



Stuart Kline, CIH, CSP, CHMM, HEM
Director, EH&S
Radiation Safety Officer

May 8, 2008

J-4

MS-16

45-30876-01

03036495

Re: Richard Brunken, MD

Richard Brunken, MD, is an Authorized User Physician at the Cleveland Clinic Foundation under Ohio Department of Health broad scope license 02110180013. The Cleveland Clinic Foundation Radiation Safety Committee has approved Dr. Brunken for 35.100, 35.200 and 35.300 uses. Authorized Users are not individually listed on the license.

If you need additional information, I would be glad to provide it.

Sincerely,

Stuart W. Kline
Director, EHS
Radiation Safety Officer

142249
NMSS/RGNI MATERIALS-002

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 rules promulgated thereunder. This license shall be deemed 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. The Cleveland Clinic Foundation	3. 02110180013
	EXPIRATION DATE
2. 9500 Euclid Avenue Cleveland, Ohio 44195 Attn: Stuart Kline Environmental Health and Safety, W18	4. July 1, 2012
	BUREAU DOCKET NUMBER
	5. DC28-12-97

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
A. Any radioactive material permitted by rule 3701:1-58-32 of the Ohio Administrative Code.	A. Any radiopharmaceutical form	A. As needed
B. Any radioactive material permitted by rule 3701:1-58-34 of the Ohio Administrative Code.	B. Any radiopharmaceutical form	B. As needed
C. Any radioactive material permitted by rule 3701:1-58-37 of the Ohio Administrative Code.	C. Any radiopharmaceutical form	C. 111 GBq (3.0 Ci)
D. Any radioactive material permitted by rule 3701:1-58-43 of the Ohio Administrative Code.	D. Any brachytherapy sources	D. 185 GBq (5.0 Ci)
E. Any radioactive material permitted by rule 3701:1-58-53 of the Ohio Administrative Code.	E. Sealed sources	E. 74 GBq (2.0 Ci)
F. Radioactive material permitted by rule 3701:1-46-11 of the Ohio Administrative Code.	F. Prepackaged kits	F. 3.7 GBq (100 mCi)
G. Radioactive material with atomic numbers between 1 through 83, inclusive.	G. Any	G. 3.7 TBq (100 Ci), not to exceed 111 GBq (3.0 Ci) of any single radionuclide, limited by condition 20.

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6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
H. Iridium-192 permitted by rule 3701:1-58-55 of the Ohio Administrative Code	H. Sealed source in Mallinckrodt Model B.V. or AEA Technology, Inc. Nucletron, Model 105,002 or equivalent	H. 888GBq (24 Ci) in 2 sources. No single source to exceed 481 GBq (13 Ci).
I. Cesium - 137	I. Sealed source in Gamma cell 3000 Elan Model I	I. 112.1 TBq (3.0 kCi), no single source to exceed 56.4 TBq (1.5 kCi).
J. Cesium - 137	J. Sealed source in J.L. Shepherd & Associates Model 6810	J. 296 TBq (8.0 kCi) in 2 sources. No single source to exceed 148 TBq (4.0 kCi)
K. Cesium - 137	K. Sealed source in Victoreen Tech/Ops Model 773 or equivalent	K. 12.3 GBq (333 mCi) in 2 sources. No single source to exceed 6.2 GBq (168 mCi)
L. Cobalt-60 permitted by rule 3701:1-58-72 of the Ohio Administrative Code	L. Sealed sources (General Electric Co. AB Elekta model No. 43047 or Elekta Model Nos. 43047, 43685, 1000029)	L. 512 TBq (13,824 Ci) 384 sources, not to exceed 1,332 TBq (36 Ci) each
M. Cesium-137	M. Sealed Source in Model ISO AECL Gamma Cell 1000A	M. 53.3 TBq (1,440 Ci) total: 2 sources, not to exceed 26.64 TBq (720 Ci) each

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. Any brachytherapy sources for therapeutic medical use permitted by rule 3701:1-58-43 of the Ohio Administrative Code.
- E. Any sealed source for diagnostic medical use permitted by rule 3701:1-58-53 of the Ohio Administrative Code.
- F. In vitro studies as permitted by rule 3701:1-46-11 of the Ohio Administrative Code.
- G. Medical diagnosis, therapy and research in humans. Research and development as permitted by rule 3701:1-40-01 of the Ohio Administrative Code, including animal studies; instrument calibration; student instruction; and in-vitro studies.
- H. One source to be used in Nucletron Micro-Selection (Model 105.999 or equivalent) for therapeutic medical use permitted by 3701:1-58-55 of the Ohio Administrative Code in a HDR remote afterloading brachytherapy irradiator and medical research in humans, and non-clinical radiobiology studies in animals and biological samples. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.
- I. For use in a Gammacell 3000 Elan irradiator for the irradiation of blood, blood components biological samples, animals and materials (excluding flammable or explosive materials).
- J. For use in installations, source replacement, and temporary storage of the J.L. Shepherd and Associates Mark I series. Submodel 25 irradiator for the irradiation of blood, blood components, biological samples, animals and materials (excluding flammable and explosive material).

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9. Authorized Use

- K. For use in Victoreen Model 64-773 Gamma Survey Instrument calibrator for calibration of survey instruments and ionization chambers.
- L. For medical use permitted by rule 3701:1-58-72 of the Ohio Administrative Code and human research studies with a Leksell Gamma PERFEXION Gamma Stereotactic Radiosurgery Unit. Sources in the shipping container as necessary for the replacement of the sources in the gamma stereotactic radiosurgery unit.
- M. For use, installation, source replacement, and temporary storage of an AECL Gamma Cell 1000A Irradiator for irradiation of blood, blood components, biological samples, animals and materials (excluding flammable and explosive materials). One source in its shipping container in possession of the licensee as necessary to the replacement of the source in the irradiator only.

CONDITIONS

10. Licensed material may only be stored and used at the licensee's facilities located at:

- | | |
|---|---|
| <p>A. 9500 Euclid Avenue
Cleveland, Ohio 44195</p> | <p>B. Northern Ohio Gamma Knife Center
Cleveland Clinic
9500 Euclid Avenue
Cleveland, Ohio 44195</p> |
| <p>C. Cleveland Clinic Lorain Family Health & Surgery Center
5700 Cooper Foster Park Road
Lorain, Ohio 44053</p> | <p>D. Cleveland Clinic Westlake Family Health Center
30033 Clemens Road
Westlake, Ohio 44145</p> |
| <p>E. Cleveland Clinic Strongsville Family Health & Surgery Center
16761 South Park Center
Strongsville, Ohio 44136</p> | <p>F. Cleveland Clinic Beachwood Family Health & Surgical Center
26900 Cedar Road
Beachwood, Ohio 44122</p> |
| <p>G. Cleveland Clinic Wooster Specialty Center
721 East Milltown Road
Wooster, Ohio 44691</p> | <p>H. Check and reference sources may be used at Cleveland Clinic Health Care System hospitals, regional facilities, and in Ohio and used at field sites located within the State of Ohio, serviced from this office.</p> |

11. The Radiation Safety Officer for this license is: Stuart Kline, M.S.

The Alternate Radiation Safety Officer for this license is: Gary Nordwig, M.S.

12. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in rule 3701:1-38-01 of the Ohio Administrative Code.
13. Individuals designated in writing to work as authorized users, as defined in rule 3701:1-58-01 of the Ohio Administrative Code, shall meet the training and experience criteria established in Chapter 3701:1-58 of the Ohio Administrative Code. Physicians shall be licensed under Chapter 3741 of the Ohio Revised Code. Dentists shall be licensed under Chapter 4715 of the Ohio Revised Code. Podiatrists shall be licensed under Chapter 4731 of the Ohio Revised Code.
14. The person(s) designated as Gamma Knife and/or HDR Physicist shall be the individuals approved by the Radiation Safety Committee and shall meet the training and experience criteria established in Chapter 3701:1-58 of the Ohio Administrative Code. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee.
15. All persons performing activities meeting the definition of "Nuclear Medicine Technologist" as specified in R.C. 4773.01 shall be licensed by, and in good standing with the State of Ohio.

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16. The Radiation Safety Officer shall conduct an annual program audit and confirmatory radiation survey of each location where radioactive material will be utilized.
17. Experimental animals or the products from experimental animals that have been administered licensed materials shall not be used for human consumption.
18. All sealed sources that are used or obtained shall have been evaluated and approved under the provisions of rule 3701:1-46-49 of the Ohio Administrative Code, or by equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.
19. The licensee shall conduct a physical inventory every 6 months to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for five (5) years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
20. In addition to the possession limits in item 8 with respect to unsealed sources, the licensee shall further restrict the possession of licensed materials to quantities below amounts requiring a decommissioning funding plan as specified in rule 3701:1-40-17 of the Ohio Administrative Code.
21. The licensee shall comply with the requirements described in the Ohio Department of Health letter dated November 16, 2005 and attached document entitled "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern."
22. 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.
23. 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: December 15, 2006
 - B. Letters dated June 19, 2007; July 5, 2007; July 19, 2007; July 30, 2007 and August 6, 2007.

For the Ohio Department of Health

DATE: 9/20/07

BY: 

Robert E. Owen, Chief
 Bureau of Radiation Protection
 on behalf of the Director of Health