Section: continued

Section: continued

120.536: Requirements for Possession of Sealed Sources and Brachytherapy Sources

Section: continued

120.011: continued

(B) Facilities wherein sources of radiation are used or stored;

(C) Radiation detection and monitoring instruments; and,

(D) Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

120.012: Additional Requirements

(A) The Agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in 105 CMR 120.000 as it deems appropriate or necessary to minimize danger to public health and safety or property.

(B) Any person who finds or detects any source of radiation that is not under the physical or administrative control of a licensee or registrant, and that is not excluded, exempted or otherwise authorized under the provisions of 105 CMR 120.000, shall immediately report such source to the Radiation Control Program.

120.013: Communications

All correspondence in compliance with 105 CMR 120.000 shall be sent to the Department of Public Health, Radiation Control Program, at the programs's current mailing address, as stated in the website ~~http://mass.gov.dph/rcp.~~ **https://www.mass.gov/orgs/radiation-control-program.**

120.014: Units of Exposure and Dose

(A) As used in 105 CMR 120.000, the unit of Exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air.

(B) As used in 105 CMR 120.000, the units of dose are:

Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).

Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rads).

Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 sievert = 100 rems).

120.054: Communications

Except where otherwise specified or covered, all communications and reports concerning 105 CMR 120.050 through 120.080 may be sent as stated in 105 CMR 120.013.

120.055: Specific Exemptions

(A) The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of 105 CMR 120.050 through 120.080 as it determines are authorized by law and will not endanger life or property or the physical protection of agreement material, and are otherwise in the public interest.

(B) A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements of 105 CMR 120.056 through 120.077. Except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of 105 CMR 120.050 through 120.080. The licensee shall implement the following requirements to secure the radioactive waste:

(1) Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

(2) Use a locked door or gate with monitored alarm at the access control point;

(3) Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

(4) Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

BACKGROUND INVESTIGATIONS AND ACCESS AUTHORIZATION PROGRAM

120.056: Personnel Access Authorization Requirements for Category 1 or Category 2 Quantities of Radioactive Materials

(A) General.

(1) Each licensee that possesses an aggregated quantity of radioactive material at or above the category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of 105 CMR 120.056 through 120.062.

(2) An applicant for a new license and each licensee that would become newly subject to the requirements of 105 CMR 120.056 through 120.062 upon application for modification of its license shall implement the requirements of 105 CMR 120.056 through 120.062, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(3) Any licensee that has not previously implemented the Security Orders or been subject to the provisions of 105 CMR 120.056 through 120.062 shall implement the provisions of 105 CMR 120.056 through 120.062 before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(B) General Performance Objective. The licensee's access authorization program must ensure that the individuals specified in 105 CMR 120.056(C)(1) are trustworthy and reliable.

(C) Applicability.

(1) Licensees shall subject the following individuals to an access authorization program:

(a) Any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and

(b) Reviewing officials.

(2) Licensees need not subject the categories of individuals listed in 105 CMR 120.060(A)(1) through (13) to the investigation elements of the access authorization program.

(3) Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.

120.056: continued

(4) Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR Part 73 in the access authorization program under 105 CMR 120.056 through 120.062.

120.057: Access Authorization Program Requirements

(A) Granting Unescorted Access Authorization.

(1) Licensees shall implement the requirements of 105 CMR 120.056 through 120.062 for granting initial or reinstated unescorted access authorization.

(2) Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by 105 CMR 120.064(C) before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

(B) Reviewing Officials.

(1) Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

(2) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. **Provide oath or affirmation certifications to the Agency using an appropriate method listed in 105 CMR 120.054.** The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every ten years in accordance with 105 CMR 120.058(C).

(3) Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

(4) Reviewing officials cannot approve other individuals to act as reviewing officials.

(5) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(a) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(b) The individual is subject to a category listed in 105 CMR 120.060(A).

(C) Informed Consent.

(1) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of 105 CMR 120.058(B). A signed consent must be obtained prior to any reinvestigation.

(2) The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

(a) If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

(b) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

(D) Personal History Disclosure. Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any

personal history information required by 105 CMR 120.056 through 120.062 is sufficient cause for denial or termination of unescorted access.

120.057: continued

(E) Determination Basis.

(1) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of 105 CMR 120.056 through 120.062.

(2) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of 105 CMR 120.056 through 120.062 and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

(3) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(4) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.

(5) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

(F) Procedures. Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

(G) Right to Correct and Complete Information.

(1) Prior to any final adverse determination, licensees shall provide each individual subject to the requirements of 105 CMR 120.056 through 120.062 with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of one year from the date of the notification.

(2) If, after reviewing his or her criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees must provide at least ten days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

(H) Records.

(1) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

120.057: continued

(2) The licensee shall retain a copy of the current access authorization program procedures as a record for three years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

(3) The licensee shall retain the list of persons approved for unescorted access authorization for three years after the list is superseded or replaced.

120.058: Background Investigations

(A) Initial Investigation. Before allowing an individual unescorted access to category 1 or category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the seven years preceding the date of the background investigation or since the individual's 18th birthday, whichever is shorter. The background investigation must include at a minimum:

(1) Fingerprinting and an FBI identification and criminal history records check in accordance with 105 CMR 120.059;

(2) Verification of True Identity. Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who he or she claims to be. A licensee shall review official identification documents (*e.g.*, driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with 105 CMR 120.061. Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection;

(3) Employment History Verification. Licensees shall complete an employment history verification, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent seven years before the date of application;

(4) Verification of Education. Licensees shall verify that the individual participated in the education process during the claimed period;

(5) Character and Reputation Determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under 105 CMR 120.056 through 120.062 must be limited to whether the individual has been and continues to be trustworthy and reliable;

(6) The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (*e.g.*, seek references not supplied by the individual); and

(7) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after ten business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

(B) Grandfathering.

(1) Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material under the Fingerprint Orders may continue to have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement.

120.058: continued

(2) Individuals who have been determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. The licensee shall document that the individual was determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement.

(C) Reinvestigations. Licensees shall conduct a reinvestigation every ten years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with 105 CMR 120.059. The reinvestigations must be completed within ten years of the date on which these elements were last completed.

120.059: Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material

(A) General Performance Objective and Requirements.

(1) Except for those individuals listed in 105 CMR 120.060 and those individuals grandfathered under 105 CMR 120.058(B), each licensee subject to the provisions of 105 CMR 120.056 through 120.062 shall fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the U.S. Nuclear Regulatory Commission for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.

(2) The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.

(3) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:

(a) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and

(b) The previous access was terminated under favorable conditions.

(4) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under 105 CMR 120.056 through 120.062, the Fingerprint Orders, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of 105 CMR 120.061(C).

(5) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

(B) Prohibitions.

(1) Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(a) An arrest more than one year old for which there is no information of the disposition of the case; or

(b) An arrest that resulted in dismissal of the charge or an acquittal.

120.059: continued

(2) Licensees may not use information received from a criminal history records check obtained under 105 CMR 120.056 through 120.062 in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

(C) Procedures for Processing of Fingerprint Checks.

(1) For the purpose of complying with 105 CMR 120.056 through 120.062, licensees shall **use an appropriate method listed in 10 CFR 37.7 to** submit to the U.S. Nuclear Regulatory Commission, Director, Division of ~~Facilities and Security~~ **Physical and Cyber Security Policy**, 11545 Rockville Pike, ~~Rockville, Maryland 20852-2738,~~ ATTN: Criminal History Program~~,~~ /Mail Stop T-~~03B46M~~**8B20**, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by ~~writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630-829-9565, or by email to FORMS.Resource@nrc.gov~~ **emailing MAILSVS.Resource@nrc.gov**. Guidance on submitting electronic fingerprints can be found at ~~http://www.nrc.gov/site-help/e-submittals.html~~ **https://www.nrc.gov/security/chp.html**.

(2) Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the ~~Security Branch, Division of Facilities and Security at 301-415-7513.~~ **Division of Physical and Cyber Security Policy by emailing Crimhist.Resource@nrc.gov.**) Combined payment for multiple applications is acceptable. The U.S. Nuclear Regulatory Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the ~~Electronic Submittals~~ **Licensee Criminal History Records Checks & Firearms Background Check Information** page at ~~http://www.nrc.gov/site-help/e-submittals.html and see the link for the Criminal History Program under Electronic Submission Systems.)~~ **https://www.nrc.gov/security/chp.html and see the link for How do I determine how much to pay for the request?).**

(3) The U.S. Nuclear Regulatory Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

120.060: Relief from Fingerprinting, Identification, and Criminal History Records Checks and Other Elements of Background Investigations for Designated Categories of Individuals Permitted Unescorted Access to Certain Radioactive Materials

(A) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials:

(1) An employee of the U.S. Nuclear Regulatory Commission or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(2) A Member of Congress;

(3) An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(4) The Governor of a State or his or her designated State employee representative;

(5) Federal, State, or local law enforcement personnel;

(6) State Radiation Control Program Directors and State Homeland Security Advisors or their designated State employee representatives;

(7) Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under section 274.i. of the Atomic Energy Act;

(8) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

120.074: continued

(C) Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

(D) Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to 105 CMR 120.074(B), shall promptly notify the receiving licensee of the new no-later-than arrival time.

(E) The licensee shall retain a copy of the documentation for pre-planning and coordination and any revision thereof, as a record for three years.

120.075: Advance Notification of Shipment of Category 1 Quantities of Radioactive Material

As specified in 105 CMR 120.075(A) and (B), each licensee shall provide advanced notification to the Agency and to the governor of a State, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the State, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

(A) Procedures for Submitting Advance Notification.

(1) The notification must be made to the Agency and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the U.S. Nuclear Regulatory Commission website at **https://scp.nrc.gov/special/designee.pdf.** ~~https://scp.nrc.gov/special/designee.pdf.~~ A list of the contact information is also available upon request from the Director, Division of Material Safety, State, Tribal and Rulemaking programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Notifications to the Agency must be made in accordance with 105 CMR 120.054.

(2) A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(3) A notification delivered by any means other than mail must reach the Agency at least four days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least four days before transport of a shipment within or through the State.

(B) Information to be Furnished in Advance Notification of Shipment. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

(2) The license numbers of the shipper and receiver;

(3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(4) The point of origin of the shipment and the estimated time and date that shipment will commence;

(5) The estimated time and date that the shipment is expected to enter each State along the route;

(6) The estimated time and date of arrival of the shipment at the destination; and

(7) A point of contact, with a telephone number, for current shipment information.

(C) Revision Notice.

(1) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the State or the governor's designee and to the Agency by an appropriate method listed in 105 CMR 120.054.

(2) A licensee shall promptly notify the governor of the State or the governor's designee of any changes to the information provided in accordance with paragraphs 105 CMR 120.075(B) and (C)(1). The licensee shall also immediately notify the Agency of any such

changes.

120.075: continued

(D) Cancellation Notice. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified and to the Agency. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

(E) Records. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three years.

(F) Protection of Information. State officials, State employees, and other individuals, whether or not licensees of the Agency, who receive schedule information of the kind specified in 105 CMR 120.075(B) shall protect that information against unauthorized disclosure as specified in 105 CMR 120.064(D).

120.076: Requirements for Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Shipment

(A) Shipments by Road.

(1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(a) Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, seven days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

(b) Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

(c) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement pre-planned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(d) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.

(e) Develop written normal and contingency procedures to address:

1. Notifications to the communication center and law enforcement agencies;
2. Communication Protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;
3. Loss of communications; and
4. Responses to an actual or attempted theft or diversion of a shipment.

(f) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(2) Each licensee that transports category 2 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(3) Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

120.076: continued

(a) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

(b) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(B) Shipments by Rail.

(1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(a) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement pre-planned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(b) Ensure that periodic reports to the communications center are made at preset intervals.

(2) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(a) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

(b) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(C) Investigations. Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

120.077: Reporting of Events

(A) The shipping licensee shall notify the appropriate LLEA and the Agency by telephone within one hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by 105 CMR 120.076(C), the shipping licensee will provide agreed upon updates to the Agency on the status of the investigation.

(B) The shipping licensee shall notify the Agency by telephone within four hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the Agency.

120.077: continued

(C) The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the Agency by telephone upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.

(D) The shipping licensee shall notify the Agency by telephone as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.

(E) The shipping licensee shall notify the Agency by telephone and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

(F) The shipping licensee shall notify the Agency by telephone as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

(G) The initial telephonic notification required by 105 CMR 120.077(A) through (D) must be followed within a period of 30 days by a written report submitted to the Agency by an appropriate method listed in 105 CMR 120.054. A written report is not required for notifications on suspicious activities required by 105 CMR 120.077(C) and (D). The report must set forth the following information:

(1) A description of the licensed material involved, including kind, quantity, and chemical and physical form;
(2) A description of the circumstances under which the loss or theft occurred;
(3) A statement of disposition, or probable disposition, of the licensed material involved;
(4) Actions that have been taken, or will be taken, to recover the material; and
(5) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(H) Subsequent to filing the written report, the licensee shall also report, by an appropriate method listed in 105 CMR 120.054, any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

RECORDS

120.078: Form of Records

Each record required by 105 CMR 120.050 through 120.080 must be legible throughout the retention period specified by each Agency regulation. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

120.079: Record Retention

Licensees shall maintain the records that are required by the regulations in 105 CMR 120.050 through 120.080 for the period specified by the appropriate regulation. If a retention period is not otherwise specified, these records must be retained until the Agency terminates the facility's license. All records related to 105 CMR 120.050 through 120.080 may be destroyed upon Agency termination of the facility license.

120.128: continued

(f) iodine-131 in units not exceeding ten microcuries (370 kBq) each.
(g) iron-59 in units not exceeding 20 microcuries (740 kBq) each.
(h) selenium-75 in units not exceeding ten microcuries (370 kBq) each.

(3) each prepackaged unit bears a durable, clearly visible label:

(a) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

(b) displaying the radiation caution symbol described in 105 CMR 120.237(A) and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

(4) the following statement or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of Manufacturer

(5) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 105 CMR 120.251.

(I) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 105 CMR 120.122(J) will be approved if:

(1) the applicant satisfies the general requirements of 105 CMR 120.125; and
(2) the criteria of 10 CFR Part 32, §§ 32.61 and 32.62 are met.

(J) Manufacture, Preparation, or Transfer for Commercial Distribution of Drugs Containing Radioactive Material for Medical Use under 105 CMR 120.500.

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 105 CMR 120.500 will be approved if:

(a) the applicant satisfies the general requirements specified in 105 CMR 120.125;
(b) the applicant submits evidence that the applicant is at least one of the following:

1. registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);
2. registered or licensed with a State agency as a drug manufacturer;
3. licensed as a pharmacy by a State Board of Pharmacy;
4. operating as a nuclear pharmacy pursuant to 247 CMR 13.00: *Registration Requirements and Minimal Professional Standards for Nuclear Pharmacies*;
5. operating as a nuclear pharmacy within a Federal medical institution; or
6. a Positron Emission Tomography (PET) drug production facility registered with a State agency.

120.128: continued

(c) the applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for safe handling and storage of the radioactive drugs by medical use licensees; and

(d) the applicant ~~satisfies~~ **commits to** the following labeling requirements:

1. a label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL", the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days the time may be omitted.

2. a label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or " DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee pursuant to 105 CMR 120.128(J)(1)(b)3. or (b)4. or (b)5.:

(a) may prepare radioactive drugs for medical use, as defined in 105 CMR 120.502, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 105 CMR 120.128(J)(2)(b) and (d), or an individual under the supervision of an authorized nuclear pharmacist as specified in 105 CMR 120.519.

(b) may allow a pharmacist to work as an authorized nuclear pharmacist if:

1. this individual qualifies as an authorized nuclear pharmacist as defined in 105 CMR 120.502; or

2. this individual meets the requirements specified in 105 CMR 120.526(B) and 120.529 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

3. this individual is designated as an authorized nuclear pharmacist in accordance with 105 CMR 120.128(J)(2)(d).

(c) the actions authorized in 105 CMR 120.128(J)(2)(a) and (b) are permitted in spite of more restrictive language in license conditions.

(d) may designate a pharmacist, as defined in 105 CMR 120.005, as an authorized nuclear pharmacist if:

1. The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

2. The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(e) shall provide to the Agency:

1. A copy of each individual's certification by a specialty board whose certification process has been recognized by the **Agency, Nuclear Regulatory** Commission or an Agreement State as specified in 105 CMR 120.526(A) ~~with the written attestation signed by a preceptor as required by 105 CMR 120.526(B)~~; **or**

2. **The Agency,** Agreement State or Nuclear Regulatory Commission license; **or**

3. **The** Nuclear Regulatory Commission master materials licensee permit; **or**

4. The permit issued by a licensee or Nuclear Regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; **or**

5. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

6. A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under 105 CMR 120.128(J)(2)(b)1. and 3. of 105 CMR 120.128(J), the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

120.128: continued

(a) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(b) check each instrument for constancy and proper operation at the beginning of each day of use.

(4) A licensee shall satisfy the labeling requirements in 105 CMR 120.128(J)(1)(d).

(~~4~~5) Nothing in 105 CMR 120.128(J) relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(K) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material[5]. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to 105 CMR 120.100 for the uses listed in 105 CMR 120.547 will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125;

(2) the applicant submits evidence that:

(a) the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or

(b) the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.

(3) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(a) adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit; and

(b) a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to 105 CMR 120.547 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by 105 CMR 120.128(K) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(L) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 105 CMR 120.500 for use as a calibration, transmission, or reference source or for the uses listed in 105 CMR 120.559, 120.568, 120.570 and 120.589 will be approved if:

(1) the applicant satisfies the general requirements in 105 CMR 120.125;

(2) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

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[5] Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioacitve material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to 105 CMR 120.547 may submit the pertinent information specified in 105 CMR 120.128(K).

120.131: Specific Terms and Conditions of Licenses

(A) Each license issued pursuant to 105 CMR 120.000 shall be subject to all the provisions of M.G.L. c. 111, §§ 3, 5M through 5P, and to all rules, regulations, orders of the Agency and license conditions as provided for in 105 CMR 120.130(B).

(B) (1) No license issued or granted under 105 CMR 120.000 and no right to possess or utilize radioactive material granted by any license issued pursuant to 105 CMR 120.131 shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of M.G.L. c. 111, §§ 3, 5M through 5P, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

(2) An application for transfer of license must include:

1. The identity, technical and financial qualifications of the proposed transferee; and
2. Financial assurance for decommissioning information required by 105 CMR 120.125(C), as applicable.

(C) Each person licensed by the Agency pursuant to 105 CMR 120.100 shall confine use and possession of the material licensed to the locations and purposes authorized in the license. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of 10 CFR Part 71 and 105 CMR 120.770.

(D) Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(E) Each licensee shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) the licensee;

(2) an entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) an affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(F) The notification specified in 105 CMR 120.131(E) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

(G) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(H) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 105 CMR 120.548. The licensee shall record the results of each test and retain each record for three years after the record is made. **The licensee shall report the results of any test that exceeds the permissible concentration listed in 105 CMR 120.548(A) at the time of generator elution, in accordance with 105 CMR 120.594(F).**

(I) (1) Authorization under 105 CMR 120.128(A) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under 105 CMR 120.128(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

1. Satisfy the labeling requirements in 105 CMR 120.128(J)(1)(d) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.
2. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet

the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 105 CMR 120.128(J)(3).

120.131: continued

(3) A licensee that is a pharmacy authorized under 105 CMR 120.128(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

1. an authorized nuclear pharmacist that meets the requirements in 105 CMR 120.128(J)(2)(b); or
2. an individual under the supervision of an authorized nuclear pharmacist as specified in 105 CMR 120.519.

(4) A pharmacy, authorized under 105 CMR 120.128(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 105 CMR 120.128(J)(2)(e).

120.385: Notifications ~~of Incidents~~

(A) The Agency shall be notified of the loss or theft of sources of radiation, overexposures, and excessive levels in accordance with 105 CMR 120.281, 120.282, 120.283, and 120.288.

(B) In addition, each licensee or registrant shall submit a written report within 30 days to the Agency whenever one of the following events occurs:

(1) A source assembly cannot be returned to the fully-shielded position and properly secured;

(2) The source assembly becomes unintentionally disconnected from the drive cable;

(3) Any component critical to safe operation of the radiographic exposure device fails to properly perform its intended function; or,

(4) An indicator on a radiation-producing machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate x-ray production.

(C) The licensee or registrant shall include the following information in each report submitted in accordance with 105 CMR 120.385(B):

(1) A description of the equipment problem;

(2) Cause of each incident, if known;

(3) Manufacturer and model number of equipment involved in the incident;

(4) Location, time, and date of the incident;

(5) Actions taken to establish normal operations;

(6) Corrective actions taken or planned to prevent recurrence; and,

(7) Names and qualifications of personnel involved in the incident.

(D) Any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year, shall notify the Agency using an appropriate method listed in 105 CMR 120.013 prior to exceeding the 180 days.

120.390: Reciprocity

All reciprocal recognition of licenses and certificates of registration by the Agency will be granted in accordance with 105 CMR 120.190 and 120.033.

120.400: X-RAYS IN THE HEALING ARTS

120.401: Purpose and Scope

105 CMR 120.400 establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with Commonwealth statutes to engage in the healing arts or veterinary medicine. The provisions of 105 CMR 120.400 are in addition to, and not in substitution for, other applicable provisions of 105 CMR 120.000.

120.402: Definitions

As used in 105 CMR 120.400, the following definitions apply:

Accessible Surface means the external surface of the enclosure or housing provided by the manufacturer.

Accessory Component means:

(1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of 105 CMR 120.400 but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable provisions of 105 CMR 120.400 but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all x-ray systems with which it may be used and that does

120.440: continued

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date.

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. REFERENCES

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

120.500: USE OF RADIONUCLIDES IN THE HEALING ARTS

GENERAL INFORMATION

120.501: Purpose and Scope

105 CMR 120.500 establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of 105 CMR 120.500 are in addition to, and not in substitution for, others in 105 CMR 120.000. The requirements and provisions of 105 CMR 120.000 apply to applicants and licensees subject to 105 CMR 120.500 unless specifically exempted. (*See* exemption in 105 CMR 120.104(C)(~~5~~**4**)).

120.502: Definitions

As used in 105 CMR 120.500, the following definitions apply:

Address of Use means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

Area of Use means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

Associate Radiation Safety Officer means an individual who:

(1) Meets the requirements in 105 CMR 120.524 and 105 CMR 120.529; and

(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

(i) A specific medical use license issued by the Agency, Nuclear Regulatory Commission or an Agreement State; or

(ii) A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

Authorized Medical Physicist means an individual who:

(1) Meets the requirements in 105 CMR 120.525(A) and 120.529; or

(2) Is identified as a medical physicist or teletherapy physicist on:

(a) A specific medical use license or equivalent permit issued by the Agency, Nuclear Regulatory Commission or Agreement State;

(b) A permit issued by the Agency, Nuclear Regulatory Commission or Agreement

120.502: continued

Manual Brachytherapy means a type of therapy in which brachytherapy sources are manually applied or inserted.

Medical Institution means an organization in which several medical disciplines are practiced.

Medical Use means the intentional internal or external administration of radioactive material, or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

Medium Dose-rate Remote Afterloader (MDR) means a device that remotely delivers a dose rate of greater than two gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the treatment site.

Mobile Medical Service means the transportation of radioactive material and its medical use at the client's address.

Ophthalmic Physicist means an individual who:

(1) Meets the requirements in 105 CMR 120.564A(A)(2) and 105 CMR 120.529; and

(2) Is identified as an ophthalmic physicist on a:

(i) Specific medical use license issued by the Agency, Nuclear Regulatory Commission or an Agreement State;

(ii) Permit issued by an Agency, Nuclear Regulatory Commission or Agreement State broad scope medical use licensee;

(iii) Medical use permit issued by a Nuclear Regulatory Commission master material licensee; or

(iv) Permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee.

Output means the Exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient Intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Preceptor means an individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, ~~or~~ a Radiation Safety Officer**, or an Associate Radiation Safety Officer**.

Prescribed Dosage means the quantity of a radiopharmaceutical activity as documented:

(1) In a written directive as specified in 105 CMR 120.521; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to 105 CMR 120.544, 120.547 and 120.552.

Prescribed Dose means:

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive; or

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive; or

(3) For manual brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed Dose-rate Remote Afterloader (PDR) means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

120.504: continued

(A) That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

(B) The research involving human subjects authorized in 105 CMR 120.504(A) shall be conducted using radioactive material authorized for medical use in the license; and

(C) Nothing in 105 CMR 120.504 relieves licensees from complying with the other requirements in 105 CMR 120.500.

(D) FDA, Other Federal, and State Requirements. Nothing in 105 CMR 120.500 relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

120.505: Implementation

(A) A licensee shall implement the provisions in 105 CMR 120.500 on October 6, 2006.

(B) When a requirement in 105 CMR 120.500 differs from the requirement in an existing license condition, the requirement in 105 CMR 120.500 shall govern.

(C) Any existing license condition that is not affected by a requirement in 105 CMR 120.500 remains in effect until there is a license amendment or license renewal.

(D) If a license condition exempted a licensee from a provision of 105 CMR 120.500 on October 6, 2006, it will continue to exempt a licensee from the corresponding provision in 105 CMR 120.500.

(E) If a license condition cites provisions in 105 CMR 120.500 that will be deleted on October 6, 2006, then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

(F) Licensees shall continue to comply with any license condition that requires it to implement procedures required by 105 CMR 120.573, 120.579, 120.580 and 120.581 until there is a license amendment or renewal that modifies the license condition.

120.506: License Required

(A) A person shall only manufacture, produce, prepare, compound, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, or as allowed in 105 CMR 120.506(B)(1) or (2)

(B) (1) Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with 105 CMR 120.500 under the supervision of an authorized user as provided in 105 CMR 120.519.
(2) Unless prohibited by license condition, an individual may prepare unsealed radioactive material for medical use in accordance with 105 CMR 120.500 under the supervision of an authorized nuclear pharmacist or an authorized user as provided in 105 CMR 120.519.

120.507: Application for License, Amendments, or Renewal

(A) An application must be signed by the applicant's or licensee's management.

(B) An application for a license for medical use of radioactive material as described in 105 CMR 120.544, 120.547, 120.552, 120.559, 120.568, 120.570 or 120.589 must be made by:

120.507: continued

(1) Filing an original and one copy of Agency application form MRCP 120.100- 4 that includes the facility diagram, equipment, and training, experience and qualifications of the Radiation safety Officer, **Associate Radiation Safety Officer(s),** authorized user(s), authorized medical physicist(s), **ophthalmic physicist(s),** and authorized nuclear pharmacist(s), and

(2) Submitting procedures required by 105 CMR ~~120.522, 120.531,~~ 120.573, 120.579, 120.580 and 120.581, as applicable.

(C) A request for a license amendment or renewal must be made by:

(1) Submitting an original ~~and one copy~~ of either:

(a) Agency form MRCP 120.100- 4; or

(b) a letter ~~requesting the amendment or renewal~~ **containing all information required by Agency form MRCP 120.100- 4**; and

(2) Submitting procedures required by 105 CMR ~~120.522, 120.531,~~ 120.573, 120.579, 120.580 and 120.581, as applicable.

(D) In addition to the requirements in 105 CMR 120.507(B) and (C), an application for a license or amendment for medical use of radioactive material as described in 105 CMR 120.589 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in**, or differ from,** 105 CMR 120.501 through 120.543 **and 105 CMR 120.590 through 120.594, identification of and commitment to follow the applicable radiation safety program requirements in 105 CMR 120.547 through 120.587 that are appropriate for the specific 105 CMR 120.589 medical use**, as well as any specific information on:

(1) Radiation safety precautions and instructions;

~~(2) Training and experience of proposed users;~~

(~~3~~**2**) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(~~4~~**3**) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(E) The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.

(F) An applicant that satisfies the requirements specified in 105 CMR 120.127(B) may apply for a Type A specific license of broad scope.

120.508: License Amendments

A licensee shall apply for and must receive a license amendment:

(A) Before it receives, prepares or uses radioactive material for a type of use that is permitted under 105 CMR 120.500, but that is not authorized on the licensee's current license issued pursuant to 105 CMR 120.500;

(B) Before **it** permit~~s~~**t**~~ing~~ anyone~~, except a visiting~~ **to work as an** authorized user, a visiting authorized medical physicist**, a visiting ophthalmic physicist,** or visiting authorized nuclear pharmacist ~~described in 105 CMR 120.511,~~ to work ~~as an authorized user, authorized medical physicist or an authorized nuclear pharmacist, respectively,~~ under the license except ~~an individual who is~~:

(1) for an authorized user, an individual who meets the requirements in 105 CMR 120.529 and 120.546(A), 120.551(A), 120.556(A), 120.557(A), 120.558(A), 120.566(A), ~~120.567,~~ 120.569(A), ~~or~~ **and** 120.587(A);

(2) for an authorized nuclear pharmacist, an individual who meets the requirements in 105 CMR 120.526(A) and 120.529;

(3) for an authorized medical physicist, an individual who meets the requirements in 105 CMR 120.525(A) and 120.529;

(4) **An individual who is** identified as an authorized user or an authorized nuclear pharmacist or authorized medical physicist **or ophthalmic physicist** on an Agency, or the U.S. Nuclear Regulatory Commission or Agreement State license that authorizes the use of

radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or,
(5) **An individual who is** identified as an authorized user or an authorized nuclear pharmacist or authorized medical physicist **or ophthalmic physicist** on a permit issued by the Agency, or the U.S. Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or the practice of nuclear pharmacy, respectively~~:~~**.**

120.508: continued

(C) Before changing a Radiation Safety Officer, except as provided in 105 CMR 120.515(C)~~.~~**;**

(D) Before permitting anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

(~~D~~**E**) Before receiving radioactive material in excess of the amount, or in a different physical or chemical form than is authorized on the license;

(~~E~~**F**) Before adding to or changing the areas of use identified in the application or on the license, except as specified in 105 CMR 120.509; ~~and~~

(~~F~~**G**) Before changing the address(es) of use identified in the application or on the license;

(~~G~~**H**) Before changing statements, representations, and procedures which are incorporated into the license; ~~and~~

(~~H~~**I**) Before releasing licensed facilities for unrestricted use~~.~~**; and**

(J) Before receiving a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

120.509: Notifications

(A) A licensee shall provide to the Agency ~~a copy of the board certification, the Agency, NRC, Agreement State license, or the permit issued by a licensee of broad scope for each individual~~ no later than 30 days after the date that the licensee permits ~~the~~ **an** individual to work as an authorized user**, authorized medical physicist, ophthalmic physicist** or an authorized nuclear pharmacist pursuant to 105 CMR 120.508(B)~~.~~**:**

(1) A copy of the board certification and, as appropriate, verification of completion of:

(i) Training for the authorized medical physicist under 105 CMR 120.525(C);

(ii) Any additional case experience required in 105 CMR 120.556(B)(1)(b)7. for an authorized user under 105 CMR 120.552; or

(iii) Device specific training in 105 CMR 120.587(C) for the authorized user under 105 CMR 120.570; or

(2) A copy of the Agency, Nuclear Regulatory Commission or Agreement State license, the permit issued by a Nuclear Regulatory Commission master material licensee, the permit issued by an Agency, Nuclear Regulatory Commission or Agreement State licensee of broad scope, or the permit issued by a Nuclear Regulatory Commission master material license broad scope permittee.

(B) A licensee shall notify the Agency by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer**, an Associate Radiation Safety Officer, an ophthalmic physicist** or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee permits an authorized user or an individual qualified to be a Radiation Safety Officer, under 105 CMR 120.524 and 105 CMR 120.529, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with 105 CMR 120.515(C);

(~~2~~**3**) The licensee's mailing address changes;

(~~3~~**4**) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 105 CMR 120.131(B); ~~or,~~

(~~4~~**5**) The licensee has added to or changed the areas where radioactive material is used in accordance with 105 CMR 120.544 and 120.547~~.~~**; or**

(6) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in 105 CMR 120.508(J).

The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

120.510: Exemptions Regarding Type A Specific Licenses of Broad Scope

A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

(A) The provisions of 105 CMR 120.507(D) regarding the need to file an amendment to the license for medical use of radioactive material as described in 105 CMR 120.589;

(B) The provisions of 105 CMR 120.508(B)**;** ~~regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or authorized medical physicist under the license;~~

(C) The provisions of 105 CMR 120.508(~~E~~**F**) regarding additions to or changes in the areas of use at the addresses specified in the license;

(D) The provisions of 105 CMR 120.509(A)**;** ~~regarding notification to the Agency for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists; and,~~

(E) The provisions of 105 CMR 120.509(B)(1) for an authorized user, an authorized nuclear pharmacist, an ophthalmic physicist or an authorized medical physicist;

(F) The provisions of 105 CMR 120.509(B)(5); and

(~~E~~**G**) The provisions of 105 CMR 120.523(A) regarding suppliers for sealed sources.

120.511: License Issuance

(A) The Agency shall issue a license for the medical use of radioactive material if:
(1) The applicant has filed Agency application form MRCP 120.100- 4 in accordance with the instructions in 105 CMR 120.507;
(2) The applicant has paid any applicable fee;

120.511: continued

(3) The applicant meets the requirements of 105 CMR 120.100; and
(4) The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety.

(B) The Agency shall issue a license for mobile services if the applicant:
(1) Meets the requirements in 105 CMR 120.511(A); and,
(2) Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with 105 CMR 120.540.

120.513: Specific Exemptions

The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in 105 CMR 120.500 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

GENERAL ADMINISTRATIVE REQUIREMENTS

120.515: Authority and Responsibilities for the Radiation Protection Program

(A) In addition to the radiation protection program requirements of 105 CMR 120.210, a licensee's management must approve in writing:
(1) Requests for license application, renewal, or amendments before submittal to the Agency;
(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and
(3) Radiation protection program changes that do not require a license amendment and are permitted under 105 CMR 120.517.

(B) A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. **A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.**

(C) For up to 60 days each year, a licensee may permit ~~an authorized user or~~ an individual qualified to be a **R**~~r~~adiation **S**~~s~~afety **O**~~o~~fficer**, under 105 CMR 120.534 and 120.529,** to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in 105 CMR 120.515(E), provided the licensee takes the actions required in 105 CMR 120.515(B), (D), (E) and (H) **and notifies the Agency in accordance with 105 CMR 120.509(B)**. ~~A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.~~

(D) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with 105 CMR 120.515(C), if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of radioactive material permitted by the license.

(~~D~~**E**) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(~~E~~**F**) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

(1) Identify radiation safety problems;
(2) Initiate, recommend, or provide corrective actions;
(3) Stop unsafe operations; and,
(4) Verify implementation of corrective actions.

(~~F~~**G**) Licensees that are authorized for two or more different types of radioactive material use under 105 CMR 120.552, 120.559, 120.570, and 120.589, or two or more types of units under 105 CMR 120.570 shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

120.515: continued

(~~G~~**H**) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed six months. The licensee shall maintain minutes of each meeting in accordance with 105 CMR 120.590(A).

(~~H~~**I**) A licensee shall retain a record of actions taken pursuant to 105 CMR 120.515(A), (B) and (~~D~~**E**) in accordance with 105 CMR 120.590(A).

120.517: Radiation Protection Program Changes

(A) A licensee may revise its radiation protection program without Agency approval if:
(1) The revision does not require an amendment under 105 CMR 120.508;
(2) The revision is in compliance with the regulations and the license;
(3) The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and,
(4) The affected individuals are instructed on the revised program before the changes are implemented.

(B) A licensee shall retain a record of each change in accordance with 105 CMR 120.590(B).

120.518: Duties of Authorized User and Authorized Medical Physicist

120.519: Supervision

(A) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 105 CMR 120.506(B)(1) shall:
(1) In addition to the requirements in 105 CMR 120.753, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures in 105 CMR 120.500, and license conditions with respect to the use of radioactive material;
(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of 105 CMR 120.500, and license conditions with respect to the medical use of radioactive material; and
(3) Require that only those individuals permitted under state and local regulations and specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients or human research subjects.

(B) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 105 CMR 120.506(B)(2), shall:
(1) Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and
(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures in 105 CMR 120.500, and license conditions.

(C) Unless physical presence as described in other sections of 105 CMR 120.500 is required, a licensee that permits supervised activities under 105 CMR 120.519(A) and (B) shall require an authorized user to be immediately available (by telephone within ten minutes) to communicate with the supervised individual, and able to be physically present within one hour of notification; and

(D) A licensee that permits supervised activities under 105 CMR 120.519(A) and (B) is responsible for the acts and omissions of the supervised individual.

120.520: Visiting Authorized User, Visiting Authorized Nuclear Pharmacist**, Visiting Ophthalmic Physicist** or Visiting Medical Physicist

(A) A licensee may permit any visiting authorized user, visiting authorized nuclear pharmacist**, visiting ophthalmic physicist** or visiting authorized medical physicist to work as an authorized user, authorized nuclear pharmacist**, ophthalmic physicist** or medical physicist, respectively, under the terms of the licensee's license for 60 days each year if:

(1) The visiting authorized user, the visiting authorized nuclear pharmacist**, the visiting ophthalmic physicist** or the visiting authorized medical physicist has the prior written permission of the licensee's management and, if the work is performed on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of an Agency, Agreement State, or U.S. Nuclear Regulatory Commission license that identifies the visiting authorized user, the visiting authorized nuclear pharmacist**, the visiting ophthalmic physicist** or the visiting authorized medical physicist by name as an authorized user for medical use, as an authorized nuclear pharmacist**, as an ophthalmic physicist**, or as an authorized medical physicist respectively; and

(3) Only those procedures for which the visiting authorized user is specifically authorized by an Agency, Agreement State, or U.S. Nuclear Regulatory Commission license are performed by that individual.

(B) A licensee need not apply for a license amendment in order to permit a visiting authorized user, a visiting authorized nuclear pharmacist**, a visiting ophthalmic physicist** or a visiting authorized medical physicist to use licensed material as described in 105 CMR 120.520(A).

(C) A licensee shall retain copies of the records specified in 105 CMR 120.520(A)~~, as specified in 105 CMR 120.590(A)~~ **for three years from the date of the last visit**.

120.521: Written Directives

(A) A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerel (30 μCi), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

(B) The written directive must contain the patient or human research subject's name and the following:

(1) For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;

(2) For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;

(3) For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

(4) For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; ~~or~~

(5) For permanent implant brachytherapy:

(a) Before implantation: The treatment site, the radionuclide, and the total source strength; and

(b) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or

(~~5~~**6**) For all other brachytherapy including LDR, MDR, and PDR:

(a) Prior to implantation: treatment site, the radionuclide, and dose; and,

(b) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose)**; and date**.

(C) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic

radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

120.521: continued

(D) The licensee shall retain the written directive in accordance with 105 CMR 120.590(C).

120.522: Procedures for Administrations Requiring a Written Directive

(A) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(B) The procedures required by 105 CMR 120.522(A) must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; ~~and~~

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 105 CMR 120.570 or 120.589~~.~~**;**

(5) Determining if a medical event, as defined in 105 CMR 120.594(A), has occurred; and

(6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

120.523: Suppliers for Sealed Sources or Devices Containing Sealed Sources for Medical Use

For medical use, a licensee may only use:

(A) Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 105 CMR 120.100 and 120.128(L) or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

(B) Sealed sources or devices non-commercially transferred from a 10 CFR Part 35 licensee or an Agreement State medical use licensee.

(C) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 105 CMR 120.100 or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State.

120.524: Training for Radiation Safety Officer **and Associate Radiation Safety Officer**

Except as provided in 105 CMR 120.528, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) **or an individual assigned duties and tasks as an Associate Radiation Safety Officer** as provided in 105 CMR 120.515 to be an individual who:

(A) Is certified by a speciality board whose certification process ~~includes all of the requirements in 105 CMR 120.524(D) and (E) and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.)~~ **has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.524(D). The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.** To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) (a) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college

credits in physical science;

(b) Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

(c) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

120.524: continued

(2) (a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
(b) Have two years of full-time practical training and/or supervised experience in medical physics~~.~~**:**

1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the **Agency,** Nuclear Regulatory Commission or an Agreement State; or
2. In clinical nuclear medicine facilities providing diagnostic ~~and/~~or therapeutic services under the direction of physicians who meet the requirements for authorized users in 105 CMR 120.528, 120.551 or 120.556; **and**
3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(B) (1) Has completed a structured educational program consisting of both:
(a) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology; and,
5. Radiation dosimetry; and,

(b) One year of full time **radiation safety** experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, Agreement State, or ~~U.S.~~ Nuclear Regulatory Commission license **or permit issued by a Nuclear Regulatory Commission master material licensee** that authorizes similar type(s) of use(s) of radioactive material**.** ~~involving the following.~~ **An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on an Agency, Nuclear Regulatory Commission or an Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee. The full time radiation safety experience must involve the following:**

1. Shipping, receiving and performing related radiation surveys;
2. Using and performing checks for proper operation of ~~dose calibrators~~ **instruments used to determine the activity of dosages**, survey meters, and instruments used to measure radionuclides;
3. Securing and controlling radioactive material;
4. Using administrative controls to avoid mistakes in the administration of radioactive material;
5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
6. Using emergency procedures to control radioactive material; **and**
7. Disposing of radioactive material;~~ or~~ **and**

~~(2) Training and Experience for Radiation Safety Officer [Reserved]~~

(2) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in 105 CMR 120.524(B)(1) and 120.524(D), and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(C)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the **Agency,** Nuclear Regulatory Commission or an Agreement State under 105 CMR 120.525(A)**,** ~~and~~ has experience ~~in radiation safety for~~ **with the radiation safety aspects of** similar types of use of byproduct material for which the licensee ~~is seeking~~ **seeks** the approval of the individual as Radiation Safety Officer **or an Associate Radiation Safety Officer,** and who meets the requirements in 105 CMR 120.524(D) ~~and (E)~~; or
(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist

identified on ~~the licensee's license and~~ **an Agency, Nuclear Regulatory Commission or an Agreement State license, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, Nuclear Regulatory Commission or an Agreement State licensee of broad scope, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee,** has experience with the radiation safety aspects of similar types of use of byproduct material for which the ~~individual has Radiation Safety Officer responsibilities; and,~~ **licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in 105 CMR 120.524(D); or**

(3) Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license. The individual must also meet the requirements in 105 CMR 120.524(D).

~~(D) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in 105 CMR 120.524(E) and in 105 CMR 120.524(A)(1)(a) and (b) or (A)(2)(a) and (b) or (B)(1) or (C)(1) or (2), and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and~~

(~~E~~**D**) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, **an Associate Radiation Safety Officer,** authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

120.525: Training for Authorized Medical Physicist

Except as provided in 105 CMR 120.528, ~~T~~the licensee shall require the authorized medical physicist to be an individual who:

(A) Is certified by a speciality board whose certification process has been recognized by the **Agency,** Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR **120.525(C).** ~~120.525(B)(2) and (C). (~~ The names of board certifications ~~which~~ **that** have been recognized by the **Agency, Nuclear Regulatory** Commission or an Agreement State ~~will be~~ **are** posted on the NRC's **Medical Uses Licensee Toolkit** Web page.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(2) Have two years of full-time practical training and/or supervised experience in medical physics;

(a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board **whose certification process has been** recognized by the **Agency, Nuclear Regulatory** Commission or an Agreement State; or

(b) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 105 CMR 120.528, 120.566 or 120.587; and

(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(B)(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and must include:

(a) Performing sealed source leak tests and inventories;

(b) Performing decay corrections;

(c) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(d) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR **120.525(B)(1) and** 120.525(C)~~, and 105 CMR 120.525(A)(1) and (2), or 120.525(B)(1) and (C), and has achieved a level of competency sufficient to function independently~~ **and is able to independently fulfill the radiation safety-related duties** as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 105 CMR 120.525, 120.528, or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.~~; and~~

(C) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

120.526: Training for an Authorized Nuclear Pharmacist

Except as provided in 105 CMR 120.528, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

120.526: continued

(A) Is certified by a specialty board whose certification process has been recognized by the **Agency,** Nuclear Regulatory Commission or an Agreement State**.** ~~and who meets the requirements in 105 CMR 120.526(B)(2). (~~ The names of board certifications ~~which~~ **that** have been recognized by the **Agency,** Nuclear Regulatory Commission or an Agreement State ~~will be~~ **are** posted on the NRC's **Medical Uses Licensee Toolkit** Web page.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(B) (1) Has completed 700 hours in a structured educational program consisting of both:

(a) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology; and
5. Chemistry of radioactive material for medical use; and

(b) Supervised practical experience in a nuclear pharmacy involving:

1. Shipping, receiving, and performing related radiation surveys;
2. Using and performing checks for proper operation of ~~dose calibrators~~ **instruments used to determine the activity of dosages**, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;
4. Using administrative controls to avoid medical events in the administration of radioactive material; and
5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in ~~105 CMR 120.526(A)(1) through (3) or~~ 120.526(B)(1) and **is able to independently fulfill the radiation safety-related duties** ~~has achieved a level of competency sufficient to function independently~~ as an authorized nuclear pharmacist.

120.528: Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist

(A)(1) An individual identified **on an Agency, Nuclear Regulatory Commission or Agreement State license or a permit issued by an Agency, Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope** ~~as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Nuclear Regulatory Commission, an Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope~~ **on or** before ~~October 24, 2002~~ **January 14, 2019** need not comply with the training requirements of 105 CMR 120.524, **120.525,** ~~through~~ **or** 120.526, respectively**, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in 105 CMR 120.524(D) or 120.525(C), as appropriate, for any material or uses for which they were not authorized prior to this date**.

~~(2) An individual identified as a Radiation Safety Officer, an authorized medical physicist,~~

~~or an authorized nuclear pharmacist on a Nuclear Regulatory Commission, an Agreement State license or a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and April 29, 2005 need not comply with the training requirements of 105 CMR 120.524 through 120.526, respectively.~~

(2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of 105 CMR 120.524 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on an Agency, Nuclear Regulatory Commission or Agreement State license or Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in 105 CMR 120.525, for those materials and uses that these individuals performed on or before October 24, 2005.

120.528: continued

(~~3~~**4**) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only ~~accelerator-producedradioactive~~ **accelerator-produced radioactive** materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Federal Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of 105 CMR 120.524**, 120.525** ~~through~~ **or** 120.526, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and **during the** time period identified in 105 CMR 120.528**(A)(4)**, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for **the** purposes of 105 CMR 120.500.

(B)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of ~~radioactive material on a Nuclear Regulatory Commission or Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee before October 24, 2002~~ **byproduct material on a license issued by the Agency, Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or before January 14, 2019,** who perform only those medical uses for which they were authorized on **or before** that date need not comply with the training requirements of 105 CMR 120.546, 120.551, 120.556**, 120.557,** ~~through~~ 120.558, **120.558A,** 120.566, 120.567, 120.569 and 120.587.

(2) Physicians, dentists, or podiatrists **not** identified as authorized users for the medical use of ~~radioactive material on a Nuclear Regulatory Commission or Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002, and April 29, 2005~~ **byproduct material on a license issued by the Agency, Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license of broad scope on or before October 24, 2005**, need not comply with the training requirements of 105 CMR 120.546, 120.551, 120.556**, 120.557,** ~~through~~ 120.558, **120.558A,** 120.566, 120.567, 120.569 and 120.587~~.~~ **for those materials and uses that these individuals performed on or before October 24, 2005, as follows:**

(a) For uses authorized under 105 CMR 120.544 or 120.547, or oral administration of sodium iodide I–131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(b) For uses authorized under 105 CMR 120.552, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(c) For uses authorized under 105 CMR 120.559 or 120.570, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British ''Fellow of the Faculty of Radiology'' or ''Fellow of the Royal College of Radiology''; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(d) For uses authorized under 105 CMR 120.568, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007**,** or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of 105 CMR 120.546, 120.551, 120.556**, 120.557,** ~~through~~ 120.558, **120.558A,** 120.566, 120.567, 120.569 and 120.587 when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in 105 CMR 120.528(B)(3), qualifies as an authorized user for those materials and uses performed before these dates, for **the** purposes of 105 CMR 120.500.

(C) Individuals who need not comply with training requirements as described in 105 CMR 120.528 may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

120.529: Recentness of Training

The training and experience specified in 105 CMR 120.500 must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

GENERAL TECHNICAL REQUIREMENTS

120.531: Quality Control of Diagnostic Equipment

Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control procedures in accordance with written procedures.

120.535: Authorization for Calibration, Transmission and Reference Sources

~~Any person authorized by 105 CMR 120.506 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:~~

~~(A) Sealed sources manufactured and distributed by persons specifically licensed pursuant to 105 CMR 120.128(L) or equivalent provisions of the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 1.11 gigabecquerels (30 mCi) each;~~

~~(B) Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 555 megabecquerels (15 mCi);~~

~~(C) Any radioactive material with a half life greater than 120 days in individual amounts not to exceed the smaller of 7.4 megabecquerels (200 μCi) or 1000 times the quantity in 105 CMR 120.196: *Appendix B*, Table 1; and~~

~~(D) Technetium-99m in amounts as needed.~~

(A) Any person authorized by 105 CMR 120.506 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use:

(1) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under 105 CMR 120.128(L) or equivalent Nuclear Regulatory Commission or Agreement State regulations;

(2) Sealed sources, not exceeding 1.11 Gbq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under 105 CMR 120.128(L) or equivalent Nuclear Regulatory Commission or Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi);

(4) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μCi) or 1000 times the quantities in 105 CMR 120.297, Appendix C; or

(5) Technetium-99m in amounts as needed.

(B) Byproduct material in sealed sources authorized by 105 CMR 120.535 shall not be:

(1) Used for medical use as defined in 105 CMR 120.502 except in accordance with the requirements in 105 CMR 120.568; or

(2) Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

(C) A licensee using calibration, transmission, and reference sources in accordance with the requirements in 105 CMR 120.535(A) and (B) need not list these sources on a specific medical use license.

120.536: Requirements for Possession of Sealed Sources and Brachytherapy Sources

(A) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency.

(B) A licensee in possession of a sealed source shall:

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and,

(2) Test the source for leakage at intervals not to exceed six months or at intervals approved by the Agency, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry.

120.543: continued

(B) For radioactive material disposed in accordance with 105 CMR 120.543(A), the licensee shall retain a record of each disposal in accordance with 105 CMR 120.590(M).

SPECIFIC REQUIREMENTS FOR THE USE OF RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION, OR EXCRETION STUDIES

120.544: Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a Written Directive is not Required

A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion:

(A)(1) Obtained from a manufacturer or preparer licensed pursuant to 105 CMR 120 128(J) or equivalent regulations of another Agreement State, or the Nuclear Regulatory Commission; or

(2) A PET radioactive drug producer licensed under 105 CMR 120.100 or equivalent regulations of the Nuclear Regulatory Commission or equivalent Agreement State requirements; or

(B) Excluding production PET radionuclides, prepared by:

(1) an authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551, or 120.556 and 120.551(C)(1)(b)7.; or

(3) An individual under the supervision, as specified in 105 CMR 120.519, of the authorized nuclear pharmacist in 105 CMR 120.544(B)(1) or the physician who is an authorized user in 105 CMR 120.544(B)(2); or

(C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

120.545: Possession of Survey Instrument

A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 1000 microsieverts (100 mrems) per hour. The instrument shall be operable and calibrated in accordance with 105 CMR 120.533.

120.546: Training for Uptake, Dilution, and Excretion Studies

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 105 CMR 120.544 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the **Agency,** Nuclear Regulatory Commission or an Agreement State~~. and who meets the requirements in 105 CMR 120.546(C)(2). (~~ The names of board certifications ~~which~~ **that** have been recognized by the **Agency,** Nuclear Regulatory Commission or an Agreement State ~~will be~~ **are** posted on the NRC's **Medical Uses Licensee Toolkit** Web page.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in 105 CMR 120.546(C)(1)(a) through (b)6.; and

(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

120.546: continued

(B) Is an authorized user under 105 CMR 120.551 or 120.556, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(C) (1) Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements 105 CMR 120.528, 120.546,120.551 or 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; **and**
6. Administering dosages to patients or human research subjects; and

(2) Has obtained written attestation~~, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.528, 120.546, 120.551 or 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.546(A)(1) or (C)(1) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 105 CMR 120.544.~~ **that the individual has satisfactorily completed the requirements in 105 CMR 120.546(C)(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 105 CMR 120.544. The attestation must be obtained from either:**

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.546, 120.551, or 120.556, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 105 CMR 120.528, 120.546, 120.551, or 120.556, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph 105 CMR 120.546(C)(1).

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED BYPRODUCT MATERIAL WRITTEN DIRECTIVE NOT REQUIRED

120.547: Use of Unsealed Byproduct Material for Imaging and Localization Studies for which a Written Directive is not Required

A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in 105 CMR 120.521 that is:

(A) Obtained from:

(1) A manufacturer or preparer licensed pursuant to 105 CMR 120.128(J) or equivalent regulations of another Agreement State, or the Nuclear Regulatory Commission;

(2) A PET radioactive drug producer licensed under 105 CMR 120.100 or equivalent regulations of the Nuclear Regulatory Commission or equivalent Agreement State requirements; or

(B) Excluding production PET radionuclides prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551 or 120.556 and 120.551(C)(1)(b)7.; or

(3) An individual under the supervision, as specified in 105 CMR 120.519, of the authorized nuclear pharmacist in 105 CMR 120.547(B)(1) or the physician who is an authorized user in 105 CMR 120.547(B)(2); or

120.547: continued

(C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

(E) Provided the conditions of 105 CMR 120.542 are met, a licensee may use radioactive aerosols or gases if specific application is made to and approved by the Agency.

120.548: Radionuclide Contaminants

(A) A licensee shall not administer to humans a radiopharmaceutical containing**:**
(1) ~~m~~**M**ore than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 µCi of Mo-99 per mCi of Tc-99m);
(2) ~~m~~**M**ore than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 µCi of Sr-82 per mCi of Rb-82 chloride); **or**
(3) ~~m~~**M**ore than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 µCi of Sr-85 per mCi of Rb-82).

~~(B) To demonstrate compliance with 105 CMR 120.548(A), the licensee preparing radioactive drugs from radionuclide generators shall:~~
~~(1) Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;~~
~~(2) Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.~~

(B) A licensee that uses molybdenum-99/ technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with 105 CMR 120.548(A).

(C) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with 105 CMR 120.548(A).

(~~C~~**D**) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with 105 CMR 120.590(N).

~~(D) A licensee shall report immediately to the Agency each occurrence of radionuclide contaminant concentration exceeding the limits specified in 105 CMR 120.548(A).~~

(E) The licensee shall report any measurement that exceeds the limits in 105 CMR 120.548(A) at the time of generator elution, in accordance with 105 CMR 120.594(F).

120.551: Training for Imaging and Localization Studies

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 105 CMR 120.547 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the **Agency,** Nuclear Regulatory Commission or an Agreement State~~. and who meets the requirements in 105 CMR 120.551(C)(2). (~~ The names of board certifications ~~which~~ **that** have been recognized by the **Agency, Nuclear Regulatory** Commission or an Agreement State ~~will be~~ **are** posted on the NRC's **Medical Uses Licensee Toolkit** Web page.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:
(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material

for imaging and localization studies as described in105 CMR 120.551(C)(1)(a) through (b)7.; and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(B) Is an authorized user under 105 CMR 120.556 and meets the requirements of 105 CMR 120.551(C)(1)(b)7., or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

120.551: continued

(C)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies; the training and experience must include, at a minimum:

(a) Classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use;
5. Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements of 105 CMR 120.528, 120.551, or 120.556 and 120.551(C)(1)(b)7.**,** or equivalent Agreement State, or Nuclear Regulatory Commission requirements**.**~~, involving~~ **An authorized nuclear pharmacist who meets the requirements in 105 CMR 120.526 or 120.528 may provide the supervised work experience for 105 CMR 120.551(C)(1)(b)7. Work experience must involve:**

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
6. Administering dosages of radioactive drugs to patients or human research subjects; **and**
7. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

~~(2) Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.528, 120.551 or 120.556 and 120.551(C)(1)(b)7., or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.551(A)(1) or (C)(1) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under 105 CMR 120.544 and 120.547.~~

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.551(C)(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 105 CMR 120.544 and 120.547. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.551, or 120.556 and 120.551(C)(1)(b)7., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 105 CMR 120.528, 120.551, or 120.556 and 120.551(C)(1)(b)7., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 105 CMR 120.551(C)(1).

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED BYPRODUCT MATERIAL
WRITTEN DIRECTIVE REQUIRED

120.552: Use of Unsealed Byproduct Material for which a Written Directive is Required

A licensee may use any unsealed radioactive material **identified in 105 CMR 120.556(B)(1)(b)7. prepared** for ~~diagnostic or therapeutic~~ medical use **and** for which a written directive is required that ~~has been~~ **is**:

(A) Obtained from a manufacturer or preparer licensed in accordance with 105 CMR 120**.**128(J) **or a PET radioactive drug producer licensed in accordance with 105 CMR 120.128(A), or equivalent Nuclear Regulatory Commission or Agreement State requirements**; or

(B) **Excluding production of PET radionuclides,** ~~P~~**p**repared by an authorized nuclear pharmacist, **or** a physician who is an authorized user and who meets the requirements specified in 105 CMR 120.551 or 120.556, or an individual under the supervision of either as specified in 105 CMR 120**.**519; or

(C) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, or Agreement State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or

(D) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA for use in research.

120.553: Safety Instruction

In addition to the requirements of 105 CMR 120.753:

(A) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who have received therapy with with a radioactive drug, and cannot be released in accordance with 105 CMR 120.540. To satisfy the requirement in 105 CMR 120.553(A), the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control to include the following:

(a) Routine visitation to hospitalized individuals in accordance with 105 CMR 120.221(A)(1) and (C);

(b) Contamination control;

(c) Waste control; and

(d) Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.

(B) A licensee shall retain a record of individuals receiving instruction in accordance with 105 CMR 120.590(P).

120.554: Safety Precautions

(A) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 105 CMR 120.540, a licensee shall:

(1) Quarter the patient or the human research subject either in:

(a) A private room with a private sanitary facility; or

(b) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with 105 CMR 120.540; and

(2) Visibly post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and

(3) Either monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste.

(B) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

120.556: Training for Use of Unsealed Byproduct Material for which a Written Directive is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of radioactive material for the uses authorized under 105 CMR 120.552 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by the **Agency,** Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 105 CMR 120.556(B)(1)(b)7. ~~and (2). (Specialty boards whose certification processes have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's Web page.)~~ **The names of board certifications that have been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.** To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in 105 CMR 120.556(B)(1)(a) through (b)5.. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-graduate

Training of the American Osteopathic Association; and

120.556: continued

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

(B)(1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of byproduct material for medical use;
5. Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556 or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements in 105 CMR 120.556(B), must also have experience in administering dosages in the same dosage category or categories (*i.e.*,105 CMR 120.556(B)(1)(b)7.) as the individual requesting authorized user status. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
7. Administering dosages of radioactive drugs to patients or human research subjects ~~involving a minimum of three casess~~ **from the three categories in 105 CMR 120.556(B)(1)(b)7. Radioactive drugs containing radionuclides in categories not included in 105 CMR 120.556(B)(1)(b) 7. are regulated under 105 CMR 120.589. This work experience must involve a minimum of three cases** in each of the following categories for which the individual is requesting authorized user status~~.~~**:**

a. Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

b. Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 [Note: *Experience with at least three cases in category (b) also satisfies the requirement in category (a)]*;

~~c. Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or~~

~~d. Parenteral administration of any other radionuclide for which a written directive is required; and~~

c. Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in ~~105 CMR 120.556(A)(1) and (B)(1)(b)7. or 120.556(B)(1) and has achieved a level of competency sufficient to independently function~~ **105 CMR 120.556(B)(1) and is able to independently fulfill the radiation safety-related duties** as an authorized user for the medical uses authorized under 105 CMR 120.552~~. The written attestation must be signed by a preceptor authorized user, who meets the requirements of 105 CMR 120.528, 120.556 or equivalent Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirements of 105 CMR 120.556(B), must have experience in administering dosages in the same dosage category or categories listed in~~

~~105 CMR 120.556(B)(1)(b)7. as the individual requesting authorized user status.~~ **for which the individual is requesting authorized user status. The attestation must be obtained from either:**

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.556, or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 105 CMR 120.528, 120.556, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 105 CMR 120.556(B)(1).

120.557: Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabequerels (33 millicurie) for which a Written Directive is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

120.557: continued

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.557(C)(1) and (2) and whose certification **process** has been recognized by **the Agency,** an Agreement State or the Nuclear Regulatory Commission**.** ~~and who meets the requirements in 105 CMR 120.557(C)(3). (~~ The names of board certifications ~~which~~ **that** have been recognized by the **Agency, Nuclear Regulatory** Commission or an Agreement State ~~will be~~ **are** posted on the NRC's **Medical Uses Licensee Toolkit** Web page.~~)~~; or

(B) Is an authorized user under 105 CMR 120.556, for uses listed in 105 CMR 120.556(B)(1)(b)7.a. or b.,~~ and~~ 120.558**,** or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(C)(1) Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include:

(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity;
(d) Chemistry of radioactive material for medical use; and,
(e) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.557, 120.558, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of 105 CMR 120.556(B) must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.a. or b. The work experience must involve:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(c) Calculating, measuring, and safely preparing patient or human research subject dosages;
(d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
(e) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; **and**
(f) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.557(C)(1) and (2),~~ and has achieved a level of competency sufficient to independently function as an authorized user for medical uses authorized under 105 CMR 120.552. The written attestation must be signed by a preceptor authorized user, who meets the requirements of 105 CMR 120.528, 120.556, 120.557, 120.558, or equivalent Agreement State or Nuclear Regulatory Commission requirements. A preceptor authorized user who meets the requirements of 105 CMR 120.556(B), must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.a. or 105 CMR 120.556(B)(1)(b)7.b.~~ **and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131 for medical uses authorized under 105 CMR 120.552. The attestation must be obtained from either:**

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.557, 120.558, or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.a. or b.; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.557, 120.558, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.a. or b., and concurs with the attestation provided

by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 105 CMR 120.557(C)(1) and (2).

120.558: Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabequerels (33 millicurie) for which a Written Directive is Required

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.558(C)(1) and (2) and whose certification has been recognized by **the Agency,** an Agreement State or the Nuclear Regulatory Commission**.**~~, and who meets the requirements in 120.558(C)(3). (~~ The names of board certifications ~~which~~ **that** have been recognized by the **Agency,** Nuclear Regulatory Commission or an Agreement State ~~will be~~ **are** posted on the NRC's **Medical Uses License Toolkit** Web page.~~)~~; or

120.558: continued

(B) Is an authorized user under 105 CMR 120.556, for uses listed in 105 CMR 120.556(B)(1)(b)7.b. or equivalent Agreement State, or Nuclear Regulatory Commission requirements; or

(C)(1) Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity;
(d) Chemistry of radioactive material for medical use; and,
(e) Radiation biology; and,

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556, or 120.558, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of 105 CMR 120.556(B), must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.b.; the work experience must involve:

(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(c) Calculating, measuring, and safely preparing patient or human research subject dosages;
(d) Using administrative controls to prevent a medical event involving the use of byproduct material;
(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; **and**
(f) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.558(C)(1) and (2), and ~~has achieved a level of competency sufficient to independently function as an authorized user for medical uses authorized under 105 CMR 120.552. The written attestation must be signed by a preceptor authorized user, who meets the requirements of 105 CMR 120.528, 120.556, 120.558, or equivalent Agreement State or Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements of 105 CMR 120.556(B), must also have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.b.~~ **is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131 for medical uses authorized under 105 CMR 120.552. The attestation must be obtained from either:**

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and has experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.b.; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.b., and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 105 CMR 120.558(C)(1) and (2).

120.558A: Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive

~~Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:~~

~~(A) Is an authorized user under 105 CMR 120.556 for uses listed in 105 CMR 120.556(B)(1)(b)7.c. or d., or equivalent Agreement State, or Nuclear Regulatory Commission requirements; or~~

~~(B) Is an authorized user under 105 CMR 120.566, 120.587, or equivalent Agreement State, or Nuclear Regulatory commission requirements and who meets the requirements in 105 CMR 120.558A(D); or~~

~~(C) Is certified by a medical specialty board whose certification process has been recognized under 105 CMR 120.566 or 120.587 or by the Nuclear Regulatory Commission or an Agreement State, and who meets the requirements in 105 CMR 120.558A(D).~~

120.558A: continued

~~(D)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:~~

~~(a) Radiation physics and instrumentation;~~

~~(b) Radiation protection;~~

~~(c) Mathematics pertaining to the use and measurement of radioactivity;~~

~~(d) Chemistry of byproduct material for medical use; and,~~

~~(e) Radiation biology; and~~

~~(2) Has work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558A, or equivalent Agreement State, or Nuclear Regulatory Commission requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 105 CMR 120.556 must have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.c.. and/or d. The work experience must involve:~~

~~(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;~~

~~(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;~~

~~(c) Calculating, measuring, and safely preparing patient or human research subject dosages;~~

~~(d) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;~~

~~(e) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;~~

~~(f) Administering dosages to patients or human research subjects that includes at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and~~

~~(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.558A(B) or (C), and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558A, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements in 105 CMR 120.556 must have experience in administering dosages as specified in 105 CMR 120.556(B)(1)(b)7.c. and/or d.~~

(A) Except as provided in 105 CMR 120.528, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(1) Is an authorized user under 105 CMR 120.556 for uses listed in 105 CMR 120.556(B)(1)(b)7.c., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(2) Is an authorized user under 105 CMR 120.566, 120.587, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and who meets the requirements in 105 CMR 120.558A(B); or

(3) Is certified by a medical specialty board whose certification process has been recognized by the Agency, Nuclear Regulatory Commission or an Agreement State under 105 CMR 120.566 or 120.587, and who meets the requirements in 105 CMR 120.558A(B).

(B) The physician:

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in 105 CMR 120.556(B)(1)(b)7.c. The training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;
(d) Chemistry of byproduct material for medical use; and
(e) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558A, or equivalent Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administrations listed in 105 CMR 120.556(B)(1)(b)7.c. A supervising authorized user who meets the requirements in 105 CMR 120.556, 120.558A, or equivalent Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:

(a) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
(b) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
(c) Calculating, measuring, and safely preparing patient or human research subject dosages;
(d) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(e) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and
(f) Administering dosages to patients or human research subjects, that include at least three cases of the parenteral administrations as specified in 105 CMR 120.556(B)(1)(b)7.c.; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.558A(B)(1) and (2), and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558A, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in 105 CMR 120.556, 120.558A, or equivalent Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or
(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 105 CMR 120.528, 120.556, 120.558A, or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 105 CMR 120.558A(B)(1) and (2).

MANUAL BRACHYTHERAPY

120.559: Use of Sealed Sources for Manual Brachytherapy

A licensee ~~shall~~ **must** use only brachytherapy sources ~~for therapeutic medical uses~~:

(A) ~~As a~~**A**pproved in the Sealed Source and Device Registry **for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry**; or

(B) In research **to deliver therapeutic doses for medical use** in accordance with an ~~effective~~

active Investigational Device Exemption (IDE) application accepted by the ~~FDA~~ **U.S. Food and Drug Administration** provided the requirements of 105 CMR 120.523(A) are met.

120.560: Surveys After Source Implant and Removal

(A) Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.

120.564: Calibration Measurement of Brachytherapy Sealed Sources

(A) Prior to the first medical use of a brachytherapy sealed source on or after October 6, 2006, a licensee shall perform the following:

(1) Determine the source output or activity using a dosimetry system that meets the requirements of 105 CMR 120.575(A);

(2) Determine source positioning accuracy within applicators; and

(3) Use published protocols accepted by nationally recognized bodies to meet the requirements of 105 CMR 120.564(A)(1) and (2).

(B) A licensee may use measurements provided by the source manufacturer [or by a calibration laboratory accredited by the American Association of Physicists in Medicine] that are made in accordance with 105 CMR 120.564(A).

(C) A licensee shall mathematically correct the outputs or activities determined in 105 CMR 120.564(A) for physical decay at intervals consistent with 1.0% physical decay.

(D) An authorized medical physicist shall perform or review the calculation measurements made pursuant to 105 CMR 120.564(A), (B), or (C).

~~(E) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with paragraphs 105 CMR 120.564(A) through (C).~~

(~~F~~**E**) A licensee shall retain a record of each calibration in accordance with 105 CMR 120.592(B).

~~(G) A licensee shall retain a record of decay calculations required by 105 CMR 120.564(E) in accordance with 105 CMR 120.592(C).~~

120.564A: Strontium-90 Sources for Ophthalmic Treatments

(A) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in 105 CMR 120.564A(B) are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

(a) is identified as an ophthalmic physicist on a specific medical use license issued by the Agency, Nuclear Regulatory Commission or an Agreement State; permit issued by an Agency, Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Nuclear Regulatory Commission master material licensee; or permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee; and

(b) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(c) has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(d) Has documented training in:

1. The creation, modification, and completion of written directives;

2. Procedures for administrations requiring a written directive; and

3. Performing the calibration measurements of brachytherapy sources as detailed in 105 CMR 120.564.

(B) The individuals who are identified in 105 CMR 120.564A(A) must:

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 105 CMR 120.564; and

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in 105 CMR 120.564A(A) will observe treatments, review the

treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(C) Licensees must retain a record of the activity of each strontium-90 source in accordance with 105 CMR 592(C).

120.565: Therapy-related Computer Systems

The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm;

(B) The accuracy of dose, dwell time, and treatment time calculations at representative points. The licensee shall perform regular quality assurance testing on the treatment planning computer. Said testing shall be in accordance with TG40 or current AAPM recommendation.

(C) The accuracy of isodose plots and graphic displays; and

(D) The accuracy of the software used to determine radioactive source positions from radiographic images.

120.566: Training for Use of Manual Brachytherapy Sources

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 105 CMR 120.559 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by **the Agency,** an Agreement State or the Nuclear Regulatory Commission**.**~~, and who meets the requirements in 105 CMR 120.566(B)(3) (~~ The names of board certifications ~~which~~ **that** have been recognized by the **Agency, Nuclear Regulatory** Commission or an Agreement State ~~will be~~ **are** posted on the NRC's **Medical Uses Licensee Toolkit** Web page.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

120.566: continued

(1) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(B) (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(a) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and,
4. Radiation biology; and

(b) 500 hours work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.566 or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical ~~institution~~ **facility authorized to use byproduct materials under 105 CMR 120.559**, involving:

~~1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;~~

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Checking survey meters for proper operation;
3. Preparing, implanting, and removing brachytherapy sources;
4. Maintaining running inventories of material on hand;
5. Using administrative controls to prevent a medical event involving the use of byproduct material;
6. Using emergency procedures to control byproduct material; and

(2) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 105 CMR 120.528, 120.566 or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 105 CMR 120.566(B)(1)(b); and

~~(3) Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.528, 120.566 or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.566(A)(1), or (B)(1) and (2) and has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under 105 CMR 120.559.~~

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.566(B)(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under 105 CMR 120.528. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.566, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 105 CMR 120.528, 120.566, or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on

Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 105 CMR 120.566(B)(1) and (2).

120.567: Training for Ophthalmic Use of Strontium-90

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under 105 CMR 120.559 to be a physician who:

(A) Is an authorized user under 105 CMR 120.566 or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

(B)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity; **and**
(d) Radiation biology; and

120.567: continued

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user who meets the requirements in 105 CMR 120.566 or 120.567, and that includes the use of strontium-90 for ophthalmic treatment of five individuals that includes:
(a) Examination of each individual to be treated;
(b) Calculation of the dose to be administered;
(c) Administration of the dose; **and**
(d) Follow-up and review of each individual's case history; and

(3) Has obtained written attestation, signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.528, 120.566, 120.567 or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in 105 CMR 120.567(B)**(1) and (2)** and ~~has achieved a level of competency sufficient to independently function~~ **is able to independently fulfill the radiation safety-related duties** as an authorized user of strontium-90 for ophthalmic use.

SEALED SOURCES FOR DIAGNOSIS

120.568: **Use of** Sealed Sources **and Medical Devices** for Diagnosis

~~A licensee shall use only sealed source for diagnostic medical uses.~~

~~(A) Approved in the Sealed Source and Device Registry; and~~

~~(B) Handled in accordance with the manufacturer's radiation safety instructions.~~

(A) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(B) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(C) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 105 CMR 120.523(A) are met.

120.569: Training for Use of Sealed Sources **and Medical Devices** for Diagnosis

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a diagnostic sealed source ~~for use in~~ **or** a device authorized under 105 CMR 120.568 to be a physician, dentist, or podiatrist who:

(A) Is certified by a medical specialty board whose certification process includes all of the requirements in 105 CMR 120.569(~~B~~**C**) and (~~C~~**D**) and whose certification has been recognized by **the Agency,** an Agreement State or the Nuclear Regulatory Commission. ~~(~~The names of board certifications ~~which~~ **that** have been recognized by the **Agency, Nuclear Regulatory** Commission or an Agreement State ~~will be~~ **are** posted on the NRC's **Medical Uses Licensee Toolkit** Web page~~.)~~; or

(B) Is an authorized user for uses listed in 105 CMR 120.547 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(~~B~~**C**) Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:
(1) Radiation physics and instrumentation;
(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and,
(4) Radiation biology; and,

(~~C~~**D**) Has completed training in the use of the device for the uses requested.

PHOTON EMITTING REMOTE AFTERLOADER UNITS,
TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

120.570: Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

~~A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic units for therapeutic medical uses:~~

~~(A) As approved in the Sealed Source and Device Registry; or~~

~~(B) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 105 CMR 120.523(A) are met.~~

(A) A licensee must only use sealed sources:

(1) Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

(2) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 105 CMR 120.523(A) are met.

(B) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 105 CMR 120.523(A) are met.

120.571: Surveys of Patients and Human Research Subjects Treated with Remote Afterloader Unit

(A) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.

(B) A licensee shall retain a record of the surveys in accordance with 105 CMR 120.590(Q).

120.572: Installation, Maintenance, Adjustment, and Repair

(A) Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) drive unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(B) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, an Agreement State, or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(C) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, an Agreement State, or the Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(D) A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 105 CMR 120.592(D).

120.573: Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(A) A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or is unattended;

(2) Permit only individuals approved by authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:

(a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(b) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(c) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(B) A copy of the procedures required by 105 CMR 120 573(A)(4) must be physically located at the unit console.

(C) A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by 105 CMR 120 573(A)(4); and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

120.573: continued

~~(D) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual"s assigned duties, in:~~

~~(1) The procedures identified in 105 CMR 120.573(A)(4); and~~

~~(2) the operating procedures for the unit.~~

(D)(1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(2) A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in:

(a) The procedures identified in 105 CMR 120.573(A)(4); and

(b) The operating procedures for the unit.

(E) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(F) A licensee shall retain a record of individuals receiving instruction required by 105 CMR 120.573(D), in accordance with 105 CMR 120.590(P).

(G) A licensee shall retain a copy of the procedures required by 105 CMR 120.573(A)(4) and (D)(2)(b) of this section in accordance with 105 CMR 120.590(R).

120.574: Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(A) A licensee shall control access to the treatment room by a door at each entrance.

(B) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded promptly when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(C) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(D) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(E) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(F) In addition to the requirements specified in 105 CMR 120.574(A) through (E), a licensee shall:

(1) For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:

(a) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and,

(b) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source

120.583: continued

(C) A licensee shall retain a record of the radiation surveys required in 105 CMR 120.583(A) in accordance with 105 CMR 120.592(K).

120.584: ~~Five Year~~ **Full** Inspection **Servicing** for Teletherapy and Gamma Stereotactic Radiosurgery Units

(A) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during ~~teletherapy~~ **each** source replacement ~~or at intervals not to exceed five years, whichever comes first,~~ to assure proper functioning of the source exposure mechanism **and other safety components. The interval between each full-inspection servicing shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit**.

(B) This inspection and servicing may only be performed by persons specifically licensed to do so by the Agency, an Agreement State, or the U.S. Nuclear Regulatory Commission.

(C) A licensee shall maintain a record of the inspection and servicing in accordance with 105 CMR 120.592(L).

120.585: Therapy-related Computer Systems

The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm;

(B) The accuracy of dose, dwell time, and treatment time calculations at representative points. The licensee shall perform regular quality assurance testing on the treatment planning computer. Said testing shall be in accordance with TG40 or current AAPM recommendation.

(C) The accuracy of isodose plots and graphic displays;

(D) The accuracy of the software used to determine radioactive source positions from radiographic images; and

(E) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

120.587: Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Except as provided in 105 CMR 120.528, the licensee shall require an authorized user of a sealed source for a use authorized under 105 CMR 120.570 to be a physician who:

(A) Is certified by a medical specialty board whose certification process has been recognized by **the Agency,** an Agreement State or the Nuclear Regulatory Commission and who meets the requirements in 105 CMR 120.587**(C)**~~(B)(3) and (C)~~. ~~(~~ The names of board certifications ~~which~~ **that** have been recognized by the **Agency, Nuclear Regulatory** Commission or an Agreement State will be posted on the NRC's **Medical Uses Licensee Toolkit** web page.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(B) (1) Has completed a structured educational program in basic radionuclide techniques

applicable to the use of a sealed source in a therapeutic medical unit that includes:

120.587: continued

(a) 200 hours of classroom and laboratory training in the following areas:
1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; **and**
4. Radiation biology; and

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 105 CMR 120.528, 120.587 or equivalent Agreement State or Nuclear Regulatory Commission requirements at a medical ~~institution~~ **facility that is authorized to use byproduct materials in 105 CMR 120.570**, involving:
1. Reviewing full calibration measurements and periodic spot checks;
2. Preparing treatment plans and calculating treatment doses and times;
3. Using administrative controls to prevent a medical event involving the use of radioactive material;
4. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
5. Checking and using survey meters; **and**
6. Selecting the proper dose and how it is to be administered; and

(2) Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in 105 CMR 120.528, 120.587 or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 105 CMR 120.587(B)(1)(b); and

~~(3) Has obtained written attestation, that the individual has satisfactorily completed the requirements in 105 CMR 120.587(A)(1) or (B)(1) and (2), and 120.587(C) and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorize user status. The written attestation must be signed by a preceptor authorized user, who meets the requirements in 105 CMR 120.528, 120.587, or equivalent Agreement State or Nuclear Regulatory requirements for an authorized user for each type therapeutic medical unit for which the individual is requesting authorized user status; and~~

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 105 CMR 120.587(B)(1) and (2) and (C); and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in 105 CMR 120.528, 120.587, or equivalent Nuclear Regulatory Commission or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 105 CMR 120.528, 120.587, or equivalent Nuclear Regulatory Commission or Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 105 CMR 120.587(B)(1) and (2).

(C) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

120.589: Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in 105 CMR 120.500 if:

(A) The applicant or licensee has submitted the information required by 105 CMR 120.507(B) through (D); and

(B) The applicant or licensee has received written approval from the Agency in a license and uses the material in accordance with 105 CMR 120.000 and specific conditions the agency considers necessary for the medical use of the material.

RECORDS

120.590: Requirements for Record Keeping

(A) Records of Authority and Responsibilities for Radiation Protection Programs.

(1) A licensee shall retain a record of actions taken by the licensee's management in accordance with 105 CMR 120.515(A) for five years. The record must include a summary of the actions taken and a signature of licensee management.

120.590: continued

(2) The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by 105 CMR 120.515(~~D~~**E**), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by 105 CMR 120.515(B) The record must include the signature of the Radiation Safety Officer and licensee management.

(3) For each Associate Radiation Safety Officer appointed under 105 CMR 120.515(B), the licensee shall retain, for five years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

(B) Records of Radiation Protection Program Safety Changes. A licensee shall retain a record of each radiation protection program change made in accordance with 105 CMR 120.517(A) for five years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

(C) Records of Written Directives. A licensee shall retain a copy of each written directive as required by 105 CMR 120.521 for three years.

(D) Records of Medical Events. A licensee shall retain a record of medical events reported in accordance with 105 CMR 120.594(A) for three years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the medical event; medical event a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(E) Record of a Dose to an Embryo/Fetus or a Nursing Child. A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with 105 CMR 120.594(B) for three years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned of the embryo/fetus or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(F) Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material. A licensee shall maintain a record of instrument calibrations required by 105 CMR 120.532 for three years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(G) Records of Survey Instrument Calibrations. A licensee shall maintain a record of instrument calibrations required by 105 CMR 120.533 for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(H) Records of Dosages of Unsealed Radioactive Material for Medical Use. A licensee shall maintain a record of dosage determinations required by 105 CMR 120.534 for three years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

(I) Records of Possession of Sealed Sources and Brachytherapy Sources.

(1) A licensee shall retain a record of the leak test required by 105 CMR 120.536(B) for three years. The record must contain the model number, and serial number if one has been

assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the results of the test, the date of the test, and the name of the individual who performed the test.

120.590: continued

(2) A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 105 CMR 120.536(E) for three years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(J) Records of Surveys for Ambient Radiation Exposure Rate. A licensee shall retain a record of each survey required by 105 CMR 120.539 for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(K) Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material.

(1) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

(a) Using the retained activity rather than the activity administered;

(b) Using an occupancy factor less than 0.25 at one meter;

(c) Using the biological or effective half-life; or

(d) Considering the shielding by tissue.

(2) A licensee shall retain a record, for three years after the date of release, that the instructions required by 105 CMR 120.540(B) were provided to a breast-feeding woman [if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five mSv (0.5 rem)].

(L) Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.

(1) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by 105 CMR 120.541(A)(1), for three years after the last provision of service.

(2) A licensee shall retain the record of each survey required by 105 CMR 120.541(A)(4) for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(M) Records of Decay-in-storage. A licensee shall maintain records of the disposal of licensed materials, as required by 105 CMR 120.543, for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

(N) Records of Radionuclide Purity. A licensee shall maintain a record of the radionuclide contaminant concentration tests required by 105 CMR 120.548**(B) and (C)** for three years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide ~~(microcuries/millicurie)~~, or ~~microgram~~ **microcuries** of contaminant per ~~megabecquerel~~ **millicurie** of desired radionuclide ~~(microgram/millicurie)~~, the time and date of the measurement, and the name of the individual who made the measurement.

(P) Records of Safety Instruction and Training. A licensee shall maintain a record of safety instructions and training required by 105 CMR 120.553, 120.562 and **the operational and safety instructions required by** 120.573 for three years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(Q) Records of Radiation Surveys of Patients and Human Research Subjects. A licensee shall maintain a record of the surveys required by 105 CMR 120.560 and 120.571 for three years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

(R) Records of Safety Procedures. A licensee shall retain a copy of the procedures required by 105 CMR 120.573(A)(4) and (D)(2)(b) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

120.592: Requirements for Record Keeping Pertaining to the Use of Sealed Sources

(A) Records of Brachytherapy Source Inventory.

(1) A licensee shall maintain a record of brachytherapy source accountability required by 105 CMR 120.561 for three years.

(2) For temporary implants, the record must include:

(a) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(b) The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them from storage.

(3) For permanent implants, the record must include:

(a) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(b) The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

(c) The number and activity of sources permanently implanted in the patient or human research subject.

(B) Records of Calibration Measurements on Brachytherapy Sources. A licensee shall maintain a record of the calibrations on brachytherapy sources required by 105 CMR 120.564 for three years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(C) Records of Decay of Strontium-90 Sources for Opthalmic Treatments. A licensee shall maintain a record of the activity of a strontium-90 source required by 105 CMR 120.564**A for the life of the source**. The record must include the date and initial activity of the source as determined under 105 CMR 120.564, and for each decay calculation, the date and the source activity **as determined by 105 CMR 120.564A**.

(D) Records of Installation, Maintenance, Adjustment, and Repair. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by 105 CMR 120.572 for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(E) Records of Dosimetry Equipment.

(1) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 105 CMR 120.575 for the duration of the license.

(2) For each calibration, intercomparison, or comparison, the record must include:

(a) The date;

(b) The manufacturer’s name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 105 CMR 120.575(A) and (B);

(c) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(d) The names of the individuals who performed the calibration, intercomparison, or comparison.

(F) Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.

(1) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by 105 CMR 120.576, 120.577 and 120.578 for three years.

(2) The record must include:

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and

instruments used to calibrate the unit;

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(c) The results and assessments of the full calibrations;
(d) The results of the autoradiograph required for low dose-rate remote afterloader units; and
(e) The signature of the authorized medical physicist who performed the full calibration.

(G) Records of Periodic Spot-checks for Teletherapy Units.
(1) A licensee shall retain a record of each periodic spot-check for teletherapy units required by 105 CMR 120.579 for three years.
(2) The record must include:
(a) The date of the spot-check;
(b) The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
(c) An assessment of timer linearity and constancy;
(d) The calculated on-off error;
(e) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
(f) The determined accuracy of each distance measuring and localization device;
(g) The difference between the anticipated output and the measured output;
(h) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
(i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(H) Records of Periodic Spot-checks for Remote Afterloader Units.
(1) A licensee shall retain a record of each spot-check for remote afterloader units required by 105 CMR 120.580 for three years.
(2) The record must include, as applicable:
(a) The date of the spot-check;
(b) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
(c) An assessment of timer accuracy;
(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit’s computer; and
(e) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(I) Records of Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.
(1) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by 105 CMR 120.581 for three years.
(2) The record must include:
(a) The date of the spot-check;
(b) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
(c) An assessment of timer linearity and accuracy;
(d) The calculated on-off error;
(e) A determination of trunnion centricity;
(f) The difference between the anticipated output and the measured output;
(g) An assessment of source output against computer calculations;
(h) Notations indicating the operability of radiation monitors, helmet microswitchs, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
(i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

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(J) Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

(1) A licensee shall retain a record of each check for mobile remote afterloader units required by 105 CMR 120.582 for three years.

(2) The record must include:

(a) The date of the check;

(b) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(c) Notations accounting for all sources before the licensee departs from a facility;

(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and

(e) The signature of the individual who performed the check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(K) Records of Surveys of Therapeutic Treatment Units.

(1) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with 105 CMR 120.583 for the duration of use of the unit.

(2) The record must include:

(a) The date of the measurements;

(b) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(c) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(d) The signature of the individual who performed the test.

(L) Records of ~~Five-year~~ **Full** Inspection **Servicing** for Teletherapy and Gamma Stereotactic Surgery Units.

(1) A licensee shall maintain a record of the ~~five-year inspections~~ **full inspection servicing** for teletherapy and gamma stereotactic radiosurgery units required by 105 CMR 120.584 for the duration of use of the unit.

(2) The record must contain:

(a) The inspector's radioactive materials license number;

(b) The date of inspection;

(c) The manufacturer's name and model number and serial number of both the treatment unit and source;

(d) A list of components inspected and serviced, and the type of service; and

(f) The signature of the inspector.

REPORTS

120.594: Reports and Notifications

~~(A) Reports and Notifications of Medical Events.~~

~~(1) Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in:~~

~~(a) A dose that differs from the prescribed dose by more than 0.05 Sv (five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and either~~

~~1. The total dose delivered differs from the prescribed dose by 20% or more;~~

~~2. The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or~~

~~3. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.~~

~~(b) A dose that exceeds 0.05 Sv (five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:~~

~~1. An administration of a wrong radioactive drug;~~

~~2. An administration of a radioactive drug containing radioactive material by the wrong route of administration;~~

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~~3. An administration of a dose or dosage to the wrong individual or human research subject;~~

~~4. An administration of a dose or dosage delivered by the wrong mode of treatment; or~~

~~5. A leaking sealed source.~~

~~(c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).~~

(A) Report and Notification of a Medical Event.

(1) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which:

(a) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in:

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

a. The total dose delivered differs from the prescribed dose by 20 percent or more;

b. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

c. The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.

2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

a. An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

b. An administration of a radioactive drug containing byproduct material by the wrong route of administration;

c. An administration of a dose or dosage to the wrong individual or human research subject;

d. An administration of a dose or dosage delivered by the wrong mode of treatment; or

e. A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

a. 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

b. 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

(b) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

1. The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

2. The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

3. An administration that includes any of the following:

a. The wrong radionuclide;

b. The wrong individual or human research subject;

c. Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

d. A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem)

to an organ or tissue.

(2) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of the medical event.

(4) The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.

(a) The written report must include:

1. The licensee's name;
2. The name of the prescribing physician;
3. A brief description of the event;
4. Why the event occurred;
5. The effect, if any, on the individual(s) who received the administration;
6. Actions, if any, that have been taken, or are planned, to prevent recurrence; **and**
7. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(5) The licensee shall provide notification of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event because of any delay in notification. To meet the requirements of ~~105 CMR 120.504(A)(5)~~ **105 CMR 120.594(A)(5)**, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) Aside from the notification requirement, nothing in 105 CMR 120.594 affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event or to that individual's responsible relatives or guardians.

(7) A licensee shall retain a record of a medical event in accordance with 105 CMR 120.590(D). A copy of the record required under 105 CMR 120.590(D) shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the medical event.

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(B) Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than five mSv (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:

(a) Is greater than five mSv (500 mrem) total effective dose equivalent; or

(b) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in 105 CMR 120.594(B)(1) or 105 CMR 120.594(B)(2).

(4) The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 105 CMR 120.594(B)(1) or 105 CMR 120.594(B)(2).

(a) The written report must include:

1. The licensee's name;
2. The name of the prescribing physician;
3. A brief description of the event;
4. Why the event occurred;
5. The effect on the embryo/fetus or the nursing child;
6. What actions, if any, have been taken, or are planned, to prevent recurrence; and
7. Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(b) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after of discovery of an event that would require reporting under 105 CMR 120.594(B)(1) or (2), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with 105 CMR 120.590(E). A copy of the record required under 105 CMR 120.590(E) shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

(C) Reports of Leaking Sources. A licensee shall file a report with the Agency within five days if a leakage test required by 105 CMR 120.536 reveals the presence of 185 Becquerel (0.005 Ci) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

(D) Reports of Patient Departure Prior to Authorized Release.

(1) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under 105 CMR 120.540(A).

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(2) The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure. The written report must include:

(a) The licensee's name;

(b) The date and time of the unauthorized departure;

(c) The projected date and time when release would have occurred;

(d) The general location address of the patient's or human research subject's home or anticipated destination following departure;

(e) The radionuclide, chemical and physical form and calculated activity at time of release;

(f) The apparent reason(s) for the departure prior to authorized release; and,

(g) A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

(E) Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.

(1) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of 105 CMR 120.221 as a result of the deceased's body.

(2) The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in 105 CMR 120.594(E)(1) has died. The written report must include:

(a) The licensee's name;

(b) The date of death;

(c) The radionuclide, chemical and physical form and calculated activity at time of death; and

(d) The names (or titles) and address(es) of known individuals who might have received exposures exceeding five mSv (500 mrem).

(F) Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

(1) The licensee shall notify by telephone the Agency and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in 105 CMR 120.548(A) at the time of generator elution. The telephone report to the Agency must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

(2) By an appropriate method listed in 105 CMR 120.013, the licensee shall submit a written report to the Agency within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by 105 CMR 120.594(F)(1).

120.600: RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

120.601: Purpose and Scope

105 CMR 120.600 provides special requirements for analytical x-ray equipment. The requirements of 105 CMR 120.600 are in addition to, and not in substitution for, applicable requirements in other Sections of 105 CMR 120.000.

120.602: Definitions

As used in 105 CMR 120.600, the following definitions apply:

120.776: General Licenses for Carriers

(A) A general license is hereby issued to any common or contract carrier not exempt under 105 CMR 120.775 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[3]

(B) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[3]

(C) Persons who transport radioactive material pursuant to the general licenses in 105 CMR 120.776(A) or (B) are exempt from the requirements of 105 CMR 120.200 and 120.750 to the extent that they transport radioactive material.

120.777: General License: Nuclear Regulatory Commission - Approved Packages

(A) A general license is hereby issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the Nuclear Regulatory Commission.

(B) This general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the provisions of 105 CMR 120.791 through 120.797.

(C) Each licensee issued a general license under 105 CMR 120.777(A) shall:

(1) Maintain a copy of the NRC issued certificate of compliance, or other approval by the Nuclear Regulatory Commission of the package, and the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

(2) Comply with the terms and conditions of the license, certificate, or other approval by the Nuclear Regulatory Commission, as applicable, and the applicable requirements of **105 CMR 120.016(L),** 105 CMR 120.771 through 120.774 and 105 CMR 120.784 through 120.797; and

(3) Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of ~~Spent Fuel Storage and Transportation~~ **Fuel Management**, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

(D) The general license in 105 CMR 120.777(A) applies only when the package approval authorizes use of the package under this general license.

(E) For a Type B or fissile material package, the design of which was approved by the Nuclear Regulatory Commission before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR 71.19.

120.779: General License: U.S. Department of Transportation Specification Container

(A) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

(B) This general license applies only to a licensee who:

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[3] Notification of an incident shall be filed with, or made to, the Agency as prescribed in 49 CFR, regardless of, and in addition to, notification made to U.S. Department of Transportation or other agencies.

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(1) Has a copy of the specification;
(2) Complies with the terms and conditions of the specification and the applicable requirements of 105 CMR 120.770; and
(3) Has a quality assurance program as required by 105 CMR 120.791.

(C) This general license in 105 CMR 120.779(A) is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.

(D) The general license specified in 105 CMR 120.779 expires on October 1, 2008.

120.780: General License - Use of Foreign Approved Package

(A) A general license is issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.23.

(B) This general license applies only to shipments made to or from locations outside the United States.

(C) Except as otherwise provided in 105 CMR 120.780, the general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the applicable provisions of 105 CMR 120.791 through 120.797.

(D) Each licensee issued a general license under 105 CMR 120.780(A) shall:
(1) Maintain a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and
(2) Comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of **105 CMR 120.016(L),** 105 CMR 120.771 through 120.774 and 105 CMR 120.784 through 120.797.

120.781: General License: Fissile Material, Limited Quantity per Package

(A) A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with 105 CMR 120.781. The fissile material need not be contained in a package which meets the standards of 10 CFR 71 Subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(B) The general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the provisions of 105 CMR 120.791 through 120.797.

(C) The general license applies only when a package's contents:
(1) Contain less than a Type A quantity of fissile material; and
(2) Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(D) The general license applies only to packages containing fissile material that are labeled with a CSI which:
(1) Has been determined in accordance with 105 CMR 120.781(E);
(2) Has a value less than or equal to ten; and
(3) For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

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(B) The licensee shall make available to the Agency for inspection, upon reasonable notice, all records required by 105 CMR 120.770 through 120.798. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

(C) The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include: results of the determinations required by 105 CMR 120.785; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for three years after the life of the packaging to which they apply.

120.790: Advance Notification of Shipment of Nuclear Waste

(A)(1) As specified in 105 CMR 120.790(B) through (D), each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, within or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(2) As specified in 105 CMR 120.790(B) through (D) each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in 105 CMR 120.790(C)(3)(c), or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(B) Advance notification is required under 105 CMR 120.790 for shipment of licensed material meeting the following three conditions:

(1) The licensed material is required by 10 CFR 71 to be in Type B packaging for transportation;

(2) The licensed material is being transported into, within, or through a state en route to a disposal facility or to a collection point for transport to a disposal facility; and

(3) The quantity of licensed material in a single package exceeds the least of the following:

(a) 3000 times the A_1 value of the radionuclides as specified in 105 CMR 120.798: *Appendix A*, Table A-1 for special form radioactive material;

(b) 3000 times the A_2 value of the radionuclides as specified in 105 CMR 120.798: *Appendix A*, Table A-1 for normal form radioactive material; or

(c) 1000 TBq (27,000 Ci).

(C) Procedures for Submitting Advance Notification.

(1) The notification must be made in writing to the office of each appropriate governor or governor's designee, the office of each appropriate Tribal official or Tribal official's designee, and to the Director of the Agency.

(2) A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(3) A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(a) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the *Federal Register* on June 30, 1995 (60 FR 34306).

(b) Contact information for each State, including telephone and mailing addresses of governors and governors' designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal official's designees, is available on the NRC website at: https://scp.nrc.gov/special/designee.pdf.

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(c) A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(4) The licensee shall retain a copy of the notification as a record for three years.

(D) Information to Be Furnished in Advance Notification of Shipment. Each advance notification of shipment of nuclear waste must contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the nuclear waste shipment;

(2) A description of the nuclear waste contained in the shipment, as specified in the regulations of DOT in 49 CFR 172.202 and 172.203(d);

(3) The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

(4) The seven-day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur;

(5) The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

(6) A point of contact, with a telephone number, for current shipment information.

(E) Revision Notice. A licensee who finds that schedule information previously furnished to a governor or governor's designee or a Tribal official or Tribal official's designee, in accordance with 105 CMR 120.790, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for three years.

(F) Cancellation Notice.

(1) Each licensee who cancels a nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and to the Director of the Agency.

(2) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for three years.

QUALITY ASSURANCE

120.791: Quality Assurance Requirements

(A) Purpose. 105 CMR 120.791 through 120.797 describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in 105 CMR 120.791 through 120.797, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to 105 CMR 120.791 through 120.797.

(B) Establishment of Program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 105 CMR 120.791 through 120.797 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

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(C) Approval of Program. Before the use of any package for the shipment of licensed material subject to 105 CMR 120.791 through 120.797, each licensee shall obtain Agency approval of its quality assurance program. Using an appropriate method listed in 105 CMR 120.013, each licensee shall file a description of its quality assurance program, including a discussion of which requirements of 105 CMR 120.791 through 120.797 are applicable and how they will be satisfied, by submitting the description to the Agency.

(D) Radiography Containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of 10 CFR 34.31(b) or equivalent Agreement State requirement, is deemed to satisfy the requirements of 105 CMR 120.777(B) and 120.791(B).

120.792: Quality Assurance Organization

(A) The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(B) The quality assurance functions are:

(1) Assuring that an appropriate quality assurance program is established and effectively executed; and

(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

120.793: Quality Assurance Program

(A) The licensee shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of 105 CMR 120.791 through 120.797. The licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(B) The licensee shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

(1) The impact of malfunction or failure of the item to safety;

(2) The design and fabrication complexity or uniqueness of the item;

(3) The need for special controls and surveillance over processes and equipment;

(4) The degree to which functional compliance can be demonstrated by inspection or test; and

(5) The quality history and degree of standardization of the item.

(C) The licensee shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.