

**Ohio Department of Health
LICENSE FOR RADIOACTIVE MATERIAL**

Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as 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 applications of Chapter 3748 of the Ohio Revised Code and all applicable rules promulgated thereunder. This license is subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.

LICENSEE	LICENSE NUMBER
1 <i>The University of Toledo Health Science Campus</i>	3 02110490006
	EXPIRATION DATE
	4. February 1, 2011
2 3000 Arlington Avenue Toledo, Ohio 43614	BUREAU DOCKET NUMBER
	5 AC02-03-99

<p>6 RADIOACTIVE MATERIAL</p> <p>A Any radioactive material permitted by rule 3701:1-58-32 of the Ohio Administrative Code.</p> <p>B Any radioactive material permitted by rule 3701:1-58-34 of the Ohio Administrative Code.</p> <p>C Any radioactive material permitted by rule 3701:1-58-37 of the Ohio Administrative Code.</p> <p>D Any radioactive material permitted by rule 3701:1-58-43 of the Ohio Administrative Code.</p> <p>E Iridium-192 permitted by rule 3701:1-58-43 of the Ohio Administrative Code.</p> <p>F Iridium-192 permitted by rule 3701:1-58-55 of the Ohio Administrative Code.</p> <p>G <i>Cesium-137</i></p> <p>H Any radioactive material permitted by rule 3701:1-46-11 of the Ohio Administrative Code.</p>	<p>7 CHEMICAL AND/OR PHYSICAL FORM</p> <p>A Any radiopharmaceutical form</p> <p>B Any radiopharmaceutical form</p> <p>C Any radiopharmaceutical form</p> <p>D Sealed sources</p> <p>E Source wire (Amersham Corporation Model ICW 100)</p> <p>F Sealed sources (Omnitron International Model SL-777V or Varian Medical Systems, Inc., Model VS2000)</p> <p>G <i>Sealed source (model 86Cs1 in an AECL Gammcell 1000 Model A irradiator)</i></p> <p>H Prepackaged Kits</p>	<p>8 MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE</p> <p>A As needed, not to exceed 3.7 GBq (100mCi) of Cobalt-57</p> <p>B As needed</p> <p>C As needed</p> <p>D As needed</p> <p>E 7.4 GBq (200 mCi)</p> <p>F Two sources not to exceed 795.5 GBq (21.5 Ci) total in one location, one source not to exceed 444 GBq (12 Ci)</p> <p>G <i>Not to exceed 26 64 TBq (720 Ci)</i></p> <p>H As needed</p>
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OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 2 of 6
	License Number: 02110490006
	Bureau Docket Number AC02-03-99
	Amendment No. 10

6 RADIOACTIVE MATERIAL	7 CHEMICAL AND/OR PHYSICAL FORM	8 MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
I. Radioactive material with atomic numbers between 3 through 83 except as specified below	I. Any	I. Not to exceed 7.4 GBq (200 mCi) per radionuclide. Total possession not to exceed 74 GBq, (2 Ci) except as noted below.
J. Hydrogen-3	J. Any	J. 55.5 GBq (1.5 Ci)
K. Cesium-137	K. Sealed source (Technical Operations, Inc. Model No 726)	K. One source not to exceed 3.552 GBq (100 mCi)
L. Cesium-137	L. Sealed source (Technical Operations, Inc. Model No. 773)	L. One source not to exceed 6.105 GBq (165 mCi)
M. Radium-226	M. Sealed Sources	M. No single source to exceed 555 kBq (15 μ Ci)
N. Nickel-63	N. Sealed source (Hewlett-Packard Model No. 18713A)	N. 555 MBq (15 mCi) each source, total not to exceed 2.775 GBq (75 mCi)
O. Nickel-63	O. Foil source (Detector Cell assembly Varian Model No. 01-001028-01)	O. 296 MBq (8 mCi) each source, total not to exceed 1.85 GBq (50 mCi)
P. Americium-241	P. Foil source (NRD, Inc. Model A-001)	P. 37 KBq (1 μ Ci) each source, total not to exceed 1.85 MBq (50 μ Ci)
Q. Americium-241	Q. Sealed source (Thermo Nutech/TMA Eberline Model DNS-5sp)	Q. One source not to exceed 799.2 kBq (21.6 μ Ci) \pm 20%
R. Gadolinium-153	R. Sealed Transmission line Source	R. 740 MBq (20 mCi) each source, Total not to exceed 11.1 GBq

9. Authorized Use

- A. Any uptake, dilution and excretion study permitted by rule 3701:1-58-32 of the Ohio Administrative Code.
- B. Any imaging and localization study permitted by rule 3701:1-58-34 of the Ohio Administrative Code.
- C. Any medical use permitted by rule 3701:1-58-37 of the Ohio Administrative Code.
- D - E. Any brachytherapy sources for therapeutic medical use permitted by rule 3701:1-58-43 of the Ohio Administrative Code.
- F. One source for therapeutic medical use permitted by rule 3701:1-58-55 of the Ohio Administrative Code, in a Varian TEM Ltd. remote afterloader unit. The source activity may not exceed 444 GBq (12 Curies) at the time of installation. One source in its shipping container for source replacement in the remote afterloader unit.
- G. *To be used in an AECL Gammacell 1000 Irradiator for the irradiation of biological material and animals for research purposes.*
- H. To be used for in vitro studies permitted by rule 3701:1-46-11 of the Ohio Administrative Code

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 3 of 6
	License Number: 02110490006
	Bureau Docket Number AC02-03-99
	Amendment No 10

9. Authorized Use

- I. To be used for medical research and therapeutic research and for research and development as described in letter dated December 21, 1990 (Item 2 of attachments).
- J. To be used for research and development as described in letter dated December 21, 1990 (Item 2 of attachments).
- K - M Check, calibration and reference sources
- N - O To be used in a gas chromatograph for sample analysis
- P To be used as static elimination devices.
- Q To be used for in-vitro biological research and development as described in letter dated September 25, 1996.
- R Gadolinium line source, to be used to calibrate a gamma camera.

CONDITIONS

- 10 Licensed material may be received, possessed, used and stored at the licensee's facilities located at:
 3000 Arlington Avenue
 Toledo, Ohio 43614
- 11
- A Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety and Radioisotope Committee, Robert J. Coombs, M.D., Chairman.
 - B The use of licensed material shall be by or under the supervision of individuals that meet the minimum criteria as specified in Chapter 3701:1-58 of the Ohio Administrative Code.
 - C The users of licensed material in or on humans shall be a physician as defined in rule 3701:1-58-01(C) of the Ohio Administrative Code.
 - D Physicians designated to use licensed material in or on humans shall meet the appropriate training and experience criteria in rule 3701:1-58-21 (B) of the Ohio Administrative Code.
 - E The Radiation Safety Officer for the activities authorized by this license is : Eddie Brentlinger
 - F The high dose rate brachytherapy physicists designated by the Radiation Safety and Radioisotope Committee shall meet the training and experience criteria specified in rule 3701:1-58-19 of the Ohio Administrative Code.
12. A
- (1) Each sealed source acquired from another person and containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transfer or indicating that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.
 - (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 3.7 MBq (100 μ Ci) or less of beta and/or gamma emitting materials or 370 kBq (10 μ Ci) or less of alpha emitting material.
 - (3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer.
- B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 185Bq (0.005 μ Ci) or greater of removable contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 4 of 6
	License Number: 02110490006
	Bureau Docket Number AC02-03-99
	Amendment No. 10

- C Each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.
- D The test shall be capable of detecting the presence of 185 Bq (0.005 μ Ci) of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of becquerels and maintained for inspection by the Department. Records may be disposed of following Department inspection.
- E If the test required by Subsection A. or C. of this condition reveals the presence of 185 Bq (0.005 μ Ci) or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A report shall be filed within 5 days of the date the leak test result is known with the Bureau of Radiation Protection Ohio Department of Health, 246 N High St , 35 Building/7th Floor, Columbus, Ohio 43266. The report shall specify the source involved, the test results, and corrective action taken.
- 13 The Radiation Safety Officer shall conduct an annual program audit and confirmatory radiation survey of each location where radioactive material will be utilized
 - 14 All persons performing activities meeting the definition of "Nuclear Medicine Technologist" as specified in R.C. 4773.01 shall be licensed and in good standing with the state of Ohio.
 - 15 All sealed sources that are used or obtained shall have been evaluated and approved by the U.S. Nuclear Regulatory Commission an equivalent agreement state regulation or NARM licensing state under the provisions of rule 3701:1-46-49 of the Ohio Administrative Code.
 - 16 Sealed sources containing licensed material shall not be opened or removed from their respective source holders by the licensee.
 - 17 Detector cells containing licensed material shall not be opened or the sources removed from the detector cell by the licensee.
 - 18 In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) , as delineated in rule 3701:1-38-18 (A) of the Ohio Administrative Code, the licensee is hereby authorized to label detector cells, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.
 - 19 The licensee is authorized to transport licensed radioactive material in accordance with Chapter 3701:1-50 of the Ohio Administrative Code.
 - 20 Except as otherwise specified in this license, the licensee shall have available and follow the instructions contained in the manufacturer's instruction manual for the chromatography device.
 - 21 The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed per rule 3701:1-58-27 (G) of the Ohio Administrative Code. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the information required in rule 3701:1-58-80 of the Ohio Administrative Code.
 - 22 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 USNRC or an Agreement State to perform such services
 - 23 The procedures contained in Manufacturer's instruction manual for the irradiator shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.
 - 24 Experimental animals or the products from experimental animals that have been administered licensed materials shall not be used for human consumption.
 - 25 The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.

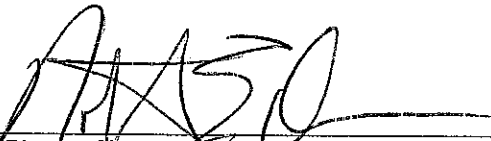
OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 5 of 6
	License Number: 02110490006
	Bureau Docket Number AC02-03-99
	Amendment No. 10

26. 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:
- 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, radioactive material shall be surveyed at the container surface with the appropriate survey 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. A record of each disposal permitted under this License Condition shall be retained for three 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.
27. The licensee may possess 795.5 GBq (21.5 Ci) Iridium-192, not to exceed 444 GBq (12 Ci) per source, for use in the Varian TEM Ltd. HDR remote afterloading brachytherapy unit, provided the individual source activity does not exceed 370 GBq (10 Ci) at the time of installation, and the source is installed by an authorized individual.
28. In addition to the possession limits in Condition 8:
- A. With respect to unsealed sources, the licensee shall further restrict the possession of licensed materials to quantities below the applicable limit specified in rule 3701:1-38-17 of the Ohio Administrative Code, for establishing decommissioning financial assurance.
 - B. With respect to sealed sources, the licensee shall further restrict the possession of licensed materials to quantities below the minimum limit specified in rule 3701:1-38-17 of the Ohio Administrative Code, for establishing decommissioning financial assurance.
29. In addition to the requirements in rule 3701:1-58-30 of the Ohio Administrative Code any patient administered gamma emitting radiopharmaceuticals or permanent brachytherapy sources shall be provided a patient release card to include:
- (1) The patient's name.
 - (2) The radionuclide administered and its activity.
 - (3) The facility name which administered the radionuclide.
 - (4) The date of the administration of the radionuclide.
 - (5) The expiration date of the card.
- The card is not applicable to those patients who are institutionalized (Hospitals, Nursing Homes, Correctional Institutions, etc.) or whose radiation levels do not exceed 0.1 mR/hr at one meter.
30. *The licensee shall comply with the requirements described in the Ohio Department of Health letter dated July 31, 2006 and attached document entitled "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern." The licensee shall complete implementation of said requirements prior to possession of radionuclides in quantities of concern at or above the limits specified in Table 1 of the attachment. Within 25 days after the implementation of the requirements of this condition, the licensee shall notify the Ohio Department of Health in writing that it has completed the requirements of this condition.*
31. 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 Ohio Department of Health's statutes, rules, and orders shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations
- A. Renewal Application dated September 2, 2005
 - B. License # 02110490006 is renewed in its entirety (Amendment #7)
 - C. Clarification of Iridium-192 possession limits for HDR unit (Amendment #8)
 - D. Director's Order dated April 21, 2006; (Amendment #9)
 - E. Letters dated May 9, 2006, July 19, 2006 and Director's Order dated July 31, 2006 (Amendment #10)

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 6 of 6
	License Number: 02110490006
	Bureau Docket Number AC02-03-99
	Amendment No. 10

For the Ohio Department of Health

DATE: 8/22/06

BY: 
Director, Ohio Department of Health