored. Only the collection site person may handle specimens prior to their securement in the mailing or shipping container or monitor or observe specimen collection (under the conditions specified in this part). In order to promote security of specimens, avoid distraction of the collection site person, and ensure against any confusion in the identification of specimens, a collection site person shall conduct only one collection procedure at any given time. For this purpose, a collection procedure is complete when the specimen container has been sealed and initialed, the chain-of-custody form has been executed, and the individual has departed the collection site.

(f) "Privacy." Procedures for collecting urine specimens shall allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided. For purposes of this appendix the following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute a urine specimen:

(1) The individual has presented a urine specimen that falls outside the normal temperature range, and the individual declines to provide a measurement of oral body temperature by sterile thermometer, as provided in paragraph (g)(14) of this appendix, or the oral temperature does not equal or exceed that of the specimen.

(2) The last urine specimen provided by the individual (i.e., on a previous occasion) was determined by the laboratory to have a specific gravity of less than 1.003 or a creatinine concentration below .2 g/L.

(3) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the sample (e.g., substitute urine in plain view, blue dye in specimen presented, etc.).

(4) The individual has previously been determined to have used a substance inappropriately or without medical authorization and the particular test is being conducted as a part of a rehabilitation program or on return to service after evaluation and/or treatment for a confirmed positive test result.

(g) "Integrity and Identity of Specimens." Licensees shall take precautions to ensure that a urine specimen is not adulterated or diluted during the collection procedure, that a blood sample or breath exhalant tube cannot be substituted or tampered with, and that the information on the specimen container and in the record book can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that authentic specimens are obtained and correctly identified:

(1) To deter the dilution of urine specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet

bowl always remains blue. There shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs. If there is another source of water in the enclosure, it shall be effectively secured or monitored to ensure it is not used (undetected) as a source for diluting the specimen.

(2) When an individual arrives at the collection site for a urine or breath test, the collection site person shall ensure that the individual is positively identified as the person selected for testing (e.g., through presentation of photo identification or identification by the employer's representative). If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive for a urine or breath test at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) After the individual has been positively identified, the collection site person shall ask the individual to sign a consent-to-testing form and to list all of the prescription medications and over-the-counter preparations that he or she can remember using within the past 30 days.

(5) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine, breath, or blood specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments outside of the room in which the blood, breath, or urine sample is collected. The individual may retain his or her wallet.

(6) The individual shall be instructed to wash and dry his or her hands prior to urination.

(7) After washing hands prior to urination, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the urine specimen.

(8) The individual may provide his/her urine specimen in the privacy of a stall or otherwise partitioned areas that allows for individual privacy.

(9) The collection site person shall note any unusual behavior or appearance in the permanent record book and on the chain-of-custody form.

(10) In the exceptional event that a designated collection site is inaccessible and there is an immediate requirement for urine specimen collection (e.g., an accident investigation), a public or on-site rest room may be used according to the following procedures. A collection site person of the same gender as the individual shall accompany the

individual into the rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain-of-custody procedures.

(11) Upon receiving a urine specimen from the individual, the collection site person shall determine that it contains at least 60 milliliters of urine. If there is less than 60 milliliters of urine in the container, additional urine shall be collected in a separate container to reach a total of 60 milliliters. (The temperature of the partial specimen in each separate container shall be measured in accordance with paragraph (f)(13) of this section, and the partial specimens shall be combined in one container.) The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., a glass of water). If the individual fails for any reason to provide 60 milliliters of urine, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(12) After the urine specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(13) Immediately after the urine specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement is critical and in no case shall exceed 4 minutes.

(14) If the temperature of a urine specimen is outside the range of 32.5°- 37.7 °C/90.5°-99.8 °F, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person and both specimens shall be forwarded to the laboratory for testing. An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(15) Immediately after a urine specimen is collected, the collection site person shall also inspect the specimen to determine its

color and look for any signs of contaminants. Any unusual findings shall be noted in the permanent record book.

(16) All urine specimens suspected of being adulterated or found to be diluted shall be forwarded to the laboratory for testing.

(17) Whenever there is reason to believe that a particular individual may alter or substitute the urine specimen to be provided, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person. Where appropriate, measures will be taken to prevent additional hydration.

(18) Alcohol breath tests shall be delayed at least 15 minutes if any source of mouth alcohol (e.g., breath fresheners) or any other substances are ingested (e.g., eating, smoking, regurgitation of stomach contents from vomiting or burping). The collection site person shall ensure that each breath specimen taken comes from the end, rather than the beginning, of the breath expiration. For each screening test, two breath specimens shall be collected from each individual no less than two minutes apart and no more than 10 minutes apart. The test results shall be considered accurate if the result of each measurement is within plus or minus 10 percent of the average of the two measurements. If the two tests do not agree, the breath tests shall be repeated on another evidential-grade breath analysis device. Confirmatory testing is accomplished by repeating the above procedure on another evidential-grade breath analysis device.

(19) If the alcohol breath tests indicates that the individual is positive for a BAC at or above the 0.04 percent cut-off level, the individual may request a confirmatory blood test, at his or her discretion. All vacuum tube and needle assemblies used for blood collection shall be factory-sterilized. The collection site person shall ensure that they remain properly sealed until used. Antiseptic swabbing of the skin shall be performed with a nonethanol antiseptic. Sterile procedures shall be followed when drawing blood and transferring the blood to a storage container; in addition, the container must be sterile and sealed.

(20) Both the individual being tested and the collection site person shall keep urine and blood specimens in view at all times prior to their being sealed and labeled. If a urine specimen is split (as described in Section 2.7(j)) and if any specimen is transferred to a second container, the collection site person shall request the individual to observe the splitting of the urine sample or the transfer of the specimen and the placement of the tamperevident seal over the container caps and down the sides of the containers.

(21) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (h) through (j) of this section.

(22) The collection site person shall place securely on each container an identification label which contains the date, the individual's specimen number, and any other identification information provided or required by the drug testing program. If separate from the labels, the tamperevident seals shall also be applied.

(23) The individual shall initial the identification labels on the specimen containers for the purpose of certifying that it is the specimen collected from him or her.

(i) The individual shall be asked to read and sign a statement on either the chain-of-custody form or in the permanent record book certifying that the specimens identified as having been collected from him or her are in fact the specimen he or she provided.

(ii) The individual shall be provided an opportunity to set forth on the urine chain-of-custody form information concerning medications taken or administered in the past 30 days.

(24) The collection site person shall enter in the permanent record book all information identifying the specimens. The collection site person shall sign the permanent record book next to the identifying information.

(25) A higher level supervisor in the drug testing program shall review and concur in advance with any decision by a collection site person to obtain a urine specimen under the direct observation of a same gender collection site person based on a reason to believe that the individual may alter or substitute the specimen to be provided.

(26) The collection site person shall complete the chain-of-custody forms for both the aliquot and the split sample, if collected, and shall certify proper completion of the collection.

(27) The specimens and chain-of-custody forms are now ready for transfer to the laboratory or the licensee's testing facility. If the specimens are not immediately prepared for shipment, they shall be appropriately safeguarded during temporary storage.

(28) While any part of the above chain-of-custody procedures is being performed, it is essential that the specimens and custody documents be under the control of the involved collection site person. The collection site person shall not leave the collection site in the interval between presentation of the specimen by the individual and securement of the samples with identifying labels bearing the individual's specimen identification numbers and seals initialled by the individual. If the involved collection site person leaves his or her work station momentarily, the specimens and chain-of-custody forms shall be taken with him or her or shall be secured. If the collection site person is leaving for an extended period of time, the specimens shall be packaged for transfer to the laboratory before he or she leaves the site.

(h) "Collection Control." To the maximum extent possible, collection site personnel shall keep the individual's specimen containers within sight both before and after the individual has urinated or provided a breath or blood sample. After the specimen is collected and whenever urine specimens are split, they shall be properly sealed and labeled. A chain-of-custody form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on the chain-of-custody form each time a specimen is handled or transferred, and every individual in the chain of custody shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(i) "Transportation to Laboratory or Testing Facility." Collection site personnel shall arrange to transfer the collected specimens to the drug testing laboratory or licensee testing facility. To transfer specimens off-site for initial screening and for a second screen and confirmatory analysis of presumptive positive specimens and for transferring suspect specimens to a laboratory for analysis under special processing [Section 2.7(d)], the specimens shall be placed in containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes, padded mailers, or bulk shipping containers with that capability) and those containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the container, the collection site person shall sign and enter the date specimens were sealed in the containers for shipment. The collection site personnel shall ensure that the chain-of-custody documentation is attached to each container sealed for shipment to the drug testing laboratory.

(j) "Failure to Cooperate." If the individual refuses to cooperate with the urine collection or breath analysis process (e.g., refusal to provide a complete specimen, complete paperwork, initial specimen), then the collection site person shall inform the Medical Review Officer and shall document the non-cooperation in the permanent record book and on the specimen custody and control form. The Medical Review Officer shall report the failure to cooperate to the appropriate management. The provision of blood specimens for use to confirm a positive breath test for alcohol shall be entirely voluntary, at the individual's discretion. In the absence of a voluntary blood test the second positive breath test shall be considered a confirmed positive.

2.5. HHS-certified Laboratory Personnel

(a) "Day-to-Day Management of the HHS-certified Laboratories."

(1) The HHS-certified laboratory shall have a qualified individual to assume professional,

organizational, educational, and administrative responsibility for the laboratories' drug testing facilities.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the appropriate State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology, or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology, and

(iv) In addition to the requirements in (i), (ii), and (iii) above, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse; and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the testing laboratory even where another individual has overall responsibility for an entire multispecialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of their testing laboratories. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in Section 2.7(0) of this appendix).

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls

and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that test results are not reported until all corrective actions have been taken and he or she can assure that the test results provided are accurate and reliable.

(b) “Test Validation.” The laboratory’s urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory’s test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) “Day-to-Day Operations and Supervision of Analysts.” The laboratory’s urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor’s degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain-of-custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) “Other Personnel.” Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) “Training.” The laboratory’s testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) “Files.” Laboratory personnel files shall include: résumé of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

2.6 Licensee Testing Facility Personnel

(a) “Day-to-Day Management of Operations.” Any licensee testing facility shall have an individual to be responsible for day-to-day operations and to supervise the testing technicians. This individual(s) shall have at least a bachelor’s degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the licensee 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.

(b) “Other Personnel.” Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(c) “Files.” Licensees’ testing facility personnel files shall include: résumé of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate and appropriate data to support determinations of honesty and integrity conducted in accordance with Section 2.3 of this appendix.

2.7 Laboratory and Testing Facility Analysis Procedures

(a) “Security and Chain-of-Custody.”

(1) HHS-certified drug testing laboratories and any licensee testing facility shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records and split samples are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. All authorized visitors and maintenance and service personnel shall be escorted at all times in the HHS-certified laboratory and in the licensee’s testing facility. Documentation of individuals accessing these areas, dates, and times of entry and purpose of entry must be maintained.

(2) Laboratories and testing facilities shall use chain-of-custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain-of-custody form each time a specimen is handled or transferred, and every individual in the chain shall be

identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain-of-custody forms for those specimens or aliquots as they are received.

(b) "Receiving."

(1) When a shipment of specimens is received, laboratory and licensee's testing facility personnel shall inspect each package for evidence of possible tampering and compare information on specimen containers within each package to the information on the accompanying chain-of-custody forms. Any direct evidence of tampering or discrepancies in the information on specimen containers and the licensee's chain-of-custody forms attached to the shipment shall be reported within 24 hours to the licensee, in the case of HHS-certified laboratories, and shall be noted on the laboratory's chain-of-custody form which shall accompany the specimens while they are in the laboratory's possession. Indications of tampering with specimens at a testing facility operated by a licensee shall be reported within 8 hours to senior licensee management.

(2) Specimen containers will normally be retained within the laboratory's or testing facility's accession area until all analyses have been completed. Aliquots and the chain-of-custody forms shall be used by laboratory or testing facility personnel for conducting initial and confirmatory tests, as appropriate.

(c) "Short-Term Refrigerated Storage."

Specimens that do not receive an initial test within 7 days of arrival at the laboratory or are not shipped within 6 hours from the licensee's testing facility and any retained split samples shall be placed in secure refrigeration units. Temperatures shall not exceed 6 °C. Emergency power equipment shall be available in case of prolonged power failure.

(d) "Specimen Processing." Urine specimens identified as presumptive positive by a licensee's testing facility shall be shipped to an HHS-certified laboratory for testing. Laboratory facilities for drug testing will normally process urine specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests at either the licensee's testing facility or an HHS-certified laboratory, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts. Special processing may be conducted to analyze specimens suspected of being adulterated or diluted (including hydration). Any evidence of adulteration or dilution, and any detected trace amounts of drugs or metabo-

lites, shall be reported to the Medical Review Officer.

(e) "Preliminary Initial Test."

(1) For the analysis of urine specimens, any preliminary test performed by a licensee's testing facility and the initial screening test performed by a HHS-certified laboratory shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The initial test of breath for alcohol performed at the collection site shall use a breath measurement device which meets the requirements of Section 2.7(o)(3). The following initial cut-off levels shall be used when screening specimens to determine whether they are negative for the indicated substances:

Initial test cut-off level (ng/ml)

Marijuana metabolites.....	100
Cocaine metabolites.....	300
Opiate metabolites.....	300*
Phencyclidine.....	.25
Amphetamines.....	1,000
Alcohol.....	0.04% BAC

*25 ng/ml is immunoassay specific for free morphine.

In addition, licensees may specify more stringent cutoff levels. Results shall be reported for both levels in such cases.

(2) The list of substances to be tested and the cut-off levels are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines made by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant the inclusion of additional substances and other concentration levels.

(f) "Confirmatory Test."

(1) Specimens which test negative as a result of this second screening shall be reported as negative to the licensee and will not be subject to any further testing unless special processing of the specimen is desired because adulteration or dilution is suspected.

(2) All urine samples identified as presumptive positive on the screening test performed by a HHS-certified laboratory shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cut-off values listed in this paragraph for each drug, and at the cut-off values required by the licensee's unique program, where differences exist. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the laboratory record as "greater than highest standard curve value."

Confirmatory test cut-off level (ng/ml)

Marijuana metabolite.....	15*
Cocaine metabolite.....	150**
Opiates:	
Morphine.....	300

Codeine.....300
 Phencyclidine.....25
 Amphetamines:
 Amphetamine.....500
 Methamphetamine.....500
 Alcohol.....0.04% BAC
 *Delta-9-tetrahydrocannabinol-9-carboxylic acid.
 **Benzoyllecgonine.

In addition, licensees may specify more stringent cut-off levels. Results shall be reported for both levels in such cases.

(3) The analytic procedure for confirmatory analysis of blood specimens voluntarily provided by individuals testing positive for alcohol on a breath test shall be gas chromatography analysis.

(4) The list of substances to be tested and the cut-off levels are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines made by the Department of Health and Human Services as advances in technology, additional experience, or other considerations warrant the inclusion of additional substances and other concentration levels.

(5) Confirmatory tests for opiates shall include a test for 6-monoacetylmorphine (MAM) if the screening test is presumptive positive for morphine.

(g) "Reporting Results."

(1) The HHS-certified laboratory shall report test results to the licensee's Medical Review Officer within 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual at the laboratory. The report shall identify the substances tested for, whether positive or negative, the cut-off(s) for each, the specimen number assigned by the licensee, and the drug testing laboratory specimen identification number. The results (positive and negative) for all specimens submitted at the same time to the laboratory shall be reported back to the Medical Review Officer at the same time when possible.

(2) The HHS-certified laboratory and any licensee testing facility shall report as negative all specimens, except suspect specimens being analyzed under special processing, which are negative on the initial test or negative on the confirmatory test. Specimens testing positive on the confirmatory analysis shall be reported positive for a specific substance. Except as provided in §26.24(d), presumptive positive results of preliminary testing at the licensee's testing facility will not be reported to licensee management.

(3) The Medical Review Officer may routinely obtain from the HHS-certified laboratory, and the laboratory shall provide, quantitation of test results. The Medical Review

Officer may only disclose quantitation of test results for an individual to licensee management, if required in an appeals process, or to the individual under the provisions of Section 3.2. (This does not preclude the provision of program performance data under the provisions of 10 CFR 26.71(d).) Quantitation of negative tests for urine specimens shall not be disclosed, except where deemed appropriate by the Medical Review Officer for proper disposition of the results of tests of suspect specimens. Alcohol quantitation for a blood specimen shall be provided to licensee management with the Medical Review Officer's evaluation.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means (e.g., teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone from HHS-certified laboratory personnel to the Medical Review Officer. The HHS-certified laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer a certified copy of the original chain-of-custody form signed by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports and attached to which shall be a copy of the test report.

(6) The HHS-certified laboratory and the licensee's testing facility shall provide to the licensee official responsible for coordination of the fitness-for-duty program a monthly statistical summary of urinalysis and blood testing and shall not include in the summary any personal identifying information. Initial test data from the licensee's testing facility and the HHS-certified laboratory, and confirmation data from HHS-certified laboratories shall be included for test results reported within that month. Normally this summary shall be forwarded from HHS-certified laboratories by registered or certified mail and from the licensee's testing facility not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

(i) Initial Testing:

- (A) Number of specimens received;
- (B) Number of specimens reported out; and
- (C) Number of specimens screened positive for:

Marijuana metabolites
 Cocaine metabolites
 Opiate metabolites
 Phencyclidine
 Amphetamines
 Alcohol

(ii) Confirmatory Testing:

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(A) Number of specimens received for confirmation;

(B) Number of specimens confirmed positive for:

Marijuana metabolite
Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine
Alcohol

(7) The statistics shall be presented for both the cut-off levels in these guidelines and any more stringent cut-off levels which licensees may specify. The HHS-certified laboratory and the licensee's testing facility shall make available quantitative results for all samples tested when requested by the NRC or the licensee for which the laboratory is performing drug testing services.

(8) Unless otherwise instructed by the licensee in writing, all records pertaining to a given urine or blood specimen shall be retained by the HHS-certified drug testing laboratory and the licensee's testing facility for a minimum of 2 years.

(h) "Long-Term Storage." Long-term frozen storage (-20°C or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Unless otherwise authorized in writing by the licensee, HHS-certified laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive. Within this 1-year period a licensee or the NRC may request the laboratory to retain the specimen for an additional period of time, but if no such request is received, the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period. Any split samples retained by the licensee shall be transferred into long-term storage upon determination by the Medical Review Officer that the specimen has a confirmed positive test.

(i) "Retesting Specimens." Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cut-off requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(j) "Split Samples." Urine specimens may be split, at the licensee's discretion, into two parts at the collection site. One half of such samples (hereafter called the aliquot) shall be analyzed by the licensee's testing facility or the HHS-certified laboratory for the licensee's purposes as described in this appendix. The other half of the sample (hereafter called the split sample) may be withheld from transfer to the laboratory, sealed, and stored in a secure manner by the licensee

until the aliquot has been determined to be negative or until the positive result of a screening test has been confirmed. As soon as the aliquot has tested negative, the split sample in storage may be destroyed. If the aliquot tests positive by confirmatory testing, then, at the tested individual's request, the split sample may be forwarded on that day to another HHS-certified laboratory that did not test the aliquot. The chain-of-custody and testing procedures to which the split sample is subject, shall be the same as those used to test the initial aliquot and shall meet the standards for retesting specimens [Section 2.7(i)]. The quantitative results of any second testing process shall be made available to the Medical Review Officer and to the individual tested.

(k) "Subcontracting." HHS-certified laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the licensee. The laboratory must be capable of performing testing of the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) and of whole blood and confirmatory GC/MS methods specified in these guidelines.

(1) "Laboratory Facilities."

(1) HHS-certified laboratories shall comply with applicable provisions of any State licensure requirements.

(2) HHS-certified laboratories shall have the capability, at the same laboratory premises, of performing initial tests for each drug and drug metabolite for which service is offered, and for performing confirmatory tests for alcohol and for each drug and drug metabolite for which service is offered. Any licensee testing facilities shall have the capability, at the same premises, of performing initial screening tests for each drug and drug metabolite for which testing is conducted. Breath tests for alcohol may be performed at the collection site.

(m) "Inspections." The NRC and any licensee utilizing an HHS-certified laboratory shall reserve the right to inspect the laboratory at any time. Licensee contracts with HHS-certified laboratories for drug testing and alcohol confirmatory testing, as well as contracts for collection site services, shall permit the NRC and the licensee to conduct unannounced inspections. In addition, prior to the award of a contract, the licensee shall carry out pre-award inspections and evaluation of the procedural aspects of the laboratory's drug testing operation. The NRC shall reserve the right to inspect a licensee's testing facility at any time.

(n) "Documentation." HHS-certified laboratories and the licensee's testing facility shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by the NRC or by any licensee for which laboratory

services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain-of-custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The HHS-certified laboratory and the licensee's testing facility shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(o) "Additional Requirements for HHS-certified Laboratories and Licensee's Testing Facilities."

(1) "Procedure manual." Each laboratory and licensee's testing facility shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual. Superseded material must be retained for three years.

(2) "Standards and controls." HHS-certified laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date.

(3) "Instruments and equipment."

(i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) Alcohol breath analysis equipment shall be an evidential-grade breath alcohol analysis device of a brand and model that conforms to National Highway Traffic Safety Administration (NHTSA) standards (49 FR 48855) and to any applicable State statutes.

(iii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks, and instructions for major troubleshooting and repair. Records shall be available on preventive maintenance.

(4) "Remedial actions." There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) "Personnel available to testify at proceedings." The licensee's testing facility and HHS-certified laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on positive breath analysis or urinalysis results reported by the licensee's testing facility or the HHS-certified laboratory.

2.8 Quality Assurance and Quality Control

(a) "General." HHS-certified laboratories and the licensee's testing facility shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain-of-custody, security, reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) "Licensee's Testing Facility Quality Control Requirements for Initial Tests." Because all positive preliminary tests for drugs are forwarded to an HHS-certified laboratory for screening and confirmatory testing when appropriate, the NRC does not require licensees to assess their testing facility's false positive rates for drugs. To ensure that the rate of false negative tests is kept to the minimum that the immunoassay technology supports, licensees shall process blind performance test specimens and submit a sampling of specimens screened as negative from every test run to the HHS-certified laboratory. In addition, the manufacturer-required performance tests of the breath analysis equipment used by the licensee shall be conducted as set forth in the manufacturer's specifications.

(c) "Laboratory Quality Control Requirements for Initial Tests at HHS-Certified Laboratories." Each analytical run of specimens to be screened shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the threshold (cut-off).

In addition, with each batch of samples, a sufficient number of standards shall be included to ensure and document the linearity

of the assay method over time in the concentration area of the cut-off. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory quality control samples, prepared from spiked urine samples of determined concentration, shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(d) "Laboratory Quality Control Requirements for Confirmation Tests." Each analytical run of specimens to be confirmed shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the threshold (cut-off).

The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(e) "Licensee Blind Performance Test Procedures."

(1) Licensees shall purchase chemical testing services only from laboratories certified by DHHS or a DHHS-recognized certification program in accordance with the HHS Guidelines. Laboratory participation is encouraged in other performance testing surveys by which the laboratory's performance is compared with peers and reference laboratories.

(2) During the initial 90-day period of any new drug testing program, each licensee shall submit blind performance test specimens to each HHS-certified laboratory it contracts within the amount of at least 50 percent of the total number of samples submitted (up to a maximum of 500 samples) and thereafter a minimum of 10 percent of all samples (to a maximum of 250) submitted per quarter.

(3) Approximately 80 percent of the blind performance test samples shall be blank (i.e., certified to contain no drug) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the licensee is testing.

(4) The licensee shall investigate, or shall refer to DHHS for investigation, any unsatisfactory performance testing result, and based on this investigation, the laboratory shall take action to correct the cause of the

unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individuals responsible for the day-to-day management and operation of the HHS-certified laboratory. Then the licensee shall send the document to the NRC as a report of the unsatisfactory performance testing incident within 30 days. The NRC shall ensure notification of the finding to DHHS.

(5) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the licensee shall promptly notify the NRC. The licensees shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the licensee may also require review and reanalysis of previously run specimens.

(6) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the licensee shall instruct the laboratory to submit to them all quality control data from the batch of specimens which included the false positive specimen. In addition, the licensee shall require the laboratory to retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's substance testing program. The licensee and the NRC may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the NRC, DHHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

2.9 Reporting and Review of Results

(a) "Medical Review Officer shall review results." An essential part of the licensees' testing programs is the final review of results. A positive test result does not automatically identify a nuclear power plant worker as having used substances in violation of the NRC's regulations or the licensee's company policies. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the Medical Review Officer prior

to the transmission of results to licensee management officials.

(b) “Medical Review Officer—qualifications and responsibilities.” The Medical Review Officer shall be a licensed physician with knowledge of substance abuse disorders and may be a licensee or contract employee. The role of the Medical Review Officer is to review and interpret positive test results obtained through the licensee’s testing program. In carrying out this responsibility, the Medical Review Officer shall examine alternate medical explanations for any positive test result (this does not include confirmation of blood alcohol levels obtained through the use of a breath alcohol analysis device). This action could include conducting a medical interview with the individual, review of the individual’s medical history, or review of any other relevant biomedical factors. The Medical Review Officer shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally prescribed medication. The Medical Review Officer shall not consider the results of tests that are not obtained or processed in accordance with these Guidelines, although he or she may consider the results of tests on split samples in making his or her determination, as long as those split samples have been stored and tested in accordance with the procedures described in these Guidelines.

(c) “Positive Test Results.” Prior to making a final decision to verify a positive test result, the Medical Review Officer shall give the individual an opportunity to discuss the test result with him or her. Following verification of a positive test result, the Medical Review Officer shall, as provided in the licensee’s policy, notify the applicable employee assistance program and the licensee’s management official empowered to recommend or take administrative action (or the official’s designated agent).

(d) “Verification for opiates; review for prescription medication.” Before the Medical Review Officer verifies a confirmed positive result and the licensee takes action for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). Clinical signs of abuse include recent needle tracks or behavioral and psychological signs of acute opiate intoxication or withdrawal. This requirement does not apply if the GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine. For other drugs that are commonly prescribed or commonly included in over-the-counter preparations (e.g., benzodiazepines in the first case, barbiturates in the second) and that are listed in the licensee’s panel of substances to be tested, the Medical Review Officer shall also determine whether there is clinical evidence—in

addition to the urine test—of unauthorized use of any of these substances or their derivatives.

(e) “Reanalysis authorized.” Should any question arise as to the accuracy or validity of a positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original sample and such retests are authorized only at laboratories certified by DHHS. The Medical Review Officer shall authorize a reanalysis of the original aliquot on timely request of the individual tested, and shall also authorize an analysis of any sample stored by the licensee.

(f) “Results consistent with responsible substance use.” If the Medical Review Officer determines that there is a legitimate medical explanation for the positive test result and that use of the substance identified through testing in the manner and at the dosage prescribed does not reflect a lack of reliability and is unlikely to create on-the-job impairment, the Medical Review Officer shall report the test result to the licensee as negative.

(g) “Result scientifically insufficient.” Additionally, the Medical Review Officer, based on review of inspection reports, quality control data, multiple samples, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation, the Medical Review Officer may request reanalysis of the original sample before making this decision. (The Medical Review Officer may request that reanalysis be performed by the same laboratory or, that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with the HHS Guidelines.) The licensee’s testing facility and the HHS-certified laboratory shall assist in this review process as requested by the Medical Review Officer by making available the individual(s) responsible for day-to-day management of the licensee’s test facility, of 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 licensee. The licensee shall maintain records that summarize any negative findings based on scientific insufficiency and shall make them available to the NRC on request, but shall not include any personal identifying information in such reports.

SUBPART C—EMPLOYEE PROTECTION

3.1 Protection of Employee Records

Licensee contracts with HHS certified laboratories and procedures for the licensee’s testing facility shall require that test

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records be maintained in confidence, as provided in 10 CFR 26.29. Records shall be maintained and used with the highest regard for individual privacy.

3.2 Individual Access to Test and Laboratory Certification Results

Any individual who is the subject of a drug or alcohol test under this part shall, upon written request, have access to any records relating to his or her tests and any records relating to the results of any relevant laboratory certification, review, or revocation-of-certification proceedings.

SUBPART D—CERTIFICATION OF LABORATORIES ENGAGED IN CHEMICAL TESTING

4.1 Use of DHHS-certified laboratories

(a) Licensees subject to this part and their contractors shall use only laboratories certified under the DHHS “Mandatory Guidelines for Federal Workplace Drug Testing Programs”, Subpart C—“Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,” (53 FR 11970, 11986–11989) dated April 11, 1988, and subsequent amendments thereto for screening and confirmatory testing except for initial screening tests at a licensee’s testing facility conducted in accordance with 10 CFR 26.24(d). Information concerning the current certification status of laboratories is available from: The Office of Workplace Initiatives, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, Maryland 20857.

(b) Licensees or their contractors may use only HHS-certified laboratories that agree to follow the same rigorous chemical testing, quality control, and chain-of-custody procedures when testing for more stringent cut-off levels as may be specified by licensees for the classes of drugs identified in this part, for analysis of blood specimens for alcohol, and for any other substances included in licensees’ drug panels.

[54 FR 24494, June 7, 1989, as amended at 56 FR 41927, Aug. 26, 1991; 58 FR 31470, June 3, 1993]

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