NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

December 13, 2019
1:00 p.m. Central Time
Nebraska State Office Building – Lower Level B
301 Centennial Mall South, Lincoln, Nebraska

The purpose of this hearing is to receive comments on proposed changes to Title 180, Chapter 19 of the Nebraska Administrative Code (NAC) – *Licenses and Radiation Safety Requirements for Irradiators.* The chapter governs the licensing and safety requirements for the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. The proposed changes remove duplicative statutory language and unnecessary language from the regulations and update formatting.

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7).

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

A copy of the proposed changes is available online at http://www.sos.ne.gov, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: **Department of Health and Human Services**	
Title: 180	Prepared by: Julia Schmitt
Chapter: 19	Date prepared: 5/8/2019
Subject: Licenses and Radiation Safety Requirements for Irradiators	Telephone: 402/471-0528

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(☒)	(☒)	(☒)
Increased Costs	(☐)	(☐)	(☐)
Decreased Costs	(☐)	(☐)	(☐)
Increased Revenue	(☐)	(☐)	(☐)
Decreased Revenue	(☐)	(☐)	(☐)
Indeterminable	(☐)	(☐)	(☐)

Provide an Estimated Cost & Description of Impact:

State Agency:

Political Subdivision:

Regulated Public:

If indeterminable, explain why:

PROPOSED REGULATION QUESTIONNAIRE

Title 180 NAC 19

1) Is the regulation essential to the health, safety, or welfare of Nebraskans?

Yes. The purpose of the regulations are to institute and maintain a program to permit development and utilization of sources of radiation for peaceful purposes consistent with the protection of occupational and public health and safety and the environment. The regulated entities operate irradiators for the sterilization of blood and medical products. The irradiators contain large amount of radioactive material. As such, it is important that the irradiators are operated in a manner that protects radiation workers, the public and the environment.

2) Do the costs of the regulation outweigh the benefits? Provide specific data and reasoning.

Radioactive materials provide benefits to the public in a number of medical and industrial settings. Misuse of radioactive materials and ionizing radiation can be life-threatening and have catastrophic environmental consequences. The regulations provide safeguards that allow the benefits while minimizing risks. Without regulation by the state, individuals would be required to meet the same standards under federal licensure at significantly great cost to the licensees. As an Agreement State, the Annual Fees levied by Nebraska for licensure and regulation are much less than those levied by the U.S. Nuclear Regulatory Commission (NRC).
Examples:

Material Type	NRC	Nebraska
Medical Use	$11,100 – 18,500	$3,900
Panoramic Irradiator	$62,000	$11,500
Irradiator, self-shielded	$6,500	$2,600
Broad Scope (Educational or Medical)	$29,700	$18,000
Industrial Radiography	$10,600	$6,500

3) Does a process exist to measure the effectiveness of the regulation? If so, explain.

Yes. Licensees and registrants are inspected for compliance with the radiation safety regulations. The performance of the Office of Radiological Health is evaluated by the Nuclear Regulatory Commission during the Integrated Materials Performance Evaluation Program (IMPEP). Performance is assessed in the following areas: technical staffing and training; status of materials inspection program; technical quality of inspections; technical quality of licensing actions; technical quality of incident and allegation activities, and; compatibility of regulations.

4) Has a less restrictive alternative been considered?

The least restrictive alternative has been chosen. Because the Agreement requires that Nebraska's regulatory program be compatible with that of the NRC, rather than always identical, there are some areas of the regulations that we are allowed more flexibility in crafting regulations that more directly meet the needs of our licensees while still being protective. Each regulation of the NRC is assigned a compatibility designation. Compatibility a regulations are basic radiation protection standard or related definitions, signs, labels or terms necessary for a common understanding of radiation protection

principles. The State regulations must be essentially identical to those of the NRC. Compatibility B regulations have significant direct trans-boundary implications. The State regulations must be essentially identical to those of the NRC. For Compatibility C regulations, the essential objectives must be adopted by the State to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met. For any Compatibility C regulations, the least restrictive regulatory alternative has been chosen.

5) Was the regulation solely promulgated due a state statutory requirement? If so, provide citations.

Yes, Neb. Rev. Stat. § 71-3505 (1) and § 71-3507 (1) requires regulations. However, even if the statute were to be changed to "may", regulations would still be needed to ensure public safety and safe radiation use by the regulated entities.

6) Was the regulation promulgated as the result of a federal mandate? If so, include copies of the applicable federal statutes and regulations.

No. However, Section 274 of the Atomic Energy Act provides a statutory basis under which the U. S. Nuclear Regulatory Commission (NRC) relinquishes to the States portions of its regulatory authority to license and regulate byproduct materials (radioisotopes); source materials (uranium and thorium); and certain quantities of special nuclear materials to States that meet certain requirements. The mechanism for the transfer of NRC's authority to a State is an agreement signed by the Governor of the State and the Chairman of the Commission, in accordance with section 274b of the Act. The NRC relinquished their authority to the State of Nebraska in 1966 when Governor Morrison signed the Agreement with the NRC. The Agreement requires that Nebraska maintain a regulatory program that is adequate to protect public health and safety and the environment and that our regulations be compatible with those of the NRC. The NRC periodically reviews the program for adequacy and compatibility with that of the NRC. As an Agreement State, if the Nebraska Regulations for Control of Radiation are not found to be compatible, the NRC can terminate the Agreement and resume regulatory authority over radioactive materials within the State. Currently, there are 38 states that have agreements with the NRC with several more states in process.

PROPOSED REGULATION
POLICY PRE-REVIEW CHECKLIST

Agency: DHHS – Division of Public Health
Title, Chapter of Regulation: Title 180 NAC 19
Subject: Licenses and Radiation Safety Requirements for Irradiators
Prepared by: Julia Schmitt
Telephone: 402-471-0528

A. Policy Changes and Impacts

1. What does the regulation do and whom does it impact? Provide a brief description of the proposed rule or regulation and its impacts on state agencies, political subdivisions, and regulated persons or entities.

   This revision re-promulgates Title 180 NAC 19 to remove any unnecessary language or any repeated statutory language from the regulations. The revision also updates formatting.

   The regulations apply persons using sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma irradiation.

2. Describe changes being proposed to current policy and briefly provide rationale.

   The regulations were reformatted and any unnecessary language or repeat of statutory language was removed from the regulations.

B. Why is the rule necessary? Explain and provide an identification of authorizing statute(s) or legislative bill(s).

1. Update of regulation (repeal of obsolete statutes, reflect current policy, editing or technical language changes, etc.)

   This revision re-promulgates Title 180 NAC 19 to update formatting and to remove any unnecessary language or any repeated statutory language from the regulations.

2. Annual changes – cost of living, hunting season schedules, etc.

   No.

3. Law was changed – federal ___ or state ___ [Cite authorizing statute(s) or legislative bill(s)] N/A

4. Extension of established policy or program, new initiatives or changes in policy (within statutory authority) No

5. Constituent initiated No

6. Financial needs – increases/decreases in fees No

7. Litigation requires changes in rules No

8. Addresses legal or constitutional concerns of Attorney General's office No

9. Implements federal or court mandate No

10. Other (explain)

C. What happens if these rules are not adopted?

Unnecessary and redundant language would remain in the regulation.

D. Policy Checklist

1. Is this an update or editorial change reflecting essentially no change in policy? Yes

2. Does the policy in the proposed regulation reflect legislative intent? Yes.

3. Is the policy proposed in the regulation a state mandate on local government? Yes Is it funded? Yes

4. Is the policy proposed in the regulation a federal mandate on local government? No Is it funded? N/A

E. Fiscal Impact. In addition to completing the required Fiscal Impact Statement (a copy must be attached to this document), the agency must address the following:

No fiscal impact.

1. Will the proposed regulation reduce, increase, or have no change in resources – funds, personnel or FTE? No change.

1. Have initial contacts been made with citizens or organizations that may be impacted by the proposed regulation? No, because the changes are

formatting and editorial. We will solicit public comment before a public hearing.

2. Does the proposed regulation impact another agency? No Explain the impact.

3. Will the proposed regulation reduce, increase, or have no change on reporting requirements of businesses?

   No Change

5. What is the agency's best estimate of the additional or reduced spending? If there is none, please note. If receipt of federal funds is contingent upon approval of the proposed regulation, then indicate the amount and nature of the federal funds affected, and enclose laws or correspondence from federal officials substantiating the information.

   No change in spending.

6. Include a description of the impact that the proposed regulation will have on the number of state employees and how the agency intends to address proposed increases or decreases in FTE.

   No Impact.

F. Unique problems or issues and recommendations.

No known problems or issues.

G. Who is expected to be affected, or to oppose or support the proposed regulation? Explain what initial informal contacts have been made with organizations or citizens who may be affected by the regulation prior to the public hearing.

No known supporters or opponents.

DHHS will solicit public comment on the proposed regulations before the public hearing.

H. Are these proposed rules a likely candidate for negotiated rulemaking? Explain. Has the process been completed? If so, explain how the issues were addressed.

No.

TITLE 180 CONTROL OF RADIATION

CHAPTER 19 LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

001. SCOPE AND AUTHORITY. The regulations are authorized by and implement the Nebraska Radiation Control Act, Nebraska Revised Statute (Neb. Rev. Stat.) §§ 71-3501 to 71-3520. This chapter contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. 180 Nebraska Administrative Code (NAC) 19 also contains radiation safety requirements for operating irradiators. The requirements of this chapter are in addition to other requirements of Title 180. In particular, the provisions of 180 NAC 1, 3, 4, 10, 13 and 18 apply to applications and licenses subject to this chapter.

001.01 OTHER REQUIREMENTS. Nothing in this chapter relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

001.02 APPLICIBILITY. This chapter applies to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators 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 are covered by this chapter.

001.03 EXCEPTIONS. This chapter does not apply to 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, medical radiology or teletherapy, radiography, the irradiation of materials for nondestructive testing purposes, gauging, or open-field, agricultural irradiations.

001.04 CONCRETE STANDARD. American Concrete Institute Standard ACI 318-89 “Building Code Requirements for Reinforced Concrete,” Chapter 21 “Special Provisions for Seismic Design” as referred to in this Chapter is incorporated by reference and available for viewing at the Department of Health and Human Services, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509.

002. DEFINITIONS. The following definitions apply:

002.01 ANNUALLY. Annually is either:
(A) At intervals not to exceed one year or

(B) Once per year, at about the same time each year, plus or minus one month.

002.02 DOUBLY ENCAPSULATED SEALED SOURCE. A doubly encapsulated sealed source is a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

002.03 IRRADIATOR. A facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type is an irradiator. The term does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

002.04 IRRADIATOR OPERATOR. An individual who has successfully completed the training and testing described in 180 NAC 19-018 and is authorized by the terms of the license to operate the irradiator without a supervisor present is an irradiator operator.

002.05 PANORAMIC DRY-SOURCE-STORAGE IRRADIATOR. An irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials is a panoramic dry-source-storage irradiator. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

002.06 PANORAMIC IRRADIATOR. An irradiator in which the irradiations are done in air in areas potentially accessible to personnel is a panoramic irradiator. The term includes beam-type irradiators.

002.07 PANORAMIC WET-SOURCE STORAGE IRRADIATOR. An irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool is a panoramic wet-source irradiator.

002.08 POOL IRRADIATOR. Any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators is a pool irradiator.

002.09 PRODUCT CONVEYOR SYSTEM. A product conveyor system is a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

002.010 RADIATION ROOM. A shielded room in which irradiations take place is a radiation room. Underwater irradiators do not have radiation rooms.

002.011 RADIATION SAFETY OFFICER. An individual with responsibility for the overall radiation safety program at the facility is a radiation safety officer.

002.012 SEALED SOURCE. Any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the radioactive material is a sealed source.

002.013 SEISMIC AREA. A seismic area is any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the U.S. Geological Survey.

002.014 UNDERWATER IRRADIATOR. An irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool is an underwater irradiator.

003. APPLICATION FOR A SPECIFIC LICENSE. Each application for a license, must be accompanied by the fee set in 180 NAC 18-005.

004. SPECIFIC LICENSES FOR IRRADIATORS. This section specifies the information that must be included in the application and the requirements for a license.

004.01 GENERAL REQUIREMENTS. The applicant must satisfy the general requirements specified in 180 NAC 3-011, (A) through (D) and the requirements contained in this chapter.

004.02 TRAINING. The application must describe the training provided to irradiator operators including:

(A) Classroom training;
(B) On-the-job or simulator training;
(C) Safety reviews;
(D) Means employed by the applicant to test each operator's understanding of the Department's regulations and licensing requirements and the irradiator operating and emergency procedures; and
(E) Minimum training and experience of personnel who may provide training.

004.03 WRITTEN OPERATING AND EMERGENCY PROCEDURES. The application must include an outline of the written operating and emergency procedures listed in 180 NAC 19-019 that describes the radiation safety aspects of the procedures.

004.04 ORGANIZATIONAL STRUCTURE. The application must describe the organizational structure for managing the irradiator, specifically, the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

004.05 ACCESS CONTROL SYSTEMS. The application must include a description of the access control systems required by 180 NAC 19-008, the radiation monitors required by 180 NAC 19-011, the method of detecting leaking sources required by 180 NAC 19-022 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

004.06 LEAK TEST PROCEDURES. If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant must establish procedures for leak testing and submit a description of these procedures. The description must include the:

(A) Instruments to be used;
(B) Methods of performing the analysis; and
(C) Pertinent experience of the individual who analyzes the samples.

004.07 LOADING AND UNLOADING. If licensee personnel are to load or unload sources, the applicant must describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading of its facility, the loading or unloading must be done by an organization specifically authorized by the Department, U.S. Nuclear Regulatory Commission or an Agreement State to load or unload irradiator sources.

004.08 INSPECTION AND MAINTENANCE CHECKING. The applicant must describe the inspection and maintenance checks including the frequency of the checks required by 180 NAC19-023.

005. START OF CONSTRUCTION. The applicant may not begin construction of a new irradiator prior to the submission to the Department of both an application for a license for the irradiator and the fee required by 180 NAC 18-005. As used in this chapter, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of site, site surveys or soil testing, site preparation, site evacuation, construction of warehouse or auxiliary structures, and other similar tasks. Any 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 license with respect to the requirements of the Nebraska Radiation Control Act, as amended, and rules, regulations, and orders issued under the Act.

006. APPLICATION FOR EXEMPTIONS. In addition to the exemption in 180 NAC 1-003.01, any application for a license or for amendment of a license authorizing use of teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this chapter. The applicant must provide adequate rationale for the proposed alternatives and demonstrate that they are likely to provide an adequate level of safety for workers and the public.

007. PERFORMANCE CRITERIA FOR SEALED SOURCES. Sealed sources must meet the performance criteria set out below.

007.01 INSTALLATION DATE. Sealed sources installed after October 30, 1996 must:
(A) Have a certificate of registration issued under the U. S. Nuclear Regulatory Commission or an Agreement State for evaluation of radiation safety information about its product.
(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-source-change irradiator;
(D) Be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and
(E) Have been leak tested and found leak-free after each of the tests described in 180 NAC 19-007.02 through 19-007.07 in prototype testing of the sealed source.

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

007.03 PRESSURE. The test source must be twice subjected for at least five minutes to an external absolute pressure of two million newtons per square meter.

007.04 IMPACT. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

007.05 VIBRATION. The test source must be subjected three times for ten 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.

007.06 PUNCTURE. A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of one meter onto the test source.

007.07 BEND. 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 two thousand newtons at its center equidistant from two support cylinders, the distance between which is ten times the minimum cross-sectional dimension of the source.

008. ACCESS CONTROL. Access must be controlled.

008.01 PHYSICAL BARRIER. Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. 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. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

008.02 BACKUP ACCESS CONTROL. 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. 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. The alarm must also alert at least one other individual who is onsite of the entry. That individual must be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

008.03 RADIATION MONITOR. 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. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high

radiation levels, must activate the alarm described in 008.02 of this chapter. The monitor may be located in the entrance, normally referred to as the maze, but not in the direct radiation beam.

008.04 ALARM. 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.

008.05 IN ROOM SOURCE CONTROL. 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.

008.06 SOURCE MOVEMENT CONTROL. 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.

008.07 SIGNAGE. Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, “CAUTION, RADIOACTIVE MATERIAL” or “CAUTION RADIOACTIVE MATERIALS” or “DANGER, RADIOACTIVE MATERIAL” or “DANGER RADIOACTIVE MATERIALS”. Panoramic irradiators must also have a sign stating "GRAVE DANGER, VERY HIGH RADIATION AREA"; however, the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

008.08 INTERLOCKS. 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.

008.09 PERSONNEL ACCESS BARRIER. Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. 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.

009. SHIELDING. Irradiators must meet shielding requirements.

009.01 OCCUPIED AREAS. The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 millirems) 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 any area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Areas where the

radiation dose rate exceeds 0.02 millisievert (2 millirems) per hour must be locked, roped off, or posted.

009.02 POOL DOSE RATE. The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 millirems) per hour when the sources are in the fully shielded position.

009.03 DRY-SOURCE SHIELD. The radiation dose rate at 1 meter from the shield of a dry-source storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 millirems) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 millirems) per hour.

010. FIRE PROTECTION. The radiation room must be protected against fires.

010.01 HEAT AND SMOKE DETECTORS. The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

010.02 FIRE EXTINGUISHING SYSTEM. The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

011. RADIATION MONITORS. Radiation must be monitored as required by the following.

011.01 PRODUCT EXIT. 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. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of 180 NAC 19-011.01.

011.02 POOL. Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

012. CONTROL OF SOURCE MOVEMENT. Source movement must be controlled as described below.

012.01 KEY. The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so

that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

012.02 POSITION DETECTOR. The console of a panoramic irradiator 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.

012.03 CONTROL CONSOLE. The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

012.04 CONTROL MARKING. Each control for a panoramic irradiator must be clearly marked as to its function.

013. IRRADIATOR POOLS. Irradiator pools must meet the specifications below.

013.01 SPECIFICATIONS. For licenses initially issued after October 30, 1996, irradiators pools must either:

(A) Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pools; or

(B) Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee must have a method to safely store the sources during repairs of the pool.

013.02 WATER OUTLETS. For licenses initially issued after October 30, 1996, irradiator pools must have no outlets more than 0.5 meter 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.

013.03 REPLENTISHMENT. A means must be provided to replenish water losses from the pool.

013.04 VISIBLE INDICATOR. A visible indicator must be provided 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.

013.05 WATER PURITY. Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens (ohms) per centimeter or less and with a clarity so that the sources can be seen clearly.

013.06 PHYSICAL BARRIER. A physical barrier, such as a railing or cover, must be used 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.

013.07 TOOLS. If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 0.02 millisievert (2 millirems) per hour.

014. SOURCE RACK PROTECTION. If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

015. POWER FAILURES. Systems must function properly in the event of a power failure.

015.01 POWER LOSS. If electrical power at a panoramic irradiator is lost for longer than ten seconds, the sources must automatically return to the shielded position.

015.02 LOCK. The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

015.03 SURVEY METER. 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.

016. DESIGN REQUIREMENTS. Irradiators whose construction begins after October 30, 1996, must meet the design requirements of this section.

016.01 SHIELDING. For panoramic irradiators, the licensee must design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of 180 NAC 19-009. If the irradiator will use more than 2 x1017 becquerels (5 million curies) of activity, the licensee must evaluate the effects of heating of the shielding walls by the irradiator sources.

016.02 FOUNDATIONS. For panoramic irradiators, the licensee must design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

16.03 POOL INTEGRITY. For pool irradiators, the licensee must design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of 180 NAC 19-013.02, and that metal components are metallurgically compatible with other components in the pool.

016.04 WATER HANDLING SYSTEM. For pool irradiators, the licensee must verify that the design of the water purification system is adequate to meet the requirements of 180 NAC 19-013.05. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

016.05 RADIATION MONITORS. For all irradiators, the licensee must evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by 180 NAC 19-011.01. The licensee must verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under 180 NAC 19-022.02, the licensee must verify that the design of

radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

016.06 SOURCE RACK. For pool irradiators, the licensee must verify that 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. For panoramic irradiators, the licensee must determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables, or alternate means of support, will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee, must review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

016.07 ACCESS CONTROL. For panoramic irradiators, the licensee must verify from the design and logic diagram that the access control system will meet the requirements of 180 NAC 19-008.

016.08 FIRE PROTECTION. For panoramic irradiators, the licensee must verify 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. The licensee must verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

016.09 SOURCE RETURN. For panoramic irradiators, the licensee must verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

016.10 SEISMIC. For panoramic irradiators to be built in seismic areas, the licensee must design 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, if current.

016.11 WIRING. For panoramic irradiators, the licensee must verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

017. CONSTRUCTION MONITORING AND ACCEPTANCE TESTING. The requirements of this section must be met for irradiators whose construction begins after October 30, 1996. The requirements must be met prior to loading sources.

017.01 SHIELDING. For panoramic irradiators, the licensee must monitor the construction of the shielding to verify that the construction meets design specifications and generally accepted building code requirement for reinforced concrete.

017.02 FOUNDATIONS. For panoramic irradiators, the licensee must monitor the construction of the foundations to verify that their construction meets design specifications.

017.03 POOL INTEGRITY. For pool irradiators, the licensee must verify that the pool meets design specifications and must test the integrity of the pool. The licensee must verify that outlets and pipes meet the requirements of 180 NAC 19-013.02.

017.04 WATER HANDLING SYSTEM. For pool irradiators, the licensee must verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

017.05 RADIATION MONITORS. For all irradiators, the licensee must verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 180 NAC 19-011.01. For pool irradiators, the licensee must verify the proper operation of the radiation monitors and the related alarm if used to meet 19-022.02. For underwater irradiators, the licensee must verify the proper operation of the over-the-pool monitors, alarms, and interlocks required by 19-011.02.

017.06 SOURCE RACK. For panoramic irradiators, the licensee must test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee must observe and test the operation of the conveyor system to assure that the requirements in 180 NAC 19-014 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.

017.07 ACCESS CONTROL. For panoramic irradiators, the licensee must test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

017.08 FIRE PROTECTION. For panoramic irradiators, the licensee must test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee must test the operability of the fire extinguishing systems.

017.09 SOURCE RETURN. For panoramic irradiators, the licensee must demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

017.10 COMPUTER SYSTEMS. For panoramic irradiators that use a computer system to control the access control system, the licensee must verify that the access control system will operate properly if offsite power is lost and must verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

017.11 WIRING. For panoramic irradiators, the licensee must verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

018. TRAINING. Operators must meet the training requirements specified below.

018.01 INSTRUCTION. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

(A) The fundamentals of radiation protection applied to irradiators including the differences between external radiation and radioactive contamination, units of radiation dose, Department dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how a irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator;
(B) The requirements of 180 NAC 10 and this chapter that are relevant to the irradiator;
(C) The operation of the irradiator;
(D) Those operating and emergency procedures listed in 180 NAC 19-019 that the individual is responsible for performing; and
(E) Case histories of accidents or problems involving irradiators.

018.02 WRITTEN TEST. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individuals responsible for performing and other operations necessary to safely operate the irradiator without supervision.

018.03 TRAINING. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual must also demonstrate the ability to perform those portions of the operating and emergency procedures the individual is to perform.

018.04 SAFETY REVIEW. The licensee must conduct safety reviews for irradiator operators at least annually. The licensee must give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:
(A) Changes in operating and emergency procedures since the last review, if any;
(B) Changes in regulations and license conditions since the last review, if any;
(C) Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;
(D) Relevant results of inspections of operator safety performance;
(E) Relevant results of the facility's inspection and maintenance checks; and
(F) A drill to practice an emergency or abnormal event procedure.

018.05 SAFETY PERFORMANCE. The licensee must evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee must discuss the results of the evaluation with the operator and must instruct the operator on how to correct any mistakes or deficiencies observed.

018.06 UNESCORTED ACCESS. Individuals that will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, must be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in 180 NAC 19-019 that they are expected to perform or comply with, and their proper response to alarms required in this chapter. Tests may be oral.

018.07 ALARM RESPONSE. Individuals who must be prepared to respond to alarms required by 180 NAC 19-008.02, 19-008.09, 19-010.01, 19-011.01, 19-011.02 and 19-022.02 must be trained and tested on how to respond. Each individual must be retested at least once a year. Tests may be oral.

019. OPERATING AND EMERGENCY PROCEDURES. Licensees must have and follow written operating procedures.

019.01 OPERATING PROCEDURES. The licensee must have and follow written operating procedures for:

(A) Operation of the irradiator, including entering and leaving the radiation room;
(B) Use of personnel 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 sources;
(F) Inspection and maintenance checks required by 180 NAC 19-023;
(G) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and
(H) Inspection of movable shielding required by 180 NAC 19-008.08, if applicable.

019.02 EMERGENCY PROCEDURES. The licensee must have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

(A) Sources stuck in the unshielded position;
(B) Personnel overexposures;
(C) A radiation alarm from the product exit portal monitor or pool monitor;
(D) Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
(E) A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;
(F) A prolonged loss of electrical power;
(G) A fire alarm or explosion in the radiation room;
(H) An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;
(I) Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and
(J) The jamming of automatic conveyor systems.

019.03 REVISIONS. The licensee may revise operating and emergency procedures without Department approval only if all of the following conditions are met:

(A) The revisions do not reduce the safety of the facility;
(B) The revisions are consistent with the outline or summary of procedures submitted with the license application;
(C) The revisions have been reviewed and approved by the radiation safety officer; and
(D) The users or operators are instructed and tested on the revised procedures before they are put into use.

020. PERSONNEL MONITORING. Licensees must monitor exposure to radiation.

020.01 IRRADIATOR OPERATORS. Irradiator operators must wear either a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be accredited for high energy photons in the normal and accident dose ranges. Instruments and equipment used for quantitative radiation measurements must meet the requirements of 180 NAC 4-021.03. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly and other dosimeters must be processed at least quarterly.

020.02 OTHER INDIVIDUALS. Other individuals who enter the radiation room of a panoramic irradiator must wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of 180 NAC 9-020, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within ± 30% of the true radiation dose.

021. RADIATION SURVEYS. Licensees must conduct radiation surveys.

021.01 OUTSIDE OF SHIELDING. A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed three years and before resuming operation after addition of new sources or any modifications to the radiation room shielding or structure that might increase dose rates.

021.02 MODIFICATIONS. If the radiation levels specified in 180 NAC 19-009 are exceeded, the facility must be modified to comply with the requirements in this chapter.

021.03 CALIBRATION. Portable radiation survey meters must be calibrated at least annually to an accuracy of ± 20% for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

021.04 WATER. Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 180 NAC 4, Table 2, Column 2 or Table 3 of Appendix 4-B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

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

022. DETECTION OF LEAKING SOURCES. Licensees must detect leaking radiation sources.

022.01 DRY-SOURCE STORAGE. Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the Department, U.S. Nuclear Regulatory Commission or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Department, U.S. Nuclear Regulatory Commission or an Agreement State to perform the test.

022.02 POOL IRRADIATORS. For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by 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. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. 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.

022.03 LEAKING SOURCE. If a leaking source is detected, the licensee must arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by the Department, U. S. Nuclear Regulatory Commission or an Agreement State licensee that is authorized to perform these functions. The licensee must promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. 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 inadvertently contaminated, the licensee must arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or product are found, the licensee must arrange to have them decontaminated or disposed of by the Department, U.S. Nuclear Regulatory Commission or an Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee must arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in 180 NAC 4, Table 2, Column 2. Appendix 4-B. See 180 NAC 3-026 for reporting requirements.

023. INSPECTION AND MAINTENANCE. Licensees must inspect and maintain the irradiator and components.

023.01 CHECKS. The licensee must perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

(A) Operability of each aspect of the access control system required by 180 NAC 19-008.
(B) Functioning of the source position indicator required by 180 NAC 19-012.02.

(C) Operability of the radiation monitor for radioactive contamination in pool water required by 180 NAC 19-022.02 using a radiation check source, if applicable.
(D) Operability of the over-pool radiation monitor at underwater irradiators as required by 180 NAC 19-011.02.
(E) Operability of the product exit monitor required by 180 NAC 19-011.01.
(F) Operability of the emergency source return control required by 180 NAC 19-012.03.
(G) Leak-tightness of systems through which pool water circulates by visual inspection.
(H) Operability of the heat and smoke detectors and extinguisher system required by 180 NAC 19-010, but without turning extinguishers on.
(I) Operability of the means of pool water replenishment required by 180 NAC 19-013.03.
(J) Operability of the indicators of high and low pool water levels required by 180 NAC 19-013.04.
(K) Operability of the intrusion alarm required by 180 NAC 19-008.09, if applicable.
(L) Functioning and wear of the systems, mechanisms, and cables used to raise and lower sources.
(M) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 180 NAC 19-014.
(N) Amount of water added to the pool to determine if the pool is leaking.
(O) Electrical wiring on required safety systems for radiation damage.
(P) Pool water conductivity measurements and analysis as required by 180 NAC 19-024.02.

023.02 MALFUNCTIONS AND DEFECTS. Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

024. POOL WATER PURITY. Licensees must maintain irradiator pool water purity.

024.01 PURIFICATION SYSTEM. Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee must take prompt actions to lower the pool water conductivity and must take corrective actions to prevent future recurrences.

024.02 CONDUCTIVITY. 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. Conductivity meters must be calibrated at least annually.

025. ATTENDANCE DURING OPERATION. Irradiators must be attended during operation.

025.01 PRODUCT MOVEMENT. Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, must be present onsite whenever:
(A) The irradiator is operated using an automatic product conveyor system; and
(B) The product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

025.02 STATIC IRRADIATIONS. At a panoramic irradiator at which static irradiations involving no movement of the product are occurring, a person who has received the training on how to respond to alarms described in 180 NAC 19-018.07 must be onsite.

025.03 UNDERWATER IRRADIATOR. At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. 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 180 NAC 19-018.06 and 19-018.07. Static irradiations may be performed without a person present at the facility.

026. ENTERING AND LEAVING THE IRRADIATOR ROOM. Licensees must meet requirements when entering and leaving the irradiator room.

026.01 ENTERING. 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.

026.02 EXITING. 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.

026.03 ENTERING DURING POWER FAILURE. 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 180 NAC 19-011.02 is operating with backup power.

027. IRRADIATION OF EXPLOSIVE OR FLAMMABLE MATERIALS. Licensees must meet requirements when irradiating explosive or flammable materials.

027.01 EXPLOSIVE MATERIAL. Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Department. 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.

027.02 FLAMMABLE MATERIAL. Irradiation of more than small quantities of flammable material, meaning a flash point below 140° Fahrenheit, is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Department. 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.

028. RECORDS AND RETENTION OF RECORDS. The licensee must maintain the following records at the irradiator for the periods specified.

028.01 LICENSE DOCUMENTS. A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Department terminates the license for documents that have not been superseded.

028.02 INDIVIDUAL'S RECORDS. Records of each individual's training, tests, and safety reviews provided to meet the requirements of 180 NAC 19-018.01 through 19-018.04, 19-018.06 and 19-018.07 until three years after the individual terminates work.

028.03 SAFETY PERFORMANCE. Records of the annual evaluations of the safety performance of irradiator operators required by 180 NAC 19-018.05 for three years after the evaluation.

028.04 OPERATING AND EMERGENCY PROCEDURES. A copy of the current operating and emergency procedures required by 180 NAC 19-019 until superseded or the Department terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by 19-019.03 (C) retained for three years from the date of the change.

028.05 DOSIMETRY. Evaluations of personnel dosimeters required by 180 NAC 19-020 must be retained until the Department terminates the license.

028.06 RADIATION SURVEYS. Records of radiation surveys required by 180 NAC 19-021 for three years from the date of the survey.

028.07 CALIBRATIONS. Records of radiation survey meter calibrations required by 180 NAC 19-021 and pool water conductivity meter calibrations required by 19-024.02 until three years from the date of calibration.

028.08 LEAK TESTS. Records of the results of leak tests required by 180 NAC 19-022.01 and the results of contamination checks required by 19-022.02 for three years from the date of each test.

028.09 INSPECTION AND MAINTENANCE. Records of inspection and maintenance checks required by 180 NAC 19-023 for three years.

028.10 REQUIRED SAFETY EQUIPMENT. Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.

028.11 RECEIPT, TRANSFER AND DISPOSAL. Records of the receipt, transfer and disposal, of all licensed sealed sources as required by 180 NAC 3-025 and 3-030.

028.12 DESIGN AND CONSTRUCTION CONTROL. Records on the design checks required by 180 NAC 19-016 and the construction control checks as required by 19-017 until the license

is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

028.13 DECOMMISSIONING. Records related to decommissioning of the irradiator as required by 180 NAC 3-018.07.

029. REPORTS. Licensees must report events.

029.01 EVENTS. In addition to the reporting requirements in other parts of Department regulations, the licensee must report the following events if not reported under of parts of Department regulations:

(A) Source stuck in an unshielded position.
(B) Any fire or explosion in a radiation room.
(C) Damage to the source racks.
(D) Failure of the cable or drive mechanism used to move the source racks.
(E) Inoperability of the access control system.
(F) Detection of radiation source by the product exit monitor.
(G) Detection of radioactive contamination attributable to licensed radioactive material.
(H) Structural damage to the pool liner or walls.
(I) Abnormal water loss or leakage from the source storage pool.
(J) Pool water conductivity exceeding 100 microsiemens (ohms) per centimeter.

029.02 TELEPHONE REPORT. The report must include a telephone report within 24 hours as described in 180 NAC 3-026.03 (A) and a written report within 30 days as described in 180 NAC 3-026.03 (B).

~~TITLE 180 CONTROL OF RADIATION~~

~~CHAPTER 19 LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS~~

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TITLE 180 CONTROL OF RADIATION

CHAPTER 19 LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

19-001 SCOPE AND AUTHORITY

19-001.01 180 NAC 19 contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. 180 NAC 19 also contains radiation safety requirements for operating irradiators. The requirements of 180 NAC 19 are in addition to other requirements of Title 180. In particular, the provisions of 180 NAC 1, 3, 4, 10, 13, 17 and 18 apply to applications and licenses subject to this 180 NAC 19. Nothing in 180 NAC 19 relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§71-3501 to 71-3520.

19-001.02 180 NAC 19 applies to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators 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.

19-001.03 180 NAC 19 does not apply to 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), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

19-001.04 American Concrete Institute Standard ACI 318-89 "Building Code Requirements for Reinforced Concrete," Chapter 21 "Special Provisions for Seismic Design" as referred to in this Chapter is herein incorporated by reference and available for viewing at the Department of Health and Human Services, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509.

19-002 DEFINITIONS: As used in 180 NAC 19, the following definitions apply:

Annually means either (1) at intervals not to exceed one year or (2) once per year, at about the same time each year (plus or minus one month).

Doubly encapsulated sealed source means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

Irradiator means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device are not accessible to personnel.

Irradiator operator means an individual who has successfully completed the training and testing described in 180 NAC 19-018 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

Panoramic dry-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

Panoramic irradiator means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

Panoramic wet-source storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

Pool irradiator means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

Product conveyor system means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

Radiation room means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

Radiation safety officer means an individual with responsibility for the overall radiation safety program at the facility.

Sealed source means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Seismic area means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the U.S. Geological Survey.

Underwater irradiator means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

SPECIFIC LICENSING REQUIREMENTS Removed.

19-003 APPLICATION FOR A SPECIFIC LICENSE: A person, as defined in 180 NAC 1-002, may file an application for a specific license authorizing the use of sealed sources in an irradiator on Form NRH-5, "Application for Material License" in 180 NAC 3. Each application for a license, must be accompanied by the fee prescribed in 180 NAC 18-005. The application and a copy must be sent to:

Department of Health and Human Services
Division of Public Health
Radiological Health
P.O. Box 95026
301 Centennial Mall South
Lincoln, NE 68509-5026

19-004 SPECIFIC LICENSES FOR IRRADIATORS: The Department will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in 180 NAC 19.

19-004.01 The applicant must satisfy the general requirements specified in 180 NAC 3-011, items 1 thru 4 and the requirements contained in 180 NAC 19.

19-004.02 The application must describe the training provided to irradiator operators including:

1. Classroom training;
2. On-the-job or simulator training;
3. Safety reviews;
4. Means employed by the applicant to test each operator's understanding of the Department's regulations and licensing requirements and the irradiator operating and emergency procedures; and
5. Minimum training and experience of personnel who may provide training.

19-004.03 The application must include an outline of the written operating and emergency procedures listed in 180 NAC 19-019 that describes the radiation safety aspects of the procedures.

19-004.04 The application must describe the organizational structure for managing the irradiator, specifically, the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

19-004.05 The application must include a description of the access control systems required by 180 NAC 19-008, the radiation monitors required by 180 NAC 19-011, the method of detecting leaking sources required by 180 NAC 19-022 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

19-004.06 If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant must establish procedures for leak testing and submit a description of these procedures to the Department. The description must include the:

1. Instruments to be used;
2. Methods of performing the analysis; and
3. Pertinent experience of the individual who analyzes the samples.

19-004.07 If licensee personnel are to load or unload sources, the applicant must describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading of its facility, the loading or unloading must be done by an organization specifically authorized by the Department, U.S. Nuclear Regulatory Commission or an Agreement State to load or unload irradiator sources.

19-004.08 The applicant must describe the inspection and maintenance checks including the frequency of the checks required by 180 NAC 19-023.

19-005 START OF CONSTRUCTION: The applicant may not begin construction of a new irradiator prior to the submission to the Department of both an application for a license for the irradiator and the fee required by 180 NAC 18-005. As used in 180 NAC 19, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: Engineering and design work, purchase of site, site surveys or soil testing, site preparation, site evacuation, construction of warehouse or auxiliary structures, and other similar tasks. Any 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 license with respect to the requirements of the Nebraska Radiation Control Act, as amended, and rules, regulations, and orders issued under the Act.

19-006 APPLICATION FOR EXEMPTIONS: In addition to the exemption in 180 NAC 1-003.01, any application for a license or for amendment of a license authorizing use of teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of 180 NAC 19. The Department will 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.

DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS Removed.

19-007 PERFORMANCE CRITERIA FOR SEALED SOURCES

19-007.01 Requirements: Sealed sources installed after October 30, 1996:

1. Must have a certificate of registration issued under the U. S. Nuclear Regulatory Commission or an Agreement State for evaluation of radiation safety information about its product.
2. Must be doubly encapsulated;
3. Must 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-source-change irradiator;
4. 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 if the sources are for use in irradiator pools; and
5. In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in 180 NAC 19-007.02 through 19-007.07

19-007.02 Temperature: The test source must be held at -40° celsius for 20 minutes, 600° celsius for one hour, and then be subjected to a thermal shock test with a temperature drop from 600° celsius to 20° celsius within 15 seconds.

19-007.03 Pressure: The test source must be twice subjected for at least five minutes to an external pressure (absolute) of two million newtons per square meter.

19-007.04 Impact: A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

19-007.05 Vibration: The test source must be subjected three times for ten 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.

19-007.06 Puncture: A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of one meter onto the test source.

19-007.07 Bend: 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 two thousand newtons at its center equidistant from two support cylinders, the distance between which is ten times the minimum cross-sectional dimension of the source.

19-008 ACCESS CONTROL

19-008.01 Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. 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. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded

position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

19-008.02 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. 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. The alarm must also alert at least one other individual who is onsite of the entry. That individual must be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

19-008.03 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. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in 180 NAC19-008.02. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

19-008.04 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.

19-008.05 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.

19-008.06 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.

19-008.07 Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL(S) “or ”DANGER, RADIOACTIVE MATERIAL(S)“ or Panoramic irradiators must also have a sign stating "GRAVE DANGER, VERY HIGH RADIATION AREA," but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

19-008.08 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.

19-008.09 Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. 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.

19-009 SHIELDING

19-009.01 The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 millirems) 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 any area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Areas where the radiation dose rate exceeds 0.02 millisievert (2 millirems) per hour must be locked, roped off, or posted.

19-009.02 The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 millirems) per hour when the sources are in the fully shielded position.

19-009.03 The radiation dose rate at 1 meter from the shield of a dry-source storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 millirems) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 millirems) per hour.

19-010 FIRE PROTECTION

19-010.01 The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

19-010.02 The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

19-011 RADIATION MONITORS

19-011.01 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. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this 180 NAC 19-011.01.

19-011.02 Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

19-012 CONTROL OF SOURCE MOVEMENT

19-012.01 The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

19-012.02 The console of a panoramic irradiator 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.

19-012.03 The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

19-012.04 Each control for a panoramic irradiator must be clearly marked as to its function.

19-013 IRRADIATOR POOLS

19-013.01 For licenses initially issued after October 30, 1996, irradiators pools must either:

1. Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pools; or
2. Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee must have a method to safely store the sources during repairs of the pool.

19-013.02 For licenses initially issued after October 30, 1996, irradiator pools must have no outlets more than 0.5 meter 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.

19-013.03 A means must be provided to replenish water losses from the pool.

19-013.04 A visible indicator must be provided 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.

19-013.05 Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens (ohms) per centimeter or less and with a clarity so that the sources can be seen clearly.

19-013.06 A physical barrier, such as a railing or cover, must be used 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.

19-013.07 If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 0.02 millisievert (2 millirems) per hour.

19-014 SOURCE RACK PROTECTION: If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

19-015 POWER FAILURES

19-015.01 If electrical power at a panoramic irradiator is lost for longer than ten seconds, the sources must automatically return to the shielded position.

19-015.02 The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

19-015.03 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.

19-016 DESIGN REQUIREMENTS: Irradiators whose construction begins after October 30, 1996, must meet the design requirements of 180 NAC 19-016.

19-016.01 Shielding: For panoramic irradiators, the licensee must design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of 180 NAC 19-009. If the irradiator will use more than 2 $x10^{17}$ becquerels (5 million curies) of activity, the licensee must evaluate the effects of heating of the shielding walls by the irradiator sources.

19-016.02 Foundations: For panoramic irradiators, the licensee must design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

19-016.03 Pool integrity: For pool irradiators, the licensee must design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of 180 NAC 19-013.02, and that metal components are metallurgically compatible with other components in the pool.

19-016.04 Water handling system: For pool irradiators, the licensee must verify that the design of the water purification system is adequate to meet the requirements of 180 NAC 19-013.05. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

19-016.05 Radiation monitors: For all irradiators, the licensee must evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by 180 NAC 19-011.01. The licensee must verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under 180 NAC 19-022.02, the licensee must verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

19-016.06 Source rack: For pool irradiators, the licensee must verify that 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. For panoramic irradiators, the licensee must determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee must review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

19-016.07 Access control: For panoramic irradiators, the licensee must verify from the design and logic diagram that the access control system will meet the requirements of 180 NAC 19-008.

19-016.08 Fire protection: For panoramic irradiators, the licensee must verify 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. The licensee must verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

19-016.09 Source return: For panoramic irradiators, the licensee must verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

19-016.10 Seismic: For panoramic irradiators to be built in seismic areas, the licensee must design 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, if current.

19-016.11 Wiring: For panoramic irradiators, the licensee must verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

19-017 CONSTRUCTION MONITORING AND ACCEPTANCE TESTING: The requirements of 180 NAC 19-017 must be met for irradiators whose construction begins after October 30, 1996. The requirements must be met prior to loading sources.

19-017.01 Shielding: For panoramic irradiators, the licensee must monitor the construction of the shielding to verify that the construction meets design specifications and generally accepted building code requirement for reinforced concrete.

19-017.02 Foundations: For panoramic irradiators, the licensee must monitor the construction of the foundations to verify that their construction meets design specifications.

19-017.03 Pool integrity: For pool irradiators, the licensee must verify that the pool meets design specifications and must test the integrity of the pool. The licensee must verify that outlets and pipes meet the requirements of 180 NAC 19-013.02.

19-017.04 Water handling system: For pool irradiators, the licensee must verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

19-017.05 Radiation monitors: For all irradiators, the licensee must verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 180 NAC 19-011.01. For pool irradiators, the licensee must verify the proper operation of the radiation monitors and the related alarm if used to meet 180 NAC 19-022.02. For underwater irradiators, the licensee must verify the proper operation of the over-the-pool monitors, alarms, and interlocks required by 180 NAC 19-011.02.

19-017.06 Source rack: For panoramic irradiators, the licensee must test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee must observe and test the operation of the conveyor system to assure that the requirements in 180 NAC 19-014 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.

19-017.07 Access control: For panoramic irradiators, the licensee must test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

19-017.08 Fire protection: For panoramic irradiators, the licensee must test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee must test the operability of the fire extinguishing systems.

19-017.09 Source return: For panoramic irradiators, the licensee must demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

19-017.10 Computer systems: For panoramic irradiators that use a computer system to control the access control system, the licensee must verify that the access control system will operate properly if offsite power is lost and must verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

19-017.11 Wiring: For panoramic irradiators, the licensee must verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

OPERATION OF IRRADIATORS Removed.

19-018 TRAINING

19-018.01 Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

1. The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, Department dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how a irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);
2. The requirements of 180 NAC 10 and 180 NAC 19 that are relevant to the irradiator;

3. The operation of the irradiator;
4. Those operating and emergency procedures listed in 180 NAC 19-019 that the individual is responsible for performing; and
5. Case histories of accidents or problems involving irradiators.

19-018.02 Before an individual is permitted to operate an irradiator without a supervisor present, the individual must pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individuals responsible for performing and other operations necessary to safely operate the irradiator without supervision.

19-018.03 Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual must also demonstrate the ability to perform those portions of the operating and emergency procedures that s/he is to perform.

19-018.04 The licensee must conduct safety reviews for irradiator operators at least annually. The licensee must give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

1. Changes in operating and emergency procedures since the last review, if any;
2. Changes in regulations and license conditions since the last review, if any;
3. Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;
4. Relevant results of inspections of operator safety performance;
5. Relevant results of the facility's inspection and maintenance checks; and
6. A drill to practice an emergency or abnormal event procedure.

19-018.05 The licensee must evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee must discuss the results of the evaluation with the operator and must instruct the operator on how to correct any mistakes or deficiencies observed.

19-018.06 Individuals that will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, must be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in 180 NAC 19-019 that they are expected to perform or comply with, and their proper response to alarms required in 180 NAC 19. Tests may be oral.

19-018.07 Individuals who must be prepared to respond to alarms required by 180 NAC 19-008.02, 19-008.09, 19-010.01, 19-011.01, 19-011.02 and 19-022.02 must be trained and tested on how to respond. Each individual must be retested at least once a year. Tests may be oral.

19-019 OPERATING AND EMERGENCY PROCEDURES

19-019.01 The licensee must have and follow written operating procedures for:

1. Operation of the irradiator, including entering and leaving the radiation room;
2. Use of personnel dosimeters;
3. Surveying the shielding of panoramic irradiators;
4. Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
5. Leak testing of sources;
6. Inspection and maintenance checks required by 180 NAC 19-023;
7. Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and
8. Inspection of movable shielding required by 180 NAC 19-008.08, if applicable.

19-019.02 The licensee must have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

1. Sources stuck in the unshielded position;
2. Personnel overexposures;
3. A radiation alarm from the product exit portal monitor or pool monitor;
4. Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
5. A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;
6. A prolonged loss of electrical power;
7. A fire alarm or explosion in the radiation room;
8. An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;
9. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and
10. The jamming of automatic conveyor systems.

19-019.03 The licensee may revise operating and emergency procedures without Department approval only if all of the following conditions are met:

1. The revisions do not reduce the safety of the facility,
2. The revisions are consistent with the outline or summary of procedures submitted with the license application,
3. The revisions have been reviewed and approved by the radiation safety officer; and
4. The users or operators are instructed and tested on the revised procedures before they are put into use.

19-020 PERSONNEL MONITORING

19-020.01 Irradiator operators must wear either a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be accredited for high energy photons in the normal and accident dose ranges (see 180 NAC 4-021.03). Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly and other dosimeters must be processed at least quarterly.

19-020.02 Other individuals who enter the radiation room of a panoramic irradiator must wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this subsection, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within ±30% of the true radiation dose.

19-021 RADIATION SURVEYS

19-021.01 A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed three years and before resuming operation after addition of new sources or any modifications to the radiation room shielding or structure that might increase dose rates.

19-021.02 If the radiation levels specified in 180 NAC 19-009 are exceeded, the facility must be modified to comply with the requirements in 180 NAC 19-009.

19-021.03 Portable radiation survey meters must be calibrated at least annually to an accuracy of ± 20% for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

19-021.04 Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 180 NAC 4, Table 2, Column 2 or Table 3 of Appendix 4-B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

19-021.05 Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.5 microsievert (0.05 millirem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 millirem) per hour.

19-022 DETECTION OF LEAKING SOURCES

19-022.01 Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the Department, U.S. Nuclear Regulatory Commission or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Department, U.S. Nuclear Regulatory Commission or an Agreement State to perform the test.

19-022.02 For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by 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. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. 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.

19-022.03 If a leaking source is detected, the licensee must arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by the Department, U. S. Nuclear Regulatory Commission or an Agreement State licensee that is authorized to perform these functions. The licensee must promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. 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 inadvertently contaminated, the licensee must arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or product are found, the licensee must arrange to have them decontaminated or disposed of by the Department, U.S. Nuclear Regulatory Commission or an Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee must arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in 180 NAC 4, Table 2, Column 2. Appendix 4-B. (See 180 NAC 3-026 for reporting requirements.)

19-023 INSPECTION AND MAINTENANCE

19-023.01 The licensee must perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

1. Operability of each aspect of the access control system required by 180 NAC 19-008.
2. Functioning of the source position indicator required by 180 NAC 19-012.02.
3. Operability of the radiation monitor for radioactive contamination in pool water required by 180 NAC 19-022.02 using a radiation check source, if applicable.
4. Operability of the over-pool radiation monitor at underwater irradiators as required by 180 NAC 19-011.02.
5. Operability of the product exit monitor required by 180 NAC 19-011.01.
6. Operability of the emergency source return control required by 180 NAC 19-012.03.
7. Leak-tightness of systems through which pool water circulates (visual inspection).
8. Operability of the heat and smoke detectors and extinguisher system required by 180 NAC 19-010 (but without turning extinguishers on).
9. Operability of the means of pool water replenishment required by 180 NAC 19-013.03.
10. Operability of the indicators of high and low pool water levels required by 180 NAC 19-013.04.
11. Operability of the intrusion alarm required by 180 NAC 19-008.09, if applicable.
12. Functioning and wear of the systems, mechanisms, and cables used to raise and lower sources.
13. Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 180 NAC 19-014.
14. Amount of water added to the pool to determine if the pool is leaking.
15. Electrical wiring on required safety systems for radiation damage.
16. Pool water conductivity measurements and analysis as required by 180 NAC 19-024.02.

19-023.02 Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

19-024 POOL WATER PURITY

19-024.01 Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee must take prompt actions to lower the pool water conductivity and must take corrective actions to prevent future recurrences.

19-024.02 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. Conductivity meters must be calibrated at least annually.

19-025 ATTENDANCE DURING OPERATION

19-025.01 Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, must be present onsite;

1. Whenever the irradiator is operated using an automatic product conveyor system; and
2. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

19-025.02 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 180 NAC 19-018.07 must be onsite.

19-025.03 At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. 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 180 NAC 19-018.06 and 19-018.07. Static irradiations may be performed without a person present at the facility.

19-026 ENTERING AND LEAVING THE RADIATION ROOM

19-026.01 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.

19-026.02 Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator must:

1. Visually inspect the entire radiation room to verify that no one else is in it; and
2. 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.

19-026.03 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 180 NAC 19-011.02 is operating with backup power.

19-027 IRRADIATION OF EXPLOSIVE OR FLAMMABLE MATERIALS

19-027.01 Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Department. 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.

19-027.02 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 Department. 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.

RECORDS Removed.

19-028 RECORDS AND RETENTION PERIODS: The licensee must maintain the following records at the irradiator for the periods specified.

19-028.01 A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Department terminates the license for documents not superseded.

19-028.02 Records of each individual's training, tests, and safety reviews provided to meet the requirements of 180 NAC 19-018.01 thru 19-018.04, 19-018.06 and 19-018.07 until three years after the individual terminates work.

19-028.03 Records of the annual evaluations of the safety performance of irradiator operators required by 180 NAC 19-018.05 for three years after the evaluation.

19-028.04 A copy of the current operating and emergency procedures required by 19-019 until superseded or the Department terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by 180 NAC 19-019.03, item three retained for three years from the date of the change.

19-028.05 Evaluations of personnel dosimeters required by 180 NAC 19-020 must be retained until the Department terminates the license.

19-028.06 Records of radiation surveys required by 180 NAC 19-021 for three years from the date of the survey.

19-028.07 Records of radiation survey meter calibrations required by 180 NAC 19-021 and pool water conductivity meter calibrations required by 180 NAC 19-024.02 until three years from the date of calibration.

19-028.08 Records of the results of leak tests required by 180 NAC 19-022.01 and the results of contamination checks required by 180 NAC 19-022.02 for three years from the date of each test.

19-028.09 Records of inspection and maintenance checks required by 180 NAC 19-023 for three years.

19-028.10 Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.

19-028.11 Records of the receipt, transfer and disposal, of all licensed sealed sources as required by 180 NAC 3-025 and 3-030.

19-028.12 Records on the design checks required by 180 NAC 19-016 and the construction control checks as required by 180 NAC 19-017 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

19-028.13 Records related to decommissioning of the irradiator as required by 180 NAC 3-018.07.

19-029 REPORTS

19-029.01 In addition to the reporting requirements in other parts of Department regulations, the licensee must report the following events if not reported under of parts of Department regulations:

1. Source stuck in an unshielded position.
2. Any fire or explosion in a radiation room.
3. Damage to the source racks.
4. Failure of the cable or drive mechanism used to move the source racks.
5. Inoperability of the access control system.
6. Detection of radiation source by the product exit monitor.
7. Detection of radioactive contamination attributable to licensed radioactive material.
8. Structural damage to the pool liner or walls.
9. Abnormal water loss or leakage from the source storage pool.
10. Pool water conductivity exceeding 100 microsiemens (ohms) per centimeter.

19-029.02 The report must include a telephone report within 24 hours as described in 180 NAC 3-026.03, item 1 and a written report within 30 days as described in 180 NAC 3-026.03, item 2.