STATE OF MAINE

SUBSTANCE USE TESTING FOR THE WORKPLACE RULE

10-144 Code of Maine Rules
Chapter 265

Department of Health and Human Services
Maine Center for Disease Control and Prevention
11 State House Station
Augusta, Maine 04333-0011

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144 Maine ~~CDC,~~Center for Disease Control and Prevention
~~Health and Environmental Testing Laboratory~~

Chapter 265: ~~Maine Drug~~ Substance Use Testing For the Workplace ~~Laboratory~~ Rule~~s~~

SUMMARY

The Department of Health and Human Services (Department) has prescribed ~~these rules and regulations~~this rule for programs and laboratories testing employees and applicants for substances of ~~abuse~~use. ~~The rules are intended to assure that employees and applicants receive reliable and accurate testing, and that privacy rights are protected.~~(26 MRS § 683(11).)

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~~A.~~SECTION 1. ~~Definitions~~PURPOSE AND DEFINITIONS~~:~~

A. Purpose. This rule is intended to ensure that employees and applicants receive reliable and accurate testing~~,~~ and ensure that privacy rights are protected.

B. Definitions. Definitions in this rule are in addition to definitions in the governing statute. As used in ~~this chapter~~this rule, unless otherwise indicated, the following terms have the following meanings:~~.~~

1. **Applicant**~~. "Applicant"~~ means any person seeking employment from an employer. The term includes any person using an employment agency's services.

2. **Confirmed positive result** means a result of a confirmation test, as defined in this rule, that indicates the presence of a substance of use in accordance with the laboratory protocols at or above the cutoff level.

3. ~~2~~**Employee**~~. "Employee"~~ means a person who is permitted, required or directed by any employer to engage in any employment for consideration of direct gain or profit.

4. ~~3.~~**Employer**~~. "Employer"~~ means any person, partnership, corporation, association or other legal entity, public or private, that employs one or more employees. The term also includes an employment agency.

5. ~~4.~~**Negative test result**~~. "Negative test result"~~ means a test result that indicates that:

~~(~~a.~~)~~ A substance of ~~abuse~~ use is not present in the tested sample; or

~~(~~b.~~)~~ A substance of ~~abuse~~ use is present in the tested sample in a concentration below the cutoff level.

6. ~~5.~~**Non-negative test result**~~. "Non-negative result"~~ means a test result that indicates the presence of a substance of ~~abuse~~use in the tested sample at or above the cutoff level of the test.

~~6. Positive test result. "Positive test result" means a test result that indicates the presence of a substance of abuse in the tested sample above the cutoff level of the test.~~

~~(a)"Confirmed positive result" means a confirmation test result that indicates the presence of a substance of abuse above the cutoff level.~~

7. **Substance ~~abuse~~ use test**~~.~~ ~~"Substance abuse test"~~ means any test procedure designed to take and analyze body fluids or materials from the body for the purpose of detecting the presence of substances of use~~abuse~~. The term does not include tests designed to determine blood alcohol concentration levels from a sample of an individual's breath.

~~(~~a.~~)~~ ~~"~~**Screening test**~~"~~ means an initial substance ~~abuse~~ use test performed through the use of immunoassay technology, chromatography, mass analysis, enzymatic technology (for blood alcohol), or a test technology of similar or greater accuracy and reliability approved by the ~~department~~Department ~~of Health & Human Services~~ as specified in ~~these~~ this rule~~s~~, ~~s~~Section 4(H)~~D (8)~~, and which is used as a preliminary step in detecting the presence of substances of use~~abuse~~.

(b.) "**Confirmation test**" means a 2ndsecond substance abuse use test performed on a separate aliquot of a specimen to identify and quantify a specific drug or drug metabolite and verify the presence of a substance of use indicated by an initial non-negative test result. A confirmation test uses through the use of gas chromatography/mass spectrometry or liquid chromatography/mass spectrometry, except that blood alcohol will be confirmed using gas chromatography that is used to verify the presence of a substance of abuse indicated by an initial positive screening test result.

8. **Substance of abuseuse.** "Substance of abuse" means any scheduled drug, alcohol or other drug, or any of their metabolites. For the purpose of this rule, the testing for and detection of cannabis (also referred to as marijuana), cannabinoid or cannabis metabolite is specific to the psychoactive component tetrahydrocannabinol (THC).

(a.) "**Alcohol**" has the same meaning as found in Title 28-A, M.R.S.A., section § 2, subsection (2): The substance known as ethyl alcohol, hydrated oxide of ethyl, or spirit of wine which is commonly produced by the fermentation or distillation of grain, starch, molasses, sugar, potatoes or other substances, and includes all dilutions and mixtures of these substances.

(b.) "**Drug**" has the same meaning as found in 32 MRS Title 32, section § 13702-A, (subsection 9 11).

(c.) "**Scheduled drug**" has the same meaning as found in Title 17-A MRS, sectionS 1101, subsection (11).

B.SECTION 2. Collection and storage of SamplesCOLLECTION AND STORAGE OF SAMPLES

A. For all testing allowed under these this rules, the specimen to be collected shallmust be the employee's or applicant's urine, oral fluids, hair and or sweat, except that, as provided by Title 26, MRSM.R.S.A., section § 683, subsection (5), employees may request that a blood sample be collected for testing for alcohol and/or marijuanacannabis metabolites, provided that a laboratory is available to the employer or applicant which is in compliance with all other sections of these this rules concerning laboratories, and which offers testing for alcohol or marijuanacannabis metabolites in compliance with such this rules. If such a blood sample is requested, the employer may not test any other sample for alcohol or marijuanacannabis metabolites.

1. The collection of any sample for use in a substance abuse use test must be conducted in a medical facility and supervised by a physician licensed under Title 32, M.R.S.A., chapter 36 or 48, or a nurse licensed under Title 32, M.R.S.A. chapter 31. A medical facility includes a first aid station located at the work site.

2. An employer may not require an employee or applicant to remove any clothing for the purpose of collecting a urine sample, except that:
(a) A an employer may require that an employee or applicant leave any personal belongings other than clothing, and any unnecessary coat, jacket or similar outer garments outside the collection area; or.

(b) If it is the standard practice of an off-site medical facility to require the removal of clothing when collecting a urine sample for any purpose, the physician or

~~nurse supervising the collection of the sample in that facility may require the employee or applicant to remove their clothing.~~

~~3.~~ No employee or applicant may be required to provide a urine sample while being observed, directly or indirectly, by another individual.

4. Urine samples ~~shall~~must be collected in new, clean containers manufactured for the purpose of urine collection. If the employer's policy calls for specimen assessment, the person in charge of collection, may, in the presence of the test subject, measure the temperature of the specimen within ~~3~~three minutes of voiding~~,~~ and the pH of the specimen, and evaluate the color and odor of the specimen. The container ~~shall~~must be sealed and labeled immediately after collection and specimen assessment in a manner which will prevent or reveal tampering with the specimen. Seals ~~shall~~must cover the cap and extend over the sides of the container and be initialed by the employee or applicant being tested. The specimen container ~~shall~~must be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. Sealing and labeling ~~shall~~must occur under the observation of the employee or applicant being tested.

5. Blood specimens, where allowed, ~~shall~~must be collected in new vacuum-activated blood collection tubes, with such preservatives as may be specified by the testing laboratory, and ~~shall~~must be sealed with tamperproof seals, covering the cap and extending over the sides of the container. Blood samples ~~shall~~must be collected~~taken~~ by a ~~licensed physician, registered physician's assistant, registered nurse, or a person certified by the Department of Human Services to draw blood under Code of Maine Rules, 10-144A, chapter 268~~qualified person in accordance with 26 MRS §683(5)(B). Each specimen container ~~shall~~must be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. Sealing and labeling ~~shall~~must occur under the observation of the employee or applicant being tested.

6. Oral fluid specimens~~, where allowed, shall~~must be collected in ~~accordance with Federal Register, 73 FR 71858, Sections 7.1 and 8.3.~~new, clean containers manufactured for the purpose of oral fluid collection. The container must be sealed and labeled immediately after collection in a manner that will prevent or reveal tampering with the specimen. Seals must cover the cap and extend over the sides of the container and be initialed by the employee or applicant being tested. The specimen container must be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. Sealing and labeling must occur under the observation of the employee or applicant being tested.

7. Hair specimens~~, where allowed, shall~~must be collected in ~~accordance with Federal Register, 73 FR 71858, Sections 7.1 and 8.3.~~new, clean containers manufactured for the purpose of hair specimen collection. The container must be sealed and labeled immediately after collection in a manner that will prevent or reveal tampering with the specimen. Seals must cover the top of the container and extend over the sides of the container and be initialed by the employee or applicant being tested. The specimen container must be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. Sealing and labeling must occur under the observation of the employee or applicant being tested. Hair specimens

must be collected using head hair, unless head hair is not available or is not at least one and a half inches long. In those cases, a urine specimen must be collected.

8. Sweat patch specimens~~, where allowed, shall~~must be collected ~~in accordance with Federal Register, 73 FR 71858, Sections 7.1 and 8.3~~ using a patch that has been specifically manufactured for sweat specimen collection. The sweat patch must be sealed within a container and labeled immediately after collection in a manner that will prevent or reveal tampering with the specimen. Seals must cover the top of the container and extend over the sides of the container and be initialed by the employee or applicant being tested. The specimen container must be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. Sealing and labeling must occur under the observation of the employee or applicant being tested.

B. ~~9.~~Immediately upon collection of each sample, a chain of custody record ~~shall~~must be established for that sample, indicating the identity of each person having control over the sample~~,~~ and the times and dates of all transfers or other actions pertaining to the sample. If warranted due to the volume of testing ~~warrants~~, chain of custody records may be maintained in a log book or other custody form for multiple specimens, provided the identity of each specimen can be documented.

1~~0~~. Samples ~~shall~~must be transported or shipped promptly to the testing laboratory in a secure fashion, so as to prevent tampering. ~~If shipment or transport is not feasible, the specimens shall be refrigerated within one hour, at less than 6° C for no more that three days, or frozen at -20° C or less, for no more than two weeks before shipment.~~

~~11~~2. At the request of the employee or applicant, a portion of the sample~~,~~ collected, sealed~~,~~ and labeled ~~according to the above procedures~~in accordance with this rule, ~~shall~~must be segregated for that person's own testing. This sample ~~shall~~must be stored and chain of custody ~~shall~~must be maintained as provided above. If the employer does not have the capability to store segregated samples for the necessary time period, such storage may be arranged with the licensed testing laboratory performing the employer's analyses, provided that all chain of custody and security requirements are otherwise met. Within ~~5~~five days after notice of the test results is given to the employee or applicant, the employee or applicant ~~shall~~must notify the employer of the testing laboratory selected for that person's own testing. The laboratory so selected ~~shall~~must comply with all the requirements of ~~these~~this rule~~s~~ relating to testing laboratories. The ~~E~~employer~~,~~ or the employer's laboratory~~, shall~~must promptly send the segregated portion of the specimen to the selected laboratory, subject to the same chain of custody and security requirements as observed for the employer's specimen.

~~C~~SECTION 3. ~~Substances for which testing is permitted~~SUBSTANCES FOR WHICH TESTING IS PERMITTED

A. Employers may require testing of employees and applicants for the following substances and groups of substances, as allowed for in ~~Department of Labor approved~~the employer's policy approved by the Maine Department of Labor. Except for assessing specimen integrity, no other testing is permitted. Employers ~~shall~~must specify to the testing laboratory which substances are to be tested for in each specimen or group of specimens.

B. ~~1~~. Substances or groups of substances ~~shall~~ include, but are not limited to, amphetamine/methamphetamine, barbiturates, cannabinoids (tetrahydrocannabinol (THC)), benzodiazepines, cocaine and/or metabolites, phencyclidine, opiates and/or metabolites, methaqualone, methadone, propoxyphene, fentanyl, buprenorphine and alcohol.

~~2~~1. Minimum reportable levels (cutoff levels) for the initial screening test will be established by laboratories and employers at levels (in urine, unless otherwise specified) no lower than the following:

A~~a~~lcohol in blood or urine	0.02 g/100m~~l~~L
Amphetamines~~/~~:	500 ng/m~~l~~L
M~~m~~ethamphetamine	500 ng/mL
MDMA	500 ng/mL
Barbiturates	300 ng/m~~l~~L
Benzodiazepines	300 ng/m~~l~~L
Buprenorphine	10 ng/mL
Cannabinoids (THC) in urine	50 ng/m~~l~~L
Cannabinoids (THC) in blood	10 ng/m~~l~~L
Cocaine and/or metabolites	150 ng/m~~l~~L
Fentanyl	2 ng/mL
Hydrocodone	300 ng/mL
Hydromorphone	300 ng/mL
Methadone	300 ng/m~~l~~L
Methaqualone	300 ng/m~~l~~L
Opiates and/or metabolites:	2000 ng/m~~l~~L
6-Acetyl-morphine	10 ng/mL
Codeine	2000 ng/mL
Morphine	2000 ng/mL
Oxycodone	100 ng/mL
Oxymorphone	100 ng/mL
Phencyclidine	25 ng/m~~l~~L
Propoxyphene	300 ng/mL

~~3~~2. Threshold detection levels for confirmatory tests will be established by laboratories at levels (in urine, unless otherwise specified) no lower than the following:

A~~a~~lcohol in blood or urine	0.02 g/100m~~l~~L
A~~a~~mphetamines:~~/~~	250 ng/m~~l~~L
M~~m~~ethamphetamine	250 ng/m~~l~~L
MDA	250 ng/m~~l~~L
MDEA	250 ng/m~~l~~L
MDMA	250 ng/m~~l~~L
B~~b~~arbiturates	300 ng/m~~l~~L
B~~b~~enzodiazepines	200 ng/m~~l~~L
Buprenorphine	5 ng/m~~l~~L
C~~c~~annabinoids (THC) in urine	15 ng/m~~l~~L
C~~c~~annabinoids (THC) in blood~~.~~	10 ng/m~~l~~L
C~~c~~ocaine and/or metabolites	100 ng/m~~l~~L
Fentanyl	0.5 ng/m~~l~~L
Hydrocodone	100 ng/m~~l~~L

Hydromorphone	100	ng/m~~l~~L
M~~m~~ethadone	300	ng/m~~l~~L
M~~m~~ethaqualone	300	ng/m~~l~~L
O~~o~~piates ~~(morphine,codeine)~~and/or metabolites:	2000	ng/m~~l~~L
6-Acetyl morphine (only if morphine>2000)	10	ng/m~~l~~L
Codeine	2000	ng/mL
~~M~~morphine	2000	ng/mL
Oxycodone	100	ng/mL
Oxymorphone	100	ng/mL
P~~p~~hencyclidine	25	ng/m~~l~~L
Propoxyphene	200	ng/mL

43. Minimum reportable levels (cutoff levels) for the initial screening test will be established by laboratories and employers at levels in hair no lower than the following:

Amphetamines	500	pg/mg
Methamphetamine	500	pg/mg
MDMA	500	pg/mg
Cannabis ~~Marijuana~~ (THC) and/or metabolites	1	pg/mg
Cocaine and/or metabolites	500	pg/mg
Hydrocodone	200	pg/mg
Hydromorphone	200	pg/mg
O~~o~~piates and/or metabolites:	200	pg/mg
Codeine	200	pg/mg
Morphine	200	pg/mg
Oxycodone	200	pg/mg
Oxymorphone	200	pg/mg
Phencyclidine	300	pg/mg

~~5~~4. Threshold detection levels for confirmatory tests will be established by laboratories at levels in hair no lower than the following:

Amphetamines:	300	ng/mg
~~Amphetamine~~	~~300~~	~~pg/mg~~
Methamphetamine	300	pg/mg
MDA	300	pg/mg
MDEA	300	pg/mg
MDMA	300	pg/mg
Cannabis (THC) ~~Marijuana~~ and/or metabolites	0.05	pg/mg
Cocaine~~:~~	500	pg/mg
~~Cocaine~~	~~500~~	~~pg/mg~~
Cocaine metabolites	50	pg/mg
Hydrocodone	200	pg/mg
Hydromorphone	200	pg/mg
Opiates and/or metabolites:	200	pg/mg
6-Acetylmorphine	200	pg/mg
Codeine	200	pg/mg
Morphine	200	pg/mg

Oxycodone	200	pg/mg
Oxymorphone	200	pg/mg
Phencyclidine	300	pg/mg

~~6~~5. Minimum reportable levels (cutoff levels) for the initial screening test will be established by laboratories and employers at levels in oral fluids no lower than the following:

Amphetamines	50	ng/mL
Methamphetamine	50	ng/mL
MDA	50	ng/mL
MDEA	50	ng/mL
MDMA~~.~~	50	ng/mL
Cocaine and/or metabolites	~~20~~15	ng/mL
Hydrocodone	30	ng/mL
Hydromorphone	30	ng/mL
Cannabis (THC) ~~Parent drug~~ and /or metabolite	4	~~n~~g/mL
Opiates and/or metabolites:	30	ng/m~~l~~L
6-Acetylmorphine	4	ng/mL
Codeine	30	ng/mL
Morphine	30	ng/mL
Oxycodone	30	ng/mL
Oxymorphone	30	ng/mL
Phencyclidine	10	ng/mL

~~7~~6. Threshold detection levels for confirmatory tests will be established by laboratories at levels in oral fluid no lower than the following:

Amphetamines:	25	ng/mL
~~Amphetamine~~	~~50~~	~~ng/mL~~
Methamphetamine	25~~50~~	ng/mL
MDA	25~~50~~	ng/mL
MDEA	25~~50~~	ng/mL
MDMA	25~~50~~	ng/mL
Cocaine and/or metabolites	8	ng/mL
Hydrocodone	15	ng/mL
Hydromorphone	15	ng/mL
Cannabis (THC) ~~Parent drug~~ and/or metabolites	2	ng/mL
Opiates and/or metabolites:	15	ng/mL
6-Acetylmorphine	~~4~~2	ng/mL
Codeine	~~40~~15	ng/mL
Morphine	~~40~~15	ng/mL
Oxycodone	15	ng/mL
Oxymorphone	15	ng/mL
Phencyclidine	10	ng/mL

~~8~~7. Minimum reportable levels (cutoff levels) for the initial screening test will be established by laboratories and employers at levels in sweat patches no lower than the following:

Amphetamines:	25	ng/patch
Methamphetamine	25	ng/patch
MDMA	25	ng/patch

Cocaine and/or metabolites	25	ng/patch
Hydrocodone	25	ng/patch
Hydromorphone	25	ng/patch
Cannabis ~~Marijuana~~ (THC) and/or metabolites	4	ng/patch
Opiates and/or metabolites	25	ng/patch
Codeine	25	ng/patch
Morphine	25	ng/patch
Oxycodone	25	ng/patch
Oxymorphone	25	ng/patch
Phencyclidine	20	ng/patch

~~9~~8. Threshold detection levels for confirmatory tests will be established by laboratories at levels in sweat patches no lower than the following:

Amphetamines:	25	ng/patch
~~Amphetamines~~	~~25~~	~~ng/patch~~
Methamphetamine	25	ng/patch
MDA	25	ng/patch
MDEA	25	ng/patch
MDMA	25	ng/patch
Cocaine and/or metabolites	25	ng/patch
Hydrocodone	25	ng/patch
Hydromorphone	25	ng/patch
Cannabis (THC~~parent drug~~) and/or metabolites	1	ng/patch
Opiates and/or metabolites	25	ng/patch
Codeine	25	ng/patch
Morphine	25	ng/patch
Oxycodone	25	ng/patch
Oxymorphone	25	ng/patch
Phencyclidine	20	ng/patch

~~D~~SECTION 4. ~~Testing Laboratories~~TESTING LABORATORIES

A. Laboratories conducting substance use testing of employees and applicants ~~for substances of abuse shall~~ must comply with all of the following requirements, except as noted.

1. ~~Licensure~~Licensure.

~~(~~a.~~)~~ Laboratories conducting substance use testing ~~for substances of abuse~~ under ~~these~~ this rule~~s~~ must be licensed by the Department ~~of Health & Human Services~~ for such testing. Application for licensure ~~shall~~must be made by the ~~L~~laboratory owner on forms prescribed by the Department~~,~~ and ~~shall~~must be accompanied by a non-refundable fee, ~~following Chapter 257: SCHEDULE OF CHARGES OF THE DIAGNOSTIC LABORATORY OF THE DEPARTMENT OF HEALTH & HUMAN SERVICES~~in accordance with the Schedule of Charges for Testing and Services Provided by the Maine Health and Environmental Testing Laboratory Rule (10-144 CMR Chapter 257), as provided by 22 M~~.~~R~~.~~S~~.A., section~~ § 565~~(formally 22 M.R.S.A., section 562)~~.

(b.) The term of the license shallwill be one year from the date of issue. Application for renewal must be received by the Department of Health & Human Services at least one month before the expiration date of the current license. Application for renewal shallmust be accompanied by a non-refundable fee, following Chapter 257: SCHEDULE OF CHARGES OF THE DIAGNOSTIC LABORATORY OF THE DEPARTMENT OF HEALTH & HUMAN SERVICESin accordance with 10-144 CMR Chapter 257, as provided by 22 M.R.S.A., section §565(formally 22 M.R.S.A., section 562).

2. Inspection

(ea.) Laboratories shallmust document compliance with all of the provisions of these this rules, and shall be are subject to inspection by representatives of the Department of Health & Human Services. Initial inspection of a laboratory applying for licensure shallmay be conducted by the Department of Health & Human Services within 60 days of the Department's receipt of the application and confirmation of necessary documentation. If the laboratory is found to be in compliance with thesethis rules, licensure shall will be effective the date of the inspection. If the laboratory is not in compliance, licensure shall will be effective on submission and completion of a satisfactory plan of correction, or such other action as shall be needed to bring the facility into compliance. Repeat inspection may be required by the Department.

(db.) Subsequent inspections shallmay be conducted at least 2two times per year, and at 3three-month intervals for the first 6six months of licensure. If the Llaboratory is found to be not in compliance in noncompliance, it must submit an acceptable plan of correction within 10° days. In the event of continuing non-compliance, the Department may seek revocation of the laboratory's license pursuant to 5 MRS M.R.S.A., chapter 375, sub-chapter 5V. In the case of laboratories located outside the sState of Maine, the laboratory willshall be liable for all travel, per diem, lodging, and other costs of the inspection. Laboratories shall be are subject to inspection at all times during operating hours.

(ec.) Laboratories shallmust notify the Department of any changes in personnel, procedures, or other factors material to the quality of testing, within 10 days of occurrence.

(fd.) Laboratories may be licensed upon application, without inspection, if the laboratory is approved by the Substance and Mental Health Services Administration's National Laboratory Certification Program Institute on Drug Abuse program for accreditation of drug testing laboratories, or licensed by the New York State Department of Health pProgram for licensing of drug substance use testing laboratories.

B. 2. Laboratories shallmust be in full compliance with the provisions of the Maine Medical Laboratory Act, 22 MRS, Chapter 411Title 22, M.R.S.A., sections 2011 - 2040.

C. 3. No employer may perform any substance abuseuse test administered to any of that employer's employees. As provided by law, employers may perform screening tests on their own applicants, provided the employer's testing facility complies with the

requirements ~~of~~in ~~s~~Section ~~D~~4 of this rule, in accordance with required statutory employment practices within 26 MRS § 683(6).

D. ~~4.~~ The ~~L~~laboratory ~~shall~~must have a ~~D~~director who ~~shall~~ assumes professional, organizational, educational~~,~~ and administrative responsibility for the laboratory's drug testing facility.

~~(a~~1.~~)~~ The ~~D~~director ~~shall~~must have documented scientific qualifications in analytical forensic toxicology. At a minimum, these qualifications are:

~~(1~~a.~~)~~ An earned doctoral degree in the physical, chemical or biological sciences from an accredited institution, with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology, or an equivalent educational background; and

~~(2~~b.~~)~~ Certification in at least one laboratory specialty by the American Board of Pathology, the American Osteopathic Board of Pathology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Forensic Toxicology; and

~~(3~~c.~~)~~ Appropriate experience in analytical forensic toxicology including experience with analysis of biological material for ~~drugs of abuse~~ substance use and 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 to qualify the individual as an expert witness in forensic toxicology.

~~(b~~2.~~)~~ The ~~D~~director must participate in the daily management and operation of the laboratory. The director is responsible for ensuring that there are sufficient personnel with adequate training and experience to supervise and conduct the work of ~~the drug~~ testing laboratory, and that a complete, signed and dated procedure manual and adequate quality assurance programs are in place. If the ~~D~~director is not a full~~-~~time employee, at least one certifying officer ~~shall~~must have equivalent qualifications.

E. ~~5.~~ The laboratory ~~shall~~must designate one or more certifying officer(s), who may be the director. The certifying officer(s) ~~shall~~must be (a) full time employee(s). The certifying officer(s) ~~shall~~must be qualified~~,~~ ~~by~~in both formal training and laboratory experience, for~~in~~ performance and supervision of ~~drug~~ substance use testing. ~~The~~A certifying officer must review the standards, blanks~~,~~ and quality control data together with the screening and confirmation test results. Upon assurance that all results are acceptable, the certifying officer certifies the test result or results before reporting.

F. ~~6.~~ A s~~S~~upervisor~~s~~ must be on the premises at all times that testing is being performed. Supervisors must possess at least a baccalaureate degree in chemistry, biochemistry~~,~~ or other physical or biological science, ~~and~~ have received at least 20 semester hours of training in chemistry~~, and have experience comparable to that required by the Maine Medical Laboratory rules for Supervisors, as found in 10-144A, CMR, Chapter 256~~. The supervisor must have training in the theory and practice of the procedures used~~,~~ and an understanding of quality control concepts. The supervisor ~~shall~~must have ~~2~~two or more

years of experience in the principles and practices of toxicology~~. Periodic verification of skills must be documented.~~ and demonstrate competency annually. This may be accomplished through proficiency testing and/or earning 8 hours continuing education credits specific to toxicology.

G. ~~7.~~ Other technical and non-technical staff must possess the necessary training and skills for the task assigned. ~~In-service continuing education programs to meet the needs of all laboratory personnel are desirable.~~ Personnel files must include the following: resume of training and experience~~,~~; certification or license, if any~~,~~; references, job descriptions~~,~~; records of performance evaluation and advancement~~,~~; and incident reports. Tests for color blindness must be administered and documented where necessary for the assurance of proper work.

H. ~~8.~~ The laboratory must have clear written procedures describing the chain of custody of all samples, the security requirements for all sections of the laboratory, including the security of record keeping, and for all laboratory testing procedures and quality assurance procedures. Screening~~,~~ and confirmatory methods of testing and assessing specimen integrity ~~shall~~must be as provided by law, except that alternative screening methodologies may be approved by the Department upon written application by the laboratory. The Department ~~shall~~will respond to such application within 30 days.

I. ~~9.~~ The laboratory must demonstrate satisfactory performance in the proficiency testing program of the National Laboratory Certification Program ~~Institute on Drug Abuse,~~or the College of American Pathologists Forensic Drug Testing~~, or the American Association for Clinical Chemistry,~~ for each substance of ~~abuse~~use for which testing services are offered and a proficiency testing program is available.

~~(a~~1.~~)~~ Documentation of enrollment in an approved proficiency testing program and copies of results must be provided annually to the Health and Environmental Testing Laboratory (HETL) by the ~~proficiency testing service,~~licensed laboratory ~~or by submission to the Department of Human Services of certified copies of such documents by the laboratory~~.

~~(b~~2.~~)~~ Satisfactory performance is defined as follows:

a.~~(1)~~ For each survey, achieving an 80~~%~~ percent accuracy rate with no false positives.

b.~~(2)~~ Perform satisfactorily for two of every three consecutive surveys.

c.~~(3)~~ For consecutive surveys, achieve an accuracy rate on each substance of 66 and 2/3 ~~%~~ percent with no false positives.

d.~~(4)~~ Prior to initial licensure, achieve an 80~~%~~ percent accuracy rate with no false positives for ~~2~~two consecutive surveys.

~~(c~~3.~~)~~ All unsatisfactory results must be investigated to determine the cause of the unsatisfactory result. In those instances where a false positive result was reported, a retrospective investigation of client specimen records must take place to determine if similar errors had occurred. This investigation must be documented and a copy of that documentation, along with a plan of corrective

action ~~shall~~must be submitted to the Department ~~of Human Services~~ within 10 working days of the laboratory's receipt of the survey results.

~~(d~~4.~~)~~ Records ~~shall~~must be maintained indicating that proficiency samples are processed as routine specimens, ~~shall~~must identify the analyst performing the test~~,~~ and indicate supervisory review and corrective action for unsatisfactory results. All records are subject to review by the D~~d~~epartment.

~~(e~~5.~~)~~ At the discretion of the Department ~~of Human Services~~, all laboratories are subject to on-site proficiency testing at any time tests are normally performed. Performance criteria ~~shall~~will be as specified in ~~B above~~this rule.

~~(f~~6.~~)~~ If a laboratory does not perform satisfactorily as defined in Section 4 (I)(2) of this rule~~B. above~~, it ~~shall~~may be subject to loss of its license to perform testing for ~~drugs~~substances of ~~abuse~~use, in general, or for the unsatisfactory analyte, pursuant to 5 MRS~~5 M.R.S.A.,~~ chapter 375, sub-chapter ~~V~~5, until two successive surveys have been satisfactorily tested.

~~(g~~7.~~)~~ If a laboratory fails to comply with ~~D~~Section 4(I) paragraphs 3, 4 or 5~~(9), (c), (d), or (e), above,~~ it may be required to file a documented plan of correction within 10 days, may be subject to conditional licensure, may lose its license to test for specific analytes~~,~~ or may lose its license to perform testing for substances of abuse, pursuant to 5 MRS ~~5 M.R.S.A.,~~ chapter 375, sub-chapter ~~V~~5.

J. ~~10~~. The laboratory ~~shall~~must have a quality assurance program which encompasses all aspects of the testing process: specimen acquisition, chain of custody, security~~,~~ and reporting of results, in addition to the screening and confirmation analytical procedures.

~~(a~~1.~~)~~ Quality control procedures will be designed, implemented~~,~~ and reviewed to monitor the conduct of each step of the process. These records ~~shall~~must be made available for review at the time of laboratory inspections.

~~(b~~2.~~)~~ Control urine specimens containing no drugs, and specimens fortified with known standards, will be analyzed with each and every batch of specimens screened. Control specimens ~~shall~~must comprise a minimum of 10 ~~%~~ percent of each day's processed specimens. Some controls with added drug or metabolite at or near the threshold (cutoff) level will be included. In addition, internal controls blind to the analyst ~~shall~~must be tested daily~~,~~ and documented by the supervisor. Implementation of procedures to ensure that carry-over does not contaminate the testing of a subject's specimen must be documented.

~~(c~~3.~~)~~ Quality control procedures must include validation of the performance of all automated sample processing and data processing equipment. Records ~~shall~~must be maintained concerning the repair and maintenance of all equipment.

K. ~~11.~~ Security measures must be maintained by the laboratory to ensure that access to areas where specimens are stored and processed, and where records are stored is strictly limited to authorized individuals only. ~~Authorization shall be documented. Visitors, maintenance and service personnel must be escorted at all times, and their visits shall be documented.~~

L. ~~12.~~ When specimens are received by the laboratory, receipts will be given, and the internal chain of custody will be established. The chain of custody ~~shall~~must document the time, date and purpose each time the specimen is handled or transferred, and identify the individuals involved.

M. ~~13.~~ All ~~positive~~non-negative specimens ~~shall~~must be retained in the original containers in secure storage ~~at freezing temperatures (-20° C or less)~~ for at least 12 months. Oral fluid and urine specimens must be stored frozen (-20° C or below). Hair specimens may be stored at room temperature. Should legal challenge occur, the specimen will be retained throughout the period of resolution of the challenge. All ~~other~~ negative samples ~~shall~~ must be disposed of within three days of ~~immediately after~~ testing.

N. ~~14.~~ All laboratory reports, including the screening, confirmation and quality control data ~~shall~~must be reviewed by a certifying officer before being certified as accurate. The report ~~shall~~must identify the name of the laboratory, the drugs and metabolites tested for, whether the test results were negative or confirmed ~~positive~~non-negative, and the cutoff levels for each substance. ~~The report shall include any available information concerning the margin of accuracy and precision of the test methods employed.~~

~~(~~a.~~)~~ Unless agreed upon by the employee or applicant, no report ~~shall~~may show the quantity of substance detected, but only the presence or absence of that substance relative to the cutoff level.

~~(~~b.~~)~~ No report ~~shall~~may show that a substance was detected in a screening test, unless the presence of the substance was confirmed in the confirmatory test. Procedures must be in place to ensure that an applicant or employee's unconfirmed ~~positive~~non-negative screening test result cannot be determined by the employer in any manner, including, but not limited to, the method of billing the employer for the tests and the time within which results are provided to the employer.

~~(~~c.~~)~~ No substance may be reported as present if the employer requesting the testing did not request analysis for that substance.

~~(~~d.~~)~~ Reports of samples segregated at the request of the applicant or employee for testing by a laboratory selected by the applicant or employee ~~shall~~must be provided to both the employer and the applicant or employee.

O. ~~15.~~ A laboratory aggrieved by any decision of the Department ~~of Health & Human Services~~ regarding ~~A~~approval ~~shall have~~ has the rights of appeal specified in ~~T~~the Maine Administrative Procedure Act, ~~Title~~ 5 MRS ch.~~, c.~~ 375, and the Administrative Hearings ~~Manual~~Regulations, 10-144 CMR chapter 1.

~~E~~SECTION 5. ~~Confidentiality~~CONFIDENTIALITY

~~1~~A. Unless the employee or applicant consents, all test results and any information acquired by an employer in the testing process is confidential~~,~~ and may not be released to any person other than the employee or applicant who was tested, a Medical Review Officer, any ~~necessary~~ authorized personnel of the employer, and a provider of rehabilitation or

treatment services. This requirement ~~shall apply~~applies to personnel of all laboratories, as well as to employers. This paragraph does not prevent:

~~(a)~~1. The release of this information when required or permitted by ~~s~~State or federal law, including release under ~~Title~~ 26 M~~.~~R~~.~~S~~.A., Section~~ § 683~~, subsection~~ (8)~~,~~ ~~paragraph~~ (D); or

~~(b)~~2. The use of this information in any grievance procedure, administrative hearing or civil action relating to the imposition of the test or the use of test results.

~~2~~B. Notwithstanding any other law, the results of any substance ~~abuse~~use test required, requested or suggested by any employer may not be used in any criminal proceeding, as provided by 26 MRS ~~26 M.R.S.A., section~~ § 685(3)(B).

~~F~~SECTION 6. ~~Interdepartmental Communication~~INTERDEPARTMENTAL COMMUNICATION

The Department ~~of Health & Human Services shall~~will inform the Department of Labor of any changes proposed or made in ~~these~~ this rule~~s~~, to ensure necessary coordination between the rules of both ~~D~~departments.

STATUTORY AUTHORITY AND HISTORY

~~STATUTORY AUTHORITY: 26 M.R.S.A. sections 681-690 and~~
~~22 M.R.S.A., section 565 (formally 22 M.R.S.A., section 562).~~
~~PL 1990, chapter 832~~

STATUTORY AUTHORITY: 26 M~~.~~R~~.~~S~~.A.~~ sections ~~681-690 and~~683(11) and 687 (1)

~~(formally 22 M.R.S.A., section 562).~~
~~PL 1990, chapter 832~~

EFFECTIVE DATE:
November 1, 1989

AMENDED:
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July 1, 1990 - Section C~~-~~(4)

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March 12, 2000 - restored missing language in C, D(8)

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