STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH SERVICES
29 HAZEN DRIVE, CONCORD, NH 03301-6504
603-271-4588

John A. Stephen
Commissioner

Mary Ann Cooncy
Director

03-25613-01
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FAX

TO: Willie Lee
Nuclear Regulatory Commission

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Date *08/01/06 11:00 AM*

Number of pages including cover sheet *8*

FROM: Sandra Ordway
Radiological Health Section
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Phone 603-271-4588
Fax Phone 603-225-2325

CC:

REMARKS: ☒ Urgent ☒ For your review ☐ Reply ASAP ☐ Please Comment

As per your telephone conversation with Dennis O'Dowd, the following is a copy of amendment 29 to NH Radioactive Material License No. 130R. Please do not hesitate to contact our office should you require any further assistance.

Thank you,
Sandy Ordway, Records Control Clerk
Radiological Health Section
(603) 271-4588

139117
NMSS/RGNI MATERIALS-002

AUDIT NO. R 383

REF.: .....

FORM RHP-2B

PAGE 1 OF 7 PAGES

NEW HAMPSHIRE DIVISION OF PUBLIC HEALTH SERVICES

RADIOACTIVE MATERIAL LICENSE

Pursuant to the New Hampshire Bureau of ~~Environmental Health~~ Radiological Health ~~Program~~ regulations and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules and regulations of the New Hampshire Radiological Health ~~Program~~ Bureau now or hereafter in effect and to any conditions specified below.

LICENSEE

1. NAME Mary Hitchcock Memorial Hospital

2. ADDRESS One Medical Center Drive
Lebanon, New Hampshire 03756

3. LICENSE NO. 130R

4. EXPIRATION DATE June 30 1992

5. FILE NUMBER Amendment No. 29
An amendment in entirety

6. RADIOACTIVE MATERIAL (ELEMENT AND MASS NUMBER)	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM AMOUNT OF RADIOACTIVITY WHICH LICENSEE MAY POSSESS AT ONE TIME
A. Any radioactive material listed in Groups I & II of Appendix H, New Hampshire Rules for the Control of Radiation (NHRCR) (See page 2)	A. Any radiopharmaceutical listed in Groups I & II of Appendix H, NHRCR, except gases and gas solutions (See page 2)	A. As necessary for uses authorized in subitem 9.A (See page 2)

9. AUTHORIZED USE

A. To be used for any diagnostic procedure as specified in Appendix H, NHRCR.

B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Appendix H, NHRCR.

C. Any therapeutic procedure listed in Group IV of Appendix H, NHRCR.

(See page 2)

CONDITIONS

10. Radioactive material shall be used at:

Site 1. 2 Maynard Street, Hanover, NH

A. Until October 31, 1991, all uses authorized by the license (except for blood irradiator).

B. For storage of radioactive material waste generated at Site 1; possession and use of radioactive material listed in subitem K, items 6, 7, 8 and 9 above.

Site 2. One Medical Center Drive, Lebanon, NH
All uses authorized by the license, except the use of Xenon gas.

NEW HAMPSHIRE
RADIOLOGICAL HEALTH ~~PROGRAM~~ Bureau

DATE OF ISSUANCE September 19, 1991

For DIANE E. TEFFT
~~MANAGER~~ Administrator

New Hampshire Bureau of Environmental Health Radiological

Supplementary Sheet

License No. 130R

6 Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum Amount of Radioactivity Which Licensee May Possess At One Time
B Any radioactive material listed in Group III of Appendix H, NHRCR	B. Any forms listed in Group III of Appendix H, NHRCR	B. 3 curies of each radioactive material authorized in subitem 6 B
C. Any radioactive material listed in Group IV of Appendix H, NHRCR	C. Any radiopharmaceutical listed in Group IV of Appendix H, NHRCR	C. As necessary for uses authorized in subitem 9 C
D. Any radioactive material listed in Group V of Appendix H, NHRCR	D. Any radiopharmaceutical listed in Group V of Appendix H, NHRCR	D. As necessary for uses authorized in subitem 9.D
E Any radioactive material listed in Group VI of Appendix H, NHRCR	E. Any sealed source listed in Group VI of Appendix H, NHRCR	E. 3 curies total for all sources authorized in subitem 6 E
FF Xenon 133	F. Any radiopharmaceutical	F. 100 millicuries
G Cobalt 57	G. Sealed source (New England Nuclear NES 206)	G. 5 millicuries
H. Cobalt 57	H. Sealed source (New England Nuclear NES 5012)	H. 10 millicuries
I. Strontium 90	I. Sealed source (Brown Bovari Corp.)	I. 7 millicuries
J. Strontium 90	J. Sealed source (Tracerlab Model RA-1A)	J. 12 millicuries
K. Strontium 90	K. Sealed sources (Amersham SIC.7)	K. No single source to exceed 10 millicuries Total: 20 millicuries
L. Cobalt 60	L. Sealed source (Tech Ops 571 source rod)	L. 15 millicuries
M. Cesium 137	M. Sealed sources (CEA-ORIS-LAPIB Model 437C)	M. 3 sources, not to exceed 1700 curies each; Total: 5100 curies
N Strontium 89	N. Strontium chloride	N. 100 millicuries total

9. AUTHORIZED USE, cont'd.

O. Any therapeutic procedure listed in Group V of Appendix H, NHRCR
P. Any procedure listed in Group VI of Appendix H, NHRCR.
F To be used for pulmonary function studies and lung imaging
G. To be used for instrument calibration.
H. To be used for instrument calibration.
I. For storage only.
J To be used in a medical applicator for treatment of superficial eye conditions.
K To be used in a thimble ionization chamber calibrator (Nuclear Enterprises Limited Model 2503) and for source exchange.
L To be used in a Tech Ops Model 571 survey meter calibration device
M To be used in a CIS-US, Inc. IBL-437C self-contained (self-shielded) irradiator for irradiation of blood and blood components.

(See page 3)

9. AUTHORIZED USE cont'd

N. For treatment of metastatic prostate cancer in clinical trials conducted in accordance with the "Notice of Claimed Investigational Exemption for a New Drug" (IND No. 35269) which has been submitted to the FDA, and which has been accepted in writing by that agency

CONDITIONS

10. Radioactive material may be used only by the physicians listed below for the uses specified:

A. Bruce J. Friedman, M.D.
Robert D. Harris, M.D.
David E. Baseman M.D.
Thomas J. Sullivan M.D.
- all diagnostic uses authorized by the license

B. Paul J Bohdiewicz, M.D.
Harte C. Crow, M.D.
Robert Jeffery, M.D.
Steven K. Sargent, M.D.
Peter Spiegel M.D.
Ben L. Suoka, M.D.
- all diagnostic uses authorized by the license therapy with P-32; treatment of hyperthyroidism and cardiac dysfunction with I-131

C. Christopher T. Coughlin, M.D.
- all therapeutic uses authorized by the license subitem N for metastatic prostate cancer therapy

D. Walter C. Paton, M.D.
James Stafford, M.D.
James Taylor M.D
- all therapeutic uses authorized by this license except subitem N

E. Sandra E. Mitchell, M.D.
Robert J. Amdur M.D.
- brachytherapy

F. James F. Aubuchon M.D.
- In vitro studies and CR-51 Tc-99m and In-111 as U.S. Food and Drug Administration (FDA) approved radiopharmaceuticals to be administered for human studies in dose ranges, routes of administration and in physical and chemical forms specified in the package inserts and listed in the New Drug Applications (NDA's) for each product.

  Such studies shall be authorized, when conducted for purposes not listed in the NDA, or subsequent to approval by an appropriately constituted and FDA listed Institutional Review Board, the approval of the licensee's human use and experimentation committee if separately constituted, and only when the licensee has obtained informed consent from the subjects prior to the studies

11. Cont'd.

C. Edward Catherwood, M.D. - diagnostic uses of Tc-99m and Tl-201 for cardiac imaging only

H The blood irradiator shall be used only by or under the supervision of:

Alexander Filimonov, Ph.D.

Operators of the unit under the supervision of this individual shall have successfully completed training as specified by application dated April 30, 1991 and shall be so listed in the licensee's records. letter dated August 27, 199

I. Radioactive material for non-human applications, including in-house survey meter calibration, may also be used by, or under the supervision of, Alexander Filimonov Ph.D.

12. The individual designated to perform the functions of Radiation Safety Office. (RSO) for activities covered by this license is Alexander Filimonov, Ph.D.

13 Sealed sources containing radioactive material shall not be opened.

14. Unless otherwise specified, all radiopharmaceuticals to be used in humans must be from suppliers approved for distribution by the U. S. Food and Drug Administration (FDA) prepared from reagent kits and/or radionuclide generators from suppliers approved for distribution by the FDA, or obtained from a licensed nuclear pharmacy.

15 The licensee shall use a calibrated dose calibrator to assay all radiopharmaceuticals that are received by the licensee in multidose quantities or prepared by the licensee from kits and generators.

16. The licensee shall report any irregularities to the Agency associated with identification, labeling, quality or assay of any radiopharmaceutical received under the authority of this license. A written report shall be submitted to the Agency within 30 days of such an occurrence.

17. Patients containing temporary brachytherapy implants shall remain hospitalized until the implants are removed. A survey of the patient shall be made and recorded at the time of release to verify the removal of all sources.

18 Prior to the release of a patient containing permanent brachytherapy implants the licensee shall perform a radiation survey about the patient using a suitably calibrated survey instrument and shall provide the patient with written safety instructions beseg upon the survey.

19. An physician named as an authorized user of radioactive material on this license shall participate in clinical trials under a "Notice of Claimed Investigational Exemption for a New Drug" (IND) unless he has filed FDA Form 1571 with the firm sponsoring the studies and has been accepted by the FDA as a

19. Cont'd.

participant in the clinical trials. The participating physicians shall obtain "informed consent" statements from all patients who are administered such IND drugs.

20. In addition to the radiopharmaceuticals, radiopharmaceutical reagent kits and radionuclide generators authorized by the medical groups in Appendix H, NHRCR the licensee is hereby authorized the possession and use of any radiopharmaceutical, kit, or generator for which a New Drug Application (NDA) has been approved by the FDA, when the product is used in accordance with the manufacturer's product package insert for the purposes specified therein

21. Patients containing Iodine 131 for the treatment of thyroid carcinoma or patients containing therapeutic quantities of Gold 198 shall remain hospitalized until the residual activity is 30 millicuries or less.

22. a. The sealed sources of radioactive material specified in Items 6.g, H, I, and L above shall be subject to the leak test, use, record keeping and inventory provisions of He-P 2035.03(d) and (e), NHRCR.

b. The sealed sources of radioactive material specified in Items 6.I and J above shall be subject to the requirements of He-P 2035.06, NHRCR

23. The licensee shall not open or remove sealed sources containing radioactive material from the irradiator.

24. Installation services and initial testing of the irradiator for proper operation of the source exposure mechanism, safety warning components, external radiation levels and removable contamination shall be performed by persons specifically licensed to perform such services by this Bureau, the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State.

25. The irradiator shall be maintained and serviced in accordance with the manufacturer's specifications and recommended service intervals.

26. All maintenance on the irradiator which involves the source, source shielding or source exposure mechanism safety circuits, control panel electrical circuits or other mechanisms that could compromise safety of the unit, shall be performed only by the unit's manufacturer or by other persons specifically licensed to perform such services by this Bureau, another Agreement State or by the NRC.

27. Written instructions shall be posted at the irradiator controls. These instructions shall inform the machine operator of the procedure to be followed if unable to return the machine to the "off" condition with these controls. These instructions shall caution individuals to avoid exposure to the primary field of radiation in and around the specimen treatment area if it is accessible, and shall include specific instructions for:

27. Cont'd.

A. Locating and using the device for manually returning the Irradiator unit to the "off" condition, if applicable.

B. Securing the area against unauthorized entry.

C. Notifying the responsible individual or Radiation Safety Officer.

28. The licensee shall cease operations with the irradiator if any safety related system of the unit is found inoperative, including sample holder or source drive mechanisms, irradiation timing systems, safety interlocks or radiation field alarms if applicable. The licensee shall report to the Bureau any malfunction which requires the termination of operations for more than 24 hours and shall submit a written report of the incident and corrective actions within 30 calendar days of such an occurrence.

29. A. Each sealed source containing radioactive material in the irradiator shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed source shall not be used until tested.

B. The test shall be capable of detecting the presence of 0.005 microcurie of contamination on the test sample. The test sample shall be taken from appropriate accessible surfaces of the device in which the sealed source(s) is permanently or semipermanently mounted or stored. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Bureau.

C. If the test reveals the presence of 0.005 microcurie 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 Bureau rules. A report shall be filed within five days of the test with the Administrator, New Hampshire Bureau of Radiological Health Health & Welfare Building, Hazen Drive Concord NH 03301 describing the equipment involved the test results and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by the licensee under Radioactive Material License No. 305R, or by persons specifically authorized by the Bureau, the NRC, or an Agreement State to perform such services.

30. Radioactive material which is transported by the licensee or delivered to a carrier for transport shall be packaged, labelled and transported in accordance with U.S. Department of Transportation (DOT) regulations.

31. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material authorized by this license in accordance with statements representations and procedures contained in the following:

31. Cont'd.

application dated	June 27, 1988
letters dated	July 27, 1988
	August 19, 1988
	November 7, 1988
	November 10, 1988
	November 16, 1988
application dated	June 18, 1990
letters dated	August 17, 1990
	November 2, 1990
	January 9, 1991
	March 6, 1991
	April 19 1991
	April 29, 1991
application dated	April 30, 1991
letters dated	May 1, 1991
	May 24, 1991
	May 28, 1991
	June 18, 1991
	June 20, 1991
	July 11 1991
	August 14, 1991
	August 26, 1991
	August 27, 1991
	September 6, 1991
	September 9, 1991
	September 10 1991
	September 13, 1991
	September 18, 1991

The New Hampshire Rules for the Control of Radiation prevail over statements contained in the above documents unless such statements are more restrictive than the rules.