4731.0313 Specific Terms and Conditions of Licenses.

Subpart 1. **Rules for license.** Each license issued pursuant to 4731.0313 shall be subject to all the provisions of 4731.0101-4731.0195, 4731.0300-4731.0320, 4731.500- 4731.0520, 4731.0700-4731.0720, 4731.0800-4731.0820, 4731.0900-4731.0920, 4731.1000-4731.1020, 4731.1200-4731.1220, now or hereafter in effect, and to all rules of the commissioner.

Subp. 2. **License restrictions.** Unless the commissioner, after securing full information about a transfer or right under a transfer, finds that the transfer is in accordance with the provisions of Chapter 4731, and gives consent in writing, no actions are permitted for:

A. A license issued or granted under 4731.0313,

B. The right to possess or utilize radioactive material, including special nuclear material,

C. Neither the license nor the radioactive material shall be transferred, assigned, or disposed of in any manner:

(1) voluntarily or involuntarily,

(2) directly or indirectly, or

(3) through transfer of control to any person.

Subp. 3. **Notification of bankruptcy.** Each licensee shall notify the commissioner 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 (U.S.C.)

A. By or against:

(1) the licensee;

(2) an entity, as that term is used in 4731.0300, Subp 5, H, (1), (b), controlling the licensee or listing the license or licensee as property of the estate; or

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

B. This notification must indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition for bankruptcy.

Subp. 4. **Authorized use of radioactive material, including special nuclear material.**

A. Each person licensed by the commissioner pursuant to parts 4731.0101-4731.0195, 4731.0300- 4731.0320, 4731.0500-4731.0520, 4731.0700-4731.0720, 4731.0800-4731.0820, 4731.0900-4731.0920, 4731.1000-4731.1020, 4731.1200- 4731.1220, shall confine use and possession of the licensed radioactive material, including special nuclear material to the locations and purposes authorized on the license. Except as otherwise provided in the license, the license issued pursuant to parts 4731.0101-4731.0195, 4731.0300-4731.0320, 4731.0500-4731.0520, 4731.0700-4731.0720, 4731.0800-4731.0820, 4731.0900-4731.0920, 4731.1000-4731.01020, 4731.1200-4731.1220, shall carry with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport of radioactive material shall be accordance with the provisions of parts 4731.1500- 4731.1520.

B. The possession, use, and transfer of any special nuclear material produced by a licensee, in connection with or as a result of use of special nuclear material received under his license, shall be subject to the provisions of the license and the regulations of parts 4731.0300-4731.0320.

Subp. 5. **Separate license required.** A. separate license is required for the following:

A. Each activity as designated by license category in part 4731.0102, subp.1.

B. Facilities for which one or more of the following applies:

(1) the facilities are not contiguous;

(2) the facilities are not under a single radiation safety program; or

(3) the facilities are not under the same management.

C. Each facility operated by an out-of-date licensee under reciprocity as specified in part 4731.0316 and does not meet the definition of a temporary job site.

D. Each large irradiator as defined in part 4731.0100.

Subp. 6. **Work location.** A separate license is not required for each temporary job ~~sites~~site(s) or for each facility that is authorized under a broad scope license.

4731.0314 Expiration and Termination of Licenses and Commissioning of Sites and Separate Buildings or Outdoor Area.

Subpart 1. **Final 60 days Preceding Expiration of License**

A. Date of expiration

(1) except as provided in 4731.0300-4731.0320, each specific license shall expire at the end of the specified day in the month and year stated therein.

(2) each specific license that has an expiration date after July 1, 1995, and is not one of the licenses described in 4731.0314, subp. 1, C , below, shall be deemed to have an expiration date that is five years after the expiration date stated on the current license.

(3) each specific license revoked by the commissioner expires at end of the day on the date of the commissioner's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by the commissioner's order.

(4) each specific license continues in effect, beyond the expiration date, if necessary, with respect to possession of radioactive material, including special nuclear material, until the commissioner notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(a) limit actions involving radioactive materials to those related to decommissioning; and

(b) continue to control entry to restricted areas until they are suitable for release in accordance 4731.0314, subp. 2, D, (5), or 4731.0314, subp. 3.

(5) the commissioner may grant a request to extend the time periods established in 4731.0314, subp. 1, B, or delay or postpone initiation of the decommissioning process if the commissioner determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 60 days before notification pursuant to 4731.0314, subp. 1, B. The schedule for decommissioning set forth in 4731.0314, subp. 1, B , may not commence until the commissioner has made a determination on the request

B. Action Required Within 60 days of License Expiration Date.

(1) no less than 60 days before the expiration date specified in the license, the licensee shall either submit an application for license renewal on the same form used for the

initial application under 4731.0308, or

(2) within 60 days of the occurrence of any of the following, each licensee shall provide notification to the commissioner in writing of such occurrence, and either:

(a) begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Chapter 4731, or

(b) submit within 12 months of notification a decommissioning plan, if required by 4731.0314, subp. 3, B, and begin decommissioning upon approval of that plan, if:

((1)) the license has expired pursuant to 4731.0314, subp. 1, A, (1) or (3); or

((2)) the licensee has decided to permanently cease principal activities, as defined in 4731.0100, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance Chapter 4731 requirements; or

((3)) no principal activities have been conducted for a period of 24 months; or

((4)) no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Chapter 4731 requirements.

C. The following specific licenses are not subject to, or otherwise affected by, the provisions of 4731.0314, subp. 1, A, (2):

(1) specific licenses for which an evaluation or an emergency plan is required in accordance with 4731.0308, subp. 2, B, (1), (b) ;

(2) specific licenses whose holders are subject to the financial requirements specified in 4731.0309, subparts 2, 3, and 4 , and the holders either:

(a) have not submitted a decommissioning funding plan or certification of financial assurance for decommissioning; or

(b) have not received written notice that the decommissioning funding plan or certification of financial assurance for decommissioning is acceptable;

(3) specific licenses whose holders are listed in SDMP List published in NUREG 1444, Supplement 1 (November 1995).

(4) specific licenses whose issuance, amendment, or renewal, as of February 15, 1996, is not categorical exclusion under 10 CFR 51.22(c)(14), and, therefore, need an environmental assessment or environmental impact statement pursuant to 10 CFR 51, subpart A.

(5) specific licenses whose holders have not had at least one U.S. Nuclear Regulatory Commission inspection of licensed activities before February 15, 1996;

(6) specific licenses whose holders, as the result of the most recent U.S. Nuclear Regulatory Commission inspection of licensed activities conducted before February 15, 2002, have been:

(a) cited for a Severity Level I, II, or III violation in a Notice of Violation;

(b) subject to an Order issued by the Nuclear Regulatory commission; or

(c) subject to a Confirmatory Action Letter issued by the Nuclear

Regulatory Commission.

(7) specific licenses with expiration dates before July 1, 1995 for which the holders have submitted applications for renewal under 10 CFR 30.37.

Subp 2. **Termination of License.**

A. The licensee shall notify the commissioner, in writing, if the licensee decides not to apply for license renewal.

B. Each licensee shall notify the commissioner immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive materials authorized under the license. The notification and request for termination of the license must include the reports and information specified in 4731.0314, subp. 2, D and E, below.

C. Coincident with the notification required in 4731.0314, subp. 1, B, and 4731.0314, subp2, C, above, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to 4731.0309, subparts 2, 3, and 4, in conjunction with license issuance or renewal or as required by 4731.0311. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established by the licensee pursuant to 4731.0314, subp. 3, C, (1), (f), below.

D. If a licensee does not submit an application for license renewal under 4731.0308, the licensee shall, on or before the expiration date specified in the license:

(1) terminate the use of radioactive material:

(2) remove radioactive contamination to the extent acceptable to the commissioner

(3) properly dispose of the radioactive material;

(4) submit a properly completed 4731.3004, 6; and

(5) submit a radiation survey report to confirm the absence of radioactive materials to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual contamination in some other manner. The licensee shall, as appropriate:

(a) for gamma radiation, report levels of radiation in units of microroentgens per hour at 10 centimeters and at 1 meter from surfaces.

(b) for alpha and beta radiation, report levels of radioactivity in units of transformations per minute or microcuries per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and

(c) specify the instruments used and certify that each instrument is properly calibrated or tested.

E. If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. The commissioner may notify the licensee, in writing, of the termination of the license.

F. Specific licenses, including expired licenses, may be terminated by written notice to the licensee when the commissioner determines that:

(1) radioactive material, including source and special nuclear materials, have been properly disposed; and

(2) reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3) information provided shows:

(a) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 4731.0314; or

(b) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release. In accordance with the criteria for decommissioning in 4731.0314.

(4) records required by 4731.0184 and 4731. 0314, subp. 5, have been received.

Subp 3. **Submission of Decommissioning Plan.**

A. If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the commissioner notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of 4731.0314, subp. 3, B, below.

B. In addition to the information submitted under 4731.0314, subp. 2, (4) and (5), above:

(1) the licensee shall submit a plan for decommissioning if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been approved previously by the commissioner and these procedures could increase potential health and safety impacts to workers or the public as in any of the following cases:

(a) procedures would involve techniques not applied routinely during cleanup and maintenance operations;

(b) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(c) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(d) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) the commissioner may approve an alternate schedule for submittal of a decommissioning plan required in 4731.0314, subp. 1, B, if the commissioner determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from the radiation to the public health and safety and is otherwise in the public interest.

(3) procedures such as those listed in 4731.0314, subp. 3, B, (1), with potentially impact health, safety impacts may not be performed prior to obtaining the decommissioning plan approval.

C. The proposed decommissioning plan for the site or separate building or outdoor area:

(1) must include:

(a) a description of the conditions of the site or separate building area

sufficient to evaluate the acceptability of the plan;

(b) a description of planned decommissioning activities;

(c) a description of the methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(d) the time required to complete the decommissioning plan;

(e) a description of the planned final radiation survey; and

(f) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(g) for decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in 4731.0314, subp. 3, C, (1), (a).

(2) may be approved by the commissioner, if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health an safety of the workers and the public will br adequately protected.

D. Except as provided in 4731.0314, subp. 3, E, below, licensees shall:

(1) complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning, when decommissioning involves the entire site.

E. The commissioner may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the commissioner determines that the alternative is warranted by consideration of the following:

(1) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(2) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) other site-specific factors which the commissioner may consider appropriate on a case-by-case basis, such as in the regulatory requirements of other governmental agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferring clean-up, and other factors beyond the control of the licensee.

Subp 4. **Completion of Decommissioning.**

A. Upon approval of the decommissioning plan by the commissioner, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall again submit the information required in 4731.0314, subp. 2,

D, (5), above, and shall:

(1) certify the disposition of all licensed material, including accumulated wastes, by submitting a completed a completed form 4731.3004, 6, or equivalent information; and

(2) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 4731.0314. The licensee shall, as appropriate:

(a) report levels of:

((1)) gamma radiation in units of microroentgen(millisieverts) per hour at one meter from surfaces, and

((2)) radioactivity, including alpha and beta in units of:

((a)) disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters removable and fixed for surfaces,

((b)) microcuries (megabecquerels) per milliliter for water, and

((c)) picocuries (becquerels) per gram for solids such as soils or concrete; and

(b) specify the survey and instrument(s) used and certify that each instrument is properly calibrated and tested.

B. If the information submitted as specified in 4731.0314, subp. 2, D, (5) or 4731.0314 subp. 4 of this section does not adequately demonstrate that the premises are suitable for release for unrestricted use, the commissioner will inform the licensee of the appropriate further actions required for termination of the license.

C. Each licensee who possesses residual radioactive material under 4731.0314, subp. 3, above, following the expiration date specified in the license shall:

(1) limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

(2) continue to control entry to restricted areas until they are suitable for release for unrestricted use and the department notifies the licensee, in writing, that the license is terminated.

D. As the final step in decommissioning, the licensee shall:

(1) certify the disposition of all licensed material, including accumulated wastes, by submitting a completed form 4731.3004, 6, or equivalent information; and

(2) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 4731.0314. The licensee shall, as appropriate:

(a) report levels of:

((1)) gamma radiation in units of microroentgen (millisieverts) per hour at one meter from surfaces, and

((2)) radioactivity, including alpha and beta, in units of:

((a)) disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters, removable and fixed, for surfaces,

((b)) microcuries (megabecquerels) per milliliter for water, and

((c)) picocuries (becquerels) per gram for solids such as soils or concrete; and

(b) specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

Subp 5. **Recordkeeping.**

A. Each licensee shall keep records of information important to the decommissioning of the facility in an identified location until the license is released for unrestricted use .

B. Before licensed activities are transferred or assigned in accordance with 4731.0313 subp. 2, licensees shall transfer all records described in 4731.0314, subp.5, D, (1), to the new licensee.

C. In this case a new licensee will be responsible for maintaining these records until license is terminated.

D. If records of relevant information are kept for other purposes, reference to these records and their location can be used. Records which must be kept include:

(1) spills or contamination

(a) location of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site.

(b) any known information on identification of involved nuclides, quantities, forms, and concentrations

(c) instances when contamination remains after cleanup procedures or when contaminants may have spread to inaccessible areas such as possible seepage into porous materials such as concrete.

(2) drawings or appropriate records:

(a) drawings of:

((1)) structures as originally built,

((2)) modifications,

((3)) equipment in restricted areas where radioactive materials are used or stored, and

((4)) locations of possible inaccessible contamination such as buried pipes which can be subject to contamination,

(b) drawings and their location can be referenced if not on site. Each relevant document need not be indexed individually.

(c) if drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) a list contained in a single document, except for areas containing only radioactive materials having half-lives of less than 65 days or sealed sources that either have not leaked or no contamination remains after any leak, and updated every 2 years, of the following:

(a) all areas designated and formerly designated restricted areas as defined 4731.0100.

(b) all areas outside of restricted areas that require documentation under 4731.0314, subp. 5;

(c) all areas outside of restricted areas where current and previous wastes have

been buried as documented under 4731.0184; and

(d) all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 4731.0314 or apply for approval for disposal under 4731.0136, subp. 2; and

(4) records of the:

(a) cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and

(b) funding method used for assuring funds if either a funding plan or certification is used.

4731.0315 **Transfer of Radioactive Material**

Subpart 1. **Authorization required.** No licensee shall transfer radioactive material, including source material and special clear material, except as authorized pursuant to this section.

Subp. 2. **Approved transfer.** Except as otherwise provided in his licensee and subject to the provisions of 4731.0315, subp. 3, A and C, below, any licensee may transfer radioactive material, including source material and special nuclear material:

A. To the commissioner after approval from the commissioner;

B. To the U.S. Department of Energy (DOE);

C. To any person exempt from these regulations to the extent permitted under such exemptions;

D. To the agency in any agreement state which regulates radioactive material pursuant to an agreement with the U.S. Nuclear Regulatory Commission (NRC).

E. To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issue by the commissioner, the NRC, an agreement state or a licensing state.

F. To any person in an agreement state subject to the jurisdiction of that state who has been exempted form licensing requirements and regulations and regulations of that state, to the extent permitted under such exemptions.

G. As otherwise authorized by the commissioner in writing.

Subp. 3. **Licensee requirements for transfer** . The licensee transferring radioactive material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material, including source material and special nuclear material, to be transferred.

A. Before transferring radioactive material, including source material and special nuclear material, to a specific licensee of the commissioner, the NRC, an agreement state, a licensing state or to a general licensee who is required to register with the commissioner, the NRC, an agreement state or a licensing state.

B. Prior to receipt of the radioactive material, including source material and special nuclear material.

C. Any of the following methods for the verification required by 4731.0315, subp. 3, above, are applicable.

(1) the transferor may possess and read a current copy of the transferee's specific or

general license, or registration certificate. The transferor shall retain a copy of each license or certificate until the next inspection.

(2) the transferor may possess a written certification by the transferee that the transferee is authorized by license or registration to receive the type, form, and quantity of radioactive material, including source material and special nuclear material, to be transferred, specifying:

(a) the license or registration certification number,
(b) issuing agency, and
(c) expiration date.

The transferor shall retain a copy of each license or certificate for four years from the date that it was obtained.

(3) for emergency shipments, the transferor may accept oral certification by the transferee, provided that the oral certification is confirmed in writing within 10 days, that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material, including source material and special nuclear material to be transferred, specifying the :

(a) license or registration certificate number,
(b) issuing agency, and
(c) expiration date.

The transferor shall retain the written confirmation of the oral certification for four years from the date of the certification.

Subp.4. **Information for transferor.** The transferor may obtain other information compiled by a reporting service from official records of the commissioner, the U.S. NRC, the licensing agency of an agreement state regarding the identity of licensees or registrants and the scope and expiration dates of the licenses or registrations. The transferor shall retain the compilation of information as a record for four years form the date that it was obtained; or

Subp. 5. **Confirmation for transferor.** The transferor may obtain and record confirmation from the commissioner, the U.S. NRC, the licensing agency of an agreement state or a licensing state that the transferor is licensed to receive the radioactive material, including source material and special nuclear material:

A. When none of the methods of verification described in 4731.0315, subparts 3 and 4, above are readily available, or

B. When a transferor desires to verify that information received by one of such methods is correct or up-to-date. The transferor shall retain the record of confirmation for four years from the date the record is made.

Subp. 6. **Shipment and transport of radioactive material.** Shipment and transport of radioactive material shall be in accordance with the provisions of 4731.1500 - 4731.1520.

4731.0316 ~~**RECIPROCITY**~~ **Reciprocity.** Applications for reciprocal recognition of licenses issued by NRC or other states may be made by completing the form in 4731.3004, 14. The form

may be obtained by contacting the MN Dept of Health, Radiation Control Section at (651) 643-2151.

Subpart 1. **Recognition of licenses issued by the NRC or other states**

A. The commissioner may reciprocally recognize radioactive materials licenses issued by the NRC or a state agency in another state under the conditions set forth in 4731.0316, subparts 2, 3, and 4 below.

B. Reciprocity license application. The commissioner will review applications for reciprocity for compliance with the regulations in Chapter 4731 in the same manner as applications from within the state. The commissioner will verify that the required information has been provided and that the application has been signed and dated by the Radiation Safety Officer or management representative.

C. Inspections of reciprocal licensees. These will be conducted in accordance with this part.

(1) inspections by the commissioner may be performed on any licensee who has been granted a reciprocal license.

(2) considerations for selecting reciprocal licenses include:

(a) potential risk to employees, the public or the environment;

(b) activities that are new or unusual for the state;

(c) the frequency of the licensee entering the state for performing activities;

(d) the length of time to complete the intended activity;

(e) the concern expressed by the public about a specific activity.

(3) the frequency of inspection for any particular licensee will be dependent on the considerations listed in 4731.0316, subp1, C, (2), above. The percentage of inspections of reciprocity licensees to be inspected each year is based on the number of candidates for inspection per year. The percentages of inspections by program code and priority will be as follows, with Priorities 1 through 3 as core inspections and the remaining priorities as non-core inspections. It is anticipated that 20 percent of the candidate licensees from the candidate pool will be inspected each year. Additional inspections will be performed as resources and time permit.

Subp.2. **Licenses of radioactive material, source and special nuclear material in quantities not sufficient to form a critical mass.**

A. Subject to Chapter 4731, any person who holds a specific license from the NRC or another agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year provided that all of the follow occur:

(1) the licensing document does not limit the activity authorized by the document to specified installations or locations;

(2) the out-of-state license notifies the commissioner in writing at least 3 days prior to engaging in the activity.

(a) the notification shall indicate the exact location of use, start date, time period, names, documentation of training, in-state address of the individual performing the activity,

radiation sources to be used within the state, operating and emergency procedures and shall be accompanied by a copy of the pertinent licensing document;

(b) the out-of-state licensee shall also notify the commissioner of any changes in the work location, schedule, radioactive material or work activities;

(c) if, for a specific case, the 3-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon written application to the commissioner obtain permissions to proceed sooner;

(d) the commissioner may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license granted under Chapter 4731.0316, subpart 2A.

(3) the out-of-state licensee complies with Chapter 4731 and with all the terms and conditions of the licensing document, except any terms and conditions that may be inconsistent with this chapter.

(4) the out-of-state licensee supplies any other information as required by the commissioner.

(5) the out-of-state licensee does not transfer or dispose of radioactive material possessed or used under the general license under this part except by transfer to a person who is either specifically licensed by the commissioner or the NRC to receive the material, or is exempt from the requirements for a license for the material under 4731.3001 D subpart 2.

(6) the out-of-state licensee pays the fee prescribed in 4731.0104, subpart 1.

B. Notwithstanding the provisions of subpart 2, any person who holds a specific license issued by the NRC or another agreement state authorizing the holder to manufacture, transfer, install or service a device described in 4731.0304, subpart 2 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service the device in this state provided that all of the following occur:

(1) the person files a report with the commissioner within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee to whom the device is transferred by name and address, the type and model number of devices transferred and the quantity and type of radioactive material contained in the device;

(2) the device has been manufactured, labeled, installed and serviced under applicable provisions of the specific license issued to the person by the NRC or an agreement state;

(3) the person provides assurance that any labels required to be affixed to the device under regulations of the authority that licensed manufacture of the device bear the following statement "Removal of this label is prohibited;"

(4) the holder of the specific license furnishes to each general licensee to whom the device is transferred or on whose premises the device is installed a copy of the general license contained in 4731.0304, subpart 2 or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device;

C. The commissioner may withdraw, limit or quality its acceptance of any specific license or equivalent licensing document issued by the NRC or an agreement state or any product distributed under the licensing document upon determining that the action is necessary to prevent undue hazard to public health and safety or property.

Subp. 3. **Licenses of naturally occurring and accelerator-produced radioactive material.**

A. Subject to Chapter 4731, any person who holds a specific license for NARM from a licensing state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized within theis state for a period not in excess of 180 days in any calendar year provided that all of the following occur:

(1) the licensing document does not limit the authorized activity to specified installations or locations;

(2) license conditions:

(a) the out-of-state licensee notifies the commissioner in writing at least 3 days prior to engaging in such activity;

(b) the notification shall indicate the location, period and type of proposed possession and use within the state and shall be accompanied by a coy or the pertinent licensing document; and

(c) if, for a specific situation, the 3-day period would impose and undue hardship on the out-of-state licensee, the licensee may upon written application to the commissioner obtain permission to proceed sooner;

(d) the commissioner may waive the 3-day notification requirement when the activities of the out-of-state licensee are routinely scheduled at the same location in the state.

(3) The out-of-state licensee complies with Chapter 4731 and with all the terms and conditions of the licensing document except any terms and conditions that may be inconsistent with this chapter;

(4) the out-of-state licensee supplies any other information as required by the commissioner;

(5) the out-of-state licensee does not transfer or dispose of radioactive material possessed or used under the general license granted in 4731.0316 except by transfer to a person who is either specifically licensed by the commissioner or by another licensing state to receive radioactive material, or exempt from the requirements for a license for radioactive material under 4731.3001, D subpart 2;

(6) the out-of-state licensee pays the fee prescribed in 4731.0104, subpart 1.

B. Notwithstanding the provisions of 4731.0316, subpart 3, A, any person who holds a specific license issued by a licensing state authorizing the holder to manufacture, transfer, install or service a device described in 4731.0304, subpart 2 within areas subject other jurisdiction of the licensing body is hereby granted to general licenses to install, transfer, demonstrate or service the device in this state provided that all of the following conditions are met:

(1) the person files a report with the commissioner within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee to whom the device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device;

(2) the device has been manufactured, labeled, installed and serviced under applicable provisions of the specific license issued to the person by a licensing state;

(3) the person assures that any labels required to be affixed to the device under regulations of the authority that licensed manufacture of the device bears the following statement: "Removal of this label is prohibited;"

(4) the holder of the specific license furnishes to each general licensee to whom the holder transfers the device or on whose premises the holder installs the device a copy of the general license contained in 4731.0304, subpart 2, or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

C. The commissioner may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by a licensing state or any product distributed under the licensing document upon determining that the action is necessary to prevent undue hazard to public health and safety or property.

Subp. 4. **Jurisdictional status.**

A. A licensee shall determine the jurisdictional status of a temporary job-site before radioactive materials may be used at a job site at any federal facility within the state. If the jurisdictional status is unknown, the licensee shall contact the federal agency that controls the site to determine if the job site is under exclusive federal jurisdiction.

B. A licensee shall obtain authorization from another agreement state or the NRC before radioactive material may be used at a temporary job site in another state. Authorization may be obtained either by applying for reciprocity or a specific license from that state or the NRC.

Subp. 5. **Reciprocity checklist.**

A. Instructions. The following information must be received by the commissioner, at least 3 days prior to work starting along with the fee stated in 4731.0104, subpart 1.

(1) failure to provide the required information and/or fee may result in denial of reciprocity privileges.

(2) any person who holds a specific license from the NRC or another agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is here by granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year.

B. Information required:

(3)	Name of company for whom service will be performed	( )
(4)	Name of individual representing that company	( )
(5)	Telephone number of that individual	( )
(6)	Exact location where services will be performed	( )
(7)	Starting date	( )
(8)	Duration of service	( )
(9)	Type of service to be performed	( )
(10)	Name of individual(s) performing service	( )
(11)	Documentation of training for individual(s) (authorized users)	( )
(12)	In-state address of individual(s) (ie. Motel name and address)	( )
(13)	Identification of sources of radiation to be used	( )
(14)	Up-to-date copy of pertinent license	( )
(15)	Copy of the licensee's operating and emergency procedures	( )
(16)	Fee for reciprocity (4731.0104, subpart 1) $_____	( )

4731.0317 Emergency Planning.

Subpart 1. **Emergency Plan Requirements.**

A. An emergency plan for responding to a release of the radioactive material submitted under 4731.0308, subp. 2, b, (1), (b), must include the following information:

(1) a brief description of the licensee's facility and area near the site;

(2) an identification of each type of radioactive materials accident for which protective actions may be needed;

(3) a classification system for classifying accidents as alert or site area emergencies;

(4) identification of the means of detecting each type of accident in a timely manner;

(5) a brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on site, and a description of the program for maintaining the equipment;

(6) a brief description of the methods and equipment to assess releases of radioactive materials;

(7) a brief description of the responsibilities of licensee personnel should an accident occur, including identification notifying offsite responsible organizations and the commissioner; also, responsibilities for developing, maintaining, and updating the plan;

(8) notification and coordination which must include:

(a) provide a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate;

(b) establish a control point;

(c) prepare a plan so that notification and coordination will not result in unavailability of some equipment that could prevent completing the notification and coordination;

(d) commit to notifying the commissioner immediately after notification of the appropriate offsite response organizations and not later than one hour after the license declares an emergency.

(9) a brief description of the types of information of facility status, radioactive releases, and recommended protective actions, if necessary to be given to offsite response organizations and to the commissioner.

(10) training for emergency plan must include the following:

(a) a brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel;

(b) familiarize personnel with site-specific emergency procedures.

(c) thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios;

(11) a brief description of the means of restoring the facility to a safe condition

after an accident;

(12) the licensee shall:

(a) make provisions for conducting quarterly communications check with offsite response organizations and biennial onsite exercises to:

((1)) test response to simulated emergencies.

((2)) check and update all necessary telephone numbers.

(b) invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required.

(c) use accident scenarios postulated as most probable for the specific site. The scenarios shall not be known to most exercise participants.

(d) critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate:

((1)) the appropriateness of the plan,

((2)) emergency procedures,

((3)) facilities,

((4)) equipment,

((5)) training of personnel, and

((6)) overall effectiveness of the response.

(e) correct deficiencies found by the critiques.

(13) a certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub L. No. 99-499, if applicable of the applicant's activities at the proposed place of use of the radioactive material.

B. The licensee shall:

(1) allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the department;

(2) provide any comments received within 60 days to the commissioner along with the emergency plan.

Subp 2. **Applications That Require Emergency Planning**

A. Application for license to possess radioactive materials in unsealed form

(1) each applicant to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 4731.3003, D, must contain either:

(a) an evaluation showing that the maximum dose to a person off-site due to a release of radioactive materials would not exceed 1 rem (10mSv) effective dose equivalent or 5 rem(50 mSv) to the thyroid; or

(b) an emergency plan for responding to a release of radioactive material.

(2) one or more of the following factors can be used to support an evaluation submitted under 4731.0317, subp.1, of this section:

(a) the radioactive material is physically separated so that only a portion could be involved in an accident;

(b) all or part of the radioactive material is not subject to release during an

accident because of the way it is stored or packaged;

(c) the release fraction in the respirable size range would be lower than the release fraction shown in 4731.3003, D, due to the chemical or physical form of the material;

(d) the solubility of the radioactive material would reduce the dose received;

(e) facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 4731.3003, D. .

(f) operating restrictions of procedures would prevent a release fraction as large as that shown in 4731.3003, D.

(g) other factors appropriate for the specific facility.

B. Application for license radioactive material in a sealed source or in a device

(1) an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains a sealed source must either:

(a) identify the source or device by manufacturer and model number as registered with NRC under 10 CFR 32.210 or with an agreement state;

(b) contain the information identified in 10 CFR 32.210.

INDUSTRIAL RADIOGRAPHY USING RADIOACTIVE MATERIALS

4731.0500 Requirements for Industrial Radiography Facilities Using Radioactive Materials

Subpart 1. **Applicability.** This part contains requirements for the use of radioactive material in industrial radiography. This part does not apply to the applications listed below which are found elsewhere in this rule. These applications are:

A. Industrial radiography using x-ray machines in 4731.0600 to 4731.0607.

B. Industrial radiography using accelerators in 4731.0900 to 4731.0907.

Subp. 2. **License or registration requirements for industrial radiography use.** The commissioner may approve an application for a specific license or registration for the use of licensed or registered material in industrial radiography if the applicant meets the following requirements. The application must include:

A. Information for meeting the licensing requirements as specified in 4731.0309, as appropriate, and any additional requirements contained in this part.

B. A program for training radiographers and radiographers' assistants and a description of this program that specifies the content of the following:

(1) initial training;

(2) on-the-job training;

(3) semi-annual safety reviews provided by the licensee or registrant;

(4) method for demonstration of the radiographer's knowledge, understanding of and the ability to comply with chapter 4731, licensing or registration requirements, and the applicant's written operating and emergency procedures;

(5) method for demonstration of the radiographers' assistants knowledge, understanding of and the ability to comply with the applicant's written operating and emergency procedures.

C. Procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

D. Written operating and emergency procedures as described in 4731.0504 and 4731.0505.

E. A program for semi-annual review inspections of the job performance of each radiographer to ensure that chapter 4731 requirements, license or registration requirements, and the applicant's written operating and emergency procedures are followed.

F. A description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities, including specified delegations of authority and responsibility.

G. If the applicant intends to perform "in-house" calibrations of survey instruments the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 4731.0133, subpart 2.

H. A description and identification of the location(s) of all field stations and permanent radiographic installations.

I. Identifications of the locations where all records and documents required by this part and other parts of this chapter will be maintained.

Subp. 3. **Records.** The licensee or registrant must ensure that the records required by this part are kept in accordance with 4731.0168 to 4731.0189. Records must be kept for four years or until the next inspection by the commissioner. Each licensee or registrant must maintain copies of records required by this part at the location specified in 4731.0500, subpart 2, item H.

4731.0501 Performance Requirements for Industrial Radiography Equipment.

Subpart 1. **Performance requirements criteria.** Equipment used in industrial radiographic operations must meet the following minimum criteria:

A. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standards Institute (ANSI), N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography." The ANSI standard is incorporated by reference, is not subject to frequent change, and is available through the Minitex interlibrary loan system.

B. Notwithstanding Item A of subpart 1, equipment used in industrial radiographic operations need not comply with §8.9.2(c) of the Endurance Test in ANSI N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

C. In addition to the requirements specified in item A of this subpart, the following requirements apply to radiographic devices, source changers, source assemblies and sealed sources. The licensee or registrant must ensure that

(1) each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing:

(a) chemical symbol and mass number of the radionuclide in the device;

(b) activity and the date on which this activity was last measured;

(c) model (or product code) and serial number of the sealed source;

(d) manufacturer's identity of the sealed source;

(e) licensee's or registrant's name, address, and telephone number;

(f) the words: "DANGER–RADIOACTIVE." on each sealed source or source assembly; and

(g) the label may not interfere with the safe operation of the exposure device or associated equipment.

(2) radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of4731.1500 to 4731.1514.

(3) any modification of radiographic exposure devices, source changers, source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

Subp 2. **Additional requirements.** In addition to the requirements specified in items A and C of subpart 1 above, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or source changers. The licensee or registrant must ensure that:

A. The coupling between the source assembly and the control cable is designed so that the source assembly will not become disconnected if cranked outside the guide tube.

B. The coupling must not be able to be unintentionally disconnected under normal and foreseeable abnormal conditions.

C. The device automatically secures the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

D. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device are equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

E. The guide tube must be:

(1) able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and

(2) able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

(3) used when moving the source out of the device.

(4) equipped with an exposure head connection that is able to withstand the tensile test for control units specified in ANSI N432-1980.

F. An exposure head or similar device that is designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations.

G. A system is in place for source changers that ensures the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

4731.0502 Individual Monitoring. The licensee or registrant, in accordance with 4731.0130, must

require a radiographer or a radiographer's assistant, during radiographic operations, to wear on the trunk of the body, dosimetry as follows:

A. At permanent radiography installations where other alarming or warning devices are in routine use, a direct read dosimeter and a NVLAP-accredited individual dosimeter.

B. At temporary jobsites, a direct reading dosimeter, a NVLAP-accredited individual dosimeter, and an operating alarm ratemeter.

4731.0503 Entrances in Permanent Radiographic Installations. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

A. An entrance control of the type described in 4731.0131, subpart 2 that reduces the radiation level upon entry into the area, or

B. Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed.

4731.0504 Operating Procedures. Each licensee or registrant must develop and follow written operating procedures. The following operating procedures must include written procedures and record making provisions. Copies of superseded procedures must be retained for four years after the change is made.

Subpart 1. **Basic Operating procedures.** The following operating procedures must include written procedures and record making provisions for the following areas:

A. The handling and use of licensed or registered sources including the use of sources, source assemblies, and radiographic exposure devices.

B. The use of remote handling tools for handling sealed sources.

C. Methods for posting and controlling access to radiographic areas.

D. Methods and list of occasions for locking and securing stored licensed or registered materials.

E. Methods for ensuring radiographer assistants are supervised.

F. Opening, modification, removal and replacement of a sealed source from a source holder, and maintenance on sealed sources or holders.

G. Maintenance of records generated by radiographic personnel including temporary jobsites.

H. Methods and occasions for conducting radiation safety surveys, as required by 4731.0132, and 4731.0510.

I. Methods for testing alarm systems at permanent radiographic installations.

J. Individual monitoring and the use of individual monitoring devices, including alarming ratemeters, in accordance with 4731.0130 and 4731.0502.

K. Identify and report to the NRC product defects and noncompliance as required by 10 CFR 21.21.

Subp 2. **Procedures for Use and Maintenance**

A. Ensure the following in accordance with 4731.1500 - 4731.1514:

(1) transport of licensed or registered materials to field stations or temporary jobsites;

(2) packaging of licensed or registered materials for transport in vehicles;

(3) placarding of vehicles when needed; and

(4) physically securing licensed or registered materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal, in accordance with 4731.1500 - 4731.1514.

B. Get, receive, and open packages containing licensed or registered materials, including depleted uranium (DU) in accordance with 4731.0123, subpart 5.

C. Record the receipt of sealed sources and devices using DU; each licensee must make and maintain transportation records showing the receipts and transfers of sealed sources and devices using DU for shielding. These records must include:

(1) the date;

(2) the name of the individual making the record;

(3) radionuclide;

(4) number of curies (becquerels) or mass (for DU); and

(5) manufacturer, model, and serial number of each sealed source.

D. Conduct inspection, maintenance and operability checks of sealed sources, radiographic exposure devices, storage containers, and transport containers, as required by 4731.0507.

Subp 3. **Specific Operating Procedures**

A. Log the source use, including:

(1) a description, including the make, model, and serial number of the radiographic exposure device or transport or storage container in which the sealed source is located;

(2) the identity and signature of the radiographer to whom the equipment was assigned; and

(3) the plant or site where used and dates of use, including the dates the equipment was removed and returned to storage.

B. Visual inventory and recording of radioactive material use.

C. Leak testing of sealed sources in accordance with 4731.0134. If the licensee or registrant performs the leak testing of sealed sources, the licensee or registrant must:

(1) establish procedures to be followed;

(2) identify the manufacturers of the leak test kits; and

(3) the model numbers of the leak test kits to be used.

D. Contamination testing of DU shielding.

E. Analysis of wipes taken of sealed sources in accordance with 4731.0134. If the licensee or registrant performs the analysis of the wipe samples, the licensee or registrant must:

(1) establish procedures to be followed; and

(2) submit a description of these procedures to the commissioner. The description must include the:

(a) instruments to be used;

(b) methods of performing the analysis; and

(c) pertinent experience of the person who will analyze the wipe samples.

Subp 4. **Procedures at field stations and temporary jobsites.** At all field stations and temporary jobsites, demonstration of maintaining the following records and documents:

A. Operating documents:

(1) the radioactive material license authorizing the use of licensed material;

(2) a copy of 4731.0109 to 4731.0186 and 4731.0500 to 4731.0514;

(3) use logs for each radiographic exposure device as required by 4731.0511;

(4) records of equipment problems identified in daily checks of equipment as required by 4731.0507, subpart 1;

(5) records of alarm system and entrance control checks required by 4731.0507, subpart 2, for permanent radiographic installations;

(6) records of individual monitoring dosimeters as required by 4731.0502; and

(7) operating and emergency procedures required by 4731.0505.

B. Data Records

(1) the latest calibration of the radiation survey instruments in use at the jobsite, as required by 4731.0510;

(2) the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by 4731.0502;

(3) latest radiation safety survey records required by 4731.0510;

(4) the shipping papers for the transportation of radioactive materials required by 4731.1501, subpart 2; and

(5) when operating under reciprocity pursuant to 4731.0316, a copy of the Agreement State or NRC license authorizing the use of licensed materials.

4731. 0505 Emergency Procedures. Each licensee or registrant must develop and follow written emergency procedures. Copies of superceded procedures must be maintained for four years after the change is made.

Subpart 1 **Basic emergency procedures** The following emergency procedures must include written procedures and record making provisions for the following areas:

A. Actions to be taken to minimize personnel exposure

B. Actions to be taken when a self-reading dosimeter is found to be off-scale or an alarm ratemeter alarms unexpectedly.

C. Actions to be taken when an entrance alarm sounds.

D. Notifications to be made to the licensee's or registrant's radiation safety officer and the commissioner according to 4731.0162, subpart 1, item A in the event of:

(1) an accident or incident;

(2) an unintentional disconnection of the source assembly from the control cable;

(3) the inability to retract the source assembly to its fully shielded position and secure it in this position; or

(4) a failure of any component required for safe operation of the device.

E. Source recovery procedures.

F. Actions to be taken when leak or contamination tests reveal greater than 0.005

microcuries (185 Bq) of removable radioactive material.

G. Actions to be taken if a sealed source is lodged or damaged, when the source is not ruptured.

H. Actions to be taken if a sealed source is ruptured including:

(1) control of contamination;

(2) minimization of inhalation and ingestion of licensed or registered materials;

(3) decontamination of the work place and environment;

(4) decontamination of equipment before release from the site;

(5) decontamination of individuals before leaving the site.

Subp 2. **Records.** Retention of a record of each action and test required by subpart 1. These records must include:

A. The date of the action or test.

B. An annotated diagram of each area surveyed.

C. Background levels.

D. Measurements:

(1) of dose rates which are keyed to the legend of a diagram, expressed in millirem (microsieverts) per hour; or

(2) of removable contamination, expressed in dpm per 100 square centimeters, or counts per minute if performed with a radiation survey instrument.

E. The serial number and model number of the instrument used to conduct the survey or analyze the samples.

F. Identification of the individual who conducted the survey.

4731.0506 Supervision of Industrial Radiography Operations.

Subpart 1. **Radiographer's assistant.** Whenever a radiographer's assistant uses radiographic exposure devices, associated equipment or sealed sources or conducts radiation surveys required by 4731.0510 to determine that the sealed source has returned to the shielded position after an exposure, the assistant must be under the personal supervision of a radiographer. The personal supervision must include:

A. The radiographer's physical presence at the site where the sealed sources are being used.

B. The availability of the radiographer to give immediate assistance if required.

C. The radiographer's direct observation of the assistant's performance of the operations referred to in this part.

Subp. 2. **Two persons.**

A. All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the commissioner.

B. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other certified radiographer or an individual who has at a minimum met the requirements of 4731.0152, subpart 2, item C. The additional trained individual must observe the operations and be capable of providing immediate

assistance to prevent unauthorized entry.

4731.0507 Inspection and Maintenance. As required by 4731.0504, subpart 2, each licensee or registrant must have written procedures for the inspection and maintenance of sources, source assemblies and source holders.

Subpart 1. **Inspection requirements.** Procedures must include the following requirements:

A. Before each use of the source:

(1) conduct a visual inspection of the integrity of the source holders, radiographic exposure devices, transport and storage containers, associated equipment and source changers, to ensure that the sources are adequately shielding and that required labeling is present;

(2) conduct an operability inspection to check the functioning of the equipment; and

(3) remove equipment that is inoperable or damaged from service until repaired, and make and keep a record in accordance with 4731.0168; listing:

(a) date of visual inspection that made the discovery;
(b) name of inspector making the discovery;
(c) equipment involved, and what defects were found; and
(d) what repairs were made.

B. Quarterly during use of the source:

(1) conduct a visual inspection and routine maintenance to ensure that there is no physical damage and the required labeling is legible. This inspection includes source holders, radiographic exposure devices, transport and storage containers, associated equipment and source changers;

(2) equipment that is inoperable or damaged must be removed from service until repaired, and a record must be made listing:

(a) date of the visual inspection that made the discovery;
(b) name of inspector making the discovery;
(c) equipment involved, and what damage was found;
(d) what inspection and maintenance operations were performed; and
(e) any actions taken to correct the damage.

C. Replacement components must meet the design specifications.

Subp 2. **Maintenance requirements**

A. The inspection and maintenance must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval in 4731.1506.

B. The alarm system in 4731.0503, item A must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals.

C. Entrance control devices that reduce the radiation level upon entry as designated in 4731.0503, item B must be tested monthly.

D. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within 7-calendar days. The facility may continue to be used during this 7-day period, provided the licensee or registrant implements the continuous

surveillance requirements of 4731.0506, subpart 2 and uses an alarming ratemeter.

E. Each licensee must make and maintain records of alarm system and entrance control device tests and retain each record for 4 years after it is made.

4731.0508 Depleted Uranium (DU) Shielding Contamination. Each exposure device using DU shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months.

A. The licensee or registrant must conduct an analysis that is:

(1) capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample; and

(2) performed by a person specifically authorized by the commissioner, an agreement state, or the NRC to perform the analysis.

B. If such testing reveals the presence of 0.005 microcuries (185 Bq) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made.

C. If the evaluation reveals that the S-tube is worn through, the device may not be used again.

D. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however, the device must be tested for DU contamination if the interval of storage exceeded 12 months.

E. A record of the DU leak-test must be made in accordance with 4731.0134, subpart 1, item B.

4731.0509 Opening of a Source or Source Holder. The following requirements must be met prior to the opening of a source or source holder:

A. The opening, repair, or modification of any sealed or unsealed source must be performed by persons specifically approved to do so by the commissioner, an agreement state or the NRC.

B. Removal of a sealed source from a source holder, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee or registrant unless a written procedure developed has been approved either by the commissioner or by an agreement state.

C. If a sealed source is stuck in the source holder, emergency actions in 4731.0505, subpart 4 must be followed. The licensee or registrant may not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee or registrant is specifically approved by the commissioner, an agreement state or the NRC to perform this operation.

4731.0510 Radiation Safety Surveys. In addition to the radiation safety surveys found in 4731.0132, the licensee or registrant must conduct radiation surveys, including but not limited to the surveys required under subpart 1, for each area where licensed or registered materials are used and stored.

Subpart 1. **Requirements of the surveys.** The surveys must:

A. Be conducted when approaching the radiographic exposure device and the guide tube after each exposure to ensure that the sealed source has returned to its shielded position.

B. Be conducted any time the source is exchanged and whenever a device is placed in a storage area as defined in 4731.0100, to ensure that the source is in its shielded position.

C. Be conducted when the encapsulation of the sealed source could be damaged as a result of operation. The licensee or registrant must conduct a contamination survey during and after the operation.

D. Ensure that the maximum exposure rate for storage containers and source changers do not exceed 200 millirem (2 millisieverts) per hour at any exterior surface, and 10 millirem (0.1 millisieverts) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

E. Record information, including:

(1) the date of the survey;
(2) the name of the individual conducting the survey;
(3) the identification number or code of the survey;
(4) the instrument used; and
(5) the location of the survey.

Subp. 2. **Requirements of the radiation survey instruments.** Radiation survey instruments must be:

A. Operable and calibrated in accordance to 4731.0133, subpart 2.

B. Capable of measuring appropriate dose rates.

C. Kept at each location where radioactive material is present to conduct the radiation surveys required by chapter 4731.

4731.0511 Visual Inventory and Records of Radioactive Material Use. Each licensee or registrant must conduct a quarterly visual inventory to account for all licensed or registered material received and possessed under the license or registration. The visual inventory must include the following information:

A. Quantity and kind of licensed or registered material;

B. Make, model number, and a serial number or a description of each sealed source used;

C. Location and date of the licensed or registered material;

D. ~~D~~Location and date of use of licensed or registered material;

~~F~~E. Date and location of radioactive material at the time of the inventory;

~~G~~F. Identify of the individual who is responsible for the licensed or registered material;

~~H~~G. Name of the individual conducting the inventory and use record required in 4731.0504, subpart 3, item A.

4731.0512 Labeling and Posting. The licensee or registrant must ensure the labeling and posting requirements in this part are met and are in addition to the requirements found in 4731.0122. The licensee or registrant:

A. May not use or store a source, source holder, or radiographic exposure device that contains licensed or registered material unless every piece of equipment containing radioactive material bears a durable, legible, and clearly visible marking or label. This marking or label must contain:

(1) radiation symbol as specified in 4731.0122; and

(2) the words "DANGER (or CAUTION) RADIOACTIVE MATERIAL NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."

B. May not transport licensed or registered material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with requirements in 4731.1500 to 4731.0514.

C. May not perform industrial radiography unless the area is conspicuously posted as required by 4731.0122. Exceptions listed in 4731.0122, subpart 4 of this chapter do not apply to industrial radiographic operations.

4731.0513 Security During Storage, Transportation and Use. The licensee or registrant must:

A. Store each source containing licensed or registered material in a storage container or transportation package, meeting the following requirements:

(1) container or package must be locked and physically secured to prevent tampering or removal of licensed or registered material from storage by unauthorized personnel;

(2) must store licensed or registered material in a manner which will minimize danger from explosion or fire.

B. Transport the package containing licensed or registered material in a locked and physically secure condition in the transporting vehicle to prevent:

(1) accidental loss;

(2) tampering; or

(3) unauthorized removal of the licensed or registered material from the vehicle.

C. Ensure that sources not in storage or being transported are under the constant surveillance and control of the licensee or registrant.

D. Ensure that each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the source from its shielded position.

(1) the exposure device and/or its container must be kept locked, and if a keyed-lock, with the key removed at all times, when not under the direct visual surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in 4731.0503; and

(2) in addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

E. Ensure that each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position.

F. Storage containers and source changers must be kept locked, and if a keyed-lock, with the key removed at all times, when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

4731.0514 Offshore Waters Operations. A licensee or registrant may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the commissioner, another agreement state, or the NRC.

INDUSTRIAL FACILITIES USING X-RAY

4731.0600 General Requirements for Industrial X-ray Equipment

Subpart 1. **Applicability.** This part establishes standards for the use of x-ray equipment in industrial settings. These requirements are in addition to the requirements of 4731.0100 to 4730.0317. For industrial equipment using radioactive material, refer to 4731.0500 to 4731.0514.

Subp. 2. **Classes.** Industrial facilities using x-ray equipment must be classified as Class A, Class B, Class C, Class D, or Class F equipment. The class of the equipment must be specified by the registrant at the time of registration.

A. Class A is equipment intended for unlimited use of industrial radiation producing equipment used for industrial radiography at maximum capacity in a permanent, shielded enclosure.

B. Class B is portable equipment intended for time-limited use, temporary operation at the facility site or a temporary job site for use of industrial radiography.

C. Class C is an industrial cabinet x-ray system or analytical x-ray equipment housed in a cabinet.

D. Class D is analytical x-ray equipment not housed in a cabinet, not to include electron microscopes manufactured after December 31, 1973.

E. Class F is x-ray equipment used with a product conveyor system, including but not limited to curing, polymer linking, quality control, or measurements of thickness or weight.

Subp. 3. **Operating and emergency procedures.** A copy of a registrant's most current written operating and emergency procedures must be supplied to the registrant's employees. The procedures must include:

A. Operating procedures on how to:

(1) handle and use each source of radiation so no individual is exposed to radiation doses in excess of the limits established in 4731.0124;

(2) conduct radiation safety surveys, in accordance with 4731.0132;

(3) control access to Classes A, B, and D x-ray equipment;

(4) lock and secure Classes A, B, D x-ray equipment;

(5) lock and secure Class C equipment that allows an individual to enter the cabinet;

(6) conduct individual monitoring when required under 4731.0125, subpart 2 or 4731.0130; and

(7) conduct exposure rate surveys after each industrial radiographic exposure to determine that x-rays are not being generated.

B. Emergency procedures on how to:

(1) notify the registrant's radiation safety officer and the commissioner in accordance with 4731.0162, subpart 1, item A, when:

(a) personnel using Class A or Class B equipment has a direct reading pocket dosimeter that goes off-scale;

(b) overexposure or an occupational dose has been exceeded; or

(c) a non-occupational worker or member of the public has been exposed.

(2) minimize the exposure of individuals in the event of an incident.

4731.0601. Inspection and Maintenance of Equipment. The registrant must ensure that the following are completed and the records made and maintained as listed in 4731.0168 to 4731.0188.
Subpart 1. **Inspection and maintenance requirements.**

A. Checks for visual defects in Classes A and B equipment prior to each day or each shift of use.

B. Quarterly inspection of proper functioning of warning devices, control devices, and components important to safety, in compliance with subpart 5 and 4731.0173.

C. Tests of alarming ratemeters to be performed before each shift to ensure they signal properly.

D. Maintenance of equipment in accordance with manufacturer's specifications, recording the name of the individual who performed the service.

E. Removal of equipment from service and labeled as defective equipment when a defect is found in a component critical to radiation safety or the function of the equipment, until repairs are made.

F. In addition to the radiation safety surveys conducted in accordance with 4731.0132; surveys must be conducted and recorded:

(1) annually not to exceed one year; and

(2) after each industrial radiographic exposure to determine that the machine is "off."

Subp 2. **Calibration of radiation survey instruments.** Radiation survey instruments must be accessible and calibrated in accordance with 4731.0133, subpart 2.

Subp. 3. **Use logs.** Each registrant that is required to use individual monitoring devices for their employees must make and maintain use logs until the next inspection by the commissioner. The log must specify:

A. A serial number or other unique identification for each piece of x-ray equipment.

B. The identity of the operator assigned to the equipment.

C. The locations and dates where the equipment was used.

D. The technique factors specifying the voltage, current, exposure time for each radiographic exposure, and number of exposures.

Subp. 4. **Safety device.** The registrant must ensure that a safety device or interlock is:

A. Not bypassed unless:

(1) prior, written approval has been obtained from the radiation safety officer. The approval must be for a specified period of time and require that the bypass terminate as soon as repairs are completed;

(2) a readily discernible sign stating "SAFETY DEVICE NOT WORKING" is posted on the device and at the control panel;

(3) radiation safety surveys are performed after the safety device is removed and after the device is restored, according to 4731.0132; and

(4) a record of the bypass must be made according to 4731.0168 to 4731.0191.

B. Provided to prevent the entry of any portion of an individual's body into the primary x-ray beam path, or causes the beam to be shut off when an object enters its path.

Subp. 5. **Warning devices.**

A. Open-beam configurations must have a readily discernible indication of:

(1) x-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in an "on-off" manner; or

(2) shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in "open-closed" manner.

B. An easily visible warning light labeled with the words "X-RAY ON" or other visible warning indicator that clearly shows the equipment is producing ionizing radiation, must be located near a switch that energizes an x-ray tube and illuminated only when the tube is energized.

C. Warning devices must be labeled so that their purpose is easily identified.

D. On equipment installed on or after March 1, 1998, warning devices must have fail-safe characteristics.

Subp. 6. **Security.** For Class A, Class B and equipment from Class C that allows an individual to enter the cabinet, the registrant must ensure that security systems are designed and used so that no operable industrial x-ray equipment is left unattended unless:

A. The equipment is locked in an inoperable condition.

B. The room or building in which the equipment is located is locked.

Subp. 7. **Records.** The registrant must ensure that the records in this part are kept in accordance with 4731.0168 to 4731.0191.

Subp. 8. **Individual monitoring.** The registrant for Class A or Class B must ensure that the individual monitoring requirements specified in 4731.0130 are met. In addition, there must be:

A. Either an alarming ratemeter that will alarm at an exposure of up to 500 mR/hr (1.29 x 10-4 C/kg/hr) or an alarming ratemeter that also integrates the total exposure up to 5,000 milliroentgens (1.29 x 10-3 C/kg).

B. A hand-held portable radiation survey meter with an audible and visible readout of exposure rate or a fixed area radiation exposure rate monitor with a visible or audible alarming indicator may be substituted for the alarming ratemeter.

C. Each registrant must make and maintain the following exposure records:

(1) direct reading dosimeter readings and yearly operability checks required by 4731.0130;

(2) records of alarming ratemeter calibrations;

(3) reports received from the NVLAP-accredited individual dosimeter processor until the commissioner terminates the license;

(4) records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged NVLAP-accredited personnel dosimeters, until the commissioner terminates the license.

4731.0602. Class A Industrial X-ray Equipment.
Subpart 1. **Applicability.** This part applies to Class A industrial x-ray equipment used for industrial radiography. The requirements of this part are in addition to the requirements of 4731.0100 to 4731.0191 and 4731.0600 to 4731.0601.

Subp. 2. **Permanent, shielded enclosure.** An x-ray source and the objects exposed must be contained in a permanent shielded enclosure.

A. Except as provided in subpart 5, the enclosure must attenuate primary and secondary radiation so that the exposure rate at any accessible external point does not exceed two milliroentgens (5.16 x 10-7 C/kg) per hour when:

(1) the beam is adjusted to give maximum exposure rate with the generator at maximum; and

(2) the equipment is placed in the shortest equipment-to-wall radiographically usable position.

B. A person must be able to exit the enclosure at all times.

C. No person is permitted to remain within an enclosure while the x-ray generator is in operation.

Subp. 3. **Interlocks.** Interlocks must be provided that either prevent entering the enclosure while the x-ray generator is in operation or terminate the generation of x-rays if the enclosure is entered.

A. Interlocks must be provided so that all entrance doors close before industrial radiographic operations are initiated or continued.

B. If a useful radiation beam is interrupted by a door opening, it must not be possible to restore the system to operation without closing the door and reinitiating irradiation by manual action at the control panel.

Subp. 4. **Visible and audible signals.** A permanent, shielded enclosure must be equipped with internal and external visible and audible signals.

A. Visual signals must be activated on generation of x-rays and remain continuously activated while x-rays are generated.

B. Audible signals must be activated if an interlock is interrupted or opened during operation.

Subp. 5. **Ceiling barrier.** If a ceiling barrier does not attenuate the exposure rate as specified in subpart 2, a posted fence or other barrier must be used to restrict access to the area above the ceiling.

4731.0603. Class B Industrial X-ray Equipment.
Subpart 1. **Applicability.** This part applies to Class B portable radiation equipment used for the time-limited, temporary operation at the facility site or temporary jobsite of industrial radiography. The requirements of this part are in addition to the requirements of 4731.0100 to 4731.0191 and 4731.0600 to 4731.0601.
Subp. 2. **Restricted areas.** During the use of Class B equipment in either temporary operations at

the facility site or at temporary jobsites, all areas in which the exposure rate exceeds two milliroentgens (5.16 x 10-7 C/kg) per hour, must have a fence, rope, signs, or other suitable personnel barrier used outside the two milliroentgens (5.16 x 10-7 C/kg) per hour iso-line to restrict entry.

4731.0604. Class C Industrial X-ray Equipment.
Subpart 1. **Applicability.** This part applies to Class C industrial radiographic and analytical x-ray systems housed in a cabinet.

A. A registrant who performs and maintains a cabinet or cabinet system certified in accordance with 21 CFR 1020.40 must comply with all design and maintenance requirements of 21 CFR 1020.40, and as subsequently amended.. These requirements are in addition to the requirements of 4731.0100 to 4731.0191 and 4731.0600 to 4731.0601.

B. A registrant who performs industrial radiography or x-ray analysis in a noncertified cabinet,must comply with all requirements of this part and the requirements of 4731.0100 to 4731.0191 and 4731.0600 to 4731.0601.

Subp 2. **Individual monitoring requirements.** When a cabinet x-ray system allows an individual or any body part to enter the interior of the cabinet, the individual must wear an alarming ratemeter and NVLAP approved individual monitoring device.

4731.0605 **Class D Industrial X-ray Equipment.**
Subpart 1. **Applicability.** This part applies to Class D analytical radiation producing equipment not housed in a cabinet. The requirements of this part are in addition to the requirements of 4731.0100 to 4731.0191 and 4731.0600 to 4731.0601.

Subp 2. **Ports.** Unused ports on radiation source housings must be closed to prevent opening by an individual other than the operator.

Subp 3. **Shutters.** For equipment with an open-beam configuration, each port on the radiation source housing must be equipped with a shutter that cannot be operated unless either a collimator or a coupling has been connected to the port.

Subp 4. **Radiation shielding of components.** The registrant must ensure that:

A. An x-ray tube housing or port cover is constructed so that, when all shutters are closed, the radiation measured at a distance of five centimeters (1.97 inches) from the surface of the x-ray tube housing or port cover does not produce a dose in excess of 2.5 millirems (0.025 mSv) in one hour.

B. The 2.5 millirems (0.025 mSv) dose limit is not exceeded at any specified tube rating.

C. Each x-ray generator has a protective cabinet that limits radiation measured at a distance of five centimeters (1.97 inches) from the protective cabinet surface so that the x-ray generator does not produce a dose in excess of 0.5 millirem (0.005 mSv) in one hour.

4731.0606 [Reserved]

4731.0607 Class F Industrial X-ray Equipment.

Subpart 1. **Applicability.** This part applies to Class F x-ray equipment used with a product conveyor system. The requirements of this part are in addition to the requirements of 4731.0100 to 4731.0191 and 4731.0600 to 4731.0601.

Subp. 2. **Class F Equipment within a housing.** When Class F industrial x-ray equipment is surrounded by a housing, it must comply with the following:

A. The radiation source and the materials being exposed to radiation must be contained within the housing.

B. The housing must attenuate the primary and secondary radiation beam so that the exposure rate through any portion of the housing is less than 0.5 milliroentgen (1.29×10^{-7} C/kg) per hour and the exposure rate through openings in the housing is less than five milliroentgens (1.29×10^{-6} C/kg) per hour at any accessible external point when the equipment is being operated at its maximum potential.

C. Interlocks must be provided on access panels in the housing. The interlocks must terminate the generation of radiation or attenuate the radiation exposure rate to five milliroentgens (1.29×10^{-6} C/kg) per hour if an access panel is opened.

D. The housing must be equipped with visible signals that activate when radiation is generated and remain activated continually while radiation is present.

Subp 3. **Class F Equipment without a housing.** When it is not practical to surround Class F industrial x-ray equipment by a housing, the following requirements apply:

A. The equipment must be equipped with visible signals that activate when radiation is generated and remain activated continually while radiation is generated.

B. All areas in which the exposure rate exceeds two milliroentgens (5.16 x 10-7 C/kg) per hour, must have fencing, a rope, signs, or other suitable personnel barrier used outside the two milliroentgens (5.16 x 10-7 C/kg) per hour iso-line to restrict entry.

IRRADIATOR REQUIREMENTS

4731.0700 Requirements for Industrial Irradiators

Subpart 1. **Applicability.**

A. This part contains requirements for the use of radioactive material in the following types of irradiators using gamma radiation to irradiate objects or materials :

(1) panoramic irradiators that have either dry or wet storage of the radioactive sealed sources;

(2) underwater irradiators in which both the source and the product being irradiated are under water; and

(3) iradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type.

B. This part does not apply to the applications listed below which are found elsewhere in this rule. These applications are:

(1) self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel) in 4731.1000 to 4731.1010;

(2) medical radiology in 4731.1200 to 4731.1214;

(3) medical teletherapy in 4731.1200 to 4731.1214;

(4) radiography (the irradiation of materials for nondestructive testing purposes) in 4731.0500 to 4731.0514;

(5) gauging in 4731.1000 to 4731.1010; or

(6) open-field (agricultural) irradiations in 4731.1000 to 4731.1010.

Subp. 2. **License requirements for irradiator uses.** The commissioner may approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the general requirements specified in 4731.0309 and the following additional requirements:

A. The applicant must submit to the commissioner a developed program for training irradiator operators that specifies the:

(1) initial training;

(2) on-the-job or simulator training;

(3) annual safety reviews provided;

(4) methods used by the applicant to test each operator's knowledge, understanding of, and ability to comply with chapter 4731 and licensing requirements and the irradiator operating and emergency procedures; and

(5) minimum training and experience of personnel who may provide training.

B. Must submit written operating and emergency procedures listed in 4731.0708.

C. Must submit a description of the organizational structure for managing the irradiator, including:

(1) the radiation safety responsibilities and authorities of the radiation safety officer; and

(2) who, within the management structure, has the authority to stop unsafe operations.

D. Must describe the training and experience required for the position of radiation safety officer.

E. Must ensure compliance with:

(1) access control systems required by 4731.0706, subpart 3 and 4731.0707, subpart 2; and

(2) radiation monitors required by 4731.0705.

F. Provide the method of detecting leaking sources required by 4731.0708, subpart 4, item B, including the sensitivity of the method.

G. Provide a current diagram of the facility that shows the locations of all required interlocks and radiation monitors.

H. Describe the qualifications and training of the personnel and the procedures to be used, if the applicant's personnel are to be loading or unloading sources.

I. Provide a copy of the contract for source loading and unloading at the applicant's facility when it is being done by an organization specifically authorized by the commissioner, an agreement state or the NRC to load or unload irradiator sources.

J. Describe the inspection and maintenance tests, including the frequency, required by 4731.0709 to be performed by the applicant.

Subp. 3. **Applications for proposed alternatives.** Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for industrial irradiation of materials or objects may include proposed alternatives for the requirements of 4731.0700 to 4731.0711. The commissioner may approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

Subp. 4. **Records.**

A. The registrant must ensure that the records required by 4731.0700 to 4731.0711 are kept in accordance with 4731.0168 to 4731.0187. Records must be kept for four years or until the next inspection by the commissioner.

B. For all irradiators, records must be made and maintained of all tests, major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve irradiators and any required radiation safety equipment for 4 years after repairs are completed and for next inspection by the commissioner.

C. For all irradiators, records must be made and maintained on the design checks required by 4731.0702, subpart 2 and the construction control checks as required by 4731.0702, subpart 3 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

4731.0701 Performance Criteria for Sealed Irradiator Sources. Sealed sources must meet the following performance criteria before use:

A. Have a certificate of registration issued under 10CFR 32.210.

B. Be doubly encapsulated.

C. Use radioactive material that is as nondispersible as practical and that is as insoluble as

practical if the source is used in a wet-source-storage or wet-souce-change irradiator.

D. If the sources are for use in irradiator pools, they must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance.

E. In prototype testing of the sealed source, it must have been leak tested and found leak-free after each of the tests described in items (1) through (6) of this subpart:

(1) temperature test. The test source must be held at -40°C for 20 minutes, 600°C for one hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds;

(2) pressure test. The test source must be twice subjected for at least five minutes to an external pressure (absolute) of two million Newtons per square meter;

(3) impact test. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source;

(4) vibration test. The test source must be subjected three times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity; in addition, each test source must be vibrated for 30 minutes at each resonant frequency found;

(5) puncture test. A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of 1 meter onto the test source;

(6) bend test. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 Newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

4731.0702 Design and Construction Requirements for Irradiator Facilities.

Subpart 1. **Start of construction.** The applicant may not begin construction of a new irradiator prior to the submission to the commissioner of both an application for a license for the irradiator and the fee required 4731.0104. Activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of chapter 4731. The term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include:

A. Engineering and design work.
B. Purchase of a site.
C. Site surveys or soil testing.
D. Site preparation, site excavation, construction of warehouse or auxiliary structures.
E. Other pre-construction tasks.

Subp. 2. **Irradiator design requirements.** Irradiators whose construction or manufacture began after July 1, 1993, must meet the design requirements of this part.

A. For all irradiators, these design requirements apply. The licensee must provide the commissioner with assurance that:

(1) foundation design gives consideration to soil characteristics, to ensure it is adequate to support the weight of the shielded walls, and pool, if applicable;

(2) evaluation of the location and sensitivity of the monitor to detect sources carried by a product conveyor system as required by 4731.0705 is completed;

(3) verification of the design is completed so that the product conveyor stops before a source on the product conveyor would cause a radiation overexposure to any person;

(~~3~~4) verification of the design is completed so that the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room so that a fire is extinguished without the entry of personnel into the room and that the system is protected from mechanical and radiation damage. The system must have a shut-off valve to control flooding into unrestricted areas;

(~~4~~5) verification of the electrical wiring and electrical equipment in the radiation room are selected to minimize failures; and

(~~5~~6) design of the product conveyor system, so that the source rack and the mechanism that moves the rack is protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism, if applicable.

B. For panoramic irradiators, these additional design requirements apply. The licensee must provide the comissioner with assurance that:

(1) verification of the design so that the shielded walls meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entrance ways to meet the radiation shielded dose requirements of 4731.0703; if the irradiator will use more than five million curies (2×10^{17} becquerels) of activity, the licensee must evaluate the effects of heating of the shielded walls by the irradiator sources;

(2) the source rack drops due to loss of power will not damage the source rack;

(3) the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds;

(4) the source rack drops due to failure of cables or alternate means of support, will not cause loss of integrity of sealed sources;

(5) review of the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and than, if the rack sticks, a means exists to free it with minimal risk to personnel;

(6) verification of the design and logic diagram indicate the access control system meets the requirements of 4731.0706, subpart 3, and 4731.0707, subpart 2;

(7) verification that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage, is completed; and

(8) verification of the design for panoramic irradiators to be built in seismic areas, so that the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318 - 89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes.

C. For pool and underwater irradiators, these additional requirements apply. The licensee must provide the commissioner with assurance that:

(1) the design of the pool assures that:

(a) the pool is leak resistant;

(b) the pool is strong enough to bear the weight of the pool water and shipping casks;

(c) a dropped cask would not fall on sealed sources; and

(d) all outlets or pipes meet the requirements of 4731.0706, subpart 1, item D and that metal components are metallurgically compatible with other components in the pool.

(2) the design of the water purification system is adequate to meet the requirements of 4731.0706, subpart 1, item G; the system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored;

(3) the radiation monitoring systems used to detect contamination under 4731.0708, subpart 4, item B, are designed to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate;

(4) there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source.

Subp. 3. **Construction monitoring and acceptance testing.** The requirements of this section must be met for all irradiators constructed or manufactured after July 1, 1993. The requirements must be met prior to loading sources.

A. The licensee must provide the commissioner with assurance that:

(1) there is monitoring of the construction of the foundations to verify that their construction meets design specifications in 4731.0702, subpart 2, item A, subitem (1);

(2) the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 4731.0705, Subpart 1; and

(3) irradiators that use a product conveyor systems, are observed and tested for the operation of the conveyor system to assure that the requirements in 4731.0702, subpart 2, item B, subitems (2) to (5) are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

B. For panoramic irradiators, these additional requirements apply. The licensee must ensure that:

(1) there is monitoring of the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete;

(2) testing of the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly;

(3) testing the ability of the heat and smoke detectors is done to:

(a) detect a fire;

(b) activate alarms; and

(c) cause the source rack to automatically become fully shielded;

(4) testing of the operability of the fire extinguishing system;

(5) that the source racks can be returned to their fully shielded positions without offsite power;

(6) panoramic irradiators that use a computer system to control the access control system, must:

(a) have an access control system that operated properly if offsite power is lost; and

(b) have a computer that has security features to prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable;

(7) that the electrical wiring and electrical equipment were installed meet the design specifications; and

(8) testing the movement of the source racks for proper operation prior to source loading, test must include lowering of the source rack due to simulated loss of power.

C. For pool or underwater irradiators, these additional requirements apply. The licensee must ensure that:

(1) the pool meets design specifications and must test the integrity of the pool;

(2) the outlets and pipes meet the requirements of 4731.0706, subpart 1, item D;

(3) the water purification system, the conductivity meter, and the water level indicators operate properly;

(4) the proper operation of the radiation monitors and the related alarm if used to meet 4731.0708, subpart 4, item B; and

(5) the proper operation of the over-the-pool monitor, alarms, and interlocks required by 4731.0705, subpart 2 for underwater irradiators.

4731.0703 Shielded Dose Rates.

Subpart 1. **For panoramic irradiators**, the radiation dose rate in areas that are normally occupied during operation may not exceed 2 millirem (0.02 millisievert) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 2 millirem (0.02 millisievert) per hour must be locked, roped off, or posted.

Subp. 2. **For dry-source-storage panoramic irradiators**, the radiation dose rate at 1 meter from the shield when the source is shielded may not exceed 2 millirem (0.02 millisievert) per hour and at 5 centimeters from the shield may not exceed 20 millirem (0.2 millisievert) per hour.

Subp. 3. **For pool irradiators**, the radiation dose at 30 centimeters over the edge of the pool may not exceed 2 millirem (0.02 millisievert) per hour when the sources are in the fully shielded position.

4731.0704 Individual Monitoring.

A. The licensee or registrant, in accordance with 4731.0130, must require each irradiator operator to wear a NVLAP-accredited individual dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator.

B. Non-operating individuals who enter the radiation room of a panoramic irradiator must wear a dosimeter, which may be a direct reading dosimeter.

(1) for groups of visitors, at least one of every 10 people who enter the radiation

room are required to wear dosimeters;

(2) if direct reading dosimeters are used to meet the requirements of item B, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

4731.0705 Radiation Monitors.

Subpart 1. **Irradiators with automatic product conveyor systems** must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. These alarms must meet the following requirements:

A. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically.

B. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance.

C. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

Subp. 2. **Underwater irradiators that are not in a shielded radiation room** must have a radiation monitor over the pool to detect abnormal radiation levels.

A. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool.

B. The audible alarm may have a manual shut-off.

C. The alarm must be capable of alerting an individual who is prepared to respond promptly.

4731.0706 Requirements for Irradiator Pools. The following subparts are in addition to 4731.0700 through 4731.0705 and 4731.0708 through 4731.0711.

Subpart 1. **General requirements for** irradiator pools must:

A. Have a watertight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

B. Be constructed so that there is a low probability of substantial leakage and have a surface designed to facilitate decontamination.

C. Have a method to safely store the sources during repairs of the pool.

D. Have no outlets greater than 0.5 meters below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

E. Be provided with a means to replenish water losses from the pool.

F. Be provided with a water level indicator in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

G. Be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

H. Be provided with a physical barrier, such as a railing or cover, around or over irradiator

pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations; and

I. Not expose handling areas of tools or poles to radiation dose rates greater than 2 millirem (0.02 millisievert) per hour.

Subp. 2. **Pool water purity.**

A. Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances.

B. The licensee must measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter.

C. Conductivity meters must be calibrated at least annually.

Subp. 3. **Access control for underwater irradiators.** Each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by 4731.0122, subpart 2. Additional requirements include:

A. A personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended.

B. Keys to the personnel access barrier may only be accessed by operators and facility management.

C. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual, not necessarily onsite, who is prepared to respond or summon assistance.

4731.0707 Requirements for Panoramic Irradiators. The following subparts are in addition to 4731.0700 through 4731.0705 and 4731.0708 through 4731.0711.

Subpart 1. **Control of panoramic irradiator source movement.**

A. The mechanism that moves the sources must:

(1) require a key to actuate

(a) only one key may be in use at any time, and only operators or facility management may possess it;

(b) the key must be attached to a portable radiation survey meter by a chain or cable;

(c) the lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position;

(d) the door to the radiation room must require the same key as the source mechanism;

(2) cause an audible signal upon activation to indicate that the sources are leaving the shielded position.

B. The console must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

C. The control console must have a control that promptly returns the sources to the shielded position.

D. Each control must be clearly marked as to its function.

Subp. 2. **Access control for panoramic irradiators.**

A. Entrance requirements

(1) each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent entry of personnel if the sources are in use. These controls include, but are not limited to, the following:

(a) product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier; it must not be possible to move the sources out of their shielded position if the door or barrier is open;

(b) opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position;

(c) the personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources;

(d) the doors and barriers must not prevent any individual in the radiation room from leaving.

(2) in addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. These would include:

(a) detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard;

(b) the alarm must also alert at least one other individual who is onsite of the entry;

(c) that individual must be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

(3) a radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. This includes the following:

(a) the monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high;

(b) attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in subitem (2);

(c) the monitor may be located in the entrance, normally referred to as the maze, but not in the direct radiation beam.

(4) before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

(5) each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

(6) each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the

control.

(7) each entrance to the radiation room of a panoramic irradiator must be posted as required by 4731.0122, subitem 2. Radiation postings for panoramic irradiators must comply with the posting requirements except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

B. After entering the irradiator:

(1) if the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location; this requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating;

(2) upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator must use a survey meter to determine that the source has returned to its fully shielded position; the operator must check the functioning of the survey meter with a radiation check source prior to entry;

(3) before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator must:

(a) visually inspect the entire radiation room to verify that no one else is in it; and

(b) activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

4731.0708 Operating and Emergency Requirements For Irradiators.

Subpart 1. **Operating procedure requirements.** The licensee must have and follow written operating procedures. Copies of superseded procedures must be retained for four years after the change is made. These procedures must include the following procedures:

A. Operation of the irradiator, including entering and leaving the radiation room.

B. Use of individual dosimeters.

C. Surveying the shielding of panoramic irradiators.

D. Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas.

E. Leak testing of sealed sources done in accordance with 4731.0134, or if an applicant wants to perform leak testing of sealed sources, the applicant must:

(1) establish procedures to be followed;

(2) identify the manufacturers of the leak test kits; and

(3) the model numbers of the leak test kits to be used.

F. Analysis of wipes taken of sealed sources done in accordance with 4731.0134, or if the applicant wants to analyze its own wipe samples, the applicant must:

(1) establish procedures to be followed; and

(2) submit a description of these procedures to the commissioner. The description must include the:

(a) instruments to be used;

(b) methods of performing the analysis; and

(c) pertinent experience of the person who will analyze the wipe samples.

G. Inspection and maintenance tests required by 4731.0709.

H. Loading, unloading, and repositioning sources, if the operations will be performed by the licensee.

I. Inspection of movable shielding required by 4731.0707, subpart 2, item B, if applicable.

J. Calibration of all survey instruments and conductivity monitors must be performed at required frequency found in 4731.0133.

Subp. 2. **Attendance during operation** of any irradiator, both an irradiator operator and at least one other individual, who is trained on response procedures and prepared to promptly render or summon assistance if the access control alarm sounds, must be present onsite:

A. Whenever the irradiator is operated using an automatic product conveyor system.

B. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

C. At a panoramic irradiator at which static irradiations, no movement of the product, are occurring, a person who has received the training on how to respond to alarms described in 4731.0151, subpart 3 must be onsite.

D. At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool.

(1) individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in 4731.0151, subpart 3;

(2) static irradiations may be performed without a person present at the facility.

Subp. 3. **Emergency procedure requirements.** The licensee must have and follow emergency or abnormal event procedures, appropriate for the irradiator type. These procedures must cover the following conditions:

A. Notification of the licensee's radiation safety officer and the commissioner according to 4731.0162 when:

(1) sources are stuck in the unshielded position;

(2) personnel are overexposed;

(3) the product exit portal monitor or pool monitor alarms;

(4) leaking sources, pool contamination, or alarm caused by contamination of pool water is detected;

(5) a low or high water level, an abnormal water loss, or leakage form the source storage pool is detected;

(6) electrical power is lost;

(7) a fire alarm or explosion occurs in the radiation room, so that a person who is prepared to summon assistance can be alerted promptly;

(8) unauthorized entry into the radiation room, area around pool, or another alarmed area is detected;

(9) automatic conveyor systems are jammed;

(10) damage to the source racks;

(11) failure of the cable or drive mechanism used to move the source racks;

(12) inoperability of the access control system;

(13) detection of radioactive contamination attributable to licensed radioactive material; and

(14) structural damage to the pool liner or walls.

B. Power failures for panoramic, pool or underwater irradiators.

C. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility.

D. If pool water conductivity rises above 20 microsiemens per centimeter, the actions by licensee to lower the pool water conductivity and the corrective actions to prevent future recurrences.

E. Actions to be taken if pool water conductivity exceeds 100 microsiemens per centimeter.

Subp. 4 **Emergency situations.** The licensee must follow their written procedures for emergencies and abnormal events as required in 4731.0708, subpart 3. The reports for those activities must be kept for 4 years or until the next inspection by the commissioner.

A. Power failures for irradiators:

(1) if electrical power is lost for longer than 10 seconds, the sources must automatically return to the shielded position;

(2) the lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure;

(3) during a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by 4731.0705, subpart 2 is operating with backup power;

(4) during a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

B. Detection of leaking sources:

(1) if the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm;

(2) the alarm set-point must be set as low as practical, but high enough to avoid false alarms; the licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures;

(3) water from the pool must be checked for contamination each day the irradiator operates; the check may be done either by using:

(a) a radiation monitor on a pool-water circulating system; or

(b) analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours.

C. If a leaking source is detected:

(1) the licensee must arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by a licensee of the commissioner, an agreement state or NRC that is authorized to perform these functions;

(2) the licensee must promptly check its personnel, equipment, facilities, and

irradiated product for radioactive contamination;

(3) no product may be shipped until the product has been checked and found free of contamination; if a product has been shipped that may have been contaminated, the licensee must arrange to locate and survey that product for contamination;

(4) if any personnel are found to be contaminated, decontamination must be performed promptly;

(5) if contaminated equipment, facilities, or products are found, the licensee must arrange to have them decontaminated or disposed of by a licensee of the commissioner, an agreement state or NRC that is authorized to perform these functions;

(6) if a pool is contaminated, the licensee must arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, appendix B to 4731.3001.

Subp. 5. **Revision of operating and emergency procedures.** The licensee may revise operating and emergency procedures without prior commissioner approval only if the licensee can assure the commissioner that:

A. The revisions do not reduce the safety of the facility.

B. The revisions are consistent with or better than the procedures submitted with the license application.

C. The revisions have been reviewed and approved by the radiation safety officer.

D. The users or operators have been instructed and tested on the revised procedures before they are put into use.

4731.0709 Inspection and Maintenance.

A. The licensee must perform the inspection and maintenance tests as required by 4731.0700 to 4731.0711. These tests include:

(1) overall operability tests:

(a) operability of each aspect of the access control system;

(b) functioning of the source position indicator;

(c) operability of the radiation monitor for radioactive contamination in pool water, using a radiation check source, if applicable;

(d) operability of the over-pool radiation monitor at underwater irradiators;

(e) operability of the product exit monitor;

(f) operability of the emergency source return control;

(g) leak-tightness of systems through which pool water circulates visual inspection;

(h) operability of the heat and smoke detectors and extinguisher system ,but without turning extinguishers on;

(2) specific tests:

(a) operability of the means of pool water replenishment;

(b) operability of the indicators of high and low pool water levels;

(c) operability of the intrusion alarm, if applicable;

(d) functioning and wear of the system, mechanisms, and cables used to raise

and lower sources;

(e) condition of the barrier to prevent products from hitting the sources or source mechanism;

(f) volume of additional water needed to determine if the pool is leaking;

(g) integrity electrical wiring on required safety systems for damage;

(h) pool water conductivity measurements and analysis; and

(i) product conveyor system must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers;

B. Malfunctions and defects found during inspection and maintenance tests must be repaired without undue delay.

4731.0710 Radiation Safety Surveys. In addition to the radiation safety survey requirements in 4731.0132, these surveys must be conducted and records made by licensees for the appropriate type of irradiators.

Subpart 1. **Requirements of the surveys.**

A. For panoramic irradiators the following radiation surveys must be conducted:

(1) before the facility starts to operate, in areas outside the shielding of the radiation room, with the sources in the exposed position;

(2) at intervals not to exceed three years, by the shielding of the irradiator;

(3) before resuming operation after addition of new sources, and

(4) after any modification to the radiation room shielding or structure that might increase dose rates.

B. For pool irradiators the following radiation surveys must be conducted:

(1) before the facility starts to operate, in areas above the pool, after the sources are loaded;

(2) at intervals not to exceed three years, by the shielding of the irradiator;

(3) before resuming operation after addition of new sources;

(4) after any modification to the radiation room shielding or structure that might increase dose rates;

(5) before release to unrestricted areas, water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination; radioactive concentrations must not exceed those specified in table 2, column 2 or table 3 in appendix B to 4731.3001;

(6) before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.05 millirem (0.5 microsievert) per hour. The resins may be released only if the monitoring does not detect radiation levels above background radiation levels. The meter used must be capable of detecting radiation levels of 0.05 millirem (0.5 microsievert) per hour.

Subp. 2. **Requirements of the radiation survey instruments.** Radiation survey instruments must be:

A. Operable and calibrated in accordance to 4731.0133, subpart 3.

B. Capable of measuring appropriate dose rates.

C. Kept at each location where radioactive material is present to conduct the radiation surveys required by chapter 4731.

Subp. 3. **Modification.** If the radiation levels specified in 4731.0703 are exceeded, the facility must be modified to comply with the requirements in 4731.0703.

4731.0711 Irradiation of Explosive or Flammable Materials.

A. Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the commissioner. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

B. Irradiation of more than small quantities of flammable material, flash point below 140°F, is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the commissioner. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

WELL LOGGING REQUIREMENTS

4731.0800 Well Logging Requirements.

Subpart 1. **Applicability.** This part contains requirements for the use of radioactive material including sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well or boring. This part does not apply to the applications listed below which are found elsewhere in this rule. These applications are:

A. The use of sealed sources auxiliary to well logging but not lowered into the wells or borings in 4731.1000 to 4731.1010.

B. The use of licensed material in tracer studies involving multiple wells, such as field flooding studies in 4731.1000 to 4731.1010.

Subp. 2. **License requirements for well logging use.** The commissioner may approve an application for a specific license for the use of licensed material in well logging if the applicant meets the following requirements. The applicant must:

A. Satisfy the general licensing requirements specified in 4731.0309, as appropriate, and any special requirements contained in this part.

B. Develop a program for training logging supervisors and logging assistants and submit to the commissioner a description of this program that specifies the content of the following:

(1) initial training;

(2) on-the-job training;

(3) annual safety reviews provided by the licensee;

(4) demonstration of the logging supervisor's knowledge, understanding of and the ability to comply with chapter 4731, licensing requirements, and the applicant's written operating and emergency procedures;

(5) demonstration of the logging assistant's knowledge, understanding of and the ability to comply with the applicant's written operating and emergency procedures.

C. Create written operating and emergency procedures as described in 4731.0803.

D. Establish a program for annual review inspections of the job performance of each logging supervisor to ensure that chapter 4731 requirements, license requirements, and the applicant's written operating and emergency procedures are followed.

E. Describe the applicant's overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

Subp. 3. **Records.** The registrant must ensure that the records required by this part are kept in accordance with 4731.0168 to 4731.0186. Records must be kept for four years or until the next inspection by the commissioner.

4731.0801 Design and Performance Criteria for Sealed Sources Other Than Sealed Sources that Contain Licensed Material in Gaseous Form. A licensee may only use sealed sources in well logging that meet the following requirements:

A. Is doubly encapsulated.

B. Contains licensed material whose chemical and physical forms are as insoluble and nondispersible as practical.

C. ~~T~~ Meets the requirements of (1), (2) or (3), as applicable:

(1) For a sealed source manufactured on or before July 14,1989, a licensee may use the sealed source, for use in well logging applications if it meets the requirements of USASI N5.10-1968, "Classification of Sealed Radioactive Sources," or the requirements in (2) or (3).

(2) For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications if it meets the oil-well logging requirements of ANSI/HPS N43.6-1997, "Sealed Radioactive Sources-Classification."

(3) For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications, if the sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

(~~1~~a) temperature test, where the test source must be held at -40° C for 20 minutes, 600° C for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600° C to 20° C within 15 seconds;

(~~2~~b) impact test, where a 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source;

(~~3~~c) vibration test, where the test source must be subjected to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes;

(~~4~~d) puncture test, where a 1 gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source; and

(~~5~~e) pressure test, where the test source must be subjected to an external pressure of 24,600 pounds per square inch absolute (1.695×10^7 pascals).

D. The requirements in items A, B and C do not apply to energy compensation sources (ECS). ECSs must be registered with the commissioner under 4731.0103 of this chapter or with the

NRC or another Agreement State.

4731.0802 Individual Monitoring.

A. The licensee or registrant, in accordance with 4731.0130, must require any individual acting as a logging supervisor or logging assistant to wear, at all times during the handling of licensed radioactive materials, a NVLAP-accredited individual dosimeter.

B. The licensee must provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.

4731.0803 Operating and Emergency procedures. Each licensee must develop and follow written operating and emergency procedures.

Subpart 1. **Operating procedures.** The operating procedures must include the following:

A. Overall procedures:

(1) the handling and use of licensed materials including the use of sealed sources in wells or borings without surface casing for protecting fresh water aquifers, if appropriate;

(2) the use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

(3) methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by 4731.0807;

(4) methods for controlling access to sources;

(5) methods and occasions for locking and securing stored licensed materials;

(6) individual monitoring and the use of individual monitoring equipment;

(7) transportation of licensed materials to field stations or temporary jobsites, packaging of licensed materials for transport in vehicles, placarding of vehicles when needed, and physically securing licensed materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal;

(8) picking up, receiving, and opening packages containing licensed materials, in accordance with 4731.0123, subpart 5;

(9) for the use of tracers, decontamination of the environment, equipment, and personnel.

B. Maintenance procedures

(1) the inspection and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars as required by 4731.0805;

(2) maintenance of records generated by logging personnel at temporary jobsites;

(3) visual inventory and recording of radioactive material use;

(4) leak testing of sealed sources done in accordance with 4731.0134, or if an applicant wants to perform leak testing of sealed sources, the applicant must:

(a) establish procedures to be followed;

(b) identify the manufacturers of the leak test kits; and

(c) identify the model numbers of the leak test kits to be used.

(5) identify and report to the NRC defects and noncompliance as required by 10 CFR

21.21.

C. Analysis of data:

(1) analysis of wipes taken of sealed sources done in accordance with 4731.0134;

(2) if the applicant wants to analyze its own wipe samples, the applicant must:

(a) establish procedures to be followed; and

(b) submit a description of these procedures to the commissioner.

(3) the description must include the:

(a) instruments to be used;

(b) methods of performing the analysis; and

(c) pertinent experience of the person who will analyze the wipe samples.

Subp. 2. **Emergency procedures.** Emergency procedures must include written instructions on events in the following areas:

A. Notifications, in the event of an accident/incident or abandonment of a source, to be made to the licensee's radiation safety officer and the commissioner according to 4731.0162.

B. Actions to be taken if a sealed source is lodged or damaged in a well, boring, or drilled hole, so that the source is not ruptured.

C. Actions to be taken if a sealed source is ruptured, including:

(1) prevention of the spread of contamination;

(2) minimization of inhalation and ingestion of licensed or registered materials;

(3) obtaining and using suitable radiation survey instruments as required by 4731.0807, subpart 2;

(4) monitoring of the mud or water circulated during removal operations for possible radioactive contamination;

(5) decontamination of the environment, if the environment is contaminated;

(6) decontamination of equipment before release from the site for unrestricted use, if the equipment was contaminated; and

(7) decontamination of personnel before leaving the site, in the event of their contamination.

D. Actions to be taken to minimize personnel exposure including exposures from inhalation and ingestion of licensed tracer materials.

E. Actions to be taken, after approval of commissioner, if abandonment of source becomes necessary. Sealing or abandonment of a well or boring must be performed by a contractor licensed by the Minnesota Department of Health according to chapters 4725 ,"Wells and Borings" and 4727 "Explorers and Exploratory Borings", and Minnesota Statutes, chapter 103I "Wells, Borings and Underground Uses".

4731.0804 Radioactive Contamination Control. If the licensee detects evidence that a sealed source has ruptured or licensed materials have caused contamination, the licensee must initiate immediately the emergency procedures required by 4731.0803.

A. If contamination results from the use of licensed material in well logging, the licensee must decontaminate all work areas, equipment, and unrestricted areas.

B. During efforts to recover a sealed source lodged in the well or boring, the licensee

must continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well or boring, if any, to check for contamination resulting from damage to the sealed source.

4731.0805 Inspection and Maintenance. Each licensee must have written procedures for the inspection and maintenance of the source and source holders. This program must include the following requirements:

A. Before each use:

(1) a visual inspection looking for defects of the source holders, logging tools, and source handling tools, to ensure that the equipment is in good working condition and that required labeling is present;

(2) if defects are found, the equipment must be removed from service until repaired, and a record must be made and kept for 4 years or the next inspection by the commissioner, listing:

(a) date of visual inspection that made the discovery;
(b) name of inspector making the discovery;
(c) equipment involved, and what defects were found; and
(d) what repairs were made.

B. Semi-annually:

(1) visual inspection and routine maintenance to ensure that there is no physical damage and the required labeling is legible, this inspection is of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars;

(2) if defects are found, the equipment must be removed from service until repaired, and a record must be made and kept for 4 years or the next inspection by the commissioner, listing:

(a) date of the visual inspection that made the discovery;
(b) name of inspector making the discovery;
(c) equipment involved, and what defects were found;
(d) what inspection and maintenance operations were performed; and
(e) any actions taken to correct the defects.

4731.0806 Opening of a Source or Source Holder.

A. The opening, repair, or modification of any sealed source must be performed by persons specifically approved to do so by the commissioner, an agreement state, or the NRC.

B. Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure developed pursuant to 4731.0803 has been approved either by the commissioner pursuant to chapter 4731 or by an agreement state, or the NRC.

C. If a sealed source is stuck in the source holder, the licensee may not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the commissioner, an agreement state, or the NRC to perform

this operation.

4731.0807 Radiation Safety Surveys. In addition to the radiation safety surveys found in 4731.0132, the licensee must make a radiation survey, including but not limited to the surveys required under subpart 1, of each area where licensed materials are used and stored.

Subpart 1. **Requirements of the surveys.**

A. Before transporting licensed materials, the licensee must make a radiation survey of the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the licensed materials.

B. If the sealed source assembly is removed from the logging tool before departure from the temporary jobsite, the licensee must confirm that the logging tool is free of contamination by energizing the logging tool detector or by using a survey meter.

C. If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee must conduct a radiation survey, including a contamination survey, during and after the operation.

D. The licensee must make a radiation survey at the temporary jobsite before and after each subsurface tracer study to confirm the absence of contamination.

Subp. 2. **Requirements of the radiation survey instruments.** The licensee must keep a radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary jobsite to make the radiation surveys required by chapter 4731. The radiation survey instrument must be capable of measuring appropriate dose rates.

A. The licensee must have available additional calibrated and operable radiation detection instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee may own the instruments or may have a procedure to obtain them quickly from a second party, in the event of an emergency.

B. The instruments must be operable and calibrated in accordance to 4731.0133.

Subp. 3. **Records.** The results of surveys required under subpart 1 must be recorded and kept in accordance with 4731.0186 and must include:

A. The date of the survey;
B. The name of the individual making the survey;
C. The identification of the survey;
D. The instrument used; and
E. The location of the survey.

4731.0808 Visual Inventory and Records of Material Use. Each licensee must conduct a semi-annual visual inventory to account for all licensed material received and possessed under the license. The licensee must make and maintain the required records in accordance with 4731.0168 to 4731.0186. This inventory and use record must include the following information:

A. Quantity and kind of licensed material.
B. Make, model number, and a serial number or a description of each sealed source used.
C. Location of the licensed material.

D. Date and location of use of licensed material.

E. Disposition of any unused sealed and unsealed licensed material.

F. Date and location of the radioactive material at the time of the inventory.

G. Identifty of the ~~authorized user~~logging supervisor who is responsible for the licensed material.

H. Name of the individual conducting the inventory and use record.

4731.0809 Labels, Security During Storage, Transportation and Use. The licensee must ensure the requirements in this part are met and are in addition to the requirements found in 4731.0123.

A. The licensee or registrant may not use or store a source, source holder, or logging tool that contains licensed material unless every piece of equipment containing radioactive material bears a durable, legible, and clearly visible marking or label. This marking or label must contain:

(1) radiation symbol as specified in 4731.0122; and

(2) the words " DANGER (or CAUTION) RADIOACTIVE MATERIAL NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."

B. The licensee or registrant may not transport licensed material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with requirements in 4731.1500 to 4731.1514.

C. The licensee or registrant must store each source containing licensed material in a storage container or transportation package, meeting the following requirements:

(1) container or package must be locked and physically secured to prevent tampering or removal of licensed material from storage by unauthorized personnel; and

(2) must store licensed material in a manner which will minimize danger from explosion or fire.

D. The licensee or registrant must transport the package containing licensed material in a locked and physically secure condition in the transporting vehicle to prevent:

(1) accidental loss;

(2) tampering; or

(3) unauthorized removal of the licensed material from the vehicle.

E. The license or registrant must ensure the logging supervisor is physically present at a temporary jobsite whenever licensed materials are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in a well or boring.

F. The licensee or registrant must ensure that during well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor maintains direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in 4731.0100.

4731.0810 Abandonment of Irretrievable Sources.

Subpart 1. **Agreement with well or boring owner or operator.** A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the well owner or operator that is employing the licensee. This agreement is in addition to other requirements in

chapter 4731. The licensee must keep this written agreement with the records for four years following the completion of the work or until the next inspection by the commissioner. The agreement must include the following information and the identification of personnel who will perform the following requirements:

A. If a sealed source becomes lodged in the well or boring, a reasonable effort will be made to recover it.

B. A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture.

C. The radiation monitoring required in 4731.0804 will be performed.

D. If the environment, any equipment, or personnel are contaminated with licensed material, they must be decontaminated before release from the site or release for unrestricted.

E. If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

(1) each irretrievable well logging source must be immobilized and sealed in place;

(2) a mechanical device to prevent inadvertent intrusion on the source must be set at some point in the well or boring above the cement plug, unless the cement plug and source are not accessible to any subsequent drilling operations; and,

(3) a permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well or boring, unless the mounting of the plaque is not practical. The size of the plaque must be at least 7 inches (17 cm) square and 1/8-inch (3 mm) thick. The plaque must contain the following information:

(a) word "CAUTION";

(b) radiation symbol in accordance with 4731.0122 without the color requirement;

(c) date the source was abandoned;

(d) name of the well or boring owner or well or boring operator, as appropriate;

(e) well or boring name and well or boring identification number(s) or other designation;

(f) identification of the sealed source(s) by radionuclide and quantity;

(g) depth of the source and depth to the top of the plug; and

(h) an appropriate warning, such as, "DO NOT RE-ENTER THIS WELL OR BORING."

(4) a report must be sent to the commissioner within 30 days, containing the information in item (3).

F. This written agreement between the licensee and the well or boring owner or operator is not required if the licensee and the well or boring owner or operator are part of the same corporate structure or otherwise similarly affiliated.

Subp. 2. **Abandonment (sealing) procedures for irretrievable sources.** If a sealed source becomes lodged in a well or boring, and when it becomes apparent that efforts to recover the sealed source will not be successful, the licensee must:

A. Notify the commissioner by telephone of the circumstances that resulted in the inability to retrieve the source and obtain approval to implement abandonment procedures of this part.

B. Obtain a variance from the sealing requirements of Minnesota Rules, Chapter 4725 or 4727, and comply with the conditions of the variance.

C. Advise the well or boring owner or operator, as appropriate, of the abandonment procedures under subpart 1.

D. Ensure that abandonment procedures are implemented within 30 days after the sealed source has been classified as irretrievable or request of the commissioner an extension of time if unable to complete the abandonment procedures.

E. Ensure that sealing or abandonment of a well or boring is performed by a contractor licensed by the Minnesota Department of Health in accordance with Chapters 4725, "Wells and Borings"or 4727, "Explorers and Exploratory Borings" and Minnesota Statutes, Chapter 103I, "Wells, Borings and Underground Uses".

Subp.3. **Commissioner approval.** A licensee may apply, contingent upon approval by the commissioner, on a case-by-case basis, of proposed procedures to abandon an irretrievable well logging source in a manner not otherwise authorized in subpart 2 of this part.

4731.0811 Use of a Sealed Source in a Well or Boring Without a Surface Casing. The licensee may use a sealed source in a well or boring without a surface casing for protecting fresh water aquifers only if the licensee follows a written procedure for reducing the probability of the source becoming lodged in the well or boring. The procedure must be approved by the commissioner prior to use, in accordance to 4731.0800, subpart 2, item C, by an agreement state or the NRC.

4731.0812 Special Uses in Well Logging.

Subpart 1. **Radioactive markers.** The licensee may use radioactive markers in wells or borings only if the individual markers contain quantities of licensed material not exceeding the quantities specified in 4731.3003, schedule 2 of this chapter and only if a variance is obtained from Minnesota Rules, Chapters 4725 or 4727. The use of markers is subject only to the requirements of 4731.0808.

Subp. 2. **Uranium sinker bars.** The licensee may use a uranium sinker bar in well logging only if it is legibly impressed with the words "CAUTION -- RADIOACTIVE-DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

Subp. 3. **Energy compensation source (ECS).** The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 100 microcuries (3.7 MBq).

A. For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 4731.0134, 4731.0808.

B. For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 4731.0134, 4731.0808, 4731.0810 and 4731.0811.

Subp. 4. **Tritium neutron generator target source.**

A. Use of a tritium neutron generator target source, containing quantities not exceeding 30 curies (1,110 MBq) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of 4731.0800 to 4731.0813, except 4731.0801 and 4731.0810.

B. Use of a tritium neutron generator target source, containing quantities exceeding 30 curies (1,110 MBq) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of 4731.0800 to 4731.0813 except 4731.0801.

4731.0813 Subsurface Tracer Studies.

A. The licensee must require all personnel handling radioactive tracer material to use protective gloves and, if required by the license, other protective clothing and equipment to protect against contamination. The licensee must take precautions to avoid ingestion or inhalation of radioactive tracer material and to avoid contamination of field stations and temporary jobsites.

B. A licensee may not knowingly inject licensed material into a well or boring unless a variance to Minnesota rules, chapter 4725 or 4727, has been approved by the commissioner.

ACCELERATOR/CYCLOTRON REQUIREMENTS

4731.0900 General Requirements for Accelerators and Cyclotrons (Positron Emission Tomography–PET)

Subpart. 1. **Applicability.** This part applies to all accelerators, including but not limited to linear accelerators, cyclotrons, including positron emission tomography (PET), van de Graff generators, electron-beam generators, and ion implanters. The requirements of this part are in addition to requirements for specific uses found in 4731.0100 to 4731.0173. If an accelerator is used for industrial radiography, the registrant must comply with parts 4731.0900 to 4731.0907 and 4731.0600 to 4731.0607.

Subp. 2. **Records.** The registrant must ensure that the records required by this part are kept in accordance with 4731.0168 to 4731.0173. Records must be kept for four years or until the next inspection by the commissioner.

4731.0901 Safety and Security

Subpart 1. **Safety and warning lights or devices.** The registrant must ensure that a safety device or interlock is:

A. Provided to prevent the entry of any portion of an individual's body into the accelerator beam path, or causes the beam to be shut off when an object enters its path.

B. Not bypassed unless:

(1) prior, written approval has been obtained from the facility radiation safety officer. The approval must be for a specified period of time and require that the bypass terminate as soon as repairs are completed;

(2) a readily discernible sign stating "SAFETY DEVICE NOT WORKING" is posted on the device and at the control panel;

(3) radiation safety surveys must be performed after the safety device is bypassed or removed and when the device is restored, repaired and replaced according to 4731.0132; and

(4) a record of the bypass must be made and maintained according to 4731.0168 to 4731.0173.

C. Warning lights or devices. The registrant must ensure that:

(1) the entry door to an accelerator room is equipped with readily observable warning lights that indicate when the useful beam is in the "on" position;

(2) in addition, each high radiation area must have an audible warning device that must be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device must be clearly heard in all high radiation areas. This warning device is not required for accelerators used on humans.

Subp. 2. **Security.** The registrant must ensure that security systems and procedures are designed and used so that:

A. No operable accelerator is left unattended unless the:

(1) accelerator is locked in an inoperable condition; or

(2) room or building in which the accelerator is located is locked.

B. High or very high radiation areas using accelerators have:

(1) control devices or alarm system installed in accordance with 4731.0131, subpart 2 and 3; or

(2) unauthorized or accidental entry prevented by use of a lock.

Subp. 3. **Accelerator controls and interlock systems.** The registrant must ensure that the accelerator has:

A. Clearly identified and easily discernible instrumentation, readouts, and controls on the control console, including an indicator of beam on/off status.

B. A safety interlock:

(1) on a circuit that allows an interlock to operate independently of all other safety interlocks;

(2) designed to prevent operation of the accelerator in the event of a defect or component failure in the system;

(3) that, once triggered, makes it possible to resume operation of the accelerator only by first manually resetting the controls at the position where the safety interlock was tripped and then resetting the controls at the main control console.

C. A safety interlock installed at each entrance, including a target room, chamber, or other area, that shuts down the accelerator when the entrance barrier is penetrated.

D. Easily identifiable emergency "off" switches with a manual reset that does not allow the accelerator to be restarted from the control console without resetting the emergency "off" switch.

Subp. 4. **Additional requirements for radiation monitoring of cyclotrons, including positron emission tomography (PET) facilities.** The registrant must ensure that:

A. Radiation levels, including stack releases, in an accelerator facility are continuously monitored.

B. Monitoring devices are electrically independent of the accelerator control and safety interlock system.

C. Means are provided to view the radiation monitoring readout at the control panel.

Subp. 5. **Shielding and safety design requirements.** The registrant must ensure that:

A. Shielding requirements of 4731.0141 are met.

B. Radiation safety survey is made when the accelerator is first capable of producing radiation.

Subp. 6. **Ventilation systems**

A. Ventilation systems must be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in 4731.3001, Appendix B, Table 1 of these regulations.

B. A registrant must not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in 4731.3001, Appendix B, Table II of these regulations, except as authorized pursuant to 4731.0126. Concentrations may be averaged over a period not greater than one year.

C. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.

D. If there is venting of radioactive materials from a stack, a continuous airborne monitor must be in place.

4731.0902 Individual Monitoring. The registrant for must ensure that the individual monitoring requirements specified in 4731.0130 are met. In addition, there must be:

A. Either an alarming ratemeter that will alarm at an exposure of up to 500 mR/hr (1.29 x 10-4 C/kg/hr) or an alarming ratemeter that also integrates the total exposure up to 5,000 milliroentgens (1.29 x 10-3 C/kg); or

B. A hand-held portable radiation survey meter with an audible and visible readout of exposure rate or a fixed area radiation exposure rate monitor with a visible or audible alarming indicator may be substituted for the alarming ratemeter.

4731.0903 Operating and Emergency Procedures. A copy of the registrant's written current operating and emergency procedures must be supplied to the registrant's employees and a copy must be available at all times at the accelerator control panel.

Subpart 1. **Operating procedures.** Operating procedures must include procedures that cover the following:

A. Operating the accelerator so that no individual is exposed to radiation doses in excess of the limits established in 4731.0124.

B. Conducting radiation safety surveys, including smear surveys, according to 4731.0132.

C. Controlling access to accelerators.

D. Locking and securing accelerators, according to 4731.0901.

E. Individual monitoring according to 4731.0902.

F. Exposure rate surveys after each accelerator run to determine that the beam has stopped.

G. Handling of unwanted radioactive material and quality control products.

H. Storage of equipment that has become contaminated with radioactivity through use.

Subp. 2. **Emergency procedures.** Emergency procedures must include procedures that cover the following:

A. Notifications to the registrant's radiation safety officer and the commissioner according to 4731.0162, when:

(1) a direct reading pocket dosimeter goes off-scale;

(2) overexposure or an occupational dose has been exceeded;

(3) a non-occupational worker or member of the public has been exposed; or

(4) stack releases exceed limits specified in 4731.3001, Appendix B, Table II; if applicable.

B. Initiation of emergency call list.

C. Actions to be taken when the emergency "off" switches are triggered.

D. Actions to be taken to minimizing the exposure of individuals in the event of an incident.

E. Actions to be taken if accelerator-produced material is spilled or involved in a transportation accident.

4731.0904 Use Logs. Each registrant with accelerators capable of energies of 500 keV or higher must make and maintain use logs until the next inspection by the commissioner. The log must specify:

A. Serial number or other unique identification for each accelerator.

B. Identity of the operator assigned to the equipment.

C. Locations and dates where the equipment was used.

D. Technique factors specifying the voltage, current, operating time for each run, and number of runs.

E. Release rate of radioactive materials emitted from discharge stacks.

F. Identification of accelerator produced material.

4731.0905 Inspection and Maintenance. The registrant must ensure that the following inspections or tests are completed at the proper frequencies and the records made and maintained as listed in 4731.0168 to 4731.0185.

A. Checking of accelerators and associated equipment for visual defects prior to each day of use.

B. Inspection of accelerators for proper functioning of warning devices, control devices, and components important to safety, in compliance with 4731.0173, at the following frequencies:

(1) inspections for cyclotrons, including PET, shall be done daily;

(2) inspections for human use of accelerators, shall be done monthly;

(3) inspections for all other accelerators, shall be done quarterly.

C. Testing of alarming ratemeters before each shift to ensure they signal properly.

D. Testing of area monitors for functionality when used at a cyclotron facility, including PET, shall be done weekly.

E. Checking of area monitors for functioning when used at all other accelerator facilities shall be done monthly.

F. Maintenance of equipment in accordance with manufacturer's specifications.

G. Calibration of radiation survey instruments and area monitors in accordance with 4731.0133.

H. Conducting of radiation safety surveys in accordance with 4731.0132 and annually not to exceed one year.

I. Providing accessibility to radiation survey instruments to conduct the radiation safety surveys, as needed.

J. Labeling and the removal of defective equipment from service, when defect is found in a component critical to radiation safety or the function of the equipment, until repairs are made.

K. Making available the current electrical circuit diagrams of the accelerator and the associated safety interlock systems and maintained at each accelerator facility.

4731.0906 Radiation Safety Surveys. These are in addition to the radiation safety survey

requirements in 4731.0132.

Subpart 1. **Requirements of the surveys.** The following surveys must be performed:

A. Measurements of airborne particulate to determine the amount of radioactivity present:

(1) measurements for cyclotrons, including PET, shall be done daily, in the area occupied by staff, when operating;

(2) measurements for all other accelerators, shall be done weekly, in the area occupied by staff.

B. Smear surveys to determine the degree of contamination done at the following frequencies:

(1) smear surveys for cyclotrons, including PET, shall be done daily, in the area occupied by staff, when operating;

(2) smear surveys for all other accelerators, shall be done weekly, in the area occupied by staff.

Subp. 2. **Requirements of the radiation survey instruments.** The licensee or registrant must keep a radiation survey instrument at each accelerator location to conduct the radiation surveys required by chapter 4731.

A. The radiation survey instrument must be capable of measuring appropriate dose rates.

B. The instruments must be operable and calibrated in accordance to 4731.0132.

4731.0907 Additional Requirement for Accelerators in Medical Treatment Settings.
The registrant shall appoint a medical committee of at least four members to evaluate and approve uses of medial accelerators for research on a person. Membership of the committee must include the facility radiation safety officer, a physician expert in therapeutic radiology, and a therapeutic radiologic physicist. Membership may include physicians who are experts in internal medicine and hematology.

SEALED AND UNSEALED SOURCE REQUIREMENTS

4731.1000 Sealed and Unsealed Sources Used in Industrial and Research Facilities
Subpart 1. **Applicability.** This part contains requirements for the use of sealed and unsealed sources in industrial and research settings, including requirements for portable and fixed gauges and laboratories. This part does not apply to the applications listed below which are found elsewhere in this rule. These applications are:

A. Industrial radiography in 4731.0500 to 4731.0513.
B. Well logging in 4731.0800 to 4731.0813.
C. Irradiators in 4731.0700 to 4731.0711.
D. Medical uses in 4731.1200 to 4731.1214.

Subp. 2. **License or registration requirements for specific industrial uses.** The commissioner may approve an application for a specific license or registration for the use of licensed material in industrial and research settings if the applicant meets the following requirements. The application must include:

A. The licensing requirements as specified in 4731.0309, as appropriate, and any additional requirements contained in this part.

B. A program for employee training and a description of this program including instructor qualifications that meets the requirements of 4731.0151, 0152, as appropriate.

C. Written operating and emergency procedures as described in 4731.1003 of this part.

D. Action levels for contamination from unsealed sources and the values requiring decontamination and initiation of emergency procedures.

E. A description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities, including specified delegation of authority and responsibility.

F. A description and identification of the location(s) of all field stations.

G. Radioactive material use record.

Subp. 3. **Records.** The registrant must ensure that the records required by this part are kept in accordance with 4731.0168 to 4731.0189. Records must be kept for four years or until the next inspection by the commissioner.

4731.1001 Design and Performance Criteria for Sealed Sources. A licensee or registrant may use only sealed sources that are registered in the NRC's sealed source and device registry. Sealed sources that contain radioactive material in gaseous form are not included in the sealed source and device registry.

4731.1002 Individual Monitoring. In addition to 4731.0130, the following must be met.
Subpart 1. **NVLAP-accredited individual monitoring device.** The licensee or registrant must require an individual to wear a NVLAP-accredited individual dosimeter when:

~~A. Working with the source:~~
~~(1) handling licensed or registered sources;~~
~~(2) using or assisting with sources, or~~

~~(3) maintaining sealed sources.~~

~~B~~A. Working around the source in fixed gauges during:

(1) installation;

(2) performance the initial survey;

(3) maintenance;

(4) servicing of the unit;

(5) relocation or removal of the sealed sources.

~~C~~B. Working with unsealed sources and also provide an additional extremity (ring) dosimeter.

Subp. 2. **Bioassay services.** The licensee must provide bioassay services to individuals using unsealed sources of licensed or registered materials.

4731.1003 Operating and Maintenance Procedures. Each licensee or registrant must develop and follow written operating and maintenance procedures. The licensee's or registrant's operating and maintenance procedures must be posted according to 4731.0122.

Subpart 1. **Operating and maintenance procedures for sealed and unsealed sources.** Procedures for both sealed and unsealed sources must include written procedures for the following areas:

A. Operating procedures, including:

(1) handling and use of licensed materials so that radiation doses do not exceed the limits established in 4731.0124;

(2) methods and list of occasions for conducting radiation safety surveys as in 4731.0132, and surveys for detecting radioactivity contamination, as required by 4731.1007;

(3) methods for controlling access to restricted areas;

(4) methods and list of occasions for locking and securing transport and storage containers and sealed sources;

(5) monitoring of an individual in accord with 4731.1002 and bioassay testing;

(6) ensuring the following in accordance with 4731.1500 - 4731.1513:

(a) transport of licensed materials to field stations or temporary jobsites;

(b) packaging of licensed materials for transport in vehicles;

(c) placarding of vehicles when needed; and

(d) physically securing licensed materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal, in accordance with 4731.1500 - 4731.1513;

(7) picking up, receiving, and opening packages containing licensed or registered materials.

B. Maintenance procedures, including:

(1) the inspection, maintenance, and operability checks of sealed and unsealed sources, source holders, survey instruments, transport containers, and storage containers;

(2) maintenance for records of the use and date of use of all of the equipment and radioactive materials utilized at each specific temporary jobsite;

(3) calibration of radiation survey instruments at least annually;

(4) posting and providing for lock-out procedures that prevent employees from entering the radiation beam during maintenance, repairs, or other work in, on, or around the radioactive source;

(5) ensuring that a copy of the operating procedures accompany the sources at all times; and

(6) actions to be taken when a source must be transferred or disposed.

Subp.2. **Special operating procedures for sealed sources** must include written procedures for the following areas:

A. Leak testing of sealed sources in accordance with 4731.0134. If the licensee or registrant performs the leak testing of sealed sources, the licensee or registrant must:

(1) establish procedures to be followed;

(2) identify the manufacturers of the leak test kits; and

(3) the model numbers of the leak test kits to be used.

B. Analysis of wipes taken of sealed sources in accordance with 4731.0134. If the licensee or registrant performs the analysis of the wipe samples, the licensee or registrant must:

(1) establish procedures to be followed; and

(2) submit a description of these procedures to the commissioner. The description must include the:

(a) instruments to be used;

(b) methods of performing the analysis; and

(c) pertinent experience of the person who will analyze the wipe samples.

Subp. 3. **Special operating procedures for unsealed sources** must include written instructions in the following areas:

A. Limiting the spread of radioactive materials from unsealed sources. This procedure must include action levels:

(1) for fixed and removable contamination; and

(2) for emergency measures if the action levels are exceeded.

B. Analysis of daily and weekly wipes for contamination. The instructions must include the following:

(1) type of instrument detection system used, in accordance with 4731.1007;

(2) background counting times and average background counts;

(3) sample counting times;

(4) sample of calculation converting results into activity or activity per unit time, if applicable;

(5) calculation of counting efficiency; and

(6) calculation of lower level of detection.

C. Monitoring of the fume hood before and after use.

D. Monitoring of any exhaust or ventilation system of a fume hood before and after use.

4731.1004 Emergency Procedures. Each licensee or registrant must develop and follow written emergency procedures. The licensee's and registrant's emergency procedures must be posted

according to 47831.0122.

Subpart 1. **Emergency procedures for both sealed and unsealed sources**

A. Emergency procedures for both sealed and unsealed sources must include written instructions on events in the following areas:

(1) notifications to be reported to the licensee's radiation safety officer and the commissioner according to 4731.0162 in the event of:

(a) an accident or incident;

(b) abandonment of a source; or

(c) levels of contamination that exceed the emergency action levels;

(2) decontamination survey procedures for equipment and affected areas;

(3) actions to be taken when a source must be transferred or disposed;

(4) retention of a record of each action and survey required by 4731.1007. These records must include:

(a) the date of the survey;

(b) an annotated diagram of each area surveyed;

(c) background levels;

(d) measurements including:

((1)) dose rates which are keyed to the legend of a diagram, expressed in millirem (microsieverts) per hour; or

((2)) removable contamination, expressed in dpm per 100 square centimeters, or counts per minute if performed with a radiation survey instrument;

(e) the serial number and model number of the instrument used to make the survey or analyze the samples; and

(f) identification of the individual who performed the survey.

Subp. 2. **Special emergency procedures for sealed sources** must include written instructions in the following:

A. Actions to be taken if a sealed source is lodged or damaged, when the source is not ruptured.

B. Actions to be taken if a sealed source is ruptured including:

(1) control of contamination;

(2) minimization of inhalation and ingestion of licensed or registered materials;

(3) decontamination of the work place and environment;

(4) decontamination of equipment before release from the site; and

(5) decontamination of individuals before leaving the site.

Subp. 3. **Special emergency procedures for unsealed sources** must include written instructions when contamination reaches emergency levels for actions:

A. To minimize an individual's exposure including exposures from inhalation and ingestion of licensed or registered materials;

B. For decontamination and resurvey procedures:

(1) for fixed contamination;

(2) for removable contamination using the following action levels:

(a) 100 dpm per 100 square centimeters of any alpha-emitting radioactive materials;

(b) 1,000 dpm per 100 square centimeters of any beta- or gamma-emitting radioactive materials;

(c) 50 dpm per 100 square centimeters of any transuranic;

(d) 2,000 dpm per 100 square centimeters of uranium; or

(e) 2,000 dpm per 100 square centimeters of any radioactive material with a half-life of less than 80 hours.

(3) for fume hood or ventilation systems;

(4) for localized areas.

4731.1005 Inspection of Sealed and Unsealed Sources. Each licensee or registrant must have a written program including the procedures for the inspection and maintenance of the each source. These procedures of the program must include the following requirements:

A. Before each use of the source:

(1) conduct a visual or electronic inspection of the integrity of the container, indication of obvious spillage or gaseous escape and the required labeling;

(2) conduct an operability inspection to check the functioning of the equipment;

(3) remove equipment that is inoperable or damaged from service until repaired, and make and keep a record in accordance with 4731.0168, listing:

(a) date of the visual or electronic inspection that made the discovery;

(b) name of inspector making the discovery;

(c) equipment involved, and what damage was found; and

(d) what repairs were made.

B. Semi-annually during use of the source:

(1) conduct a visual or electronic inspection and routine maintenance to ensure that there is no physical or operational damage and the required labeling is legible;

(2) remove equipment that is inoperable or damaged from service until repaired, and make and keep a record in accordance with 4731.0168, listing:

(a) date of the visual or electronic inspection that made the discovery;

(b) name of inspector making the discovery;

(c) equipment involved, and what damage was found;

(d) what inspection and maintenance operations were performed; and

(e) any actions taken to correct the damage.

C. Specifications of the manufacturer must be followed.

4731.1006 Opening of a Source or Source Holder. The following requirements must be followed prior to the opening of a source or source holder:

A. The opening, repair, or modification of any sealed or unsealed source must be performed by persons specifically approved to do so by the commissioner, an agreement state or the NRC.

B. Removal of a sealed source from a source holder, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure developed has been approved either by the commissioner or by an agreement

state.

C. If a sealed source is stuck in the source holder, emergency actions in 4731.1004must be followed. The licensee may not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the commissioner, an agreement state or the NRC to perform this operation.

4731.1007 Radiation Safety Surveys. In addition to the radiation safety surveys found in 4731.0132, the licensee or registrant must make the following radiation surveys, for each area where licensed or registered materials are used and stored.

Subpart 1. **Requirements of the surveys for both sealed and unsealed sources.**

A. Surveys must be made when:

(1) installing;
(2) maintaining;
(3) servicing;
(4) at the initial use; or
(5) relocating or removing the source.

B. Surveys for the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the licensed or registered materials must be made before transporting licensed or registered materials.

C. The records of the survey results required under this subpart must be kept in accordance with 4731.0168 and must include:

(1) the date of the survey;
(2) the name of the individual conducting the survey;
(3) the identification number or code of the survey;
(4) the instrument used; and
(5) the location of the survey.

Subp. 2. **Special radiation safety surveys for sealed sources** must be conducted when:

A. The assembly is removed from the source holder before departure from a temporary jobsite. The licensee or registrant must confirm by using a survey meter that the source holder is free of contamination.

B. The encapsulation of the sealed source could be damaged as a result of operation. The licensee or registrant must conduct a contamination survey during and after the operation.

Subp. 3. **Special radiation safety surveys for unsealed sources** must be conducted:

A. Before and after use at a temporary jobsite.

B. At the end of each day using radiation instruments for all areas where materials are used or received.

C. At the end of each day using a wipe survey to locate removable contamination for all areas where radioactive materials are used when survey instruments do not detect contamination.

D. Each week with a radiation survey instrument for all areas where radioactive materials or radioactive waste are stored, including fume hoods and ventilation areas.

E. Each week using a wipe survey for removable contamination for all areas where

radioactive materials or waste are routinely used or stored.

F. With an instrument capable of measuring dose rates as low as 0.1 millirem (1 μSv) per hour.

G. To monitor individuals for contamination prior to their leaving the restricted area.

Subp. 4. **Requirements of the radiation survey instruments.**

A. A licensee or registrant who is authorized to use:

(1) portable and fixed gauges must use portable radiation survey instruments with appropriate ranges;

(2) unsealed sources must have instruments that are sensitive enough to detect activity levels required for contamination control and to measure radioactive materials listed on the license.

B. The instruments must be operable and calibrated in accordance with 4731.0133.

4731.1008 Visual or Electronic Inventory and Records of Radioactive Material Use. Each licensee or registrant must conduct a semi-annual visual or electronic inventory and account for all licensed or registered material, sealed or unsealed, received and possessed under the license or registration. The licensee or registrant must make and maintain the required records in accordance with 4731.0168 and 4731.0181. The visual or electronic inventory and record of use must include the following information:

A. Quantity and kind of licensed or registered material.

B. Make, model number, and a serial number or a description of each sealed source used.

C. Location of the licensed or registered material.

D. Dates of use of the licensed or registered material.

E. Transfer or disposal of any unused sealed and unsealed licensed or registered material.

F. Date of the inventory.

G. Identification of the individual who is responsible for the licensed material.

H. Name of the individual conducting the inventory and use record.

I. Signature of RSO or designee.

4731.1009 Labels and Security During Storage, Transportation and Use. The licensee or registrant must ensure the requirements in this part are met and are in addition to the requirements found in 4731.0122.

Subpart 1. **Label and package** The licensee or registrant:

A May not use or store a source, source holder, or gauge that contains licensed material unless every piece of equipment containing radioactive material bears a durable, legible, and clearly visible marking or label. This marking or label must contain:

(1) radiation symbol as specified in 4731.0122; and

(2) the words " DANGER (or CAUTION) RADIOACTIVE MATERIAL NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."

B May not transport licensed material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with requirements in

4731.1500 to 4731.1513.

Subp. 2 **Storage.** The licensee or registrant must store each radioactive material source in a storage container or transportation package, meeting the following requirements:

A. Container or package must be locked and physically secured to prevent tampering or removal of licensed material from storage by unauthorized personnel.

B. Must store licensed material in a manner which will minimize danger from explosion or fire.

Subp. 3. **Transport of the source.** The licensee or registrant must transport the package containing licensed material in a locked and physically secure condition in the transporting vehicle to prevent:

A. Accidental loss.

B. Tampering.

C. Unauthorized removal of the licensed material from the vehicle.

Subp. 4. **Security.** The licensee or registrant must ensure that sources not in storage or being transported are under the constant surveillance and immediate control of the licensee; or are locked to prevent use, tampering, or removal by unauthorized personnel.

4731.1010 Storage and Control of Volatiles and Gases

A. A licensee or registrant must store volatile radioactive materials and radioactive gases in the shipper's radiation shield and container or an equivalent shield and container.

B. A licensee or registrant must store and use radioactive volatiles and gases in a glove box or fume hood that will maintain airborne concentrations within the limits prescribed by 4731.3001, A, Table I, Column 2, and Table II, Column 1.

C. The glove box or fume hood must provide for collection and decay of the volatile or gas.

D. A licensee or registrant must dispose of radioactive materials in accord with 4731.0136. Monitoring must be performed for materials which have been released through venting from a fume hood or ventilation system.

USE OF RADIONUCLIDES IN THE HEALING ARTS

4731.1200 Applicability for the use of radionuclides in the healing arts. This rule contains the requirements and provisions for the medical use of radioactive material and for the issuance of specific licenses authorizing the medical use of radioactive material. The requirements and provisions of 4731.1200-4731.1220 are in addition to and not in substitution for other requirements in Chapter 4731. Nothing in 4731.1200-4731.1220 relieves the licensee from complying with applicable state, FDA, other federal requirements governing radioactive drugs or devices.

4731.1201 License for Medical Use of Radioactive Materials

Subpart 1. **License required.** Licensing requirements can be found in 4731.0300-4731.0320.

A. A person may manufacture, produce, acquire, receive, possess, prepare, use or transfer

radioactive material for medical use only in accordance with a specific license issued by the commissioner or NRC, or an agreement state or as allowed in 4731.1201, subp. 1, B,(1) and (2), below.

B. A specific license is not needed for an individual who:

(1) receives, possesses, uses, or transfers radioactive material in accordance with the regulations in Chapter 4731 under the supervision of an authorized user as provided in 4731.1202, subp 4, unless prohibited by license condition; or

(2) prepares unsealed radioactive material for medical use in accordance with the regulations Chapter 4731 under the supervision of an authorized nuclear pharmacist or authorized user as provided in 4731.1202, subp. 4, unless prohibited by license condition.

Subp 2. **Application for license, amendment, 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 materials as described in 4731.1211, subparts 1 and 3, 4731.1212, subparts 1,2, and 4, 4731.1213, subp. 1, and 1201, subp 7, must include:

(1) an application on form 4731.3004, 4, that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

(2) procedures required by 4731.1203, subp. 6, and 4731.1210, subparts 1,2, and 4, as applicable.

C. A request for a license amendment or renewal must include:

(1) an application on 4731.3004, 4, or a letter requesting the amendment or renewal; and

(2) procedures required by 4731.1203, subp. 6, and 4731.1210, subparts 1, 2, and 4, as applicable.

D. In addition to the requirements in 4742.1202, subp.2, B and C, above, an application for a license or amendment for medical use of radioactive material as described in 4731.01210, subp. 7 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in 4731.1201-4731.1206.

(1) the applicant must also provide specific information on:

(a) radiation safety precautions and instructions;

(b) methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(c) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(2) the applicant or licensee must also provide any other information requested by the commissioner for review of the application.

E. An applicant that satisfies the requirements specified in 4731.0310, subp. 2 may apply for a Type A specific license of broad scope.

Subp 3. **License amendments.** A licensee shall apply for and must receive a license amendment:

A. Before the licensee receives, prepares, or uses radioactive material for a type of use that

is permitted under 4731.1200-4731,1220, but not authorized on the licensee's current license, issued under Chapter 4731;

B. Before the licensee permits anyone to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist under the license, except an individual who is:

(1) an authorized user who meets the requirements in.:

(a) 4731.1207, subparts 1 A, 2 A, 3 A, 4 A, 5 A, 12 A, 13 A, 14 A, and 4731.0152, subp. 1, D;

(2) an authorized nuclear pharmacist who meets the requirements in 4731.0152, subp. 1, D and subp. 7, B;

(3) an authorized medical physicist who meets the requirements in 4731.0152.subp. 1, D, and subp. 7, A;

(4) identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist:

(a) on the commissioner, NRC or agreement state license or equivalent permit that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively;

(b) on a permit issued by the commissioner, NRC, an agreement state specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(c) on a permit issued by a commissioner master material licensee that is authorized to permit the use of radioactive materials in medical use or in the practive of nuclear pharmacy; or

(d) by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

C. Before radiation safety officers are changed, except as provided in 4731.1202, subp. 1, C;

D. Before radioactive material is ordered in excess of the amount, or radionuclide or form that is different than the radionuclide or form authorized on the license;

E. Before additions or changes are made to the areas identified in the application or on the license, except for areas where radioactive material is used in accordance with 4731.1212, subparts 1 and 2;

F. Before address(es) identified in the application or on the license are changed; and

G. Before revision of procedures required by 4731.1203, subp. 6, and 4731.1210, subparts 1, 2, and 4. as applicable, where such revision reduces radiation safety.

Subp 4. **Notification of license changes**

A. A licensee shall provide the commissioner a copy of

(1) the board certification,

(2) the commissioner or agreement state license,

(3) the permit issued by a commissioner's master material licensee; or

(4) the permit issued by a commissioner's master material licensee broad scope licensee for each individual, no later than 30 days after the date that the licensee permits the individual to work as an:

(a) authorized user,
(b) authorized nuclear pharmacist, or
(c) authorized medical physicist, under 4731.1201, subp. 3, B.

B. A licensee shall notify the commissioner by letter no later than 30 days after:

(1) an authorized user, an authorized nuclear pharmacist, a radiation safety officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(2) the licensee's mailing address changes;

(3) the licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 4731.0300, subp. 1,G; or

(4) the licensee has deleted or otherwise changed the areas where radioactive material is used in accordance with 4731.1212, subparts 1 and 2.

C. The licensee shall mail the documents required in this part to the Radiation Control Unit, Asbestos, Indoor Air, Lead, and Radiation Section, Minnesota Department of Health.

Subp 5. **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 4731.1202, subp. 2, D regarding the need to fille an amendment to the license for medical use of radioactive materials as described in 4731.1201, subp. 7.

B. The provisions of 4731.1201, subp. 3, B;

C. The provisions of 4731.1201, subp. 3, E regarding additions to or changes in the areas of use only at the addresses specified in the license;

D. The provisions of 4731.1201, subp. 4, A;

E. The provisions of 4731.1201, subp. 4, B, (1), for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

F. The provisions of 4731.1201, subp. 4, B, (4); and

G. The provisions of 4731.1211, subp. 2, A.

Subp 6. **License issuance.**

A. The commissioner may issue a license for the medical use of radioactive material if:

(1) the applicant has filed form 4731.3004, 4. in accordance with the instructions in 4731.1201, subp. 2;

(2) the applicant has paid any applicable fee as provided in 4731.0104, subp. 1 ;

(3) the commissioner finds the applicant equipped and committed to observe the safety standards established by the commissioner in this chapter for the protection of the public health and safety; and

(4) the applicant meets the requirements of 4731.0300-4731.0320.

B. The commissioner may issue a license for mobile medical services if the applicant:

(1) meets the requirements in 4731.1201, subp. 6, A, above; and

(2) provides assurances that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with 4731.1204, subp, 2.

Subp 7 **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 which is not specifically addressed in 4731.1200-4731.1220, if:

A. The applicant or licensee has submitted the information required by 4731.1201, subp. 2, B - D; and

B. The applicant or licensee has received written approval from the commissioner in a license or license amendment and uses the material in accordance with the regulations and specific conditions the commissioner considers necessary for the medical use of the material.

4731.1202 Radiation Safety Program

Subpart 1. **Authority and responsibilities for the radiation safety program.**

A. In addition to the radiation safety program requirements of 4731.0131, subp. 1, a licensee's responsible administrator must approve in writing:

(1) requests for license application, renewal, or amendments before submittal to the commissioner

(2) any individual before allowing that individual to work as authorized user, authorized nuclear pharmacist, authorized medical physicist; and

(3) radiation safety program changes that do not require a license amendment and are permitted under 4731.1202, subp. 2

B. A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation safety 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.

C. For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under 4731.0128, subp, 7 and 4731.0152, subp. 1, D, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in 4731.1202, subp. 1, G, below, if the licensee takes the actions required by 4731.1202, subp.1, B, E, G, and H, below and notifies the commissioner in accordance with 4731.1201, subp. 4, B.

D. A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with 4731.1202, subp 1, C, above, 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.

E. A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer.

F. Licensees that are authorized for two or more different types of uses of radioactive materials under 4731.1202, E, F, and H, or two or more types of units under 4731.1202, H, 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 management who is neither an authorized user nor a Radiation Safety Officer. The committee may include other members the licensee considers appropriate.

G. 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.

H. A licensee shall retain a record of actions taken pursuant to 4731.1202, subp. 1, A, B, and E above, in accordance with 4731.1214, subp. 1, C.

Subp 2. **Radiation safety program changes.**

A. A licensee may revise the facility radiation safety program without commissioner approval if:

(1) the revisions do not require an amendment under 4731.1201, subp. 3;

(2) the revisions are in compliance with the regulations and the license;

(3) the revisions have been reviewed and approved by the Radiation Safety Officer and licensee's responsible administrator; 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 4731.1214, subp. 1,

Subp 3. **Radiation review committee.** Every facility in which radioactive material and medical accelerators are used must have a committee which coordinates the use of radioactive material and medical accelerators within the facility and ensures the radiation safety of the patients and persons involved during the use of the radioactive material and accelerators.

Subp 4. **Preparation of radioactive material under 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 or as allowed by 4731.1201, subp. B, shall:

(1) instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of radioactive material; and

(2) require the supervised individual to follow:

(a) the instructions of the supervising authorized user for medical uses of radioactive material,

(b) written radiation protection procedures established by the licensee, regulations of this chapter; ~~and~~

(c) written directive procedures;

(d) regulations of this chapter; and

(~~c~~e) license conditions with respect to the medical use of radioactive material.

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 4731.1201, subp. 1, B, (2), shall:

(1) instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's use of radioactive material; and

(2) require the supervised individual to follow:

(a) the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use,

(b) the written radiation protection procedures established by the licensee ~~and;~~ (c) the regulations of this chapter~~,~~; and

(~~c~~d) the license conditions.

C. A licensee that permits supervised activities under 4731.1202, subp. 4, A and B, above, is responsible for the acts and omissions of the supervised individual.

Subp 5. Reserved

Subp 6. **Written directives**

A. A written directive must be prepared, dated, and signed by an authorized user prior to administration of :

(1) I-131 sodium iodide greater than 30 Microcuries (1.11 Megabequerels Mbq),

(2) any therapeutic dosage of unsealed radioactive material, or

(3) 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 is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be 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 any administration quantities greater than 30 microcuries (1.11 MBq) of sodium iodide I-131: the dosage;

(2) for an administration of a therapeutic dosage of an unsealed radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical, dosage, and route of administration;

(3) for gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site.

(4) for teletherapy: the total dose, dose per fraction, number of fractions, treatment site;

(5) for high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) for all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

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

(b) after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and the total source strength and exposure time, or the total dose.

C. A written revision to an existing written directive may be made if the revision is dated and signed and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of a 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 is acceptable~~; and~~

~~(2)~~ The information in the oral revision must be documented as soon as possible in writing in the patient's record~~; and~~

~~(3) a.~~ A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

D. The licensee shall retain the written directive in accordance with 4731.1214, subp. 1, E.

Subp. 7. **Procedures for administrations requiring a written directive.**

A. For any administration requiring a written directive, the licensee must 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 4731.1202, subp. 7, A, must, at a minimum, address:

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

(2) verifying that the administration is 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 devices authorized by 4731.1211, subp. 3.

C. A licensee shall retain a copy of the procedures required under 4731.1202, subp 7, A, above, in accordance with 4731.1214, subp. 1, H.

4731.1203 Requirements for Patient or Human Subject Research Program.

Subpart 1. **Provisions for the protection of human research subjects.**

A. A licensee may conduct research involving human research subjects only of the licensee uses radioactive materials specified on the license and for the uses authorized on the license.

B. If the research is conducted, funded, supported, or regulated by a federal or another agreement state agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee must, before conducting research:

(1) obtain review and approval of the research from an "Institutional Review Board, " as described in the Federal Policy; and

(2) obtain "informed consent" as described in the Federal Policy, from the human research subject.

C. If the research will not be conducted, funded, supported, or regulated by a federal or

another agreement state agency , the licensee must, before conducting research, apply for and receive a specific amendment to the license for medical use obtained from the commissioner. The amendment request must include a written commitment that the licensee will, before conducting research:

(1) obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) obtain "informed consent," as defined in the Federal Policy from the human research subject.

D. Nothing in 4731.1203, subp. 1 relieves licensees from complying with the other rules in 4731.1200-4731.1220.

Subp 2. **Safety instruction for patients and human research subjects who have been given unsealed radioactive materials and who cannot be released under 4731.1204, subp. 2.** In addition to 4731.0151, subp. 1:

A. A licensee must provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under 4731.1204, subp. 2. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) patient or human research subject control;

(2) visitor control including:

(a) routine visitation to hospitalized individuals in accordance with 4731.0126,subp. 1, A; and

(b) visitation authorized in accordance with 4731.0126, subp. 1, C;

(3) contamination control;

(4) waste control; and

(5) notification of the Radiation Safety Officer, or his 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 4731.1214, subp. 1, B.

Subp 3. **Safety precautions for patients and human research subjects receiving unsealed radioactive material and who cannot be released under 4731.1204, subp 2.**

A. For each patient or human research subject that cannot be released in accordance with 4731.1204, subp. 2, a licensee must:

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

(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 therapy with unsealed radioactive material and who also has received therapy with unsealed radioactive material and who also cannot be released under 4731.1204, subp. 2;

(2) visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign;

(3) note on the door or in 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

(4) either:

(a) monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity 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

(b) handle such material and items as radioactive waste.

B. A licensee must notify the Radiation Safety Officer or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

Subp 4. **Safety instruction for patients and human research subjects receiving brachytherapy.** In addition to the requirements in 4731.0151, subp. 1:

A. The licensee must provide radiation safety instruction initially and at least annually, to personnel caring for patients or human research subjects that are receiving brachytherapy therapy and cannot be release in accordance with 4731.1204, subp. 2. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the following information:

(1) size and appearance of the brachytherapy source;

(2) safe handling and shielding instructions;

(3) patient or human research subject control;

(4) visitor control, including both:

(a) routine visitation of hospitalized individuals in accordance with 4731.0126,subp.1, A; and

(b) visitation authorized in accordance with 4731.0126, subp. 1, C; and

(5) notification of the authorized user and Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

B. A licensee must retain a record of individuals receiving instruction in accordance with 4731.1214, subp. 1, B.

Subp 5. **Safety precautions for patients and human research subjects receiving brachytherapy.**

A. For each patient or human research subject receiving brachytherapy and cannot be released under 4731.1204, subp. 2, a licensee must:

(1) not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy; and

(2) visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

(3) note on the door or in 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.

B. A licensee must have available applicable emergency response equipment available near each treatment room to respond to a source:

(1) dislodged from the patient; and

(2) lodged within the patient following removal of the source applicators.

C. A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency or dies.

Subp 6. **Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.**

A. A licensee must:

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

(2) permit only individuals approved by the 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. These procedures 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 contracted if the unit or console operates abnormally.

B. A copy of the procedures required by 4731.1203, subp. 6, A, (4), above, must be physically located at the unit console.

C. A licensee must post instructions at the unit console to inform the operator of:

(1) the location of the procedures required by 4731.1203, subp. 6, A, (4), above; and

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

D. A licensee must provide instruction and practice drills, 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 4731. 1203, subp. 6, A, (4), above, and

(2) the operating procedures of 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 4731.1203, subp. 6, D, above, in accordance with 4731.1214, subp. 1, B.

G. A licensee must retain a copy of the procedures required by 4731.1203, subp. 6, A, (4),

and D, (2), in accordance with 4731.1214, subp. 6, D.

Subp 7. **Safety precautions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.**

A. A licensee must control access to the treatment room by a door at each entrance.

B. A licensee must 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 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 must 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 must 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 must only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

F. In addition to the requirements specified in 4731. 1203, subp. 7, A - E, above, a licensee must;

(1) for 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 applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) for high dose-rate remote afterloader devices, require:

(a) an authorized user and an authorized medical physicist 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 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 continuation of all patient treatments involving the unit.

(3) for gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) notify the Radiation Safety Officer, or his/her designee, and an authorized user

as soon as possible if the patient or human research subject has a medical emergency or dies.

G. The licensee must have applicable emergency response equipment available near each treatment room to respond to source:

(1) remaining in the unshielded position; or

(2) lodged within the patient following completion of the treatment.

4731.1204 Radiation Safety Surveys on Patients or Human Research Subjects.

Subpart 1. **Radiation surveys of patients and human research subjects treated with remote afterloaders.**

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

B. A licensee must retain a record of patient or human research subject surveys in accordance with 4731.1214, subp. 2, C.

Subp 2. **Release of individuals containing unsealed radioactive materials or implants containing radioactive material.**

A. A licensee may authorize the release from its control of any individual who has been administered radioactive materials or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5mSv).

NUREG-1556, Vol 9(draft), "Consolidated Guidance About Materials Licenses: Program-specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem(5mSv).

B. A licensee must provide the released individual, or the individual's parent or guardian, with instructions, including written instructions:

(1) on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1mSv).

(2) on actions to be taken if the total effective dose equivalent to a breast-feeding infant or child could exceed 0.1 rem (1mSv) assuming there were no interruption of breast-feeding. The instructions must also include:

(a) guidance on the interruption or discontinuation of breast-feeding; and

(b) information on the potential consequences, if any, of failure to follow the guidance.

C. A licensee must maintain a record of the basis for authorizing the release of the individual, in accordance with 4731.1214, subp. 2, C, (1).

D. The licensee must maintain a record of instructions provided to breast-feeding women in accordance with 4731.1214, subp. 2, C, (2).

4731.1205 Radiation Safety Surveys for Equipment.

Subpart 1 **Radiation surveys**

A. In addition to the survey requirement in 4731.0132, subp. 2, a person licensed under Chapter 4731 must make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

B. The licensee must make the survey required by 4731.1205, subp. 1, A, above, at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could:

(1) expose the source,

(2) reduce the shielding around the source(s), or

(3) compromise the radiation safety of the unit or the source(s).

C. A licensee must retain a record of the radiation surveys required by 4731.1205, subp. 1, A, above, in accordance with 4731.1214, subp. 6, B

Subp 2. **Five-year service for teletherapy and gamma stereotactic radiosurgery units.**

A. A licensee must have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

B. This inspection and servicing may be performed only by persons specifically licensed to do so by the commission, NRC or an agreement state.

C. A licensee must keep a record of the servicing in accordance with 4731.1214, subp. 6. C.

Subp 3. **Therapy-related computer systems.** The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minium, 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;

C. The accuracy of isodose plots and graphic displays; and

D. The accuracy of the software used to determine sealed source positions from radiographic images; and

E. If electronic transfer is used, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

4731.1206 Radiation safety program requirements. In addition to the requirements in 4731.0311, the following provisions are required.

Subpart 1. **Labeling of vials and syringes**

Each syringe and vial that contains unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

Subp 2. **Surveys for ambient radiation exposure rate.**

A. In addition to surveys required in 4731.0132, a licensee must survey with a radiation detection survey instrument at the end of each day of use. A licensee must survey all areas where unsealed radioactive materials requiring a written directive were prepared for use or administered.

B. A licensee does not need to perform the surveys required by 4731.1206, subp. 2, A in an area(s) where patients or human research subjects can not be released pursuant to 4731.1204, subp. 2..

C. A licensee must retain a record of each survey in accordance with 4731.0169, subp. 4.

Subp 3. **Provision of mobile service**

A.A licensee providing mobile service must:

(1) obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address of use and clearly delineates the authority and responsibility of the licensee and the client;

(2) check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each address of use or on each day of use, whichever is more frequent. At a minimum, the check for proper function required here must include a constancy check;

(3) check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) before leaving a client's address of use, survey all areas of use to ensure compliance with requirements in 4731.0101-4731.0195.

B. A mobile nuclear medicine service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client must be received and handled in conformance with the client's license.

C. A licensee providing mobile nuclear services shall retain the letter required in 4731.1206, subp. 3, A, (1), and the record of each survey required in 4731.1206, subp. 3, A, (4),in accordance with 4731.1214, subp. 1, A.

Subp 4. **Decay-in-storage**

A. licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity, if the licensee:

(1) monitors radioactive material at the surface before disposal; and

(2) determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding;

(3) removes or obliterates all radiation labels, except for radiation label on materials that are within containers and that will be managed as biomedical waste after they have released from the licensee.

B. A licensee shall retain a record of each disposal permitted under 4731.1206, subp. 4, A. in accordance with 4731.1214, subp. 3, E.

Subp 5. **Installation, maintenance, and repair for therapeutic medical devices**

A. Only a person specifically licensed by the commissioner, the NRC, or 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) driving 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 commissioner, the NRC, or an agreement state 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, a person specifically licensed by the commissioner, the NRC or an agreement state 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 of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 4731.1214, subp. 4, G.

4731.1207 Training for Certain Medical Procedures

Subpart 1 **Training for uptake, dilution, and excretion studies.** Except as provided in 4731.0152, subp. 8, the licensee shall require the authorized user of unsealed radioactive material for the uses authorized under 4731.1212, subp. 1, to be a physician who:

A. Is certified by a medical speciality board whose certification process includes all of the requirements in 4731.1207, subp. 1, C, and whose certification has been recognized by the commissioner, NRC or an agreement state; or

B. Is an authorized user under 4731.1207, subpart 2 or subpart 3, or equivalent NRC or agreement state requirements; or

C. Training and experience

(1) has completed 60 hours of training and experience 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 in 4731,1207, subparts 1, 2, and 3, or equivalent NRC or agreement state requirements, involving:

((1)) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

((2)) calibrating instruments used to determine the activity of

dosages and performing checks for proper operation of survey meters;

((3)) ~~calibrating~~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 of radioactive drugs to patients or human research subjects; and

(2) has obtained written certification, signed by a preceptor authorized user, that the requirements in 4731.1207, subpart 1, 2 or 3, or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 4731.1207, subp. 1, C, (1) above, and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized in 4731.1212, subp. 1;

Subp 2. **Training for Imaging and localization studies.** Except as provided in 4731.0152, subp. 8, the licensee shall require the authorized user of unsealed radioactive materials for the uses authorized under 4731.1212, subp. 2, to be a physician who:

A. Is certified by a medical specialty board whose certification process includes all of the requirements in 4731.1207, subp. 2, C, below, and whose certification has been recognized by the commissioner, NRC, or an agreement state; or

B. Is an authorized user under 4731.1207, subp. 3, or NRC, equivalent agreement state requirements; or

C. Training and experience

(1) has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for the 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 materials for medical use;

((5)) radiation biology; and

(b) work experience, under the supervision of an authorized user, who meets the requirements in 4731.1207, subparts 2 and 3, or equivalent NRC or agreement state requirements, involving:

((1)) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

((2)) calibrating dose instruments used 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 safely 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 certification, signed by a preceptor authorized user, that the requirements in 4731.1207, subparts 2 and 3, or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 4731.1207, subp. 2, C, (1), above and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authoroized in 4731.1212, subparts 1 and 2.

Subp 3. **Training for use of unsealed radioactive material for which a written directive is required.** Except as provided in 4731.0152, subp 8, the licensee shall require the authorized user of unsealed radioactive material for the uses authorized under 4731.1212,subp. 4, to be a physician who:

A. Is certified by a medical specialty board whose certification process includes all of the requirements in 4731.1207, subp. 3, B, below, and whose certification has been recognized by the commissioner, NRC, or an agreement state; or

B. Training and experience

(1) has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive 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; and

((4)) chemistry of radioactive materials for medical use; and

((5)) radiation biology; and

(b) work experience, under the supervision of an authorized user who meets the requirements in 4731.1207, subp. 3, A, 4731.1207, subp. 3, B, or equivalent NRC, or agreement state requirements. A supervising authorized user, who meets the requirements of 4731.1207, subp.3, B, must have experience in administering dosages in the same dosage category or categories, i.e. 4731. 1207, subp. 3, B, (2[redacted]), (g[redacted]), ((1)), ((2)), ((3)), and ((4)), 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)) calibrating 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 radioactive material;

((5)) using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

((6)) eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

((7)) administering dosages of radioactive drugs to patients or human research subjects involving 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 33 millicuries (1.22 GBq) of sodium iodide (I-131);

((b)) oral administration of greater than 33 millicuries (1.22 GBq) of sodium iodide (I-131). Experience with at least 3 cases in 4731.1207, subp. 3, B, (2), (g [redacted]), ((2)), also satisfies the requirement in category 4731.1207, subp. 3, B, (2), (g[redacted]), ((1)), above;

((c)) parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

((d)) parenteral administration of any other radionuclide; and

(2) has obtained written certification that the individual has satisfactorily completed the requirements in 4731.1207, subp. 3, B, above, and has achieved a level of competency sufficient to function independently as an authorized user for the medical users authorized under 4731.1212, subp. 4. The written certification must be signed by a preceptor authorized user who meets the requirements of 4731.1207, subp. 3, A, or 4731.1207, subp. 3, B, or equivalent NRC or agreement state requirements. The preceptor authorized user, who meets the requirements in 4731.1207, subp. 3, B, must have experience in administering dosages in the same dosage category or categories , i.e., 4731.1207, subp. 3, B, (2),(g[redacted]), ((1)), ((2)), ((3)), or ((4)), as the individual requesting authorized user status.

Subp 4 **Training for use of manual brachytherapy sources.** Except as provided in 4731.0152, subp. 8, the licensee shall require the authorized user of a manual brachytherapy source for the uses authorized under 4731.1213, subp. 1, to be a physician who:

A. Is certified by a medical specialty board whose certification process includes all of the requirements in 4731.1207, subp. 4, B, below, and whose certification has been recognized by the commissioner, NRC or an agreement state; or

B. Training and experience

(1) has completed a structured educational program in basic radionuclide handling techniques applicable to the use of ~~annual~~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;

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 4731.1207, subp. 4, or equivalent NRC or agreement state requirements at a medical institution, involving:

((1)) ordering, receiving, and unpacking radioactive materials safely and preforming 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 radioactive material;

((6)) using emergency procedures to control radioactive material; and

(2) has obtained three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 4731.1207, subp. 4, or equivalent NRC or agreement state 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 Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 4731.1207, subp. 4, B, (1), (b); and

(3) has obtained written certification, signed by a preceptor authorized user who meets the requirements in 4731.1207, subp. 4 or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 4731.1207, subp. 4, B, (1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 4731.1213, subp. 1.

Subp 5. **Training for use of sealed sources for diagnosis.** Except as provided in 4731.0152, subp. 8, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under in 4731.1211, subp. 1, to be a physician, dentist, or podiatrist who:

A. Is certified by a speciality board whose certification process includes all of the requirements in 4731.1207, subp. 5, B, below, whose certification has been recognized by the commissioner, NRC, or an agreement state.

B. Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

(1) radiation physics and instrumentation;

(2) radiation protection;

(3) mathematics pertaining to the use and measurement of radioactivity;

(4) radiation biology; and
(5) training in the use of the device for the uses requested.

Subp 6. Reserved
Subp 7 Reserved
Subp 8 Reserved
Subp 9 Reserved
Subp 10. Reserved

Subp 11 **Training for Ophthalmic use of strontium-90.** Except as provided in 4731.0152, subp. 8, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

A. Is an authorized user under 4731.1207, subp. 4, or equivalent NRC or agreement state requirements; or

B. Training and experience:

(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;
(d) mathematics pertaining to the use and measurement of radioactivity; and
(e) radiation biology;

(2) supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

(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 certification, signed by a preceptor authorized user who meets the requirements in 4731.1207, subp. 4, 4731.1207, subp.11, or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 4731.1207, subp. 11, A and B, above, and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Subp. 12. **Training for the Oral Administration of Sodium Iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 MBq).** Except as provided in 4731.0152, subp. 8, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries(1.22 MBq), to be physician who:

A. Is certified by a medical speciality board who certification process includes all of the requirements in 4731.1207, subp. 12, C, below, and whose certification has been recognized by the commissioner, or NRC or an agreement state; or

B. Is an authorized user under 4731.1207, subp.3, A, 4731.1207, subp. 3, B, for uses listed

in 4731.1207, subp. 3, B, (2), (g), ((1)) or ((2)), or 4731.1207, subp. 13, or equivalent NRC or agreement state requirements; or

C. Training

(1) has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for purposes 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 radiioactivity;

(d) chemistry of radioactive materials for medical use; and

(e) radiation biology; and

(2) has work experience, under the supervision of an authorized user who meets the requirements in 4731.1207, subp. 3, A, 4731.1207, subp. 3, B, 4731.1207, subp. 12, 4731.1207, subp. 13, or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 4731.1207, subp. 3, B, (2), (g), ((1)) or ((2)). The work experience must involve:

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

(b) calibrating instruments used to determine the activity of dosages and performing checks for the proper operation for 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 radioactive materials;

(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 3 cases involving the oral administration of less than or equal to 33 millicuries (1.22 MBq) of sodium iodide I-131; and

(3) has obtained written certification that the individual has satisfactorily completed the requirements in 4731.1207, subp.12, C, (1) and (2) and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 4731.1212, subp. 4. The written certification must be signed by a preceptor authorized user who meets the requirements in 4731.1207, subp. 3, 4731.1207, subp. 3, B, 4731.1207, subp12, 4731.1207, subp. 13 or equivalent NRC or agreement state requirements. A preceptor authorized user, who meets the requirement in 4731.1207, subp. 3, B, must have experience in administering dosages as specified in 4731.1207, subp. B (2), (g), ((1 or ((2)).

Subp. 13 **Training for the Oral Administration of Sodium Iodide (I-131) requiring a written directive in quantities greater than 33 mMillicuries(1.22 ~~MBq~~GBq).** Except as provided in ~~4731~~4731.0152, subp. 8, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 ~~MBq~~GBq), to be a physician who:

A. Is certified by a medical speciality board who certification process includes all of the requirements in 4731.1207, subp. 13, C, below, and whose certification has been recognized by the commissioner, NRC or an agreement state; or

B. Is an authorized user under 4731.1207, subp. 3, A, 4731.1207, subp. 3, B, for uses listed in 4731.1207, B, (2), (g), ((2)), or equivalent NRC or agreement state requirements; or

C. Training and experience:

(1) has successfully completed 80 hours of 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 materials for medical use; and

(e) radiation biology; and

(2) has work experience, under the supervision of an authorized user who meets the requirements in 4731.1207, subp. 3, A, 4731.1207, subp. 3, B, 4731.1207, subp. 13, or equivalent NRC or agreement state requirements. A supervising authorized user, who meets the requirements in 4731.1207, subp. 3, B, must have experience in administering dosages as specified in 4731.1207, subp. 3, B, (2), (g), ((2)). The work experience must involve:

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

(b) calibrating instruments used to determine the activity of dosages and performing checks for proper operation for 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 radioactive materials;

(e) using procedures to contain spilled radioactive materials safely and using proper decontamination procedures; and

(f) administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 33 millicuries (1.22 ~~MBq~~GBq) of sodium iodide I-131; and

(3) has obtained written certification that the individual has satisfactorily completed the requirements in 4731.1207, subp.13, C, (1) and (2) and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 4731.1212, subp. 4. The written certification must be signed by a preceptor authorized user who meets the requirements in 4731.1207, subp. 3, A, 4731.1207, subp. 3, B, 4731.1207, subp. 13, or equivalent NRC or agreement state requirements. A preceptor authorized user, who meets the requirements in 4731.1207, subp. 3, B, must have experience in administering dosages as specified in 4731.1207, subp. 3, B, (2), (g), ((2)).

Subp. 14 **Training for use of remote afterloaders units, teletherapy units, and gamma stereotactic radiosurgery units.** Except as provided in 4731.0152, subp. 8, the licensee shall

require an authorized user of a sealed source for a use authorized under 4731.1211, subp. 3, to be a physician who:

A. Is certified by a medical specialty board whose certification process includes all of the requirements in 4731.1207, subp. 14, B, below, and whose certificatioin has been recognized by the commissioner, NRC, or an agreement state; or

B. Training and experience.

(1) has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed soruce in a therapeutic medical unit 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 of work experience, under the supervision of an authorized user who meets the requirements in 4731.1207, subp. 14, or equivalent NRC or agreement state requirements at a medical institution, 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 materials;

((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 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 4731.1207, subp. 14, or equivalent NRC or agreement state 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 of the Committee on Postdoctural Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 4731.1207, subp. 14, B, (1), (b); and

(3) has obtained written certification that the individual has satisfactorily completed the requirements in 4731.1207, subp. 14, b, (1) and (2), 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 authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in 4731.1207, subp. 14 or equivalent NRC or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

4731.1208 Possession and Maintenance of Instruments.

Subpart 1. **Possession, use, and calibration of instruments used to measure the activity of unsealed radioactive material.**

A. For direct measurements performed in accordance with 4731.1208,subp. 4, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

B. A licensee shall calibrate the instrumentation required in 4731.1208, subp. 1, A, above, in accordance with the nationally recognized standards or the manufacturer's instructions.

C. A licensee must retain a record of each instrument calibration required in 4731.1208, subp.1, in accordance with 4731.1214, subp. 4, A.

Subp 2. **Calibration of survey instruments**

A. A licensee must calibrate the survey instruments used to show compliance with this part and 4731.0132, before first use, annually and following repair. A licensee must:

(1) calibrate all scales with readings up to 1000 mrem (10 mSv) per hour with a radiation source;

(2) calibrate two separate readings on each scale that will be used to show compliance with this part; and

(3) conspicuously note on the instrument the date of calibration.

B. A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent. exposure rate differs from the calculated exposure rate by more than 10 percent.

C. A licensee must retain a record of each survey instrument calibration in accordance with 4731.1214, subp. 4, B.

Subp 3. Reserved

Subp 4, **Determination of dosages of unsealed radioactive material for medical use**

A. A licensee must determine and record the activity of each dosage before medical use.

B. For a unit dosage, this determination must be made by;

(1) direct measurement of radioactivity; or

(2) a decay correction, based on the activity or activity concentration determined by;

(a) a manufacturer or preparer licensed pursuant to 4731.0311, subp. 9, or equivalent NRC, or agreement state requirements; or

(b) a commissioner, NRC, or an agreement state licensee for use in research in accordance with the Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

C. For other than unit dosages, this determination must be made by:

(1) direct measurement of radioactivity;

(2) combination of measurement of radioactivity and mathematical calculations; or

(3) combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under 4731.0311, subp. 9, or

equivalent NRC, or agreement state requirements.

D. Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

E. A licensee must retain a record of the dosage determination required by 4731.1214, subp. 3, A.

Subp 5. **Authorization for calibration, transmission, and reference sources.** Any person authorized by 4731.1201, subp. 1, for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, transmission and reference use:

A. Sealed sources, that do not exceed 30 mCi (1.11 GBq) each, manufactured and distributed by a person licensed pursuant to 4731.0311, subp. 10, or equivalent NRC or agreement state regulations

B. Sealed sources, that do not exceed 30 mCi (1.11 GBq) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under 4731.0311, subp 10 providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

C. Any radioactive material with a half-life of not longer than 120 days in individual amounts not to exceed the smaller of ~~200Ci~~200 μCi (7.4 MBq) or 1000 times the quantities in 4731.3001, C.

D. Technetium-99m in amounts as needed.

Subp 6 **Requirements for possession of sealed sources and brachytherapy sources.**

A. A licensee in possession of any sealed source or brachytherapy source must follow the radiation safety and handling instructions supplied by the manufacturer.

B. A licensee in possession of a sealed source must:

(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 6 months before transfer to the licensee; and

(2) test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the commissioner, NRC, or an agreement state in the Sealed Source and Device Registry.

C. To satisfy the leak test requirements in 4731.1208, subp, 6 B, above, the licensee must measure the sample so that the leakage test can detect the presence of 0.005 microcuries (185 Bq) of radioactive material on the sample.

D. A licensee must retain leakage test records in accordance with 4731.1214, subp. 3, B,

E. If the leakage test reveals the presence of 0.005 Microcuries (185 Bq) or more of removable contamination, the licensee must:

(1) immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with 4731.0134, subp. 1, C; and

(2) notify the commissioner immediately and file a report within 30 days of the leakage test in accordance with 4731. 0162, subp. 1.

F. A licensee need not perform a leakage test on the following sources:

(1) sources containing only radioactive material with a half-life of less than 30 days;

(2) sources containing only radioactive material as a gas;

(3) sources containing 100 ~~Ci~~ μCi (3.7 MBq) oe less of beta or gamma-emitting materuial or 10 ~~Ci~~ μCi (0.37 MBq) or less of alpha-emitting material;

(4) seeds of iridium-192 encased in nylon ribbon; and

(5) sources stored and not being used. The licensee must, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within 6 months before the date of use or transfer.

G. A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, must conduct a semi-annual physical inventory of all such sources in the licensee's possession. The licensee must retain each inventory record in accordance with 4731.1214, subp. 3, B.

Subp 7. **Dosimetry equipment for therapeutic medical devices**

A. Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee must have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) the system must have been calibrated:

(a) using a source or system traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies or by a calibration laboratory accredited by the American Association of Physicist in Medicine (AAPM)

(b) within the previous 2 years, and

(c) after any servicing that may have affected system calibration; or

(2) the system must have been calibrated within the previous 4 years; 18-30 months after that calibration,

(a) the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM.

(b) the results of the innercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2%.

(c) the licensee may not use the intercomparison result to change the calibration factor.

(d) when intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic devices, the licensee must use a comparable unit with beam attenuator or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

B. The licensee must have a dosimetry system available for spot-check measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with 4731.1208, subp. 7, A, above. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in

4731.1208, subp. 7, A.

C. The licensee must retain a record of each calibration, intercomparison, and comparison in accordance with 4731. 1214, subp. 4, A.

4731.1209 Calibration of Therapeutic Medical Devices

Subpart 1. **Full calibration measurements on teletherapy units.**

A. A licensee authorized to use a teletherapy unit for medical use must perform full calibration measurements on each teletherapy unit:

(1) before the first medical use of the unit; and

(2) before medical use under the following conditions:

(a) whenever spot-check measurements indicate that the output differs by more than 5 % from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(c) following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(d) at intervals not exceeding 1 year.

B. To satisfy the requirement of 4731.1209, subp. 1, A, above, full calibration measurements must include determination of:

(1) the output within +/- 3% for the range of field sizes and for the distance or range of distances used for medial use;

(2) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) the uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) timer accuracy and linearity over the range of use;

(5) on-off error; and

(6) the accuracy of all distance measuring and localization devices in medical use.

C. A licensee must use the dosimetry system described in 4731.1208, subp. 7, A, to measure the output for one set of exposure conditions. The remaining radiation measurements required in 4731.1209, subp. 1, B, (1), may be made using a dosimetry system that indicates relative dose rates.

D. A licensee must make full calibration measurements required by 4731.1209, subp. 1, A, above, in accordance with published protocols approved by nationally recognized bodies.

E. A licenses must mathematically correct the outputs determined in 4731.1209, subp. 1, B, (1), for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 % decay for all other nuclides.

F. Full calibration measurements required by 4731.1209, subp. 1, A, and physical decay corrections required by 4731.1209, subp. 1, E, must be performed by the authorized medical physicist.

G. A licensee must retain a record of each calibration in accordance with 4731.1214, subp. 4, E.

Subp 2. **Full calibration measurements on remote afterloader units.**

A. A licensee authorized to use a remote afterloader for medical use must perform full calibration measurements on each unit:

(1) before the first medical use of the unit;

(2) before medical use under the following conditions:

(a) following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(b) following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly, and

(3) at intervals not exceeding 1 quarter for high dose-rate, mediumdose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) at intervals not exceeding 1 year for low dose-rate remote afterloader units.

B. To satisfy the requirement of 4731.1209, subp. 2, A, above, full calibration measurements must include, as applicable, determination of:

(1) the output within 5%;

(2) source positioning accuracy to within 1 millimeter;

(3) source retraction with backup battery upon power failure; and

(4) length of the source transfer tubes;

(5) timer accuracy and linearity over the typical range of use;

(6) length of the applicators; and

(7) function of the source transfer tubes, applicators, and transfer tube-applicator ~~surfaces~~interfaces.

C. A licensee shall use the dosimetry system described in 4731.1208, subp. 7, A to measure the output.

D. A licensee shall make full calibration measurements required by 4731.1209, subp. 2, A, above, in accordance with published protocols accepted by nationally recognized bodies.

E. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in 4731.1209, subp. 2, B, above, a licensee shall perform an autoradiograph of the source(s) to verify inventory ane source(s) arrangement at intervals not exceeding 1 quarter.

F. For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 4731.1209, subp. 2, A through E, above.

G. A licenses must mathematically correct the outputs determined in 4731. 1209, subp. 2, B, (1), above, for physical decay at intervals consistent with 1 % physical decay.

H. Full calibration measurements required by 4731.1209, subp. 2, A, above, and physical decay corrections required by 4731.1209, subp. 2, G, above, must be performed by the authorized medical physicist.

I. A licensee must retain a record of each calibration in accordance with 4731.1214, subp. 4, E.

Subp 3. **Full calibration measurements of gamma stereotactic radiosurgery units.**

A. A licensee authorized to use a gamma stererotactic radiosurgery

unit for medical use must perform full calibration measurements on each unit:

(1) before the first medical use of the unit;

(2) before medical use under the following conditions:

(a) whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(b) following replacement of the sources or following reinstallations of the gamma stereotactic radiosurgery unit in a new location; and

(c) following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) at intervals not exceeding 1 year with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

B. To satisfy the requirement of 4731.1209, subp. 3, A, above, full calibration measurements must include determination of:

(1) the output within 3%;

(2) relative helmet factors;

(3) isocenter coincidence;

(4) timer accuracy and linearity over the range of use;

(5) on-off error;

(6) trunnion centricity;

(7) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) helmet microswitches;

(9) emergency timing circuits; and

(10) stereotactic frames and localization devices (trunnions).

C. A licensee must use the dosimetry system described in 4731.1208, subp. 7, A, to measure the output for one set of exposure conditions. The remaining radiation measurements required in 4731.1209, subp. 3, B, (1), above, may be made using a dosimetry systems that indicates relative dose rates.

D. A licensee must make full calibration measurements required by 4731.1209, subp. 3, A, in accordance with published protocols accepted by national recognized bodies.

E. A licensee must mathematically correct the outputs determined in 4731.1209, subp. 3, B, (1), at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1% physical decay for all other radionuclides.

F. Full calibration measurements required by 4731.1209, subp. 3, A, and physical decay corrections required by 4731.1209, subp. 3, E, above, must be performed by the authorized medical physicist.

G. A licensee must retain a record of each calibration in accordance with 4731.1214, subp. 4, E.

Subp 4. **Calibration measurements of brachytherapy sources.**

A. Before the first medical use of a brachytherapy source on or after October 24,2002, a licensee must have:

(1) determined the source output or activity using a dosimetry system that meets the requirements of 4731.1208, subp. 7, A;

(2) determined source positioning accuracy within applicators; and

(3) used published protocols curently accepted by nationally recognized bodies to meet the requirements of 4731.1209, subp. 4, A, (1) and (2), above.

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 4731.1209, subp. 4, A, above.

C. A licensee must mathematically correct the outputs or activities determined in 4731.1209, subp. 4, A, above, for physical decay at intervals consistent with 1 percent physical decay.

D. A licensee must retain a record of each calibration in accordance with 4731.1214, subp. 4, D.

4731.1210 Periodic Spot-checks for Therapeutic Medical Devices

Subpart 1. **Periodic spot-checks for teletherapy units**

A. A licensee authorized to use teletherapy units for medical use must perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(1) timer constancy, and timer linearity over the range of use;

(2) on-off error;

(3) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) the accuracy of all distance measuring and localization devices used for medical use;

(5) the output for one typical set of operating conditions measured with the dosimetry system described in 4731.1208, subp. 7, B; and

(6) the difference between the measurement made in 4731.1210, subp. 1, A, (5), the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at least full calibration corrected mathematically for physical decay).

B. A licensee must perform measurements required by 4731.1210, subp. 1, A, in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

C. A licensee must have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist must promptly notify the licensee in writing of the results of each spot-check.

D. A licensee authorized to use a teletherapy unit for medial use must perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

(1) electrical interlocks at each teletherapy room entrance;

(2) electrical or mechanical stops installed for the purpose of limiting

use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) viewing and intercom systems;

(5) treatment room doors form inside and outside the treatment room; and

(6) electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

E. If the results of the checks required in 4731.1210, subp. 1, D, indicate the malfunction of any system, a licensee must lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

F. A licensee must retain a record of each spot-check required by 4731.1210, subp. 1, A and D, in accordance with 4731.1214, subp. 5, C.

Subp 2. **Periodic spot-checks for remote afterloader units.**

A. A licensee authorized to use remote afterloader unit for medical use must perform spot-checks on each unit:

(1) before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day ;

(2) before each patient treatment with a low dose-rate remote afterloader unit; and

(3) after each source installation.

B. A licensee shall perform the measurements required by 4731.1210, subp. 2, A, in accordance with written procedures established by the authorised medical physicist. That individual need not actually perform the spot-check measurement

C. A licensee must have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of the spot-check..

D. To satisfy the requirements of 4731.1210, subp. 2, A, spot-checks must, at a minimum, assure proper operation of:

(1) electrical interlocks at each remote afterloader unit room entrance;

(2) source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) emergency response equipment;

(5) radiation monitors used to indicate the source position;

(6) timer accuracy; and

(7) clock time, date and time, in the unit's computer; and

(8) decayed source(s) activity in the unit's computer.

E. If the results of the checks required in 4731.1210, subp. 2, D, indicate the malfunction of any system, a licensee must lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

F. A licensee must retain a record of each check required by 4731.1210, subp. 2, D, and

a copy of the procedures required by 4731.1210, subp. 2, in accordance with 4731.1214, subp. 5, B.

Subp 3. Reserved

Subp 4. **Periodic spot-checks for gamma stereotactic radiosurgery units**

A. A licensee authorized to use gamma stereotactic radiosurgery units for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

(1) monthly,

(2) before the first use of the unit on a given day; and

(3) after each source installation.

B. The licensee must:

(1) perform the measurements required by 4731.1210, subp. 4, A, above, in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements; and

(2) have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist mst notify the licensee as soon as possible in writing of the results of each spot-check .

C. To satisfy the requirements of 4731.1210, subp. 4, A, (1), spot-checks must, at a minimum:

(1) assure proper operation of:

(a) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(b) helmet microswitches;

(c) emergency timing circuits; and

(d) stereotactic frames and localizing devices (trunnions)

(2) determine:

(a) the output for one typical set of operating conditions measure with the dosimetry system described in 4731.1208, subp. 8, B;

(b) the difference between the measurement made in 4731.1210, subp. 4, C, (2), (a), and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(c) source output against computer calculation;

(d) timer accuracy and linearity over the range of use;

(e) on-off error; and

(f) trunnion centricity

D. To satisfy the requirements of 4731.1210, subp. 4, A, (2) and (3), spot-checks must assure proper operation of:

(1) electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) source exposure indicator lights on the gamma stereotactoic radiosurgery unit, on the control console, and in the facility;

(3) viewing and intercom systems;

(4) timer termination;

(5) radiation monitors used to indicate room exposures; and

(6) emergency off buttons.

E. A licensee must arrange for repair of any system identified in 4731.1210, subp. 4, C, that is not operating properly as soon as possible.

F. If the results of the checks required in 4731.1210, subp. 4, D, indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

G. A licensee must retain a record of each check required by 4731.1210, subp. 4, C and D, in accordance with 4731.1214, subp. 5, C.

Subp 5, **Additional Technical requirements for mobile remote afterloaders.**

A. A licensee providing mobile remote afterloader service must:

(1) check survey instruments before medical use at each address of use or on each day of use, which ever is more frequent; and

(2) account for all sources before departure from a client's address of use.

B. In addition to the periodic spot-checks required by 4731.1210, subp. 2, a licensee authorized to use mobile afterloaders for medical use must perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

(1) electrical interlocks on treatment area access points;

(2) source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) viewing and intercom systems;

(4) applicators, source transfer tubes, and transfer-applicator interfaces;

(5) radiation monitors used to indicate room exposures;

(6) source positioning (accuracy); and

(7) radiation monitors used to indicate whether the source has returned to a safe shielded position.

C. In addition to the requirements for checks in 4731.1210, subp. 5, B, a licensee must ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

D. If the results of the checks required in 4731.1210, subp. 5, B, above, indicate the malfunction of any system, a license shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

E. A licensee must retain a record of each check required by 4731.1210, subp. 5, B, in accordance with 4731.1214, subp. 6, A.

4731.1211 Use of Sealed Sources for Medical Applications

Subpart 1. **Use of sealed sources for diagnosis.** A licensee must use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

Subp 2. **Suppliers for sealed sources or devices for medical use.** For medical use, a licensee may use only:

A. Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 4731.0300- 4731.0320, and 4731.0311, subp. 10, or equivalent requirements of NRC or an agreement state;

B. Sealed sources or devices noncommercially transferred from a commissioner's medical use licensee; or

C. Teletherapy sources manufactured and distributed in accordance with a license issued under 4731.3000-4731.3020, or equivalent requirements of NRC or an agreement state.

Subp 3 **Use of a sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit.** A licensee must use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapuetic medical uses:

A. As approved in the Sealed source and Device Registry; or

B. In research in accordance with an active Investigational Device Exemption(IDE) application accepted by the FDA provided the requirements of 4731.1211, subp. 2, A.

Subp. 4. **Decay of strontium-90 sources for ophthalmic treatments.**

A. 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 under 4731.1209, subp. 4.

B. A licensee shall obtain a record of the activity of each strontium-90 source in accordance with 4731.1214, subp. 4, H.

4731.1212 Use of Unsealed Sources for Medical Applications

Subpart 1. **Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required.** Except for quantities that require a written directive under 4731.1202,subp. 6, a licensee may use any unsealed radioactive material, including NARM, prepared for medical use for uptake, dilution, or excretion studies that is:

A. Obtained from a manufacturer or preparer licensed pursuant to 4731.0311, subp. 9, equivalent NRC ~~or~~, agreement state or equivalent state requirements; or

B. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 4731.1207, subparts 2 and 3, or an individual under the supervision of either as specified in 4731.1202, subp 4.

C. Obtained from and prepared for a commissioner's, NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or in Investigational New Drug(IND) protocol accepted by FDA; or

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

Subp 2 **Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required.** Except for quantities that require a written directive under 4731.1202, subp.6, B, a licensee may use any unsealed radioactive material prepared for medical

use for imaging and localization studies that is:

A. Obtained from a manufacturer or preparer licensed pursuant to 4731.0311, subp. 9, or equivalent NRC or agreement state requirements; or

B. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 4731.1207, subparts 2 or 3, or an individual under the supervision of either as specified in 4731.1202, subp. 4.

C. Obtained from and prepared by a commissioner's , NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug(IND) accepted by the FDA; or

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

Subp 3. **Permissible molybdenum-99 concentration**

A. A licensee may not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobequerel of molybdenum-99 per megabecquerel of technetium-99m).

B. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with 4731.1212, subp. 3, A.

C. If a licensee that is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with 4731.1214, subp. 3, D.

Subp 4. **Use of unsealed radioactive material for which a written directive is required.** A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

A. Obtained from a manufacturer or preparer licensed pursuant to 4731.0311, subp. 9; or equivalent NRC or agreement state requirements; or

B. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 4731.1207, subparts 2 and 3, or an individual under the supervision of either as specified in 4731.1202, subp. 4.

C. Obtained from and prepared by the commissioner's, NRC or agreement state licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by the FDA; or

D. Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by the FDA.

4731.1213 Brachytherapy

Subpart 1. **Use of sources for manual brachytherapy.** A licensee must use only brachytherapy sources for therapeutic medical uses :

A. As approved in the Sealed Source and Device Registry; or

B. In research in accordance with an active Investigational Device exemption (IDE) application accepted by the FDA provided the requirements of 4731.1211, subp. 2 are met.

Subp 2. **Surveys of patients or human research subjects after source implant and removal.**

A. Immediately after implanting sources in a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject and the room of use to confirm that no sources have been misplaced.

B. Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

C. A licensee must retain a record of patient or human research subject surveys in accordance with 4731.1214, subp. 2, B

Subp 3. **Brachytherapy sources acountability**

A. A licensee must maintain accountability at all times for all brachytherapy sources in storage or use.

B. As soon as possible after removing sources from a patient or a human research subject, a licensee must return brachytherapy sources to a secure storage area.

C. A licensee must maintain a record of the brachytherapy source accountability in accordance with 4731.1214, subp. 3, C.

4731.1214 Records

Subpart 1. **Administrative records**

A. Records of mobile medical services.

(1) a licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address of use, in accordance with 4731.1206, subp. 3, A, (1) . Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 4 years after the last provision of service or until the commissioner's inspection.

(2) a licensee shall retain the record of each survey required by 4731.1206, subp. 3, A, (4), for four years or until the next inspection. The record must include:

(a) the date of the survey;
(b) the results of the survey
(c) the instrument used to make the survey; and
(d) the name of the individual who performed the survey.

B. Records of safety instruction. A licensee shall maintain a record of instructions and training required by 4731.1203, subparts 2, 4, and 6, for four years or until the next inspection by the commissioner. The record must include:

(1) a list of the topics covered;
(2) the date of the instruction;
(3) the names(s) of the attendee(s); and
(4) the name(s) of the individual(s) who provided the instruction.

C. 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 4731.1202, subp. 1, A, for 5 years. The record must include a summary of the

actions taken and a signature of licensee management.

(2) the licensee shall retain a current copy of the authorities, duties, and responsibilities of the Radiation Safety Officer, as required in 4731.1202, subp. 1, E , and a signed copy of the radiation safety officer's willingness to be responsible for implementing the radiation safety program, as required by 4731.1202, subp. 1, B. The records must include the signature of the radiation safety officer and licensee management.

D. Records of radiation protection program changes. A licensee shall retain a record of each radiation protection program change made in accordance with 4731.1202, subp. 2, A, for 5 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.

E. Records of written directives. A licensee shall retain a copy of each written directive as required by 4731.1202, subp. 6, for 4 years or until the next commissioner's inspection.

F. Reserved

G. Reserved

H. Records for procedures for administrations requiring a written directive. A licensee shall retain a copy of the procedures required by 4731.1202, subp. 7, A for the duration of the license.

Subp 2 **Survey records**

A. reserved

B. Records of the release of individuals containing unsealed radioactive materials or implants containing radioactive material.

(1) a licensee shall retain a record in accordance with 4731.1204, subp. 2, that describes the bases for authorizing the release of individuals 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 1 meter
(c) using the biological or effective half-life; or
(d) considering the shielding by tissue.

(2) a licensee shall retain a record that the instructions required by 4731.1204, subp. 2, B, were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could results in a total effective dose equivalent exceeding 0.5 rem (5mSv).

(3) a licensee shall retain records of the release of individuals containing pharmaceuticals or implants in accordance with 4731.1214, subp. 2, B, (1) and (2), for four years after the date of release and until the next inspection by the commissioner

C. Records of surveys after source implant and removal. A licensee must maintain a record of the surveys required by 4731.1204, subparts 2 and 3 for 4 years or until the next inspection by the commissioner. 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.

Subp 3. **Records of radioactive material**

A. Records of dosages of unsealed radioactive material for medical use

(1) a licensee shall maintain a record of dosage determinations required by 4731.1208, subp. 4, for 4 years or until the next inspection by the commissioner.

(2) the record must contain:

(a) radiopharmaceutical;

(b) patient's or human research subject's name or identification number if one has been assigned;

(c) prescribed dosage, the determined dosage, or a notation that the total activity is less than 30 ~~curies~~μcuries (1.1 MBq);

(d) date and time of the dosage determination; and

(e) name of the individual who determined the dosage.

B. Records of leaks tests and inventory of sealed sources and brachytherapy sources

(1) a licensee shall retain records of leak tests required by 4731.1208, subp. 6, B, for 4 years or until the next inspection. The records 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 measured activity of each test sample, a description of the method used to measure each test sample, the date of the test, and the name of the individual who performed the test.

(2) a licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 4731.1208, subp. 6, G, for 4 years or until the next inspection. The inventory records must contain the model number of each source, and the 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.

C. Records of brachytherapy source accountability.

(1) a licensee shall maintain a record of brachytherapy source accountability required by 4731.1213, subp. 3, for four years or until the next inspection.

(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 returned to storage, 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 form 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 not implanted, 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.

D. Records of molybdenum-99 concentrations. A licensee shall maintain a record of the molybdenum-99 concentration tests required by 4731.1212, subp. 3, B, for four years or until the next inspection. The record must include for each measured elution of technetium-99m:

(1) the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (or kilobecquerel of molybdenum per megabecquerel of technitium-99;

(2) the time and date of the measurement; and

(3) the name of the individual who made the measurement.

E. Records of decay-in-storage. A licensee shall maintain records of the disposal of licensed materials made in accordance with 4731.1206, subp. 4, for 4 years or until the next inspection. The record must include:

(1) the date of the disposal;
(2) the radionuclides disposed;
(3) the survey instrument used;
(4) the background dose rate;
(5) the dose rate measured at the surface of each waste container; and
(6) the name of the individual who performed the disposal.

Subp 4. **Calibration records**

A. Records of instrument calibrations. A licensee shall maintain a record of instrument calibrations required by 4731.1208, subp. 1, for 4 years or until the next inspection by the commissioner. The records must include the model and serial numbers of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

B. Records of radiation survey instrument calibrations. A licensee shall maintain a record of radiation survey instrument calibrations required by 4731.1208, subp. 2, for 4 years, or until the next inspection. 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.

C. Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(1) a licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 4731.1208, subp. 7, 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 4731.1208, subp. 7, 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 name(s) of the individual(s) who performed the calibration, intercomparison, or comparison.

D. Records of calibration measurements of brachytherapy sources.

(1) a licensee shall maintain a record of the full calibrations on brachytherapy sources required by 4731.1209, subp. 4, for four years after the last use of the source.

(2) the records must include:

(a) the date of the calibration;
(b) the manufacturer's name;
(c) model number;

(d) serial number for the source and instruments used to calibrate the source; the source output; source positioning accuracy within applicators; and

(e) the signature of the authorized medical physicist

E. Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

(1) a license shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by 4731.1209, subparts 1, 2, and 3, for four years or until the next inspection by the commissioner..

(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, ane gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit(s);

(c) the results and an assessment 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.

F. Reserved

G. Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery unit. 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 4731.1206, subp. 5, for 4 years or until the next inspection by the commissioner. 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.

H. Records of decay of strontium-90 sources for ophthmalic treatments.

(1) a licensee shall maintain a record of the activity of a strontium-90 source required by 4731.1211, subp. 4, for the life of the source.

(2) the record must include:

(a) the date and initial activity of the source as determined under 4731.1209, subp. 4; and

(b) for each decay calculation, the date and the source activity as determined under 4731.1211, subp.4.

Subp 5. **Spot check records**

A. 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 4731.1210, subp. 1, for four years or until the next inspection.

(2) the record must include:

(a) the date of the spot-check;

(b) the manufacturer's name;

(c) model number;

(d) serial number for the teletherapy unit, source;

(e) instruments used to measure the output of the teletherapy unit;

(f) an assessment of time linearity and constancy;

(g) the calculated on-off error;

(h) a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(i) the determined accuracy of each distance measuring and localization device;

(j) the difference between the anticipated output and the measured output;

(k) 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

(l) the name of the individual who performed the periodic spot-check; and

(m) the signature of the authorized medical physicist who reviewed the record of the spot-check.

(3) a licensee must retain a copy of the procedures required by 1210. Subp. 1, B, until the licensee no longer possesses the teletherapy unit.

B. 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 4731.1210, subparts 2 and 3, for four years or until the next inspection.

(2) the record must include:

(a) the date of the spot-check;

(b) the manufacturer's name;

(c) model number and serial number for the remote afterloader unit, source, and instrument used to measure the output of the remote afterloader unit;

(d) an assessment of timer accuracy;

(e) notations indicating the operability of each entrance door electrical interlock, source retraction mechanism, radiation monitors, source exposure indicator lights, viewing and intercom systems ~~is~~, and clock and decayed source activity in the unit's computer; if applicable;

(f) the name of the individual who performed the periodic spot-check; and

(g) the signature of the authorized medical physicist who reviewed the record of the spot-check

C. 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 4731.1210, subp. 4, for four years or until the next inspection.

(2). The record must include:

(a) the date of the spot-check;

(b) the manufacturer's name;

(c) model number and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(d) an assessment of timer linearity and accuracy;

(e) the calculated on-off error;

(f) a determination of trunnion centricity;

(g) the difference between the anticipated output and the measured output;

(h) an assessment of source output against computer calculations;

(i) notations indicating the operability of radiation monitors, helmet microswitches, 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

(j) 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.

(3) a licensee must retain a copy of the procedures required by 4731.1210, subp 2, 4, until the licensee no longer possess the gamma stereotactic radiosurgey unit.

Subp 6. **Retention of inspection records for selected procedures**

A. Records of additional technical requirements for mobile remote afterloaders

(1) a licensee shall retain a record of each check for mobile remote afterloaders required by 4731.1210, subp. 5, for four years or until the next inspection by the commissioner.

(2) the record must include:

(a) the date of the check;

(b) the manufacturer's name;

(c) model number or remote afterloader;

(d) serial number of the remote afterloader;

(e) notations accounting for all sources before the licensee departs from a facility;

(f) notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(g) the signature of the individual who performed the check.

B. Records of surveys of therapeutic treatment units.

(1) a licensee shall maintain a record of radiation surveys of treatment units made in accordance with 4731.1205, subp..1, for the duration of use of the unit.

(2) the record must include:

(a) the date of the measurements;

(b) the manufacturer's name;

(c) model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(d) each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(e) the signature of the individual who performed the test.

C. Records of 5-year inspection for teletherapy and gamma stereotactic surgery units.

(1) a licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by 4731.1205, subp. 2, for the duration of use of the unit.

(2) the record must contain:

(a) the inspector's radioactive material license number
(b) the date of inspection;
(c) the manufacturer's name;
(d) model number of both the treatment unit and source;
(e) serial number of both the treatment unit and source;
(f) a list of components inspected and serviced, and the type of service; and
(g) the signature of the inspector.

D. Records of safety procedures. The licensee shall retain a copy of the procedures required by 4731.1203, subp. 6, A,(4), and D, (2), until the licensee no longer possesses the remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

X-ray and General Licensed Device Provisions

4731.1300 Registrant's Safety Requirements

Subpart 1. **Registrant responsibility.** The registrant is responsible for directing the operation of all x-ray and accelerator systems under the registrant's administrative control.

A. The registrant or the registrant's agent must ensure that the requirements specified in this part are met in the operation of all diagnostic and therapeutic x-ray systems and medical accelerators.

B. The registrant or the registrant's agent must ensure that the requirements in 4731.1300 subpart 2, 4731.0130, subparts 1 and 3, and 4731.0137 are met in the operation of all industrial x-ray systems and non-medical accelerators.

C. The registrant must supply the personnel with individual personnel monitoring dosimeters and require the personnel to wear the dosimeter in accordance with 4731.0130.

Subp. 2. **X-ray system and accelerator compliance.** An x-ray system or accelerator that does not meet the provisions of this chapter shall not be operated for diagnostic, therapeutic, or industrial purposes.

Subp. 3. **Individuals who may apply radiation.** Only those individuals who are licensed practitioners of the healing arts or individuals who have successfully passed an examination specified in parts 4731.0150 subpart 2 through subpart 5, may intentionally apply radiation to an individual.

Subp. 4. **Procedure and safety instruction.** All individuals who operate an x-ray system shall be initially instructed and annually retrained in facility-specific and system-specific safe operating procedures, emergency procedures for malfunctioning equipment, and quality assurance procedures. Written safety procedures for the facility and x-ray systems shall be provided by the registrant to the individuals specified in subpart 3 including:

A. Information on the effects of radiation exposure to the human body and the embryo-fetus;
B. Projections where holding devices cannot be used; and
C. Any restrictions of the operating technique required for the safe operation of the particular

x-ray system.

D. All x-ray operators must be instructed as to the proper placement, size and type of gonad shielding to be used. Documentation of the instruction must be retained for review by the commissioner.

Subp. 5. **Radiographic technique chart.** A radiographic technique chart shall be provided in the vicinity of the x-ray system's control panel which specifies, for all examinations performed with that system, the following information:

A. The patient's anatomical size and corresponding technique factors to be used;

B. The type of the screen-film combination, or direct exposure x-ray film for dental intraoral radiography, to be used;

C. The grid focal distance and the grid ratio to be used, if any;

D. The source-to-image distance to be used; and

E. For automatic exposure control (AEC) or phototimed units, the percent differences between the AEC increments.

For computed tomography systems, a current technique chart for each routine examination, and the computed tomography conditions of operation must be provided.

Subp. 6. **Exposure of individuals other than the patient.** All radiographic procedures and therapeutic x-ray procedures must meet the requirements of this subpart.

A. Except for the patient, only the staff and ancillary personnel required for the medical, dental, and veterinary medicine procedure or training shall be in the room during the radiographic exposure.

B. All staff and ancillary personnel required for assistance with the radiographic procedures shall be positioned so no part of the body, including the hands, will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent material.

C. All staff and ancillary personnel who must remain in the room to assist during radiographic, fluoroscopic, portable, or computed tomography procedures must be protected from scattered radiation by protective aprons or whole body protective barriers of not less than 0.5 millimeter lead equivalence.

D. Patients and individuals who are not involved in diagnostic radiographic procedures or demonstrations using either stationary or portable x-ray equipment, who cannot leave the room and who cannot be protected by adequate distance for the exam being performed must be protected from scattered radiation by protective lead aprons or whole body protective barriers of at least 0.25 millimeters lead equivalence.

E. During any radiographic or fluoroscopic exposure, any door which is part of the protective barrier must be closed.

F. No individual other than the patient shall be in a therapy treatment room during exposures from a therapeutic x-ray system operating above 50 kVp.

G. Thyroid and eyes must be protected if the potential exposure to the worker would exceed 10 percent of the dose limits listed in part 4731.0124 through 4731.0125.

Subp. 7. **Gonad protection.** Except for cases in which it would interfere with the diagnostic

procedure, during radiographic procedures in which the gonads are in or within two inches (5cm) of the useful beam, gonad shielding of not less than 0.5 millimeter lead equivalence must be used for patients who have procreative potential.

Subp. 8. **Holding**. When a patient, film cassette, or intraoral film must be provided with auxiliary support during a radiation exposure, items A to E apply.

A. Mechanical holding devices shall be used when the technique permits.

B. Written safety procedures, as required by 4731.1300, subpart 4, must indicate the requirements for selecting the individual holding and the procedure that individual shall follow.

C. The human holder must be protected as required by 4731.1300, subpart 6.

D. No individual shall be used routinely to hold intraoral film, film cassettes, or patients.

E. In those cases where the patient must hold the film cassette, any portion of the body, other than the area of clinical interest struck by the useful beam, shall be protected by not less than 0.5 millimeter lead equivalent material.

F. If a patient must be held in position during therapeutic x-ray treatment, mechanical supporting or restraining devices shall be used.

Subp. 9. **Prevention of unauthorized use**. Therapy x-ray systems shall not be left unattended unless they are secured against unauthorized use.

Subp. 10. **Facility design requirements**. The registrant must ensure that the applicable structural shielding requirements specified in 4731.0137 through 4731.0141 are met.
If an analysis of operating conditions indicates the possibility of an individual receiving a dose over the limits in 4731.0124 through 4731.0126 , the commissioner may require that structural shielding modifications be made.

4731.1301 Radiological Practice Standards.

Subpart 1. **Procedures and auxiliary equipment** designed to minimize patient and personnel exposure commensurate with ALARA to achieve the needed diagnostic information shall be used.

A. The speed of screen-film combinations, or direct exposure x-ray film in intraoral dental radiography, shall be the fastest speed consistent with the diagnostic objective of the examinations.

B. Intensifying screens shall be used in combination with the compatible film, with the exception of dental intraoral films and radiation therapy port films.

C. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

D. Protective aprons and gloves shall be monitored annually for lead protection integrity. A record of the monitoring shall be maintained until the next inspection by the commissioner.

E. Viewboxes must be kept clean and be of uniform intensity. Bulbs must be of the same color. Luminance of the viewboxes located where films are checked for quality must be similar to those located where radiographs are interpreted.

F. Portable x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x-ray system.

G. Radiographic systems subject to 4731.1301, subp. 2, other than fluoroscopic, dental intraoral, and dental panoramic systems must not be used in procedures where the source-to-skin distance is less than 30 centimeters (11.8 inches), except as described in 4731.1301.

Subp. 2. **Darkroom standards.**

A. The darkroom for film development must be free of extraneous light so fog is not added to film during handling and processing.

B. Darkroom safelight filters must be compatible with the films being processed.

C. The darkroom for film development must be tested for film fog:

(1) at least every six months;

(2) any time fog is suspected;

(3) whenever there is a change in film speed;

(4) at time of change of a safelight bulb or filters;

(5) any time the integrity of any seal around the processor, other equipment, or the darkroom may have been compromised.

D. The amount of fog (increase in optical density) for a two-minute fog test must not exceed 0.05 for facilities doing mammographic film development and 0.08 for all other radiographic film development.

E. Film processing must meet the following requirements:

(1) all film must be processed to achieve optimal sensitometric performance;

(2) the film manufacturer's published recommendations for processing time and temperature must be followed;

(3) chemicals must be mixed according to the chemical manufacturer's recommendations;

(4) the daily sensitometry must be charted, reviewed, and corrective action taken, if necessary, before patients' films are processed; and

(5) all radiographs must be free of artifacts that could cause a misinterpretation.

F. The darkroom fog test and sensitometry must, at a minimum, be performed on the film most sensitive to light and processor changes

4731.1302 Ordering of Radiographic Examinations. The registrant shall be responsible for ensuring that the following requirements on ordering radiographic or fluoroscopic examinations are met except when the radiographic examination is part of a healing arts screening program approved by the commissioner.

A. The order for a radiographic examination can be made only by a physician, dentist, veterinarian, chiropractor, podiatrist, or osteopath. A physician assistant, or registered physician assistant must show eligibility to order radiographic procedures through a written delegation agreement.

B. The radiographic provider must not carry out a radiographic procedure ordered by a physician assistant, or registered physician assistant unless a copy of a written delegation agreement is on file with the facility.

C. The order for a radiographic procedure must include clearly stated clinical indications for the examination and be available to procedure personnel at the time of the examination.

4731.1303 Required Quality Assurance Program

Subpart 1. **Applicability.** Each registrant conducting radiographic, fluoroscopic or therapeutic x-ray procedures must implement a site-specific quality assurance program which includes:

A. A quality assurance manual that contains written policies and procedures for radiation protection and describes the quality assurance program;

B. The equipment performance tests specified in 4731.1308 - 4731.1311;

(1) The quality assurance manual described in this subpart must include the required tests and the minimum performance criteria specified in 4731.1308 - 4731.1311 for the registrant's radiographic or therapeutic equipment and processing equipment. The registrant is not limited to the equipment performance tests required in 4731.1308 - 4731.1311 but may also include tests from item C. The registrant is required to meet the minimum performance criteria specified in 4731.1308 - 4731.1311, when applicable..

B. The manual must specify the minimum frequency of equipment performance tests. In addition, the tests must be done after any change in the facility or equipment which might cause an increase in radiation hazard or a change in equipment that results in the minimum performance criteria not being met.

C. Radiation safety surveys as specified in 4731.0132 subparts 1 and 3;

D. Calibrations as required in 4731.1304;

E. In-service education for employees as specified in 4731.0151;

F. The numeric results of equipment performance tests and the correction of any deficiencies as specified in the quality assurance manual; and

G. The calibration record of any electronic equipment used in the equipment performance tests within the preceding two years. The calibration of any electronic equipment must be in accordance with 4731.0133, subpart 1.

H. The records required in 4731.0169, subp. 5. The facility must retain records showing the correction of any deficiencies until the next inspection by the commissioner.

In addition to items A to H, each registrant with therapeutic x-ray equipment must also make spot checks as specified in 4731.1306. Accelerators used in medical settings must have separate equipment performance procedures as specified in 4731.0900 - 4731.0907.

Subp. 2. **The registrant and the registrant's employees** must be familiar with the contents and recommendations of any of the following applicable publications:

A. NCRP report 99, "Quality Assurance for Diagnostic Imaging Equipment," (December 30, 1988);

B. "Quality Assurance Program for Diagnostic Radiology Facilities," by Roger L. Burkhart, Ph.D., United States Department of Health, Education and Welfare, public health service, food and drug administration, publication number 80-8110 (February 1980);

C. "A Basic Quality Assurance Program for Small Radiology Facilities," by Roger L. Burkhart, Ph.D., United States Department of Health, Education and Welfare, public health service, food and drug administration, publication number 83-8215 (1983).

The registrant may incorporate portions of the publications specified in this subpart into the facility's quality assurance manual described in subpart 1, item A. The publications are available at

the Biomedical Library of the University of Minnesota, Minneapolis, Minnesota, or through the Minitex interlibrary loan system.

4731.1304 Calibrations for Diagnostic Radiographic Systems
The registrant must ensure that calibrations are performed on a diagnostic radiographic system whenever that system does not meet the minimum performance criteria specified in 4731.1308 and when there is any change or replacement of components which could cause a change in the radiation output of that system.

4731.1305 Calibrations for Therapeutic X-ray Systems
Subpart 1. **Calibrations for therapeutic x-ray systems of less than 1.0 MeV.** Each registrant operating a therapeutic x-ray system of less than 1.0 MeV must ensure that the calibrations specified in this subpart are performed.

A. The calibration of the radiation output of a therapeutic x-ray system must be performed:

(1) at intervals not to exceed 12 months;

(2) after any change or replacement of components which could cause a change in the radiation output; and

(3) with a calibrated dosimetry system. The calibration of the dosimeter must be traceable to its calibration standard at the National Institute of Standards and Technology (NIST). Verification of the dosimeter calibration must be performed every two years.

B. The calibration and beam characteristics of the therapeutic x-ray system must include, but not be limited to:

(1) dose rate as a function of field size, technique factors, filter, and treatment distance used;

(2) the degree of congruence between the radiation field and the field indicated by the localizing device if the device is present;

(3) an evaluation of the uniformity of the largest radiation field used;

(4) verification of the applicability of the inverse square law;

(5) verification of the accuracy of any source-to-skin distance (SSD) indicators;

(6) evaluation of timer or end effects; and

(7) verification of half value layer (HVL).

C. A copy of the current therapeutic x-ray system's dosimetry data must be available.

Subp. 2. **Calibrations for therapeutic x-ray systems greater than 1.0 MV.** Each registrant operating a therapeutic x-ray system of greater than 1.0 MV must ensure that the calibrations specified in this subpart are performed.

A. The calibration of systems subject to 4731.1310 must be performed according to protocols TG-21 and TG-25 endorsed by the American Association of Physicists in Medicine. The protocol known as TG-21 is titled "A Protocol for the Determination of Absorbed Dose from High Energy Photon and Electron Beams" and TG-25 is titled "Clinical Electron-Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group No. 25." The protocols are published in American Association of Physicists in Medicine, Medical Physics, volume 10, number 6, pages 741 to 771 (1983) and volume 18, number 1, pages 73 to 102 (1991). The TG-21 protocol and the TG-25 protocol are incorporated by

reference and are available at the Biomedical Library of the University of Minnesota, Minneapolis, Minnesota, or through the Minitex interlibrary loan system. The protocols are not subject to frequent change. The calibration protocol must be performed:

(1) before the system is first used for the irradiation of a patient;

(2) at time intervals which do not exceed 12 months; and

(3) after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.

B. Calibration radiation measurements required by item A must be performed using a dosimetry system traceable to its calibration standard at the National Institute of Standards and Technology (NIST). The dosimetry system must:

(1) have a calibration factor for cobalt-60 gamma rays traceable to a standard maintained by the National Institute of Standards and Technology (NIST);

(2) have a calibration which has been verified every two years by an Accredited Dosimetry Calibration Laboratory (ADCL) or by intercomparison with another dosimetry system that has been calibrated by an ADCL within two years;

(3) be calibrated after any servicing that may have affected its calibration; and

(4) have constancy checks as specified in 4731.1311, subp.3.

C. The documentation of each therapy beam must include, but not be limited to, the following determinations:

(1) verification that the equipment is operating in compliance with the design specifications for the light localizer, all readouts, the optical distance indicator, laser and cross-hairs alignment with the isocenter (when applicable), radiation isocenter variation with collimator, gantry and table support rotation, beam flatness, and symmetry at a specified depth;

(2) the variation with field size of the absorbed dose rate at a reference depth in-phantom (or air) as a fraction of its value for the field size used to determine the calibration as specified in 4731.1305, subp. 2;

(3) the uniformity of the radiation field and any dependency on the direction of the useful beam;

(4) verification that existing depth-dose data and isodose charts applicable to the specific system continue to be valid or are updated to existing system conditions; and

(5) verification of transmission for all accessories such as wedges, block trays, and compensators.

D. A copy of the most recent beam data must be available.

4731.1306 Therapeutic X-ray System Spot Checks of Calibration

Subpart 1. **Spot checks of calibration for therapeutic x-ray systems of less than 1.0 MV.** The registrant must ensure that spot checks of calibration are performed on therapeutic x-ray systems. Spot checks must be performed at a minimum frequency of every six months and meet the requirements specified in this subpart.

A. Spot-check procedures must be in writing, must be maintained in the facility in accordance with 4731.1306, and must be available to the commissioner on request.

B. Parameters exceeding the tolerance specified in4731.1311 must be corrected to within the tolerance specified before the system is used for patient irradiation.

C. Whenever a spot check indicates a change in the operating level of a system which exceeds the minimum tolerance level specified in 4731.1311, the system must be recalibrated as required in 4731.1320.

D. Items to be spot checked include those calibrations and beam characteristics in 4731.1320.

Subp. 2. **Spot checks of calibration for therapeutic x-ray systems greater than 1.0 MV.** The registrant must ensure that spot checks of calibration are performed on systems subject to 4731.1306 during calibrations and at intervals not to exceed one month. Spot checks must meet the requirements specified in items A to G:

A. Spot-check procedures must be in writing.

B. The spot-check procedures must specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

C. At intervals not to exceed one month, spot checks must be made of absorbed dose measurements at a minimum of two depths in a phantom.

D. Where a system has built-in devices that provide a measurement of any parameter during irradiation, the measurement must not be used as a spot-check measurement.

E. A parameter exceeding a tolerance level specified in 4731.1311 must be corrected to within the tolerance level before the system is used for patient irradiation.

F. Whenever a spot check indicates a change in the tolerance level of a system which exceeds the minimum tolerance level as specified in 4731.1311, the system must be recalibrated as required in 4731.1321.

G. Where a spot check involves a radiation measurement, the measurement must be obtained using a dosimetry system satisfying the requirements of 4731.1305 subp. 2.

4731.1307 Computed Tomography (CT) Equipment Performance Measurements and Calibrations. This part applies to computed tomography facilities and must be done in addition to the requirements in 4731.1307. The registrant must ensure that the equipment performance measurements and calibration procedures specified in this part are performed and they include:

Subpart 1. **General equipment performance measurements and calibration procedures:**

A. Those measurements and calibration procedures must be in writing and are specified in 4731.1307 for CT scanners at the frequency specified and those aspects of processing at the frequency specified. In addition, the equipment performance measurements and calibration procedures must be done after any change in the facility or equipment which might cause an increase in radiation hazard or a change in equipment that results in the minimum performance criteria not being met.

B. The computed tomography dose index in the two positions in 4731.1308, subp.8, item D. The CT dosimetry phantom must be oriented so that the measurement point of 1.0 centimeter beneath the surface is in the angular location where the computed tomography dose index is maximum. For the purpose of determining the computed tomography dose index, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be used.

C. The procedures specified in 4731.1308, subp 8.

D. Radiation output measurements.

(1) measurements of radiation output from a computed tomography x-ray system must be performed as specified in 4731.1308, subp. 8 and after any change or replacement of components which could cause a change in the radiation output.

(2) the measurement of the radiation output of the computed tomography x-ray system must be performed with a calibrated dosimetry system. The dosimetry system must have been calibrated within the preceding two years. The calibration of the dosimetry system must be in accordance with 4731.0133.

(3) computed tomography dosimetry phantoms must be used in determining the radiation output of the computed tomography x-ray system. The phantoms must comply with Code of Federal Regulations, title 21, section 1020.33.

(a) all dose measurements must be performed with the computed tomography dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(b) computed tomography dosimetry phantoms must provide a means for the placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.

(c) any effects on the doses measured due to the removal of phantom material to accommodate dosimeters must be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(4) the dose measurements must be made for the head and body technique used at the facility. The image quality measurements must be made using a typical clinical technique in the head and body scan modes of operation.

Subp. 2 **Additional C.T. operator equipment performance measurements.** In addition to the equipment performance measurements described in subpart 1, the equipment performance measurements specified in items A and B must be performed by an operator.

A. The operator's computed tomography equipment performance procedures must be those with the monthly or daily frequencies in 4731.1308, subp. 8, and include all processing procedures noted in 4731.1308.

B. The registrant or radiation safety officer must review and initial all of the operator's equipment performance measurements at least quarterly. An operator's equipment performance measurements must include acquisition of images obtained with the CT dosimetry phantoms using the same processing mode and CT conditions of operation as are used to perform the equipment performance measurements required by subpart 1.

4731.1308 Diagnostic Equipment Performance Tests for Quality Assurance Program.
Subpart 1. **Frequency of tests.** The tests in subparts 1a to 12 are to be made at the time of installation and at the specified intervals thereafter.

Subp. 1a. Image receptors.

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Screen-film contact	Annually	No significant areas of poor contact as measured by 8 wires/inch copper mesh, or 7 holes/inch for regular film and 40 wires/inch copper mesh for mammography
B. Screen-film-cassette	Annually	Densities within speed match ± 0.10 O.D. for all cassettes used for each diagnostic task

Subp. 2. **Automatic processing.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Darkroom fog	Semi-annually	< 0.08 O.D. increase in density (measured at approximately 1.00 O.D.) after 2 minutes using film exposed on-site at the time of test. For mammography the O.D. increase must be < 0.05
B. Sensitometry and densitometry	Before processing first film	Density ± 0.15 O.D. using film exposed on-site at time of the day of test. As of July 1, 1993, veterinary facilities are not required to perform this test
C. Temperature check	At the time of sensitometry	Follow manufacturer's recommendations

Subp. 3. **Manual processing.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA

A. Darkroom fog	Semi-annually	< 0.08 O.D. increase in density (measured at approximately 1.00 O.D.) after 2 minutes using film exposed on-site at time of test
B. Sensitometry and densitometry	Before processing first film of the day	Density ± 0.15 O.D. using film exposed on-site at time of test. As of July 1, 1993, veterinary facilities are not required to perform this test
C. Temperature check	Before processing each batch of film	Follow manufacturer's time and temperature chart

Subp. 4. **All diagnostic radiographic tubes; required when applicable.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. SID accuracy	Biennially	± 2% of measured value
B. X-ray and light field alignment	Biennially	± 2% of SID any one direction, ±3% of SID, both directions (total)
C. X-ray and image receptor alignment	Biennially	± 2% of SID
D. Collimator dial accuracy	Biennially	± 2% of SID
E. Reproducibility	Biennially	Coefficient of variation < 5%
F. mR/mAs	Biennially	±10% of baseline
G. Linearity	Biennially	± 10% over clinical range

H. Linearity-for mAs only units manufactured after May 3, 1994	Biennially	Average ratios of exposure to the indicated mAs obtained in any two consecutive mAs settings shall not differ by more than 0.10 times their sum, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.
I. Timer accuracy	Biennially	Single Phase: use Table 4730.1692 or ± 10% of setting. Three phase, high frequency, and constant potential: use ± 5% of selected time when measured > than 100 milliseconds. At times shorter than 100 milliseconds, use manufacturers' specifications.
J. Half-value layer	Biennially	Use part 4731.1313, subp 6, item A
K. kVp accuracy	Biennially	± 5% of indicated kVp for noncertified equipment. For certified equipment follow manufacturer's specified limits
L. Phototimer reproducibility, if present	Biennially	± 5% of average exposure
M. AEC (phototimer) increments	Biennially	± 10% of manufacturer's stated increments
N. Illuminance of certified collimator	Biennially	> 15 footcandles

O. Film density vs. thickness change on AEC	Biennially	± 0.30 O.D. of the averaged exposures over the range specified by the manufacturer
P. Film density vs. kVp change on AEC	Biennially	± 0.30 O.D. of the averaged exposures when measured at > 1.2 O.D. and over the range as specified by the manufacturer
Q. Spot film reproducibility (fluoro units with manual mode)	Annually	± 5% of average exposure
R. Phototimer back-up timer cut off	At time of installation	terminates exposure at < 600 mAs
S. AEC density at normal or "0"	Biennially	> 1.0 O.D.

Subp. 5. **For facilities with fluoroscopes and C-arm fluoroscopes, except radiation therapy simulators, manufactured before May 19, 1995.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Maximum output at tabletop or equivalent minimum SSD	Annually and every tube change	< 5 R (1.3 mC kg-1) per minute for manual; < 10 R (2.6 mC kg-1) per minute for Automatic Exposure Rate Control systems
B. High level control maximum output at tabletop or equiva-	Annually and every tube change	< 20 R (5.0 mC kg-1) per minute

lent minimum SSD		
C. Fluoroscopic image size	Annually and every tube change	Error between fluorographic beam size and observed image size must be no more than ±3% of SID for all modes and at any tower height
D. Actual spot-film size vs indicated	Annually	Error between actual fluorographic beam size at image receptor and indicated image size must be no more than ± 3% of SID for all modes and at any tower height
E. Spot-film reproducibility	Annually	±5% of average exposure
F. Phototimer reproducibility, if present	Annually	±5% of average exposure
G. Fluoroscopic high contrast resolution and distortion	Annually	15 centimeter (six inch) intensifier: center 30 and edge 24 (wires per inch) copper mesh; 23 centimeter (nine inch) intensifier: center 24 and edge 20 (wires per inch) copper mesh
H. Half-value layer	Annually and after every tube change	Use part 4731.1313, subp. 6, item A
I. kVp accuracy	Annually and after every tube change	± 5% for noncertified equipment. For certified equipment follow manufacturer's specified limits.

Subp. 5a **For facilities with fluoroscopes and C-arm fluoroscopes, except radiation therapy simulators, manufactured on or after May 19, 1995.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Maximum output at tabletop or equivalent minimum SSD	Annually and at every tube change	> 5 R/min must have Automatic Exposure Rate Control; > 10 R/min must have high level control; if no high level control maximum is < 10 R/min.
B. High level control maximum output at tabletop or equivalent minimum SSD	Annually and at every tube change	< 20 R/min
C. All other tests as indicated in subpart 5		

Subp. 6. **For facilities with mammography systems. All tests on mammographic units must follow the Mammography Quality Standards Act of 1992, United States Code, title 42, section 263b, and regulations adopted thereunder.**

Subp. 7. **For facilities with tomography systems other than computed tomography.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Section level	Annually	± 5 mm
B. Level incrementation	Annually	± 2 mm
C. Section thickness	Annually	Follow manufacturer's specifications
D. All tests in part 4730.1691, subpart 4, if applicable		

E. Spatial plane resolution	Annually	40 mesh screen or better

Subp. 8. **For facilities with computed tomography scanners.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Accuracy of scout localization view	Annually	± 1 mm
B. Accuracy of distance measurements	Annually	± 1 mm
C. CT dose index	Annually	± 20% from manufacturer's recommendations
D. CT number dependence on slice thickness	Annually	Mean ±3 CT numbers averaged over 100 pixels
E. CT number calibration and noise	Daily	Water: 0 ± 5 CT numbers; Noise: ± 3 standard deviations of the mean of the baseline noise variance measurements
F. CT number uniformity and artifacts	Monthly for mobile units. Annually for fixed base units	Variation ±5 CT numbers between the mean values of measurements made at center and edge of phantom that is at least 20 cm. in diameter among a mean of 100 pixels. Artifacts: no noticeable artifacts
G. Hard copy output and visual display	Daily	Luminance and contrast not significantly different.

Subp. 9. **For facilities with cinefluorographic and special procedure systems.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Cinefluorographic exposure rates	Annually	Approximately 10 to 20 μR (2.6 to 5.0 nC/kg) per frame at intensifier for nine inch (23 cm) mode; approximately 20 to 30μR (5 to 8 nC/kg) per frame at intensifier for six inch (15 cm) mode
B. All tests in subparts 4, 5, and 5a, if applicable		
C. Film changer screen-film contact	Annually	No significant areas of poor contact as measured by 8 wires/inch copper mesh or 7 holes/ inch
D. High contrast resolution for cinefluorographic and digital systems	Annually	No significant difference between static and dynamic conditions
E. Optical density of films over duration of filming run	Annually	<± 0.2 O.D. difference

Subp. 10. **For facilities with dental intraoral systems.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Film processing	Before the first film of the day	Between 0.75 and 1.05 O.D. on the test tool or follow test tool manufacturer's

		recommendations
B. Filtration (HVL)	Biennially	Use part 4731.1313, subp 6, item A
C. Radiation exposure at end of cone	Biennially	Use part 4731.1315, subp4, item C
D. Timer reproducibility and accuracy	Biennially	± 10% of indicated timer setting
E. kVp accuracy	Biennially	± 5% of indicated kVp for noncertified equipment. For certified equipment follow manufacturer's specified limits
F. Reproducibility	Biennially	Coefficient of variation < 5%
G. Fog test	Semi-annually	Use criteria in subp2, item A for automatic processing; subp 3, item A for manual processing
H. Dental mA linearity	Biennially	± 10% over the clinical range

Subp. 11. **For facilities with dental extraoral systems including panoramic systems.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Film processing		Use automatic and manual processing as specified in subparts 2 and 3. A step wedge may be used in place of the sensitometry and

		densitometry test in subparts 2, item B, and 3, item B
B. Same test types and minimum performance criteria as Diagnostic Radiographic Tubes in subpart 4		
C. Fog test	Semi-annually	Use criteria in subp 2, item A for automatic processing; subp 3, item A for manual processing

4731.1309 Exposure Time Control Limits for Single Phase Full-wave Rectified Generators.

Exposure time (seconds)	Acceptance limits
1/5	24±1 dot
1/10	12±1 dot
1/20	6±0 dots
1/30	4±0 dots

Note: when using a spinning top, the x-ray pulses are imaged as dots on the film as the small hole in the top is moved rapidly (rotated) over the film. Source: National Council on Radiation Protection, Report No. 99, Table 7.3, December 30, 1988.

4731.1310 Therapy Equipment Performance Tests and Limits for Measurement Equipment.

Subpart 1. **Local standard (Loc. Std.).**

TEST	MINIMUM TEST INTERVAL	TOLERANCE
A. AAPM - accredited Dosimetry calibration Laboratory calibration	Every two years	D
B. Linearity	Every four years	0.5 percent
C. Venting	Every four years	D
D. Extracameral signal	Initial use	0.5 percent

E. Leakage	Each use	0.1 percent
F. Recombination	Initial use	Documented
G. Collecting potential	Each use	D

Subp. 2. **Other field instruments.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Local standard comparison	Every 2 years	one percent
B. Linearity	Every two years	D
C. Venting	Every two years	D
D. Extracameral signal	Every two years	D
E. Leakage	Each use	0.1 percent
F. Recombination	Initial use	Documented
G. Collecting potential	Each use	D

Subp. 3. **Relative dosimetric equipment.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Thermoluminescent	Dosimeter	
(1) Calibration	Each batch or box	D
(2) Linearity	Initial use	D
B. Film		
(1) Dose and response	Each batch or box	D
(2) Densitometer linearity	Every year	D
C. Air Ionization Chamber system		
(1) Linearity	Every year	D
(2) Extracameral signal	Initial use	1 percent

D. Diode System		
(1) Energy dependence	Initial use	D
(2) Extracameral signal	Initial use	D
(3) Linearity	Initial use	D

Subp. 4. **Survey instruments.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Calibration	Every year	D
B. Linearity	Every year	D
C. Constancy	Each use	5 percent
D. Battery voltage	Each use	D

Subp. 5. **Positioning equipment.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Accuracy	Each use	2 mm
B. Hysteresis	Each use	2 mm

Subp. 6. **Phantoms and attenuators.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Thickness	Initial use	D
B. Density	Initial use	D
C. Phantom stacked density	Initial use	D
D. Detector fit	Initial use	D

Subp. 7. **Accessory equipment.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Thermometer		
(1) Calibration	Initial use	0.1 degree/C
B. Barometer (mercury)		
(1) Calibration Hg	Initial use	1 mm Hg

C. Barometer (aneroid)		
(1) Calibration Hg	Initial use	1 mm Hg
(2) Intercomparison	Annually	1 mm Hg

D = Documented and correction applied or noted in report of measurement, when appropriate.

Source: Derived from American Association of Physicists in Medicine, Report No. 13, Table I, pp. 21-22, 1984 and TG-40, Medical Physics, volume 21, number 4, Tables I, II, and IV, pages 581 to 618 (1994).

4731. 1311 Equipment Performance Tests For External Beam Teletherapy and Simulation Systems.

Subpart 1. **Dosimetry.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. General axis dose calibration	Annually	2 percent
B. Constancy checks-photons		
(1) Dose per monitor unit along central axis	Weekly	3 percent
(2) Depth dose	Monthly	2 percent
(3) Beam uniformity	Monthly	3 percent
(4) Monitor chamber linearity	Annually	1 percent
(5) Timer linearity and error	Annually	1 percent

Subp. 2. **Geometry.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Field positioning aids		
(1) Light field and radiation field agreement	Monthly	2 mm
(2) Mechanical distance pins, lasers, and SSD lights	Monthly	2 mm
(3) Scale readouts		2 mm/1 degree angle

B. Machine alignment		
(1) Jaw symmetry	Annually	2 mm
(2) Coincidence of collimator (jaw) and gantry axes with isocenter	Annually	2 mm
(3) Stability of gantry arm and bearing under rotation	Annually	2 mm
(4) Couch motion and tabletop sag	Annually	2 mm

Subp. 3. **Constancy checks-electrons.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Beam uniformity	Monthly	5 percent
B. Depth dose	Monthly	2 mm at therapeutic depth
C. Dose per monitor unit constancy check	Weekly	3 percent

Subp. 4. **Treatment accessories.** *

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Wedge transmission factor	Annually	2 percent
B. Transmission factor constancy for all treatment accessories	Annually	2 percent

Subp. 5. **Simulators.**

TEST TYPE	FREQUENCY	TOLERANCE
A. Localizing lasers	Daily	2 mm
B. Distance indicator	Daily	2 mm

C. Field size indicator	Monthly	2 mm
D. Gantry/collimator angle indicators	Monthly	1 degree
E. Cross-hair centering	Monthly	2 mm diameter
F. Focal spot-axis indicator	Monthly	2 mm
G. Fluoroscopic image quality	Monthly	Established baseline
H. Collision avoidance	Monthly	Functional
I. Light/radiation field coincidence	Monthly	2 mm or 1 percent
J. Collimator rotation isocenter	Annual	2 mm diameter
K. Gantry rotation isocenter	Annual	2 mm diameter
L. Couch rotation isocenter	Annual	2 mm diameter
M. Coincidence of collimator, gantry, couch axes, and isocenter	Annual	2 mm diameter
N. Table top sag	Annual	2 mm
O. Vertical travel of couch	Annual	2 mm
P. Exposure rate	Annual	Established baseline
Q. Table top exposure with fluoroscopy	Annual	Established baseline
R. Kvp and mAs calibration	Annual	Established baseline
S. High and low contrast resolution	Annual	Established baseline

* Attenuation in blocks, wedge factors, and compensator data must be checked annually. A visual inspection of the mechanical integrity of these accessories must be done monthly.

Source: Derived from American Association of Physicists in Medicine, Report No. 13, Table II, page 29 (1984) and TG-40, Medical Physics, volume 21, number 4, Tables I, II, III, and IV, pages 581 to 618 (1994).

4731.1312 Healing Arts Screening

Subpart 1. **General Requirements.** Any person who desires to perform diagnostic x-ray screening in Minnesota must seek commissioner approval before x-ray screening may proceed. All

applicants must meet the requirements specified in 4731.0100 - 4731.1315 and 4731.1318 - 4731.1319. In addition:

A. All applicants must be registered with the commissioner before application for screening is initiated; and

B. The registrant must submit an application to the commissioner requesting permission to perform diagnostic x-ray screening.

Subp. 2. **Content of application.** In the application for screening the registrant must:

A. Provide his or her business name and address. If the registrant is a corporation or other business or nonbusiness association, the name of the person and phone number representing the association must be given.

B. Give the location of the proposed screening and the name and telephone number of a contact person at each location.

C. State the purpose of the proposed screening program planned. The purpose must include a detailed statement specifying the compelling health reasons, health benefits, and health emergency, if any, that justifies the radiation exposure to which any individual will be subjected by the proposed screening.

D. Explain why alternate screening methods that do not require the use of radiation are not being used.

E. Name all practitioners of the healing arts who will interpret the radiographic images.

F. Name all individuals responsible for making the exposures of the patients during the screening process.

G. State the proposed interval for which permission to perform screening is requested.

H. List the radiographic projections or views being proposed in the screening program.

I. Specify the x-ray equipment to be used in connection with the proposed x-ray screening.

J. Describe the retention or disposition of the images and other records pertaining to the screening x-ray examinations after the screening project is completed.

K. Describe the population to be examined in the screening program, including age, sex, physical condition and any criteria to determine correct patient population.

L. Provide exposure measurements of the exposure at skin entrance (ESE) and specific organ doses, for the type of screening proposed. These exposures must be consistent with those produced with state-of-the-art techniques. If no guidelines are available for exposure measurements, the commissioner may request peer review to establish such guidelines.

M. Provide a written evaluation of the radiation safety survey and the quality assurance program as required by 4731.0132; 4731.0169, subp.6; 4731.1300; 4731.1304; and 4731.1308. This must have been performed within three months prior to the application.

N. Any individual screened must be personally informed by the registrant of the results, interpretation, or findings. The screening application must:

(1) describe how this information will be communicated to the individual who has been screened;

(2) describe where the results, interpretation, or findings will be sent; and

(3) describe what arrangements will be made to ensure that the individual who has been screened will be informed as to the need for further medical and health care evaluation or

treatment.

Subp. 3. **Additional information.** The commissioner may request the submission of additional information and data subsequent to the submission of the original or renewal application.

Subp. 4. **Notification of commissioner's decision.** The registrant shall be notified in writing of the commissioner's decision. If an application is granted, the notification shall specify the time, not to exceed one year, for which the application will be effective.

Subp. 5. **Changes in screening program.** The registrant is responsible for informing the commissioner of any changes in the screening program from that which was described in the content of the application in subpart 2. The registrant must obtain commissioner approval of the changes before the commencement of the requested changes in the screening program.

Subp. 6. **Denial of approval.** The commissioner may deny or revoke approval of any healing arts screening program if the registrant fails to or refuses to comply with this chapter.

Subp. 7. **Appeal procedure.** The registrant may appeal the denial, revocation, or refusal to approve an application or renewal application by requesting a contested case hearing under the provisions of the Administration Procedure Act, Minnesota Statutes, chapter 14. The registrant shall submit, within 15 days of the receipt of the department's decision, a written request for a hearing. The request for a hearing shall set forth in detail the reasons why the registrant contends the decision of the department should be reversed or modified.

Subp. 8. **Renewal of screening application.** Any request for the renewal of a screening program application shall be submitted in writing before its expiration date. Renewal requests shall contain the information specified in subpart 2.

Subp. 9. **Commissioner-approved healing arts screening.** The commissioner may inspect the healing arts screening program while in progress to ensure that it is carried out as described in the registrant's application and in compliance with this chapter.

Subp. 10. **Withdrawal of approval for conditions allowing overexposure.** Approval may be withdrawn immediately if, after an inspection, the commissioner finds the existence of conditions that would result in serious overexposure. All screening procedures shall be terminated immediately upon receipt of the written notice of existence of such overexposure. The applicant may request a contested case hearing within five days after receipt of the notice. The request for hearing does not stay the commissioner's order of immediate cessation of the screening program. The hearing shall be scheduled within ten days of receipt of the request for the hearing.

Subp. 11. **Withdrawal of approval for noncompliance with application.** Approval for healing arts screening may be withdrawn if, after an inspection, the commissioner finds discrepancies between the screening program as implemented and as described in the application in this part or

for violation of this chapter. A hearing shall be held if requested by the applicant within three days after the receipt of the notice of withdrawal of approval. The hearing may be held upon granting the applicant three days' notice. If a hearing is requested, withdrawal of approval shall not take effect until a final order is issued by the commissioner.

4731.1313 General Equipment Requirements for All Diagnostic Radiographic Systems.
Subpart 1. **Applicability.** All diagnostic radiographic systems must meet the requirements in this part.

Subp. 2. **Warning label.** The control panel containing the main power switch must bear the warning statement which is legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

Subp. 3. **Battery charge indicator.** On battery-powered x-ray generators, visual means must be provided on the control panel to indicate whether the battery is adequately charged for proper operation.

Subp. 4. **Leakage radiation from the diagnostic source assembly.** The leakage radiation from the diagnostic source assembly measured at a distance of one meter (39.4 inches) in any direction from the source must not exceed 100 milliroentgens (25.8 uC/kg) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance must be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches).

Subp. 5. **Radiation from components other than the diagnostic source assembly.** The radiation emitted by a component other than the diagnostic source assembly must not exceed two milliroentgens (0.516 uC/kg) in one hour at five centimeters (1.97 inches) from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance must be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches).

Subp. 6. **Beam quality, half-value layer.** The half-value layer of the useful beam for a given kVp must not be less than the values shown in item A. If it is necessary to determine a half-value layer at a kVp which is not listed in item A, linear interpolation or extrapolation may be made.

A. Values for half-value layer of useful beam for x-ray tube:

Design operating range (kVp)	Measured kVp	Half-value layer (millimeter of aluminum) Other x-ray	Specified Dental Systems

		Systems	
Below 50	30	0.3	1.5
	40	0.4	1.5
	50	0.5	1.5
51-70	51	1.2	1.5
	60	1.3	1.5
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

B. All intraoral dental radiographic systems installed on and after December 1, 1980, must have a minimum half-value layer not less than 1.5 millimeters aluminum.

C. For capacitor energy storage equipment, compliance with the requirements of this subpart must be determined with the capacitors fully charged and with a technique which discharges at least half of the energy stored in the capacitors (half of the maximum milliampere-second).

D. The half-value layer of the useful beam must be measured with all the materials in the beam which are always present between the source and the patient.

Subp. 7. **Beam quality, filtration controls.** For x-ray systems which have variable kVp and variable filtration for the useful beam, means must be provided to prevent an exposure unless the filtration required to obtain the half-value layer specified in subpart 6, item A, is in the useful beam for the given kVp which has been selected.

Subp. 8. **Multiple tubes.** Where two or more x-ray tubes are controlled by one exposure switch, the tube or tubes which have been selected must be clearly indicated before initiation of the exposure. The indication must be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

Subp. 9. **Mechanical support of tube head.** The tube housing assembly supports must be adjusted so it remains stable during an exposure unless tube housing movement is a designed function of the x-ray system.

Subp. 10. **Technique factors.** The technique factors in items A to C apply to all diagnostic radiographic systems.

A. The technique factors to be used during an exposure must be indicated before an exposure begins. If automatic exposure controls are used, the technique factors which are set before exposure must be indicated.

B. If automatic exposure controls are used in a system installed after September 10, 1991, in addition to the requirements of item A:

(1) the exposure time or milliampere-second must be displayed for x-ray generators with a constant milliamperage; and

(2) the milliampere-second must be displayed for falling load generators.

C. The requirement of item A may be met by permanent markings on systems having fixed technique factors. Indication of technique factors must be visible from the operator's position except in the case of spot films made by the fluoroscopist.

Subp. 11. **Timers.** The requirements in this subpart for timers apply to all general radiographic, intraoral dental, and veterinary medicine radiographic systems.

A. A means must be provided to terminate the exposure at a preset time interval, a preset product of milliamperage and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

B. An exposure must not be possible when the timer is set to a zero or off position, if either position is provided.

C. Except for dental panoramic systems, termination of the exposure must cause automatic resetting of the timer to its initial setting or to zero.

Subp. 12. **Reproducibility.** With a timer setting of 0.5 seconds or less, the difference between the maximum exposure time (Tmax) and the minimum exposure time (Tmin) must be less than or equal to 20 percent of the average exposure time (T) when four timer tests are performed:

$$(T_{max} - T_{min}) < 0.2\ T.$$

Subp. 13. **X-ray control.** The x-ray control must meet the requirements in this subpart.

A. The exposure control switch must be a dead-man type which requires continuous pressure to complete the exposure.

B. Each x-ray control console other than dental intraoral systems must be located in such a way as to meet the requirements in this item.

(1) stationary x-ray systems must have the x-ray control permanently mounted behind the protective barrier so the operator remains behind that barrier during the entire exposure.

(2) portable x-ray systems that produce more than 25 milliamperes-minutes per week at the same location must meet the requirement of subitem (1).

(3) portable x-ray systems that produce less than 25 milliamperes-minutes per week at the same location, must meet the requirement of subitem (1), or be provided with a 6.5 foot (2.0 m) high protective barrier which is placed at least six feet (1.8 m) from the tube housing assembly and at least six feet (1.8 m) from the patient.

C. The x-ray control console must provide visual indication observable at or from the

operator's protected position whenever x-rays are produced.

D. All x-ray control console panel indicator lights must be operational.

Subp. 14. **Exposure Reproducibility.** The coefficient of variation must not exceed 0.05 when all technique factors are held constant.

Subp. 15. **Additional requirements for general purpose x-ray system.** A facility with a general purpose x-ray system must also comply with items A to C.

A. Means must be provided to limit the x-ray field in the plane of the image receptor so the field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

B. Means must be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or means must be provided to both size and align the x-ray field so the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

C. The requirements of items A and B may be met with a system that meets the requirements for a general purpose x-ray system as specified in 4731.1314, subp. 4. When alignment means are also provided, the requirements of items A and B may be met with either:

(1) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the system is designed with each device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(2) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the system is designed. Permanent, clearly legible markings must indicate the image receptor size and SID for which each aperture is designed and must indicate which aperture is in position for use.

4731.1314 General Requirements for Certified Diagnostic Radiographic Systems Other Than Fluoroscopic, Dental intraoral, Veterinary Medicine, or Computed Tomography Systems. Subpart 1. **Applicability.** This part applies to all diagnostic x-ray systems certified according to standards provided by United States Code, title 42, section 263f. The requirements in this part are in addition to the requirement in parts 4731.0100 to 4731.1313, subparts 1 through 15. This part does not apply to fluoroscopic, dental intraoral, veterinary medicine, or computed tomography x-ray systems.

Subp. 2. **Diagnostic Radiographic Systems.** Only diagnostic radiographic systems incorporating one or more certified components must comply with the requirement in this subpart which relate to those certified components.

A. The radiographic system must be operated on an adequate power supply as specified by the manufacturer. The coefficient of variation of radiation exposures must be no greater than 0.05 for any specific combination of selected technique factors.

B. When the radiographic system allows a choice of x-ray milliamperage settings and is operated on a power supply as specified by the manufacturer according to the requirements of

applicable federal performance standards for any fixed kVp within tthe range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the milliampere-seconds product obtained at any two consecutive milliamperage settings must not differ by more than 0.10 times their sum:

$$(\bar{x}_1 - \bar{x}_2) \leq 0.10\,(\bar{x}_1 + \bar{x}_2)$$

where $\bar{x}_1$ and $\bar{x}_2$ are the average mR/mAs values obtained at each of two consecutive milliamperage settings.

C. Deviation of technique factors for kVp must be those the manufacturer has specified for that system. For other technique factors, the deviation must have a coefficient of variation of no more than five percent.

D. The x-ray control console must provide a signal audible to the operator that the exposure has terminated.

E. A certified diagnostic radiographic system and its associated certified components used on humans must be maintained in compliance with applicable requirements of the Federal X-ray Equipment Performance Standard, Code of Federal Regulations, title 21, chapter 1, subchapter J, in effect at the time of manufacture.

Subp. 3. **Beam limitation.** The useful beam must be limited to the patient's area of clinical interest.

Subp. 4. **General purpose stationary x-ray systems.** General purpose stationary x-ray systems must meet the standards in items A to E.

A. A means for stepless adjustment of the size of the x-ray field must be provided.

B. A method must be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field must not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

C. Except when spot-film devices or special attachments for mammography are in service, a method must be provided to:

(1) indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

(2) align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID; and

(3) indicate the SID to within two percent.

D. The beam-limiting device must numerically indicate the field size at the plane of the image receptor to which it is adjusted.

E. The indication of field size dimensions and SIDs must be:

(1) specified in inches or centimeters; and

(2) such that aperture adjustments result in x-ray field dimensions at the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent or less of the SID when the beam axis is perpendicular to the plane of the image receptor

Subp. 5. **Diagnostic radiographic systems designed for one image receptor size.** Diagnostic

radiographic systems designed for only one image receptor size at a fixed SID must be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and must align the center of the x-ray field with the center of the image receptor to within two percent of the SID. Alternatively, such systems must be provided with means to both size and align the x-ray field so the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

Subp. 6. **Stationary and portable general purpose x-ray systems.** Stationary and portable general purpose x-ray systems must have means to limit the useful beam.

A. There must be provided a means of stepless adjustment of the size of the x-ray filed. The minimum field size at a SID of 100 centimeters (39.4 inches) must be equal to or less than five by five centimeters(1.97 inches).

B. When a light localizer is used to define the x-ray field, it must provide an average illumination of not less than 160 lux (15.0 foot candles) above ambient at 100 centimeters (39.4 inches) or at the maximum SID, whichever is less. The average illumination must be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems installed on and after may 27, 1980, are exempt from this requirement.

C. The edge of the light field at 100 centimeters (39.4 inches) or at the maximum SID, whichever is less, must have a contrast ratio, corrected for ambient lighting, of not less than four in the case of beam-limiting devices designed for use on stationary x-ray systems, and a contrast ratio of not less than three in the case of beam-limiting devices designed for use on portable x-ray systems. The contrast ratio is defined as I_1 / I_2 where I_1 is the illumination three millimeters (0.12 inches) from the edge of the light field toward the center of the field; and I_2 is the illumination three millimeters (0.12 inches) from the edge of the light field away from the center of the field. Compliance must be determined with a measuring instrument aperture of one millimeter (0.04 inches) in diameter.

Subp. 7. **For general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and table (if so equipped).** The system must be certified according to Code of Federal Regulations, title 21, section 1020.30(c). The system must meet the standards in items A through F.

A. When positive beam limitation is provided, it must meet the criteria in units (1) to (6).

(1) the image receptor must be inserted into a permanently mounted cassette holder.

(2) the image receptor length and width must each be less than 50 centimeters (19.7 inches).

(3) the x-ray beam axis must be within plus or minus three degrees of vertical and the SID must be 90 centimeters to 130 centimeters (35.4 inches to 51.2 inches) inclusive; or the x-ray beam axis must be within plus or minus three degrees of horizontal and the SID must be 90 centimeters to 205 centimeters (35.4 inches to 80.7 inches) inclusive.

(4) the x-ray beam axis must be perpendicular to the plane of the image receptor to within plus or minus three degrees.

(5) neither tomographic nor stereoscopic radiography is being performed.

(6) the positive beam limitation system must not be intentionally overridden. This

override provision is subject to the provisions of item C.

B. Positive beam limitation must prevent the production of x-rays when:

(1) the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimensions by more than three percent of the SID except as permitted by item D; or

(2) the sum of the length and width differences as stated in unit (a) without regard to sign exceeds four percent of the SID.

C. If a method of overriding the positive beam limitation system exists, that method must be designed for use only in the event of positive beam limitation system failure or if the system is being serviced. If the positive beam limitation system is in a position that the operator considers part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator:

(1) a key must be used to override the positive beam limitation;

(2) the key must remain in place during the entire time the positive beam limitation system is overridden; and

(3) that the key or key switch must be clearly and durably labeled as follows: "FOR X-RAY FIELD LIMITATION SYSTEM FAILURE."

D. Compliance with item B, must be determined when the equipment indicates the beam axis is perpendicular to the plane of the image receptor and the provisions of item A, are met. Compliance must be determined no sooner than five seconds after insertion of the image receptor.

E. The positive beam limitation system must be capable of operation, at the discretion of the operator, so that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters (39.4 inches) must be equal to or less than five centimeters by five centimeters (1.97 inches by 1.97 inches).

F. The positive beam limitation system must be designed so that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in item B, then any change of image receptor size of SID must cause the automatic return.

Subp. 8. **For mammography x-ray systems installed after September 5, 1978.** For x-ray systems installed after September 5, 1978, designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system must be limited so the exposure five centimeters (1.97 inches) from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 nC/kg) for each activation of the tube. Exposure must be measured with the system operated at the minimum SID for which it is designed. Compliance must be determined at the maximum kVp for the system and at the maximum rated product of milliamperage and exposure time (milliampere-seconds) for that kVp. Compliance must be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches).

Supb. 9. **Automatic or semiautomatic collimators (PBL).** If the facility chooses, automatic or semiautomatic collimators (PBL) may be permanently changed to a manual mode. This requires

the automatic system to be permanently disabled. The collimator must be relabeled with a durable material "manual operation required" so that it is clearly observable to the operator.

Subp. 10. **Radiation exposure, x-ray controls.** An x-ray control must be incorporated into each x-ray system so an exposure can be terminated by the operator at any time during exposures of greater than one-half second. During serial radiography means must be provided to permit completion of any single exposure of the series in process before terminating the series.

Subp. 11. **Radiation exposure, automatic exposure controls.** When an automatic exposure control is provided:

A. Indication must be made on the control panel when this mode of operation is selected;

B. The minimum exposure time for all radiographic systems, other than that specified in item E, must be equal to or less than 1/60 second or a time interval required to deliver five milliampere-seconds, whichever is greater

C. Either the product of the kVp, milliamperage, and exposure time must be limited to not more than 60 kWs per exposure, or the product of x-ray milliamperage and exposure time must be limited to not more than 600 mAs per exposure;

D. A visible signal must indicate when an exposure has been terminated at the limits required by item C, and manual resetting must be required before further automatically timed exposures can be made; and

E. If the kVp is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation must be equal to or less than a time interval equivalent to two pulses.

Subp.12. **Source-to-skin distance.** All portable x-ray systems must be provided with means to maintain a minimum source-to-skin distance equal to or greater than 30 centimeters (11.8 inches).

Subp. 13. **Radiation from capacitor energy storage equipment in standby status.** Radiation emitted from the x-ray tube when the exposure switch or timer is not activated must not exceed a rate of two milliroentgens (0.5 uC/kg) per hour at five centimeters (1.97 inches) from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

4731.1315 Intraoral Dental Radiographic Systems

Subpart 1. **Applicability.** This part applies to x-ray systems used for intraoral dental radiography. Requirements for extraoral dental radiographic systems are covered in part 4731.1313 and 4731.1314. This part applies in addition to the requirements in 4731.0100 to 4731.1314.

Subp. 2. **Source-to-skin distance.** X-ray systems designed for use with an intraoral image receptor must be provided with a position-indicating-device to limit source-to-skin distance to not less than 18 centimeters (7.1 inches).

Subp. 3. **Field limitation.** Radiographic systems designed for use with an intraoral image receptor

must be provided with and used with collimation to limit the x-ray field such that:

A. If the minimum source-to-skin distance is 18 centimeters (7.1 inches) or more, the x-ray field, at the minimum, must be containable in a circle having a diameter of no more than seven centimeters (2.76 inches); or

B. With rectangular position-indicating-devices, the longer side must not exceed 5.1 centimeters (two inches); and

C. The x-ray system must be operated so the useful beam at the patient's skin does not exceed the requirements of this subpart.

Subp. 4. **Safety controls.** The registrant must ensure that the safety controls in this subpart are followed.

A. Intraoral film holders and bite blocks must be used except when endodontic procedures do not permit. Film must not be routinely held by hand.

B. The tube housing and the position-indicating-device must not be hand-held during an exposure and must be stable before the exposure is initiated and during the exposure.

C. The exposure at the end of the cone for a bitewing technique must not exceed the values listed in Table 4731.1316:

TABLE 4731.1316

kVp	"D" Speed Film ESE (milliroentgens)	"E" Speed Film ESE (milliroentgens)	"D/E or E+" Speed Film ESE (milliroentgens)
50	425 - 575	220 - 320	220 - 320
55	350 - 500	190 - 270	190 - 270
60	310 - 440	165 - 230	165 - 230
65	270 - 400	140 - 200	140 - 200
70	240 - 350	120 - 170	120 - 170
75	170 - 260	100 - 140	100 - 140
80	150 - 230	90 - 120	90 - 120
85	130 - 200	80 - 105	80 - 105
90	120 - 180	70 - 90	70 - 90
95	110 - 160	60 - 80	60 - 80
100	100 - 140	50 - 70	50 - 70

Notes:

(1) Exposures are specified as free-in-air exposures without backscatter.

(2) The indicated kVp is often significantly different from the actual kVp. The kVp must be tested at the time the output per film is measured to determine the correct exposure range to be applied.

4731.1316 Veterinary Medicine Radiographic Installations

Subpart 1. **Applicability.** This part applies to x-ray systems used for diagnostic veterinary

medicine radiography and applies in addition to the requirements in 4731.0100 to 4731.1314.

A. Requirements for fluoroscopic veterinary medicine systems are covered in 4731.1317.

B. Requirements for therapeutic veterinary medicine shall be the same as those in 4731.1319 and 4731.1320.

C. Requirements for dental intraoral veterinary medicine shall be the same as those in 4731.1315.

Subp. 2. **Beam limitation.** Collimators must be provided to restrict the useful beam to the area of clinical interest and must provide the same degree of protection as is required of the tube housing.

A. If a variable-aperture beam limiting collimator is used, the projected light and x-ray field must not exceed the smallest dimension of the x-ray film cassette by greater than two percent of the distance of the x-ray tube to the film (SID) in any direction.

B. A method must be provided to:

(1) indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

(2) align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID; and

(3) indicate the SID to within two percent.

C. If a fixed dimension beam limiting collimator is used, it must meet the additional requirements in this item.

(1) The collimator must be labeled to indicate the field size and the SID for which it is designed.

(2) The collimator must be used only for the field size and the SID for which it is designed.

(3) The x-ray field must not exceed the x-ray film cassette by greater than two percent of the distance of the x-ray tube to the film SID in the x-ray film cassette's smallest dimension.

(4) The requirements in 4731.1315, subpart 4, items D and E.

D. In the case of horizontal beam x-rays, a mechanical cassette holding device must be used to ensure that no part of the body of the individual steadying the cassette is exposed to primary beam x-rays.

E. If necessary, and any involved individual is properly attired in protective apron and gloves of at least 0.5 mm lead equivalency, this does not preclude the operation of the radiographic system by one of the individuals holding the animal patient using a foot switch.

Subp. 3. **Operating procedures.** The registrant must ensure that the operating procedures in this subpart are applied.

A. The operator must not stand in the path of the useful beam during radiographic exposures.

B. No individual other than the operator must be in the radiographic room while exposures are being made unless the individual's assistance is required.

C. When an animal must be held in position by an individual during radiography, that individual must wear protective gloves and apron of at least 0.5 mm lead equivalency, and the

individual must be positioned so no part of the body, protected or unprotected, will be struck by the useful beam.

4731.1316. Fluoroscopic X-ray Systems Except Radiation Therapy Simulators
Subpart 1. **Applicability.** This part applies to all fluoroscopic x-ray systems in addition to the requirements in 4731.0100 to 4731.1314.

Subp. 2. **Limitation of useful beam, primary barrier.** For all fluoroscopes, the requirements in items A and B must be met.

A. The fluoroscopic imaging assembly must be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

B. The x-ray tube used for fluoroscopy must not produce x-rays unless the barrier is in position to intercept the entire useful beam.

Subp. 3. **Limitation of useful beam, x-ray field.** All fluoroscopes must be provided with image intensification equipment to view the fluoroscopic images.

A. For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image intensifier may exceed that of the visible area of the image intensifier by more than three percent of the SID during fluoroscopy or digital imaging. The sum of the excess length and the excess width must be no greater than four percent of the SID. In addition, means must be provided to permit further limitations of the field:

(1) beam-limiting devices installed after May 22, 1979, and incorporated in equipment with either a variable SID or a visible area of greater than 300 square centimeters (46.5 square inches), must be provided with means for the stepless adjustment of the x-ray field.

(2) all equipment with a fixed SID and a visible area of 300 square centimeters (46.5 square inches) or less must be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters (19.4 square inches) or less. Stepless adjustment must, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five by five centimeters (1.97 by 1.97 inches) or less.

(3) for fluoroscopic x-ray systems manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(4) compliance must be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment must be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

B. Spot-film devices which are certified components must meet the additional requirements in subitems (1) to (4):

(1) means must be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment must be automatically accomplished, except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the

film. For spot-film devices installed after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size must be only at the operator's option.

(2) it must be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID must be equal to, or less than, five by five centimeters (1.97 by 1.97 inches).

(3) the center of the x-ray field in the plane of the film must be aligned with the center of the selected portion of the film to within two percent of the SID.

(4) on spot-film devices installed after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance must be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

C. If a means exists to override any of the automatic x-ray field size adjustments required in this subpart, that means must:

(1) be designed for use only in the event of system failure;

(2) incorporate a signal visible at the fluoroscopist's position which indicates whenever the automatic field size adjustment is overridden; and

(3) be clearly and durably labeled as follows: "FOR X-RAY FIELD LIMITATION SYSTEM FAILURE."

Subp. 4. **Activation of the fluoroscopic tube.** X-ray production in the fluoroscopic mode must be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist must be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.

Subp. 4a. **Entrance exposure rate allowable limits on fluoroscopic systems manufactured before May 19, 1995.** The registrant must ensure that the entrance exposure rate allowable limits in this subpart are met.

A. Equipment with automatic exposure rate control (AERC). Fluoroscopic equipment that is provided with AERC shall not be operable at any combination of tube potential and current that results in an exposure rate in excess of ten roentgens per minute (10 R/min) or 2.58 x 10-3 coulomb per kilogram (C/kg) per minute at the point where the center of the useful beam enters the patient, except:

(1) during recording of fluoroscopic images when using photographic film; or

(2) when an optional high-level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that results in an exposure rate in excess of 5 R/min (1.29 x 10-3 C/kg per minute) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls is required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

B. Equipment without AERC (manual mode). Fluoroscopic equipment that is not

provided with AERC shall not be operable at any combination of tube potential and current that results in an exposure rate in excess of 5 R/min (1.29 x 10-3 C/kg per minute) at the point where the center of the useful beam enters the patient, except:

(1) during the recording of fluoroscopic images; or

(2) when an optional high-level control is activated. Special means of activation of high-level controls is required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

C. Equipment with both an AERC mode and a manual mode. Fluoroscopic equipment that is provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that results in an exposure rate in excess of 10 R/minute (2.58 x 10-3 C/kg per minute) in either mode at the point where the center of the useful beam enters the patient, except:

(1) during the recording of fluoroscopic images when using photographic film; or

(2) when the mode or modes have an optional high-level control, in which case that mode or modes shall not be operable at any combination of tube potential and current that results in an exposure rate in excess of 5 R/minute (1.29 x 10-3 C/kg per minute) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls is required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level is being employed.

D. Compliance with this subpart shall be determined as follows:

(1) movable grids and compression devices shall be removed from the useful beam during the measurement;

(2) if the source is below the x-ray table, the exposure rate shall be measured at one centimeter above the tabletop or cradle;

(3) if the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

(4) in a C-arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly; and

(5) in a lateral type of fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the center line of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the center line of the x-ray table.

Subp. 5. **Entrance exposure rate allowable limits on fluoroscopic systems manufactured after May 19, 1995.** The registrant must ensure that the entrance exposure rate allowable limits in this subpart are met.

A. Fluoroscopic equipment operable at any combination of tube potential and current that results in an exposure rate greater than 5 R/minute (1.29 x 10-3 C/kg per minute) at the point where the center of the useful beam enters the patient shall be equipped with automatic exposure rate control (AERC). Provision for manual selection of technique factors may be provided.

B. Fluoroscopic equipment shall not be operable at any combination of tube potential and current that results in an exposure rate in excess of 10 R/minute (2.58 x 10-3 C/kg per minute) at the point where the center of the useful beam enters the patient, except:

(1) during the recording of images from an x-ray image-intensifier tube using photographic film; or

(2) when an optional high-level control is activated. When the high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that results in an exposure rate in excess of 20 R/minute (5.16 x 10-3 C/kg per minute) at the point where the center of the useful beam enters the patient. Special means of activation of high-level control is required. The high-level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

C. Compliance with item B, subitem (2), shall be determined as follows:

(1) movable grids and compression devices shall be removed from the useful beam during the measurement;

(2) if the source is below the x-ray table, the exposure rate shall be measured at one centimeter above the tabletop or cradle;

(3) if the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

(4) in a C-arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly; and

(5) in a lateral type of fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the center line of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the center line of the x-ray table. Variable SID units shall not exceed 10 R/minute at any SID.

D. During fluoroscopy and cinefluorography, x-ray tube potential and current must be continuously indicated. Deviation of x-ray tube potential and current from the indicated values must not exceed the maximum deviation as stated by the manufacturer according to Code of Federal Regulations, title 21, section 1020.30, paragraph (h), item (3).

E. Periodic measurement of the maximum exposure rate must be performed in the manual mode, automatic exposure rate control, and high-level control mode, if applicable.

(1) the measurements must be made annually and after any maintenance of the system which might affect the exposure rate.

(2) the results of these measurements must be in the record required in 4731.0168 and 4731.0169. The measurement results must be stated in Roentgens per minute or mC/kg per minute and must include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed must be included in the results.

(3) materials must be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

(4) the periodic measurement of the maximum entrance exposure rate must be made under the conditions that satisfy the requirements of item D. For x-ray systems that do not incorporate an automatic exposure rate control, the kilovoltage and milliamperage must be manually adjusted to produce the maximum entrance exposure rate.

Subp. 6. **Barrier transmitted radiation rate limits.** The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, must not exceed 3.34 x 10-3 percent of the entrance exposure rate at ten centimeters (3.9 inches) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute (0.25 mC/kg) of entrance exposure rate.

Subp. 7. **Measuring compliance of barrier transmission.** Compliance with subpart 6 shall be determined according to this subpart.

A. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier must be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches).

B. If the source is below the tabletop or cradle, the measurement must be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters (11.8 inches) above the tabletop or cradle.

C. If the source is above the tabletop or cradle and the SID is variable, the measurement must be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it must not be closer than 30 centimeters (11.8 inches).

D. The attenuation block must be positioned in the useful beam ten centimeters (3.9 inches) from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

Subp. 8. **Indication of kilovoltage and milliamperage.** For fluoroscopic x-ray systems manufactured and installed after February 25, 1978, during fluoroscopy and cinefluorography, the kilovoltage and the milliamperage must be continuously indicated.

Subp. 9. **Source-to-skin distance.** The source-to-skin distance must not be less than:

A. 38 centimeters (15 inches) on stationary fluoroscopes;

B. 35.5 centimeters (14 inches) on stationary fluoroscopes manufactured prior to August 1, 1974;

C. 30 centimeters (11.8 inches) on all portable fluoroscopes; and

D. 20 centimeters (7.9 inches) for image intensified fluoroscopes used for specific surgical applications. The written safety procedures must provide precautionary measures to be adhered to when image intensified fluoroscopes are used for specific surgical applications. The 20 centimeter (7.9 inch) spacer cone must be replaced with the 30 centimeter (11.8 inch) spacer cone immediately after the end of the fluoroscopic surgical procedure.

Subp. 10. **Fluoroscopic timer.** Means must be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device must not exceed five minutes without resetting. A signal audible to the fluoroscopist must indicate the completion of any preset cumulative on-time. The signal must continue to sound while x-rays are produced, until the timing device is reset.

Subp. 11. **Control of scattered radiation.** The procedures in this subpart must be used to control scattered radiation from all fluoroscopes.

A. When a fluoroscopic table with an undertable x-ray tube is used, the bucky opening must be shielded to attenuate the scattered radiation by at least 70 percent. Lead drapes must be attached to the intensifier tower to attenuate scattered radiation by at least 70 percent.

B. For other undertable configurations, provisions must be made through equipment design or radiation protection measures to ensure that individuals do not receive a dose in excess of the allowable dose limits listed in 4731.0124.

(1) any individual who must be in the room during a fluoroscopic procedure must wear a protective apron of not less than 0.5 millimeter lead equivalence.

(2) all fluoroscopic x-ray equipment must be provided with a bucky-slot cover panel, if applicable, and either lead drapes attached to the intensifying tower or self-supporting shields of not less than 0.5 millimeter lead equivalent material.

C. For single-tube above table combination radiographic and fluoroscopic x-ray systems used in the fluoroscopic mode, protective aprons of not less than 0.5 millimeter lead equivalence must be used to ensure that any individual who must be in the room during a fluoroscopic procedure does not receive a dose greater than the allowable dose limits listed in 4731.0124. In addition, portable lead shields, barriers, or aprons of not less than 0.5 millimeter lead equivalence must be used.

D. For portable C-arm fluoroscopes, provision must be made through the use of protective aprons of not less than 0.5 millimeter lead equivalence to ensure that any individual other than the patient who may be exposed during a fluoroscopic procedure does not receive a dose in excess of the allowable dose limits listed in 4731.0124.

Subp. 12. **Radiation therapy simulation systems.** A radiation therapy simulation system is exempt from the requirements of subpart 5, provided:

A. The system is designed and used so no individual other than the patient is in the simulation room when the system is producing x-rays; and

B. A system which does not meet the requirements of subpart 10 has a means to indicate the cumulative time that an individual patient has been exposed to x-rays. Procedures

must require in such cases that the timer be reset between examinations.

4731.1318 Computed Tomography Systems

Subpart 1. **Applicability.** This part applies to all computed tomography systems in addition to the requirements in 4731.0100 to 4731.1314.

Subp. 2. **Termination of exposure.** A visible signal must indicate when the x-ray exposure has been terminated. The operator must be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

Subp. 3. **Tomographic plane indication and alignment.** The provisions in items A to C apply.

A. For any single slice tomogram system, means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

B. For any multiple slice tomogram system, means must be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

C. If a device using a light source is used to satisfy either item A or B, the light source must provide illumination levels of not less than 160 lux (15.0 foot candles) above the room ambient illumination level.

Subp. 4. **Beam-on and shutter status indicators.** The x-ray control and gantry must visually indicate whenever x-rays are produced and, if applicable, whether the shutter is open or closed. All emergency buttons or switches must be clearly labeled as to their functions.

Subp. 5. **Indication of computed tomography conditions of operation.** The computed tomography x-ray system must be designed so the computed tomography conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of the scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of computed tomography conditions of operation must be visible from any position from which scan initiation is possible.

Subp. 6. **Extraneous radiation.** When data is not being collected for image production, the radiation adjacent to the tube port must not exceed the leakage radiation from the diagnostic source assembly that is measured at a distance of one meter (39.4 inches) in any direction from the source. That leakage must not exceed 100 milliroentgens (26 uC/kg) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance must be determined by a measurement averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches).

Subp. 7. **Maximum surface computed tomography dose index identification.** The angular position where the maximum surface computed tomography dose index occurs must be identified to allow for reproducible placement of a computed tomography dosimetry chamber.

Subp. 8. **Additional requirements for computed tomography x-ray systems containing a gantry manufactured after September 3, 1985.**

A. The total error in the indicated location of the tomographic plane or reference plane must not exceed five millimeters (0.2 inches).

B. If the x-ray production period is less than one-half second, the indication of x-ray production must be actuated for at least one-half second. Indicators at or near the patient side of the gantry must be discernible to the operator.

C. The deviation of indicated scan increment versus actual increment must not exceed plus or minus one millimeter (0.04 inches) with a mass of 100 kilograms (220 pounds) resting on the support device. The patient support device must be incremented from a typical starting position to the maximum incremented distance or 30 centimeters (11.8 inches), whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this incremented distance.

D. Premature termination of the x-ray exposure by the operator must necessitate resetting of the computed tomography conditions of operation before the initiation of another scan.

Subp. 9. **Audio communication.** Within the computed tomography area, provision must be made for two-way audio communication between the patient and operator at the control panel.

Subp. 10. **Patient observation.** Within the computed tomography area, provision must be made for a shielded window containing the same lead equivalence as the adjoining walls so the operator at the control panel may directly observe the patient, any other individual in the room, and any doorways into the room. A closed circuit television system may be used as a secondary means of observing the patient.

Subp. 11. **Location of control panel and x-ray control.** The control panel and x-ray control must be mounted in a permanently protected area outside the computed tomography room. The operator is required to remain in that protected area during the entire exposure.

Subp. 12. **Operating procedure information.** Information about the operation, radiation safety surveys, and equipment performance measurements of the system must be available at the control console. This information must contain:

A. The dates of the last radiation safety survey and equipment performance measurements;

B. Written results of the most recent radiation safety survey and equipment performance measurements including:

(1) those specified in part 4731.1307.

(2) photographic images obtained from the photographic image recording device; and

(3) images stored in digital form.

C. Instructions on the use of the computed tomography phantoms, including a schedule of equipment performance checks appropriate for the system, allowable variations for the indicated measurements, and the results of the last two years' equipment performance measurements in addition to the original equipment performance and acceptance test measurements, images, and digital data; and

D. The distance in millimeters between the tomographic plane and the reference plane if a reference plane is used.

Subp. 13. **Corrective action.** If the equipment performance measurements required by 4731.1307, of the computed tomography systems identify that a measurement has exceeded a tolerance specified in 4731.1308, subp.8, the registrant must correct the measurement to within the tolerances specified in 4731.1308. Correction of the problem must take place within five working days and must be verified by performing the equipment performance measurements specified in 4731.1307.

4731.1319 Therapeutic X-ray Systems of Less Than 1.0 MV

Subpart 1. **Applicability.** In addition to the requirements in 4731.0100 to 4731.1318, this part applies to all therapeutic x-ray systems of less than 1.0 MV.

Subp. 2. **Leakage radiation.** When the tube is operated at its leakage technique factors, the instantaneous exposure rate leakage radiation must not exceed the value specified at the distance specified in this subpart for the classification of that x-ray system.

A. Leakage radiation for contact therapeutic x-ray systems must not exceed 100 milliroentgens (25.8 uC/kg) per hour at five centimeters (1.97 inches) from the surface of the tube housing assembly.

B. Zero to 150 kVp systems installed prior to September 10, 1991, must have a leakage radiation which does not exceed 1.0 roentgen (0.258 mC/kg) in one hour at one meter (39.4 inches) from the source.

C. Zero to 150 kVp systems installed on or after September 10, 1991, must have a leakage radiation which does not exceed 100 milliroentgens (25.8 uC/kg) in one hour at one meter (39.4 inches) from the source.

D. 151 to 999 kVp systems must have leakage radiation which does not exceed one roentgen (0.258 mC/kg) in one hour at one meter (39.4 inches) from the source. However, systems that operate in excess of 500 kVp may have a leakage radiation rate at one meter (39.4 inches) from the source not to exceed 0.1 percent of the useful beam one meter (39.4 inches) from the source.

Subp. 3. **Leakage from permanent beam limiting devices.** Permanent fixed diaphragms or cones used for limiting the useful beam must provide the same or a higher degree of protection as required for the tube housing assembly in subpart 2.

Subp. 4. **Removable beam limiting devices.** Removable beam limiting devices must, for the portion of the useful beam to be blocked by these devices, transmit not more than five percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

Subp. 5. **Adjustable beam limiting devices.** Adjustable beam limiting devices installed after

September 10, 1991, must meet the requirements of subpart 4. Adjustable beam limiting devices installed before September 10, 1991, must, for the portion of the x-ray beam to be blocked by these devices, not transmit more than five percent of the useful beam at the maximum kilovoltage and maximum treatment filter.

Subp. 6. **Filter system.** The filter system must be designed so:

A. the filters cannot be accidentally displaced at any possible tube orientation;

B. the radiation at five centimeters (1.97 inches) from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under any operating condition; and

C. each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle must appear on the wedge or wedge tray.

Subp. 7. **Tube immobilization.** The tube housing assembly must be capable of being immobilized for stationary treatments.

Subp. 8. **Focal spot marking.** The tube housing assembly must be marked so it is possible to determine the location of the focal spot to within five millimeters (0.2 inches), and such marking must be readily accessible for use during calibration procedures.

Subp. 9. **Beam block.** If the x-ray tube of a contact therapeutic x-ray system is hand-held during irradiation, the operator must wear protective gloves and apron. When practical, a cap of at least 0.5 millimeters lead equivalence must cover the aperture window of the tube housing of such apparatus when the apparatus is not being used.

Subp. 10. **Timer.** A timer which has a display must be provided at the treatment control panel. The timer must:

A. Have a preset time selector and an elapsed time indicator;

B. Be a cumulative timer which activates with the production of radiation and retains its reading after the irradiation is interrupted or terminated;

C. Terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation;

D. Permit accurate presetting and determination of exposure times within an accuracy of one second;

E. Not permit an exposure if set at zero; and

F. Not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.

Subp. 11. **Control panel functions.** The control panel must have:

A. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

B. An indication of whether x-rays are being produced;

C. Meters that indicate kVp and mA;

D. Means for terminating an exposure at any time;

E. A locking device which will prevent unauthorized use of the x-ray system; and

F. For x-ray systems installed after September 10, 1991, a positive display of all specific filters in the beam.

Subp. 12. **Multiple tubes.** A control panel may energize more than one x-ray tube if the x-ray tubes are located in the same room. In this situation, the following must apply:

A. It must be possible to activate only one x-ray tube at any time;

B. There must be an indication at the control panel identifying which x-ray tube is energized; and

C. There must be an indication at the tube housing assembly when that tube is energized.

Subp. 13. **Source-to-skin distance.** There must be means of determining the source-to-skin distance to within two millimeters (0.08 inches).

Subp. 14. **Shutters.** Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds, the beam must be automatically attenuated by a shutter having a lead equivalence of not less than that of the tube housing assembly. In addition:

A. After the system is at operating parameters, the shutter must be controlled electrically by the operator from the control panel; and

B. An indication of the shutter position must appear at the control panel.

Subp. 15. **Low-filtration x-ray tubes.** Each x-ray system equipped with a beryllium or other low-filtration window must be clearly labeled as "beryllium window" or "low-filtration window" on the tube housing assembly and at the control panel.

Subp. 16. **Entrance interlocks.** For therapeutic x-ray systems capable of operation above 150 kVp, interlocks or safety devices must be provided so all access to the radiation therapy rooms are blocked before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening or tripping of a safety device, it must not be possible to restore the system to operation without reactivating the safety device and reinitiating irradiation by manual action at the control panel. When any entrance door is opened while the x-ray tube is activated, the exposure at a distance of one meter (39.4 inches) from the source must be reduced to less than 100 milliroentgens (0.001 sieverts or one millisievert) per hour.

Subp. 17. **Operating procedures.** The tube housing assembly of contact therapeutic equipment must not be held by hand during operation unless the system is designed to require such holding and the kVp of the system does not exceed 50 kVp. In such cases, the holder must wear protective gloves and apron of not less than 0.5 millimeter lead equivalence at 100 kVp.

Subp. 18. **Additional requirements.** The x-ray system must not be used in the administration of radiation therapy unless the requirements of 4731.1305 and 4731.1306, have been met.

4731.1320 X-ray And Electron Therapy Systems With Energies Of 1.0 MV/1.0 MEV And

Above.

Subpart 1. **Applicability.** In addition to the requirements in 4731.0100 to 4731.1318, the requirements in this part shall apply to the use of therapeutic x-ray systems with energies of 1.0 MV and above.

Subp. 2. **System requirements; leakage radiation to the patient area.** All x-ray and electron therapy systems or any part of a system must meet the requirements in this subpart.

A. Systems or any part of a system installed after September 10, 1991, must meet the following requirements:

(1) for operating conditions producing maximum leakage radiation, the absorbed dose in rads (cGy) due to any leakage radiation component, including x-rays, electrons, and neutrons, at any point in a circular plane of two meters (78.7 inches) radius centered on or perpendicular to the central axis of the beam at the isocenter (patient plane), or nominal treatment distance and outside the maximum useful beam size must not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane surface.

(2) measurements, excluding those for neutrons, must be averaged over an area up to but not exceeding 100 square centimeters (15.5 square inches) at the positions specified in this item. Measurements of the portion of the leakage radiation dose contributed by neutrons must be averaged over an area up to but not exceeding 200 square centimeters (31 square inches).

(2) For each system, the registrant must determine or obtain from the manufacturer the leakage radiation existing at the positions specified in subitem (1) for the operating conditions specified in that subitem.

B. Systems installed before September 10, 1991, must meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (cGy) due to leakage radiation, excluding neutrons, at any point in a circular plane of a two meter (78.7 inch) radius centered on a plane perpendicular to the central axis of the beam two meters (78.7 inches) from the virtual source, and outside the maximum size useful beam, must not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements must be averaged over an area up to but not exceeding 100 square centimeters (15.5 square inches) at the positions specified in this item.

(2) For each system, the registrant must determine or obtain from the manufacturer the leakage radiation existing at the positions specified in subitem (1) for the operating conditions specified in that subitem.

Subp. 3. **Leakage of radiation outside the patient area for systems or any part thereof installed after September 10, 1991.** For systems or any part of a system installed after September 10, 1991, the system must meet the requirements in this subpart.

A. The absorbed dose in rads (cGy) due to leakage radiation, except in the area specified in subpart 2, item A, subitem (1), when measured at any point one meter (39.4 inches) from the path of the charged particle, before the charged particle strikes the target or window, must not exceed 0.1 percent of the maximum absorbed dose in rads (cGy) of the neutrons and must not

exceed 0.1 percent of the maximum absorbed dose in rads (cGy) of the photons of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in subpart 2, item A, subitem (1).

B. The registrant must determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in item A for specified operating conditions. Radiation measurements, excluding neutrons, must be averaged over an area up to but not exceeding 100 square centimeters (15.5 square inches). Neutron measurements must be averaged over an area up to but not exceeding 200 square centimeters (31 square inches).

Subp. 4. **Beam limiting devices.** Adjustable or interchangeable beam limiting devices must be provided, and the devices must transmit no more than five percent of the useful beam at the nominal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient. The neutron component of the useful beam must be excluded from the calculation of the five percent limitation.

Subp. 5. **Filters.** All x-ray and electron therapy systems must have filters that meet the requirements in this subpart.

A. All compensating removable filters must be clearly identified. Documentation available at the control panel must contain a description of the filter. For wedge filters, the wedge angle must appear on the wedge or wedge tray.

B. If the absorbed dose rate data required by subpart 17 relates exclusively to operation with a field flattening or beam scattering filter in place, the filter must be removable only with the use of tools.

C. For systems or any part of a system installed after September 10, 1991, which uses a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:

(1) irradiation must not be possible until a selection of a filter has been made at the treatment control panel;

(2) an interlock system must be provided to prevent irradiation if the filter selected is not in the correct position;

(3) a display must be provided at the treatment control panel showing the filters in use; and

(4) an interlock must be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

Subp. 6. **Electron beam quality.** The registrant must determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, when electrons and photons are being generated.

Subp. 7. **Radiation monitors.** All therapeutic x-ray systems must be provided with radiation monitors in the radiation head.

A. Systems or any part of a system installed after September 10, 1991, must measure all therapeutic radiation beams with at least two radiation monitors. The radiation monitors

must be incorporated into two separate dose monitoring systems.

B. Systems installed prior to September 10, 1991, must be provided with at least one radiation monitor. This radiation monitor must be incorporated into a primary dose monitoring system.

C. The radiation monitor and the dose monitoring system into which that radiation monitor is incorporated must meet the following requirements:

(1) each radiation monitor must be removable only with tools and must be interlocked to prevent incorrect positioning.

(2) each radiation monitor must form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

(3) each dose monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation.

(4) for dose monitoring systems installed after September 10, 1991, the design of the dose monitoring system must assure that:

(a) the malfunctioning of one dose monitoring system does not affect the correct functioning of the second dose monitoring system; and

(b) the failure of any element common to both dose monitoring systems which could affect the correct function of both dose monitoring systems terminates irradiation.

(5) Each dose monitoring system must have a legible display at the treatment control panel. For dose monitoring systems installed after September 10, 1991, each display must:

(a) maintain a reading until intentionally reset to zero;

(b) have only one scale and no scale multiplying factors;

(c) use a design so that any increased dose is displayed by increasing numbers and must be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and

(d) display the dose monitoring information required by this subitem at the control panel and be retrievable in at least one dose monitoring system for a five-minute period of time in the event of a power failure.

(6) The internal dose monitoring system must be capable of delivering a dose that varies by less than two percent over a 12-hour period.

Subp. 8. **Beam symmetry.** For any system installed after September 10, 1991, that has the capacity to produce useful beams with asymmetry exceeding five percent, the asymmetry of the radiation beam in two orthogonal directions must be monitored before the beam passes through the beam limiting device. The asymmetry must be measured for a 30 square centimeter (4.65 square inch) field at a depth of ten centimeters (3.9 inches) at the points that correspond to 80 percent of the full width half maximum (FWHM) of central axis value.

Capabilities must be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam in the same plane exceeds five percent of the central axis dose rate, indication of the dose rate difference is made at the control panel; and if the dose rate difference exceeds five percent, the irradiation

is terminated.

Subp. 9. **Selection and display of dose monitor units.** All x-ray and electron therapy systems must provide for the selection and display of dose monitor units according to this subpart.

A. Irradiation must not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

B. The preselected number of dose monitor units must be displayed at the treatment control panel until reset manually for the next irradiation.

C. On systems installed after September 10, 1991, following an irradiation terminated by the dose monitoring system, it must be necessary to manually reset the preselected dose monitor units after irradiation is terminated and before irradiation can be reinitiated.

Subp. 10. **Termination of irradiation by the dose monitoring system or systems during stationary beam therapy.** All x-ray and electron therapy systems must meet the requirements in this subpart regarding termination of irradiation by dose monitoring systems during stationary beam therapy.

A. Each primary system must terminate irradiation when the preselected number of dose monitor units has been detected by the system.

B. If original design of the system included a second dose monitoring system, that system must be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units, whichever is smaller, above the preselected number of dose monitor units set at the treatment control panel has been detected by the second dose monitoring system.

C. Systems installed after September 10, 1991, must have a second dose monitoring system which terminates irradiation when not more than ten percent or 25 dose monitor units, whichever is smaller, above the preselected number of dose monitor units set at the treatment control panel has been detected by the second dose monitoring system.

D. Systems installed after September 10, 1991, must have an indicator on the control panel that shows which dose monitoring system has terminated irradiation.

Subp. 11. **Interruption switches.** All x-ray and electron therapy systems must have switches that allow the interruption of irradiation and meet the requirements in this subpart.

A. It must be possible to interrupt irradiation and equipment movement at any time from the operator's position at the treatment control panel.

B. Emergency off switches must be placed on or near the treatment console. Inside the treatment room, emergency off switches must be placed on or near both sides of the treatment couch, and on or near both sides of the gantry stand.

Subp. 12. **Termination switches.** All x-ray and electron therapy systems must have termination switches that make it possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

Subp. 13. **Timer.** All x-ray and electron therapy systems must have a timer that meets the

requirements in this subpart.

A. A timer which has a visual display must be provided at the treatment control panel. The timer must have a preset time selector and an elapsed time indicator.

B. The timer must be a cumulative timer which activates with the production of radiation and returns its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator to zero.

C. For systems installed after September 10, 1991, after termination of irradiation and before irradiation can be reinitiated, it must be necessary to manually reset the preset time selector.

D. The timer must terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

E. For systems installed after September 10, 1991, if the backup timer is automatically set by control circuitry, the additional time must not be more than ten percent above the time determined by dividing the number of monitor units (MU) by the monitor unit irradiation rate.

Subp. 14. **Selection of radiation type.** Therapy systems capable of emitting both x-rays and electrons must allow for the selection of the radiation type according to the requirements in this subpart.

A. Irradiation must not be possible until a selection of radiation type has been made at the treatment control panel.

B. An interlock system must be provided to ensure that the equipment can emit only the radiation type which has been selected.

C. An interlock system must be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

D. An interlock system must be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.

E. An interlock system must be provided to ensure electron beam irradiations do not take place with inappropriate beam modifiers such as wedges in the beam.

F. The radiation type selected must be displayed at the treatment control panel before and during irradiation.

Subp. 15. **Selection of energy.** Systems capable of generating radiation beams of different energies must allow for the selection of the energy value according to the requirements in this subpart.

A. Irradiation must not be possible until a selection of energy has been made at the treatment control panel.

B. An interlock system must be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

C. The nominal energy value and photon or electron modality selected must be displayed at the treatment control panel before and during irradiation.

Subp. 16. **Selection of stationary beam therapy or rotational beam therapy.** Systems capable of both stationary beam therapy and rotational beam therapy must allow for the selection of stationary beam therapy or rotational beam therapy according to the requirements in this subpart.

A. Irradiation must not be possible until a selection of stationary beam therapy or rotational beam therapy has been made at the treatment control panel.

B. An interlock system must be provided to ensure that the equipment can operate only in the mode which has been selected.

C. An interlock system must be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

D. The mode of operation must be displayed at the treatment control panel.

E. For systems installed after September 10, 1991, an interlock system must be provided to terminate irradiation if:

(1) movement of the gantry occurs during stationary beam therapy; or

(2) movement of the gantry stops during rotational beam therapy unless such stoppage is a preplanned function.

F. Rotational beam therapy must be controlled to provide accurate total dose and arc angle.

(1) for systems installed after September 10, 1991, where the angle of rotation terminates the radiation, the maximum difference between the delivered and expected monitor units (MU) must not exceed three percent or one monitor unit, whichever is greater. The expected MU is calculated by multiplying the set value of MU/degree by the set value of total gantry rotation angle. The observed terminal gantry angle must be within plus or minus three degrees of expected. This requirement applies for all arcs of 45 degrees or more at all MU/degree values indicated as "clinically usable" by the manufacturer.

(2) for systems installed after September 10, 1991, where the dose monitoring system terminates the irradiation, the maximum difference between the observed and expected angle of rotation of the gantry shall not exceed plus or minus three degrees. The expected angle of rotation is calculated by dividing the set value of monitor units by the set value of MU/degree. The agreement of elapsed MU to MU set must be three percent, or 1.0 MU, whichever is greater. This requirement applies for all arcs of 45 degrees or more at all MU/degree values indicated as "clinically usable" by the manufacturer.

Subp. 17. **Absorbed dose rate.** Systems installed after September 10, 1991, must have a component from which readings of the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors in subpart 7 may form a portion of this system. The requirements in items A and B also apply.

A. The dose monitor unit rate must be displayed at the treatment control panel.

B. If the system can deliver under any conditions an absorbed dose rate at the nominal treatment distance of more than ten percent above the value specified by the manufacturer for any equipment parameters used, a device must be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated must be in a record maintained by the registrant.

Subp. 18. **System checking facilities.** Capabilities shall be provided so all radiation safety interlocks can be checked for correct operation. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

Subp. 19. **Operating procedures.** Any therapy system with energies greater than one MV shall not be used in the administration of radiation therapy unless the requirements of 4731.0131; 4731.1305, subp.2; and 4731.1306, subp 2, have been met.

4731.1500 Transportation of Radioactive Materials

Subpart 1. **Packaging and transportation subject to state and federal rule.** The packaging and transportation of radioactive material are subject to the provisions of Chapter 4731 and are also subject to the requirements of other agencies such as the U.S. Nuclear Regulatory Commission, U.S. Department of Transportation (U.S. DOT), the and the U.S. Postal Service. The requirements of part 4731.1500-4731.1518 are in addition to, and not in substitution for, other requirements.

Subp 2. **Modification of requirements.** The licensee shall conform to the standards and requirements of the U.S. DOT specified in part 4731.1501, subp. 2 to the same extent as if the shipment or transportation were subject to U.S. DOT regulations. A request for any modification, waiver, or exemption referred to in those requirements, must be filed with, or made to the commissioner.

Subp 3. **A_1 and A_2 values.** Determinations of A_1 and A_2 values are found in parts 4731.3001, I, and 4731.3002, 1.

4731.1501 General Requirements

Subpart 1. **Deliver to carrier.** No person shall deliver radioactive material to a carrier for transport or transport radioactive material except as authorized in a general license or specific license issued by the commissioner or as exempted in part 4731.1513.

Subp. 2. **Comply with U. S. DOT regulations.** Each licensee who transports radioactive material outside of the site of usage, as specified in the license from the commissioner, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements, of the U.S. DOT regulations in 49 CFR parts 170 through 189 appropriate to the mode of transport.

A. The licensee shall comply with the U.S. DOT in the following areas:

(1) packaging - 49CFR Part 173 : subparts A, and B and I.

(2) marking and labeling - 49CFR Part 172: Subpart D, §§ 172.400 through 172.407, §§ 172.436 through 172.440, and subpart E.

(3) placarding - 49CFR Part 172: subpart F, especially §§ 172.500 through 172.519, 172.556, and Appendices B and C.

(4) accident reporting - 49CFR Part 171: §§ 171.15 and 171.16.

(5) shipping papers and emergency information - 49CFR Part 172: subparts C and G.

(6) hazardous material employee training - 49CFR Part 172: subp H.

(7) hazardous material shipper /carrier registration - 49CFR Part 107: subp G.

B. The licensee shall comply with U.S. DOT regulations pertaining to the following modes of transportation:

(1) rail - 49CFR Part 174: subparts A through D and K.

(2) air - 49CFR Part 175.

(3) vessel - 49CFR Part 176: subparts A through F and M.

(4) public highways - 49CFR Part 177 and Parts 390 through 397.

C. If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in subpart 4731.1501 Subpart 2, item A to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with , or made to the commissioner of health.

Subp 3. **Instructions to open package** . Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with part 4731.0123, subp 5, E.

4731.1502 Quality Assurance Requirements

Subpart 1. **Quality assurance program.** Each licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective equipment or other ancillary materials relating to the shipment of packages containing radioactive material are promptly identified and corrected.

Subp 2. **Scope of quality assurance program.** The licensee shall identify the scope of the equipment, ancillary material and other components to be covered by the quality assurance program.

Subp 3. **Document and implement quality assurance program.** Each 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 packaging is used.

Subp 4. **Commissioner approval.** Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the commissioner of its quality assurance program.

Subp 5. **Records.** The licensee shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use

of a package for shipment of radioactive material shall be maintained for a period of 4 years after shipment.

4731.1503 Preliminary Determinations. Before the first use of any packaging for the shipment of radioactive material:

A. The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects which could significantly reduce the effectiveness of the package;

B. Where the maximum normal operating pressure will exceed 35 kilopascal (5 pounds per square inch) gauge, the licensee shall test the containment system at an internal pressure of at least 50 percent higher than the maximum normal operating pressure to verify that capability of that system to maintain its structural integrity at that pressure; and

C. The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by the U.S. NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the U.S. NRC.

4731.1504 Routine Determinations. Before each shipment of radioactive material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this part and of the license. The licensee shall determine that:

A. The package is proper for the contents to be shipped;

B. The package is in an unimpaired physical condition except for superficial defects such as marks or dents;

C. Each closure device of the packaging, including any required gasket , is properly installed and secured and free of defects;

D. Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

E. Any pressure relief device is operable and set in accordance with written procedures;

F. The package has been loaded and closed in accordance with written procedures;

G. For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

H. Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements of 10 CFR 71.45;

I. The level of nonfixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable, and within the limits specified in U.S. DOT regulations in 49CFR173.443;

J. External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in 10CFR71.47 at any time during transportation; and

K. Accessible package surface temperatures will not exceed the limits specified in 10CFR71.43(g) at any time during transportation.

4731.1505 General License for Use of Nuclear Regulatory Commission Approved Packages

Subpart 1. **License to transport or deliver.** Any person who has a license from the commissioner is issued a general license 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 U.S. NRC.

Subp 2. **Approved quality assurance program.** This general license applies only to a licensee who has a quality assurance program approved by the U.S. NRC. as satisfying the provisions of 10CFR71.101-10CFR71.137

Subp 3. **Compliance with conditions.** This general license applies only to a licensee who:

A. Has a copy of the certificate of compliance, or other approval of the package, and has 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 before shipment;

B. Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of 10CFR71.5 and 10CFR71.12-10CFR71.24

C. Submits in writing to U.S. NRC, before the licensee's first use of the package, the licensee's name and license number and the package identification number specified in the package approval.

D. The general license in part 4731.1505, subp 1 only when the package approval authorizes use of the package.

E. For a Type B or fissile material package, the design of which was approved by the U.S. NRC before April 1, 1996, the general license is subject to the additional restrictions of 4731.1506.

4731.1506 General License for the Use of Previously Approved Type B Packages

Subpart 1. **Conditions for Type B package.** A Type B package previously approved by the U.S. NRC., but not designated as B(U) or B(M) in the identification number of the U.S.NRC. Certificate of Compliance, may be used under the general license of part 4731.1505 above, with the following additional conditions:

A. Fabrication of the packaging was satisfactorily completed before August 31, 1986, and its model number marked as required in part 4731.1509;

B. The package used for a shipment to a location outside the United states is subject to multilateral approval, as defined in U.S. DOT regulations at 49CFR173.403; and

C. A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

Subp 2. **Package previously approved by NRC.**A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the U.S. NRC but without the designation "–85"" in the identification number of the Certificate of Compliance may be used under the general license of part 4731.1505 with the following additional conditions:

A. Fabrication of the package is satisfactorily completed by April 1, 1999, and it's model

number marked as requested in part 4731.1503, C .

B. A package for a shipment to a location outside the United States is subject to multilateral approval as defined in U.S. DOT regulations at 49CFR173.403.

C. A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

4731.1507 General License for the Use of U.S. Department of Transportation Specification Container

Subpart 1. **Use U.S. DOT specification containers.** Any person who has a license from the commissioner is issued a general license 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 49CFR Parts 173 and 178 is issued a general license to use U.S. DOT specification containers.

Subp 2. **Requires approved quality assurance program.** This general license applies only to a licensee who has a quality assurance program approved by the commissioner as satisfying the provisions of part 4731.1502.

Subp 3. **Comply with specification conditions.** This general license applies only to a licensee who:

A. Has a copy of the specification;

B. Complies with the terms and conditions of the specification and the applicable requirements of parts 4731.0162, C, 4731.0185, 4731.1500, 4731.1501, 4731.1503, 4731.1504, 4731.1511, 4731.1512, and 4731.1514.

Subp 4. **Specification container use within United States.** The general license in part 4731.1506, subp 1, 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 1173.403.

4731.1508 General License Use of Foreign Approved Package

Subpart 1. **Use of foreign approved packages** . Any person who has a license from the commissioner is issued a general license to transport, or 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 that has been revalidated by the U.S. DOT as meeting the applicable requirements of 49 CFR 171.12 is issued a general license to use foreign approved packages.

Subp 2. **Requires approved quality assurance program.** Except as otherwise provided in parts 4731.1500-4731.1518, the general license applies only to a licensee who has a quality assurance program approved by the commissioner as satisfying the applicable provisions of part 4731.1502.

Subp 3. **Use to ship to or from outside United States.** This general license applies only to shipments made to or from locations outside the United States.

Subp 4. **Comply with certificate conditions.** This general license applies only to a licensee who:

A. Has 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

B. Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of parts 4731.1500, 4731.1501, 4731.1503, 4731.1504, 4731.1511, 4731.1512, 4731.1514. With respect to the quality assurance provisions of part 4731.15102, the licensee is exempt from design, construction, and fabrication considerations.

4731.1509 Applicability of Operating Controls and Procedures for Fissile Material.

A. A license subject to part 4731.1503, who, under a general or specific license, transports licensed material or delivers licensed material to a carrier for transport, shall comply with the requirements of parts 4731.0500, 4731.1501, 4731.1503, 4731.1504, 4731.1511, 4731.1512, 4731.1514 and parts 4731.0100-4731.0102, and 4731.0105-4731.0109.

B. Assumptions as to unknown properties. When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication

4731.1510 General License for Use of Fissile Material, Limited Quantity Package

Subpart 1. **Transport or deliver fissile material.** Any person who has a license from the commissioner is issued a general license to transport fissile material, or to deliver fissile material to a carrier for transport, without demonstrating compliance with 10CFR71.31-10CFR71.77, if the material is shipped in accordance with part 4731.1511 is issued a general license use of fissile material, limited quantity package.

Subp 2. **Requires approved quality assurance program.** The general license applies only to a licensee who has a quality assurance program approved by the commissioner as satisfying the provisions of 10CFR71.101- 10CFR71.137.

Subp 3. **Package limited to Type A package.** This general license applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:

A. Up to 40 grams of uranium-235; or

B. Up to 30 grams of uranium-233; or

C. Up to 25 grams of the fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A_1 quantity of plutonium may be present; or

D. A combination of fissile radionuclides in which the sum of the ratios of the

amount of each radionuclide to the corresponding maximum amounts in part 4731.1510, subp. 3, A, B, and C, above, does not exceed unity.

Subp 4. **Package limited to Type A quantity.** For packages where fissile material is mixed with substances having an average hydrogen density greater than water, this general license applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:

A. Up to 20 g of uranium-235

B. Up to 18 g of uranium-233

C. Up to 18 g of fissile radionuclides of plutonium, or

D. A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amounts in part 4731.1510, subp. 4, A, B. and C, above , does not exceed unity.

Subp 5. **Contains no beryllium, graphite, or enriched hydrogenous material** . Except for the beryllium contained within the special form plutonium-beryllium sources authorized in part 4731.1510, subp. 3, this general license applies only when beryllium, graphite, or hydrogenous material enriched in deuterium is not present in quantities exceeding 0.1 percent of the fissile material mass.

Subp 6. **Special conditions**

A. Except as specified in part 4731.1510, subp. 6, B, below, for plutonium-beryllium sources authorized in part 4731.1510, subparts 3 and 4, this general license applies only when a packages labeled with a transport index not less that the number given by the following equation, where the package contains x grams of uranium-235, y grams of uranium-233, and z grams of the fissile radionuclides of plutonium.

Minimum Transportation Index = (0.25x + 0.33y + 0.4z). (where the package contains x grams of uranium-235, y grams of uranium-233, and z grams of the fissile radionuclides of plutonium.)

B. For a package in which the only fissile material is in the form of encapsulated plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.025 times the number of grams of the fissile radionuclides of plutonium.

C. Packages which have a transport index greater than 10 are not authorized under the general license provisions in 4731.1505 - 4731.1511, and 4731.3001, D.

4731.1511 General License for use of packages for Fissile Material, Limited Moderator per Package, and Fissile Material, Limited Quantity, Controlled Shipment Subpart 1. **Limited fissile material, limited moderator per package** . Any person who has a license from the commissioner is issued a general license to transport fissile material, or to deliver fissile material to a carrier for transport, without complying to 10CFR71.41-10CFR71.77 if the material is shipped in accordance with 4731.1510 is issued a general license for use of packages for fissile material, limited moderator per package and fissile material, limited quantity, controlled shipment.

Subp. 2. **Approved quality assurance program.** The general license in subpart 1, above, applies only to a licensee who has a quality assurance program approved by the commissioner as satisfying the provisions of 4731.1502.

Subp. 3. **Limited quantity conditions.** This general license applies only when the licensee complies with 4731.1502 and all of the following requirements are met:

A. The package contains no more than a Type A quantity of radioactive material.

B. Neither beryllium nor hydrogenous material enriched in deuterium is present.

C. The total mass of graphite present does not exceed 150 times the total mass of uranium-235 plus plutonium.

D. Substances having a higher hydrogen density than water are not present, except that polyethylene may be used for packing or wrapping.

E. Uranium-233 is not present, and the amount of plutonium does not exceed 1 percent of the amount of uranium-235.

F. The amount of uranium-235 is limited as follows:

(1) if the fissile radionuclides are not uniformly distributed, the maximum amount of uranium-235 per package may not exceed the value given in the following table:

Table 1

Uranium enrichment in weight percent of uranium-235 not exceeding	Permissible maximum grams of uranium-235 per package
24	40
20	42
15	45
11	48
10	51
9.5	52
9	54
8.5	55
8	57
7.5	59
7	60
6.5	62
6	65
5.5	68
5	72
4.5	76
4	80
3.5	88
3	100

2.5	120
2	164
1.5	272
1.35	320
1	680
0.92	1200

(2) if the fissile radionuclides are distributed uniformly, the maximum amount of uranium-235 per package may not exceed the value given in the following table:

Table 2

Uranium enrichment in weight percent of uranium-235 not exceeding	Permissible maximum grams of uranium-235 per package
4	84
3.5	92
3	112
2.5	148
2	240
1.5	560
1.35	800

G. The transport index of each package based on criticality considerations is taken as ten times the number of grams of uranium-235 in the package divided by the maximum allowable number of grams per package in accordance with Table 1 or Table 2 above as applicable.

Subp. 4. **Comply with 10 CFR 71.22.** A general licensee who transports fissile material, limited quantity, controlled shipment shall comply with 10 CFR 71.22

4731.1512 Air Transport of Plutonium

Subpart. 1. **Limitations for plutonium transport.** Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this part or included indirectly by citation of 49CFR chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air, or delivered to a carrier for air transport, unless:

A. The plutonium is contained in a medical device designed for individual human application; or

B. The plutonium is contained in a material in which the specific activity is not greater than 0.002 microcuries per gram (70 Bq/g) of material and in which the radioactivity is essentially uniformly distributed; or

C. The plutonium is shipped in a single package containing no more than an A_2

quantity of plutonium in any isotope or form, and is shipped in accordance with part 4731.1501; or

D. The plutonium is shipped in a package specifically authorized for shipment of plutonium by air in the Certificate of Compliance for that package issued by the Nuclear Regulatory Commission.

Subp. 2. **Comply with 10 CFR 73.24.** Nothing in part 4731.1504, A, is to be interpreted as removing or diminishing the requirements of 10CFR73.24.

Subp. 3. **Comply with 49 CFR 175.704.** For a shipment of plutonium by air which is subject to part 4731.1512, subp.1, D, the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, the U.S. DOT regulations applicable to the air transport of plutonium.

4731.1513 ~~Exemptions For Low Level Radioactive Materials~~

~~Subpart 1.~~ Exemptions For Low Level Radioactive Materials .Package with less than 0.002 microcurie per gram. A licensee is exempt from the requirements of parts 4731.1500-4731.1518 with respect to shipment or carriage of a package containing radioactive material having a specific activity not greater than 0.002 microcurie per gram (70 Bq/gm).

~~Subp 2. **Only exempt fissile material.** A licensee is exempt from all requirements of parts 4731.1500- 4731.1518, other than parts 4731.1501 and 4731.1512 with respect to shipments or carriage of the following packages, provided the packages contain no fissile material, or the U.S. NRC fissile material exemption standards 10CFR71.53 are satisfied:~~

~~A. A package containing no more than a Type A quantity of radioactive material; or~~

~~B. A package in which the only radioactive material is low specific activity (LSA) material or surface contaminated objects (SCO), provided the external radiation level at 3 m from the unshielded material or objects does not exceed 1 rem/h (10 mSv/h); or~~

~~C. A package which contains only americium or plutonium in special form with an aggregate radioactivity not to exceed 20 curies (740 Gbq), when it is transported between locations within the United States.~~

~~Subp. 3. **Low-specific activity or surface contaminated objects.** A license is exempt from all requirements of parts 4731.1500- 4731.1518, other than part 4731.1501, subp. 2, and1512, with respect to shipment or carriage of low-specific-activity (LSA) material in group LSA-I, or surface contaminated objects (SCOs) in group SCO-I as defined in part 4731.0100.~~

4731.1514 Advance Notification of Shipment of Radioactive Waste (1514)

Subpart 1. **Notice to governor.** As specified in part 4731.1514, subparts B, C, and D, each licensee shall provide advance notification to the governor of a state, or the governor's designee, of the shipment of licensed material, through, or across the boundary of the state, before the transport, or delivery to a carrier, form transport, of licensed material outside the confines of the license's plant or other place of use or storage.

Subp 2. **Irradiated fuel and special conditions.** Advance notification is required under part 4731.1514 for shipments of irradiated fuel in quantities less than that subject to advance notification requirements of 10CFR73.37(f). Advance notification is also required under this section for shipments of licensed material, other than irradiated fuel, meeting the following three conditions:

A. The licensed material is required by part 4731.1514 to be in Type B packaging for transportation;

B. The licensed material is being transported to or across a state boundary enroute to a disposal facility or to a collection point for transport to a disposal facility; and

C. The quantity of licensed material in a single package exceeds the least of the following:

(1) 3000 times the A_1 value of the radionuclides as specified in part 4731.3002, 1, for special form radioactive material;

(2) 3000 times the A_2 value of the radionuclides as specified in part 4731.3002, 1, for normal form radioactive material, or

(3) 27.000 curies (1000 TBq) .

Subp 3. **Procedures for submitting advance notification.** The notification must:

A. Be made in writing to the office of each affected state governor or governor's designee and to the commissioner.

B. Be delivered by mail and must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

C. Be delivered by messenger must reach the office of the governor or of the governor's designee at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur.

(1) a list of the names and mailing addresses of the governor's designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30,1995 (60 FR34306).

(2) the list will be published annually in the Federal Register on or about June 30 to reflect changes in information.

(3) the list of the names and mailing addresses of the governor's designees is available on request from the Director, Office of State Programs, U.S. NRC, Washington, DC 2055-0001.

D. The licensee shall retain a copy of the notification as a record for 4 years or until the next inspection.

Subp 4. **Information to be furnished in advance notification of shipment** . Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

A. The name, address, and telephone number of the shipper, carrier and receiver of the irradiated reactor fuel or nuclear waste shipment;

B. A description of the irradiated reactor fuel or nuclear waste contained in the

shipment as specified by the regulations of the U.S. DOT in 49 CFR 172.202 and 172.203(d);

C. The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

D. The 7-day period during which arrival of the shipment at state boundaries is estimated to occur;

E. The destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and

F. A point of contact, with a telephone number, for current shipment information.

Subp 5. **Revision notice.** A licensee who finds that schedule information previously furnished to a governor or a governor's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the state or of the governor'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 4 years or until next inspection.

Subp 6. **Cancellation notice.**

A. Each licensee who cancels an irradiated reactor fuel or 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, and to the commissioner.

B. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled. The licensee shall retain a copy of the notice as a record for 4 years

~~4731~~04731.3001, G.

Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests

I. Manifest

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest ~~(OMB Control Numbers 3150 - 0164, - 0165, and - 0166)~~ reflecting information requested on thr applicable ~~NRC~~ ~~F~~forms ~~540~~4731.3004,12, A (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and ~~541~~4731.3004, 12, B (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an ~~applicable NRC Form 542~~4731.3004, 12, C (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). ~~NRC~~ Forms ~~540~~4731.3004, 12, A and ~~540A~~4731.3004, 12, A1, must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, ~~NRC Forms 541 and 541A and 542 and 542A~~forms 4731.3004, 12, B and 4731.3004, 12, B1 and 4731.3004, 12, C and 4731.3004, 12, C1, may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by ~~MDH~~the commissioner to comply with the manifesting requirements of this part when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the "waste generator" or "generator," as defined in this part; or

(c) Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

~~NRC~~ Forms ~~540~~4731.3004, ~~540A~~12, ~~541, 541A, 542~~A and ~~542A~~A1, B and B1, C and C1, and the accompanying instructions, in hard copy, may be obtained from the Information and Records Management Branch, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415 - 7232.

This appendix includes information requirements of the U.S. Department of Transportation (DOT), as codified in 49 CFR part 172. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency regulations,

as codified in 40 CFR parts 259, 261 or elsewhere, is not addressed in this ~~section~~appendix, and must be provided on the required EPA forms. However, the required EPA forms must accompany the form 4731.3004, 12, Uniform Low-Level Radioactive Waste Manifest required by ~~this c~~Chapter 4731.

As used in this appendix, the following definitions apply:

Chelating agent has the same meaning as that given in ~~§61~~4731.~~2~~0100 of this chapter.

Chemical description means a description of the principal chemical characteristics of a low-level radioactive waste.

Computer-readable medium means that the regulatory agency's computer can transfer the information from the medium into its memory.

Consignee means the designated receiver of the shipment of low-level radioactive waste.

Decontamination facility means a facility operating under a Commission or Agreement State license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this part, is not considered to be a consignee for LLW shipments.

Disposal container means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

EPA identification number means the number received by a transporter following application to the Administrator of EPA as required by 40 CFR part 263.

Generator means a licensee operating under a Commission or Agreement State license who (1) is a waste generator as defined in this part, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

High integrity container (HIC) means a container commonly designed to meet the structural stability requirements of ~~§61~~4731.~~56 of this chapter~~0136, subp 7, and to meet U.S. Department of Transportation requirements for a Type A package.

Land disposal facility has the same meaning as that given in ~~§61.2 of this chapter.~~

~~NRC Forms 540, 540A, 541, 541A, 542, and 542A are official NRC Forms~~4731.0100.

Forms 4731.3004, 12, A and A1, B and B1, C and C1 are official forms referenced in this appendix. Licensees need not use originals of these ~~NRC F~~forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, ~~NRC F~~forms ~~541 (and 541A)~~4731.3004, 12, B and ~~NRC F~~B1 and forms ~~542 (~~4731.3004, 12,

C and ~~542A)~~C1 may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

Package means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

Physical description means the items called for on ~~NRC F~~form ~~541~~4731.3004, 12, B to describe a low-level radioactive waste.

Residual waste means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

Shipper means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

Shipping paper means ~~NRC F~~form ~~540~~4731.3004, 12, A and, if required, ~~NRC F~~form ~~540A~~4731.3004, 12, A1, which includes the information required by DOT in 49 CFR part 172.

Source material has the same meaning as that given in ~~§40.4 of this chapter~~4731.0100.

Special nuclear material has the same meaning as that given in ~~§70.4 of this chapter~~4731.0100.

Uniform Low-Level Radioactive Waste Manifest or

~~u~~*Uniform manifest* means the combination of ~~NRC F~~forms ~~540~~4731.3004, ~~541~~12, A, 4731.3004, 12, B, and, if necessary, ~~542~~4731.3004, 12, C, and their respective continuation sheets as needed, or equivalent.

Waste collector means an entity, operating under a ~~Commission~~commissioner, NRC, or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

Waste description means the physical, chemical and radiological description of a low-level radioactive waste as called for on ~~NRC F~~form ~~541~~4731.3004, 12, B.

Waste generator means an entity, operating under a ~~Commission~~commissioner, NRC, or ~~A~~agreement State license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a

licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

Waste processor means an entity, operating under a ~~Commission~~commissioner, NRC, or ~~A~~agreement State license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

Waste type means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

Information Requirements

A. General Information

The shipper of the radioactive waste, shall provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

B. Shipment Information

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages/disposal containers;

3. The total disposal volume and disposal weight in the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides H - 3, C - 14, Tc-99, and I - 129 contained in the shipment; and

6. The total masses of U - 233, U - 235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal Container and Waste Information

The shipper of the radioactive waste shall provide the following information on the

uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

8. The approximate volume of waste within a container;

9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container, the masses of U - 233, U - 235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and

12. For wastes consigned to a disposal facility, the classification of the waste pursuant to ~~§61~~4731.~~55 of this chapter~~0136, subp. 6. Waste not meeting the structural stability requirements of ~~§61~~4731.~~56(b) of this chapter~~0136, subp. 7, B, must be identified.

D. Uncontainerized Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by

weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to ~~§61~~4731.~~55 of this chapter~~0136, subp. 6. Waste not meeting the structural stability requirements of ~~§61~~4731.~~56(b) of this chapter~~0136, subp. 7, B, must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U - 233, U - 235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-Generator Disposal Container Information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators" (including "waste generators") as defined in this part). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

(a) The volume of waste within the disposal container;

(b) A physical and chemical description of the waste, including the solidification agent, if any;

(c) The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(d) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in ~~10 CFR 61~~4731.~~56(b)~~0136, subp. 7, B; and

(e) Radionuclide identities and activities contained in the waste, the masses of U - 233, U - 235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

II. Certification

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the U.S. Department of Transportation, NRC, and the ~~Commission~~commissioner. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

III. Control and Tracking

A. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1 through 9 of this section. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4 through 9 of this section. A licensee shall:

1. Prepare all wastes so that the waste is classified according to ~~§61~~4731.~~55~~0136, subp. 6, and meets the waste characteristics requirements in ~~§61~~4731.~~56 of this chapter~~0136, subp. 7;

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater then Class C waste, in accordance with ~~§61~~4731.~~55 of this chapter~~0136, subp. 6;

3. Conduct a quality assurance program to assure compliance with ~~§§61~~4731.~~55~~0136, subparts 6 and ~~61.56 of this chapter~~7 (the program must include management evaluation of audits);

4. Prepare the ~~NRC~~4731.3004, 12, Uniform Low-Level Radioactive Waste Manifest as required by this appendix;

5. Forward a copy or electronically transfer the form 4731.3004, 12, Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (i) receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

6. Include ~~NRC F~~form ~~540~~4731.3004, 12, A, (and ~~NRC Form 540A~~4731.3004, 12, A1, if required) with the shipment regardless of the option chosen in paragraph A.5 of this section;

7. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of ~~NRC F~~form ~~540~~4731.3004, 12, A;

8. Retain a copy of or electronically store the 4731.3004, 12, Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the

record of transfer of licensed material as required by ~~10 CFR Parts 30, 40, and 70 of this chapter~~4731.0315; and

9. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of ~~NRC F~~form ~~540~~4731.3004, 12, A;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the 4731.3004, 12, Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

4. Include ~~NRC F~~form ~~540~~4731.3004, 12, A (and ~~NRC F~~form ~~540A~~4731.3004, 12, A1, if required) with the shipment regardless of the option chosen in paragraph B.3 of this section;

5. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of ~~NRC F~~form ~~540~~4731.3004, 12, A;

6. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by ~~10 CFR parts 30, 40, and 70 of this chapter~~4731.0315;

7. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

8. Notify the shipper and the ~~Administrator of the nearest Commission Regional Office listed in appendix D of this part~~commissioner when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

C. Any licensed waste processor who treats or repackages waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of ~~NRC F~~form ~~540~~4731.3004, 12, A;

2. Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements.

For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in paragraph I.E. of this appendix;

3. Prepare all wastes so that the waste is classified according to ~~§61~~4731.~~55 of this chapter~~0136, subp.6, and meets the waste characteristics requirements in ~~§61~~4731.~~56 of this chapter~~0136, subp. 7;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with ~~§§61~~4731.~~55~~0136, subparts 6 and ~~61.57 of this chapter~~8;

5. Conduct a quality assurance program to assure compliance with ~~§§61~~4731.~~55~~0136, subparts 6 and ~~61.56 of this chapter~~7, (the program shall include management evaluation of audits);

6. Forward a copy or electronically transfer the form 4731.3004, 12, Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

7. Include ~~NRC F~~form ~~540~~4731.3004, 12, A (and ~~NRC F~~form ~~540A~~4731.3004, 12, A1, if required) with the shipment regardless of the option chosen in paragraph C.6 of this section;

8. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of ~~NRC F~~form ~~540~~4731.3004, 12, A;

9. Retain a copy of or electronically store the from 4731.3004, 12, Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by ~~10 CFR parts 30, 40, and 70 of this chapter~~4731.0315;

10. For any shipment or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

11. Notify the shipper and the ~~Administrator of the nearest Commission Regional Office listed in appendix D of this part~~commissioner when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of ~~NRC F~~form ~~540~~4731.3004, 12, A to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the form 4731.3004, 12,

Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by 4731.0183, subp. 10 ~~CFR 61.80(l)~~, until the ~~Commission~~commissioner terminates the license; and

3. Notify the shipper and the ~~Administrator of the nearest Commission Regional Office listed in appendix D of this part~~commissioner when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

E. Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the ~~nearest Commission Regional Office listed in Appendix D to this part~~commissioner. Each licensee who conducts a trace investigation shall file a written report with the ~~appropriate NRC Regional Office~~commissioner within 2 weeks of completion of the investigation.

~~[60 FR 15664, Mar. 27, 1995, as amended at 60 FR 25983, May 16, 1995]~~

~~Effective Date Note: At 60 FR 15664, Mar. 27, 1995, appendix G to part 20 was added, effective March 1, 1998, and at 60 FR 25983, May 16, 1995, III E. was added to appendix G, effective March 1, 1998.~~