

# UNITED STATES NUCLEAR REGULATORY COMMISSION

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REGION III 801 WARRENVILLE ROAD LISLE, ILLINOIS 60532-4351 June 1, 2000

Ronald R. Bresell
Radiation Safety Officer
University of Wisconsin - Madison
Safety Department
30 North Murray Street
Madison, WI 53715

Dear Mr. Bresell:

Enclosed is Amendment No. 111 to your NRC Material License No. 48-09843-01 in accordance with your request. Please note that the changes made to your license are printed in **bold** font.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

This amendment authorizes the possession limit increase for phosphorus-32 in Subitem No. 8.D. of your license, as requested in your letter dated March 1, 2000.

However, please note that we were unable to approve the addition of your new radioactive waste decay -in - storage (DIS) facility at \_\_\_\_\_\_\_ Madison, Wisconsin at this time because the information in your letter dated March 1, 2000, was insufficient to complete our review. If you wish to pursue this authorization please address the information requested in the attached enclosure and submit it as "additional information to Control No. 306192." We will then continue our review.

Ex 2

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

- Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
- 2. Notify NRC, in writing, within 30 days:
  - a. When a Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
  - b. When the mailing address listed on the license changes.

Information in this record was deleted in accordance with the Freedom of Information

Act. exemptions 3

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- 3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.
- 4. Request and obtain a license amendment before you:
  - a. Change Radiation Safety Officers;
  - b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license:
  - c. Add or change the address or addresses of use identified in the license application or on the license; or
  - d. Change ownership of your organization.
- 5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure

for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

/RA/

Colleen C. Casey Materials Licensing Branch

License No. 48-09843-01 Docket No. 030-03465

## **Enclosures:**

- 1. Amendment No. 111
- 2. DIS Information Needed

## **DIS Information Needed**

Please note that, in preparing your response to the information requested below, you may find it helpful to consult the Model Procedures in Appendix V, NUREG 1556, Vol. 11, Final. Appendices L, O, P, and S, among others, may also assist you. If you decide to use NUREG 1556, Vol. 11, content in your response, please identify it as such.

1. Primarily, please update and revise the procedures, commitments and representations made in your letters dated July 26, 1993, and November 8, 1993, especially where adjustment for the new facility's diagrams, ventilation systems, layout, security, etc. are appropriate. If a previous procedure or commitment will remain exactly the same and will not be impacted by the move to the facility, you may so stipulate and re-state the procedure or commitment "as 15."

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Please show the "flow" of radioactive waste ("radwaste") through the new facility, starting with its collection and receipt from generators, pathways into each waste stream and ending with each stream's final disposal method.

You may also disregard making references to your incineration program and the Herrick Drive facility to the extent that they are not impacted by the move to the

facility. As discussed with you during my May 19, 2000, site visit, no medical wastes will be received, processed or stored at the new facility and need not be addressed in your response. If my understanding in this matter is incorrect, please contact me immediately.

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2. Please resubmit your diagrams for the DIS facility, including all use and storage areas (receipt, repackaging, adjacent areas, waste processing, "decayin-storage (DIS), etc. Include the ventilation and fire protection systems for these areas, as well as a description of the operational checks you will perform on these systems to ensure operability. Please do not submit blueprints or copies of blueprints. Hand-drawn diagrams, similar to those accompanying your letters dated July 26, 1993, and November 8, 1993, would be acceptable.

EXL

Please indicate the direction of north; the scale drawn to or actual dimensions; the locations of all lockable access points, loading dock, exterior windows (and their elevation); whether exterior windows are sealed or may be opened; the locations of fume hoods (may be limited to those hood(s) used for radioactive waste only); the location and functional identity of all adjacent unrestricted areas; the layout and function of each restricted area; and the expected locations of all relevant equipment, survey instrumentation and the vial crusher.

If certain of these functional areas and equipment locations may undergo minor changes in the future, please so state, confirm that the Radiation Safety Committee will evaluate and approve such changes beforehand and confirm that you will provide us with an updated facility diagram after such minor changes are effected. An example

- would be if additional restricted area space may be converted from supplies storage to shelving for dry, solids DIS storage.
- 3. Please describe your procedures for complying with 10 CFR 20.1203 and 20.1204 for procedures that may release volatile or gaseous radioactive materials to restricted and unrestricted areas. You should include a description of the type of surveys (e.g., environmental or breathing zone), frequency of surveys, the individuals who will perform the surveys, equipment to be used, and the procedures for evaluating the results against your ALARA thresholds and 10 CFR Part 20 limits, noted above.
- 4. Please describe your procedures for complying with 10 CFR 20.1302 for releases of licensed material in liquid effluents to unrestricted areas such as streams, rivers, or sanitary sewerage treatment facilities that are privately owned or operated by your institution such as septic tanks, leach fields, etc.). Include a description of the types of surveys to be performed, the frequency of the surveys, the individuals responsible for performing the surveys, the equipment to be used, and the procedures for evaluating the results against your ALARA thresholds and 10 CFR Part 20 limits, noted above.
- 5. Please confirm that you will maintain records of the results of these surveys to demonstrate compliance with regulatory requirements.
- 6. Please provide a complete description of the routine area survey program. Identify the areas to be surveyed, the frequency, the types and trigger levels of radiation and contamination that will require corrective action, and provisions for maintaining records of the survey results.
- 7. Please describe any significant radwaste treatment procedures at your facility, such as compaction, evaporation, solidification, liquid scintillation vial crushing, etc. Include the following in your description:
  - Treatment method and the type, quantities, and concentrations of waste to be treated;
  - b. Special equipment required, including a description of the type, manufacturer and model and capacity;
  - c. An analysis of the potential for airborne release of licensed material;
  - d. Equipment location within your waste processing area(s) and a ventilation and filtration system description, including your procedure for monitoring filter blockage and exchange;
  - e. Methods used to monitor releases to unrestricted work areas and internal and external monitoring of workers;
  - f. Surveys, types and frequencies performed for contamination control:

- g. Instructions provided to equipment operators, including instructions for protective clothing, checks for proper functioning of equipment, uncompacted waste handling methods and examinations performed for container defects.
- 8. Please submit a copy of the emergency procedures you have established. Indicate any training you provide to local police and fire department staff relative to emergency response activities at the new facility. Please confirm that you will post a copy of your emergency procedures along with contact names and telephone numbers. Also, please describe the likely types of emergency scenarios for the new facility that will require response by outside agencies and confirm that you have procedures established for coordinating these events with those agencies.

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**U.S. NUCLEAR REGULATORY COMMISSION** 

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Amendment No. 111

#### Licwater

## **MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee			In accordan March 1, 200		tter dated
University of Wisconsin-Madisor	ו		3. License nun	nber 48-098	343-18 is amended
Safety Department			in its entirety	to read as	s follows:
2. 30 North Murray Street			4. Expiration da	ate May 31	, 2002
Madison, WI 53715			5. Docket No.	030-03465	5/030-17753
			Reference N	lo. 070-00	052/070-00134
Byproduct, source, and/or special nuclear material	7. Chei	mical and/or pl	nysical form		mum amount that licensee may ess at any one time under this se
A.					
B. Hydrogen-3	В.	Any		В.	5000 curies
.C. Carbon-14	· C.	Any		C.	5 curies
D. Phosphorus-32	D.	Any	er er	D.	7 curies
E. F.		٠.			EKQ 1
H. Americium-241	H.	Any		H.	250 millicuries
J. Curium-244 K.	J.	Any		J.	1 millicurie
L.					

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	X.	Curium-244	X.	Sealed sources ( Products Model I XAN-244-MG, XA AL, X-KIT-2 and 244-NT)	Nos. AN-244-	X.	No sing 4 millic total					7
	} <b>Y</b> . }	Americium-241	Υ.	Sealed sources repursuant to 10 C 32.210 or with an Agreement State incorporated in a compatible portal gauging device in 9.Y of the license	FR and ble tem	Υ.	No sing 50 milli millicuri	curie	es, 4		exceed	ŧ
	Z.	Uranium	Z.	Uranium metal encapsulated in a cans		Z.	2550 ki	logra	ams			
	AA.	Uranium depleted in uranium-235	AA.	Solid metal		AA.	22 kilog	jram	S			
	BB.	Any byproduct material listed in 10 CFR 30.71 Schedule B	BB.	Any		BB.	Not to a 30.71, squantiti	Sche			R	
	CC.	Polonium-210	CC.	Plated foil source	•	CC.	Not to e millicuri possess 200 milli	es p sion	er fo	il. To		
	EE.	Technetium-99m	DD.	Any		DD.	As need	ded	income of the second	6		

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Byproduct, source, and/or special nuclear material	7. Chemical and/or physi	cal form 8.		um amour ss at any c				
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GG. Californium-252	GG. Sealed sour pursuant to 32.210 or w Agreement incorporated compatible pauging developments.	ith an State and I in a portable rice in Item	GG.	Two so exceed each.				\$ C
HH. Americium-241	HH. Sealed sour pursuant to 32.210 or w Agreement incorporated compatible gauging dev 9.HH of the	ith an State and I in a portable rice in Item	нн.	Two so exceed				each.
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JJ. Polonium-208	JJ. Plated or en source on di		JJ.	No sing 50 millio exceed	curie	s, tota	al not	to /
KK. Polonium-210	KK. Plated or en source on di		KK.	No sing 50 millio exceed	curie	s, tota	al not	to /

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9. Au	thorized Use:				··			<del></del>			<del></del>
Δ 1	through J.	To be used for	r medical	research and res	earch and de	velon	nent se	defina	ad in	10 (	CER
7. (		Part 30, Section	on 30.4 ir	ncluding animal st ources as a service	udies and stu						; ;
K.				trument calibratio periments requirin		unctio	n with a	subci	ritical		
L.				in a cyclotron and ples and laborato					for u	se i	n
M.	To be used for	or shielding in	linear ac	celerators and ele	ectron microso	opes.					
N.	To be used for	or instrument s	standardi	zation and calibra	tion.						
Ο.		or mass specti urement of net		of geologic sample	es, laboratory	analy	sis of irr	adiate	d sar	nple	•
P.	To be used in irradiation of		uding hig	hly flammable or	irradiator for explosive ma			instru	nents	s an	ed Ex
Q.	Medical use	described in 10	O CFR 35	5.100.							
R.	Medical use	described in 10	OFR 35	5.200.							
S.	Medical use	described in 10	) CFR 35	5.300.							
Т.	Medical use o	described in 10	) CFR 35	5.400.							
U.	Medical use	described in 10	) CFR 35	i.500 in devices w ear Regulatory Co						ed fo	or

V. In vitro studies.

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- W. One source to be used in a premote afterloading brachytherapy device for interstitial, intraluminal and intracavitary radiotherapy, and surface radiotherapy applications as described in letter dated May 10, 1993, and for irradiation of materials, dosimeters, and animals. The source activity may not exceed at the time of installation. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.
- X. To be used for calibration of instruments and for possession incident to transfer of the sources to individuals specifically licensed by the NRC or an Agreement State.
- Y. To be used for measuring physical properties of materials in portable gauging devices that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess, and use the devices.
- Z. To be used in a subcritical assembly for student instruction.
- AA. Shielding in a Picker Model C-9000 teletherapy unit.
- BB. To be used for in vitro studies of lake algae, bacterial metabolism, and trace metal uptake.
- CC. To be used in electrospray ionization mass spectrometry for DNA sequencing.
- DD. For veterinary diagnostic studies as described in letters dated October 29 and December 19, 1996.
- EE. For veterinary therapy treatments of hyperthyroidism in felines as described in letters dated October 29 and December 19, 1996.
- FF. To be used for measuring physical properties of materials in portable gauging devices that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess, and use the devices.
- GG. and HH. To be used for measuring physical properties of materials in portable gauging devices that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess, and use the devices.
- II. One source to be used in a tradiation of materials, excluding highly flammable or explosive

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materials. The source activity may not exceed at the time of installation. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

- JJ. through QQ. To be used for research and development of a micro-battery in accordance with letters dated September 17, 1999, and facsimile dated October 12, 1999.
- RR. through EEE. To be used as calibration and quality control sources in an alpha spectrometry system.
- FFF. For use as samples for testing and evaluation in accordance with the letters dated September 17, 1999, and December 20, 1999.

# **CONDITIONS**

EXZ

10. A. Licensed material may be used only at

- B. Patients administeredzcesium-137 and iridium-192 brachytherapy implants/may be hospitalized at the Veterans Administration Hospital, Madison, Wisconsin.
- C. The licensee is authorized to possess and use 75 millicuries of hydrogen-3, 50 millicuries of phosphorous-32, and 25 millicuries of carbon-14, phosphorous-33, sulfur-35, nickel-63, cadmium-109 and mercury-203, at for the purpose of conducting in vitro studies of lake algae, bacterial metabolism, and trace metal uptake.
- D. Licensed material listed in Subitems Y., FF., GG. and HH., of Item Nos. 6, 7, 8, and 9 may be used at temporary job sites of the licensee anywhere in the State of Wisconsin for the purpose of measuring physical properties of materials.
- E. The licensee may use the snow water content device containing up to millicuries of europium-152/154 temporary job sites of the licensee anywhere in the State of Wisconsin.
- F. Licensed material listed in Subitem BB. may be used at temporary job sites of the licensee anywhere in the State of Wisconsin.
- G. The licensee is authorized to possess and use/1 millicurie of carbon-14 at the Madison, Wisconsin in accordance with letters dated April 30, 1985 and April 12, 1996.

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- H. Licensed material listed in Subitem Z. (subcritical assembly) shall be used at the licensee's facilities located at the loc
- I. The licensee may store radioactive waste at facility as described in letter dated November 8, 1993.
- J. The licensee is authorized to possess and use itium labeled norepinephrine to conduct exception studies described in Section 35.100 of 10 CFR Part 35, of the University of Wisconsin, Green Bay, in accordance with letters dated April 3 and 12, 1996, August 29, 1996, June 3, 1996, January 17, 1997, and February 11 and 26, 1997.
- 11. A. Licensed material for non-human use shall be used by, or under the supervision of individuals designated by the University Radiation Safety Committee, Bruce Thomadsen, Chairman.
  - B. Licensed material for human use shall be used by or under the supervision of individuals designated by the Medical Center Radiation Safety Committee, Michael Wilson, M.D., Chairman.
  - C. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.
  - D. Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.
  - E. The Radiation Safety Officer for this license is Ronald Bresell.
  - F. The Alternate Radiation Safety Officer for this license is Abdul BenZikri.
- 12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.
  - B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
  - C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
  - D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
  - E. Sealed sources need not be leak tested if:
    - (i) they contain only hydrogen-3; or

- (ii) they contain only a radioactive gas; or
- (iii) the half-life of the isotope is 30 days or less; or
- (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
- (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, IL 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
- 13. Detector cells containing licensed material shall not be opened or the sources removed from the detector cell by the licensee.
- 14. Sealed sources containing licensed material shall not be opened.
- 15. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.
- 16. The licensee shall limit in-house repair and maintenance by University of Wisconsin personnel, on to those individuals who have successfully completed the repair/maintenance course. Further, repairs and maintenance shall be limited to those activities and procedures covered by the manuals provided with the training course.
- 17. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 18. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash provided:

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- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
- B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
- C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
- D. A record of each disposal permitted under this License Condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
- 19. A. Pursuant to 10 CFR 20.1302(c), and 10 CFR 20.2002, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, Column I, 10 CFR Part 20.
  - B. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with Atomic Nos. 1-83, other than those isotopes listed below, as ordinary waste in a landfill, provided the concentrations of the isotopes, expressed in μCi per gram of ash, at the time of disposal, do not exceed the numerical values listed in Table II, Column 2, 10 CFR 20, Appendix B. Isotopes not included are hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver-108m, niobium-94, iodine-129, technetium-99, and thallium-204, for which the concentrations must not exceed 10 percent of the values listed in Table II, Column 2, 10 CFR Part 20, Appendix B.
- 20. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
- 21. Licensed material shall not be used in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.
- 22. A. Access to the rooms housing the shall be controlled by a door at each entrance.

B. The entrance to the irradiation rooms shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance doors. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed at the source on-off control is reset at the control panel.

C. Electrical interlocks on the entrance door to the irradiator rooms shall be tested for proper operation at least once a month. Records of test results shall be maintained for inspection by the Commission.

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	n the event of malfunction of the door interlock, the isondition and not used, except as may be necessary system, until the interlock system is shown to be fund	for repair or replacement of the interlock
23. Prior	to initiation of a treatment program (for the	and prior to initiation of use (for the

- A. A radiation survey shall be made of:
  - (1) The source housing, with the source in the shielded position. The maximum radiation levels at 100 centimeters from the surface of the source head shall not exceed 0.25 milliroentgens per hour.

radiation surveys and tests shall be performed in accordance with the following:

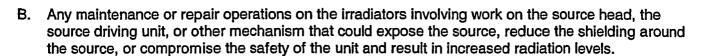
- (2) All areas adjacent to the treatment rooms with the source in the "irradiation" position. The survey shall clearly establish:
  - (a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.1201, Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standard for Protection Against Radiation" (10 CFR 20).
  - (b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.1301(a) of 10 CFR 20.
- B. Records of survey results shall be maintained for inspection by the Commission.

), and subsequent to each source exchange for the

- 24. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services:
  - A. Installation and replacement of sources contained in the irradiation devices.

and

and the



- 25. The licensee shall install in the afterloader rooms a permanent radiation monitor capable of continuously monitoring source status.
  - A. A radiation monitor must provide visible notice of an afterloader unit malfunction that results in an exposed or partially exposed source, and must be observable by an individual entering the afterloader room.
  - B. The radiation monitor must be equipped with a backup power supply separate from the power supply to the afterloader unit. This backup power supply may be a battery system.

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- C. The radiation monitor must be checked with a dedicated check source for proper operation each day before the afterloader unit is used for treatment of patients.
- D. A licensee shall maintain a record of the check required by paragraph C. for three years. The record must include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.
- E. If a radiation monitor is inoperable, the licensee shall require any individual entering the afterloader room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in paragraph D. of this section.
- F. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.
- 26. A. Access to the teletherapy room shall be controlled by a door at each entrance. Such doors shall be normally closed.
  - B. Each entrance to the teletherapy room shall be equipped with an electrical interlock system that will turn the teletherapy machine's primary beam of radiation "off" immediately upon opening of any entrance door. The interlock system shall be connected in such a manner that the teletherapy machine's primary beam of radiation cannot be turned "on" until all treatment room entrance doors are closed and the beam "on-off" control is reset at the control panel.
  - C. Electrical interlocks on entrance doors to the teletherapy room shall be tested for proper operation at least once every 6 months. Records of test results shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
  - D. In the event of malfunction of any door interlock, the teletherapy machine control shall be locked in the "off" condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
- 27. The following shall be performed only by persons specifically licensed by the Commission or an Agreement State to perform such services:
  - A. Installation, relocation, or removal of teletherapy units containing sources.
  - B. Source exchange.
  - C. Any maintenance or repair operations on a teletherapy unit involving work on the source drawer, the shutter, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.
- 28. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to

conform that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

- 29. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
  - A. Application dated February 16, 1994 (excluding licensee's Quality Management Program, Health Physics Procedures Manual, and Radiation Safety for Radiation Workers Manual) with attached Radiation Safety Regulations dated January 1997; and
  - B. Letters dated April 30, 1985, May 10, 1993, November 8, 1993, April 3 and 12, 1996, August 12, 1996, August 29, 1996, June 3, 1996, October 29, 1996, December 19, 1996, January 17, 1997, February 11 and 26, 1997, March 13, 1997, April 8, 1997, April 17, 1997, May 8, 1997, February 19, 1997, Facsimiles dated April 11, 1997 (with attachments), August 8, 1997, July 23, 1997, September 20, 1997, January 30, 1998 (with attachments, including Sealed Source and Device Registry Certificates), May 26, 1998, June 9, 1998, April 23, 1999 (excluding item numbers I., II., III., and V. and attached AAPM report TG-59), May 18, 1999, September 17, 1999, facsimile dated October 12, 1999, and December 20, 1999.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Bv	/na/			
-,	Colleen C. Casey			
	Materials Licensing Branch			
	Region III			

Date <u>June 1, 2000</u>