MetroHealth Medical
2500 MetroHealth Drive, Cleveland, Ohio 44109-1998

216 398-6300

Radiology

August 3, 1994

OPTIONAL FORM 99 (7-90)

**FAX TRANSMITTAL** # of pages ▶ 9

| To | From |
|---|---|
| Steve Baggett | D. A. Askura |
| Dept./Agency | Phone # |
| Fax # 301-415-5369 | Fax # |

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

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Check No. 010785
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Date Check Rec'd 8/30/94
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By: AL

Re: Amendment to License 34-03749-10

Dear Sirs:

We are requesting that our license 34-03749-10 be amended to allow for possession of a Gadolinium-153 sealed line source not to exceed 75 millicurie. The source is to be used in Nuclear Medicine as a transmission source to provide information to computer software that will allow attenuation correction during patient scanning. To accurately reconstruct a tomographic image during Nuclear Medicine SPECT imaging, corrections must be made of the differences in photon attenuation within the patient. Photon attenuation can cause a uniform distribution of radioactivity within the patient to appear non-uniform. Using an external transmission source, the thickness of the patient can be found, correcting for attenuation of the emitted photons. A line source is placed on the gamma camera gantry, opposite one detector head and will rotate with the gantry during the rotational scan, remaining opposite the detector head. The source will be shielded when not in use. While scanning, the source is shielded except for a shutter which only open enough to irradiate one gamma camera head during the rotation of that head about the patient. The gamma camera head acts as a beam blocker, absorbing the emitted radiation. Picker International, Inc , supplies hardware and software to support the source, but the proposed source is supplied by Isotopes Products Laboratory, Burbank, CA. Picker has made the complete system commercially available as the STEP (Simultaneous Transmission and Emission) system for the Prism 3000 XP SPECT gamma camera.

The source will be used in a room that houses a gamma camera and patients injected with radioactive material and is already posted according to 10 CFR 20. Upon Installation, the radiation exposure levels will be measured 1 meter from the source, at the patient table, at the operators console, both with the shutter open and closed to insure that the room is properly posted. Source holder will be surveyed daily during the daily laboratory survey. Wipe test of the source and source holder will be done every six months. Procedures used for opening and receiving packages will be done prior to unpacking the source and source container will be surveyed prior to shipment back to the vendor.

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An Isotope Products Laboratories, Burbank, Ca source HEGL-0022 or equivalent will be used. A drawing of the source is included. Specifications of the requested source are:

Nuclide: Gd-153
Contained Activity: 60 mCi ± 15 %
Overall Length: 267 mm
Active Length: 235 mm
Overall Diameter: 6.35 mm
Active Diameter: 5.33
Uniformity: Emission of 100 Kev line to be within ± 3% for 1 cm segments.

Again, we requesting that our current license be amended to include the possession of a Gd-153 sealed line source not to exceed 75 millicurie. During a source change, we request that we be able to temporally exceed 75 millicurie for a period not to exceed 96 hours to cover the receipt, unpacking, installation of the new source and repacking, shipment of old source back to manufacturer.

A check for $500 is enclosed to cover the cost of the amendment. If any additional information is required, please feel free to contact me by mail at the above address, by phone on (216) 459-4519 or by FAX on (216) 459-4072.

Sincerely,

Ernest J. Wiesen

Ernest J. Wiesen
Radiation Safety Officer
MetroHealth Medical Center

# MATERIALS LICENSE

Amendment No. 18

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.

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| Licensee | |
|---|---|
| 1. MetroHealth Medical Center<br>Radiation Safety Office<br><br>2. 2500 MetroHealth Drive<br>Cleveland, OH 44109 | In accordance with letter dated August 3, 1994<br>3. License number 34-03749-10 is amended in its entirety to read as follows:<br><br>4. Expiration date September 30, 1998<br><br>5. Docket or Reference No 030-13873 |

| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
|---|---|---|
| A. Any byproduct material identified in 10 CFR 35.100 | A. Any radiopharmaceutical identified in 10 CFR 35.100 | A. As needed |
| B. Any byproduct material identified in 10 CFR 35.200 | B. Any radiopharmaceutical identified in 10 CFR 35.200 | B. As needed |
| C. Any byproduct material identified in 10 CFR 35.300 | C. Any radiopharmaceutical identified in 10 CFR 35.300 | C. As needed |
| D. Any byproduct material identified in 10 CFR 35.400 | D. Any brachytherapy source identified in 10 CFR 35.400 | D. 2.0 curies |
| E. Any byproduct material identified in 10 CFR 31.11 | E. Prepackaged Kits | E. As needed |

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
34-03749-10
Docket or Reference number
030-13873

Amendment No. 18

| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
|---|---|---|
| F. Any byproduct material, Atomic Nos. 3 through 83, inclusive, with a half-life less than 120 days | F. Any | F. Not to exceed 20 millicuries per radionuclide. Total possession not to exceed 2 curies, except as noted below:<br>Phosphorus-32 150 millicuries<br>Iodine-125 75 millicuries<br>Sulfur-35 200 millicuries |
| G. Carbon-14 | G. Any | G. 200 millicuries |
| H. Calcium-45 | H. Any | H. 5 millicuries |
| I. Cobalt-57 | I. Any | I. 10 millicuries |
| J. Hydrogen-3 | J. Any | J. 500 millicuries |
| K. Chromium-51 | K. Any | K. 30 millicuries |
| L. Nickel-63 | L. Foil sources contained in electron capture detector cells (which have been evaluated by and registered with the NRC or an Agreement State) | L. No single source to exceed 15 millicuries, maximum of 150 millicuries |
| M. Hydrogen-3 | M. Sealed sources (U.S. Radium Lab Model No. 508-3 detector cells) | M. No single source to exceed 150 millicuries, maximum of 1500 millicuries |
| N. Iridium 192 | N. Sealed sources (Byk Mallinckrodt Model C1 LBV) | N. Two sources not to exceed 10 curies each |
| O. Any byproduct material, Atomic Nos. 3-83 | O. Solid/liquid Waste | O. See Item 9.O. |
| P. Gadolinuim-153 | P. Sealed rod source (Isotope Products Labs. Model No. 3409) | P. Two sources not to exceed 75 millicuries each |

MATERIALS LICENSE
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9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

C. Medical use described in 10 CFR 35.300.

D. Medical use described in 10 CFR 35.400.

E. To be used for in vitro studies.

F. through K. To be used for research and development as defined in 10 CFR Part 30, Section 30.4, animal studies, and instrument calibration.

L. and M. For storage only.

N. One source to be used in a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial and intracavitary radiotherapy. One source in its shipping container to be in possession of the licensee, as necessary for replacement of the source in the irradiation device.

O. For possession incident to interim storage of waste in accordance with statements, representations and procedures contained in letter dated June 1, 1994.

P. To be used for instrument calibration.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at MetroHealth Medical Center, 2500 MetroHealth Drive, Cleveland, Ohio.

11. A. Licensed material shall only be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Ernest Wiesen, Chairperson. The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.

B. The licensee's Radiation Safety Committee shall approve all potential users prior to the use of byproduct material.

C. The Radiation Safety Officer for this license is Ernest Wiesen.

D. Physicians designated to use licensed material in or on humans shall meet the appropriate training and experience criteria in 10 CFR Part 35, Subpart J.

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 the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.

C. 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.

D. 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, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records may be disposed of following Commission inspection.

F. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to Perform such services.

13. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), 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.

14. Detector cells containing licensed material shall not be opened or the sources removed from the detector cell by the licensee.

15. Exhaust from detector cells containing tritium foils shall be vented through a laboratory fume hood or other suitable means designed to reduce potential exposure to personnel to the lowest practicable level.

16. 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.

17. Detector cells containing a titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by NRC.

18. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the quantities and kinds of byproduct material, manufacturer's name and model numbers, location of the sources and/or devices, and the date of the inventory.

19. The licensee shall maintain records of information related to decommissioning at 2500 MetroHealth Drive, Cleveland, Ohio as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

20. A. Access to the rooms housing the MicroSelectron High Dose Rate afterloading brachytherapy unit shall be controlled by a door at each entrance.

B. The entrance to the irradiation room 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 door. 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 and the source "on-off" control is reset at the control panel.

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

D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" position 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.

21. Prior to initiation of a treatment program, and subsequent to each source exchange for the MicroSelectron High Dose Rate afterloading brachytherapy unit, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

(1) The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 100 centimeters from the surface of the main source safe shall not exceed 0.25 milliroentgen per hour.

(2) All areas adjacent to the treatment room 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 10 CFR 20.101.

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b).

B. Records of the survey results shall be maintained for inspection by the Commission for the duration of the license.

22. 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 the sealed sources contained in the MicroSelectron High Dose Rate afterloading brachytherapy unit(s).

B. Any maintenance or repair operations on the MicroSelectron High Dose Rate afterloading brachytherapy unit(s) listed in Item 9., Subitem(s) N involving work on the source safe, the source driving unit, 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.

23. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

24. The licensee shall submit all changes to the membership of the Rad ation Safety Committee for review and approval by the Commission.

25. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

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26. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 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, byproduct 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. 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 July 20, 1992;

B. Letters dated February 10, 1993 (excluding reference to exemption from radiation surveys indicated in item 1), May 7, 1993, August 2, 1993, October 29, 1993, June 1, 1994, August 3, 1994, and September 14, 1994; and

C. Letter received May 13, 1993.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date November 8, 1994

By [signature]
Materials Licensing Section, Region III

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## Review of the Ohio Imaging submittal for a device review

**Model Name:** STEP

**Device Type:** Transmission Line Source Holding Device

**Purpose:** Image clarity accessory (thickness compensator) for various models of the SPECT camera

**Useful Life:** 10 years or longer

**Source Manu.:** Isotope Products, Burbank, CA
CA 406S1655
FDA approved

**Isotopes Used: and their Activ.** 75 mCi (± 15%) Gd-153
25 mCi (± 15%) Co-57
14-20 mCi (± 15%) Tc-99m
Radiation Symbol is provided on the end of the device above the shutter position indicator knob.

**Description:** The transmission line source holding device is a shutter shield affixed to the rotating gantry of a triple headed scintillation camera patient imaging system. The device is mounted such that the source is positioned along the line of the focal point of one of three fan beam collimators affixed one to each of the camera heads. It is equipped with shielding, shutter and mechanical and electrical interlocks. The device is portable to the extent that it can be detached from the gantry by the operator for secure storage when not in use.

**Purpose:** To provide during image acquisition a photon beam (transmission) of differing energy from that of the radiopharmaceutical administered to the patient (emission) that can be used to improve resolution losses normally experienced in radionuclide tomography studies due to the non-uniform absorption characteristics of tissues and structures surrounding the organ of interest in patient imaging studies.

The extremities of operators of the equipment may briefly pass through the beam if assistance to the patient is needed.

**Maximum Radiation Levels:** 2.0 mRem/hour at 5.0 centimeters from any surface as generated by a 20 mCi of Gd-153 (**NOTE: The device requires ~75 mCi Gd-153**). Levels from similar activities of Co-57 and Tc-99m were less.

Possible Applicable Regulatory Requirements:

10 CFR 35.57: "Authorization for calibration and reference sources"

Allows for:

1) use of sealed sources manufactured and distributed by a 32.74 licensee that do not exceed 15 mCi each;
2) any byproduct material listed in 35.100 and 35.200 with a half-life of 100 days or less in individual amounts not to exceed 15 mCi;
3) any byproduct material listed in 35.100 and 35.200 with a half-life longer than 100 days in individual amounts not to exceed 200 microCuries each; and
4) Tc-99m in individual amounts not to exceed 50 mCi.

10 CFR 35.500: "Use of sealed sources for diagnosis"

Allows for the use of Gd-153, I-125, or Am-241 in bone mineral analyzers or portable imaging devices.

Is it a calibration, reference or sealed source for diagnostic imaging?

The SOCs for the proposed and final rule for the 1987 revision of Part 35 do not necessarily provide a basis for either conclusion.

10 CFR 35.57 SOC: describe the material as sources that are needed to "check and test radiation instruments and mark images."

10 CFR 35.500 SOC: a "new type of use" to incorporate the recent development of medical devices that use a sealed source to create a beam of ionizing radiation. It does not explicitly state that these sources are to be used for diagnosis; however, this section was created to capture the "new" bone imaging analyzers used to determine bone density and portable I-125 devices typically used by surgeons as an imaging device to assist in bone manipulation during surgery.

Conclusion:

These sources do not fit either category. Rather than have the manufacturer seek a 10 CFR 32.74 license to distribute the device, NRC could license it as a "line-item" on the license stating the maximum allowable activity accounting for the appropriate number of devices potentially possessed or used by the licensee.

The question then is, "What do we do about those licensees using it now, without our knowledge and approval?" I suggest we do something generic to recognize the use of this device without making an issue out of it due to the low safety significance.