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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352

JUL 12 2004

Richard Vetter, Ph.D., CHP  
Radiation Safety Officer  
Mayo Clinic Rochester  
200 First Street, SW  
Rochester, MN 55905

Dear Dr. Vetter:

Enclosed is Amendment No. 63 to your NRC Material License No. 22-00519-03 in accordance with your request. Please note that the changes made to your license are printed in bold font.

The regulatory references in Part 20 relative to disposal by incineration were changed as a result of the revision in entirety of Part 20 (1991). In addition, the NRC policy regarding the disposal of incinerator ash was revised in January 1997. Neither of these revisions were addressed during the most recent license renewal process (Amendment No. 60 issued May 16, 2002), which is our opportunity to insure that your license incorporates the most recent policies and regulatory references. In order to insure that your license reflects these revisions, we have addressed them in this amendment. Please note in particular Conditions 21. and 22. of your license which have been amended to incorporate the appropriate Part 20 references relative to your incineration program and incorporate the revised ash disposal policy.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please contact me at the U.S. Nuclear Regulatory Commission, Region III office (630) 829-9868 so that I can provide appropriate corrections and answers.

Sincerely,

Patricia J. Pelke  
Materials Licensing Branch

License No. 22-00519-03  
Docket No. 030-02195

Enclosures:

Amendment No. 63

Information in this record was deleted  
in accordance with the Freedom of Information  
Act, exemptions 2  
FOIA- 2005-0293

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AUG 24 2004

Richard J. Vetter, Ph.D., CHP  
Radiation Safety Officer  
Mayo Clinic Rochester  
200 First Street SW  
Rochester, MN 55905

Dear Dr. Vetter:

It has come to our attention that Amendment No. 60 to NRC License No. 22-00519-03 issued on May 16, 2002, contained an error.

License Condition 12.C. named G. A. Wiseman, M.D., as Chairperson of the Radiation Safety Committee in error. Enclosed is a corrected copy of your NRC license naming Michael Haddock, M.D. as the Chairperson of the Radiation Safety Committee. We apologize for any inconvenience this may have caused you.

Sincerely,

A handwritten signature in cursive script that reads "William P. Reichhold".

William P. Reichhold

Materials Licensing Branch

License No. 22-00519-03  
Docket No. 030-02195

Enclosure: Corrected copy of NRC License

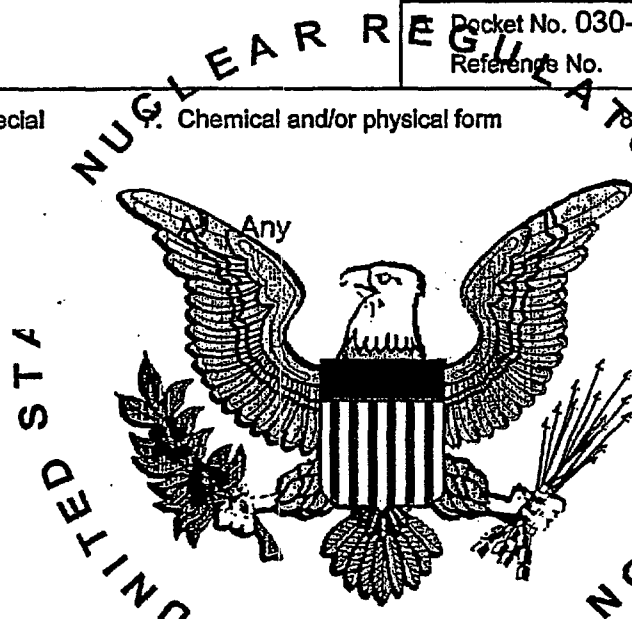
MATERIALS LICENSE

CORRECTED COPY

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, 36, 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.

<p>Licensee</p> <p>1. Mayo Clinic Rochester</p> <p>2. 200 First Street SW Rochester, MN 55905</p>	<p>In accordance with letter dated April 27, 2004,</p> <p>3. License number 22-00519-03 is amended in its entirety to read as follows:</p> <p>4. Expiration date May 31, 2012</p> <p>Pocket No. 030-02195 Reference No.</p>
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- 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
- B. Americium-241
- C. Hydrogen-3
- D. Any byproduct material with Atomic Numbers between 3-83, inclusive
- A. Any
- B. Sealed source (registered pursuant to Section 32.210 of 10 CFR Part 32 or an Agreement State equivalent)
- C. Foil
- D. Sealed sources (registered pursuant to Section 32.210 of 10 CFR Part 32 or an Agreement State equivalent)
- A. 4 per radionuclide.
- Total possession not to exceed, except as listed below:
 

Hydrogen-3	5 curies
Rhenium-188	3 curies
Samarium-153	10 curies
Technetium-99m	40 curies
Tungsten-188	3 curies
Xenon-133	2 curies
- B. 4 sources not to exceed 100 millicuries each
- C. 2 curies
- D. No single source to exceed [ ] except as listed below; total possession not to exceed [ ]
 

Iodine-125	2.0 curies
Palladium-103	2.0 curies

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6. Byproduct, source, and/or special nuclear material

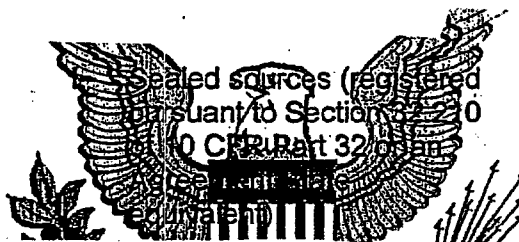
7. Chemical and/or physical form

8. Maximum amount that licensee may possess at any one time under this license

WA  
E.  
F.  
G.  
H.  
I.  
J.  
K.

Gadolinium-153

STATE



I. 12 sources not to exceed 600 millicuries each

1  
C  
M  
M  
1

9. Authorized Use:

A. through B. Medical diagnosis, therapy, and research in humans. Research and development as defined in Section 30.4 of 10 CFR Part 30, including animal studies; student instruction and instrument calibration.

C. To be used in gas chromatographs.

D. Medical use as defined in Section 35.2 of 10 CFR Part 35 (which includes diagnosis, therapy, and research in humans); animal studies and instrument calibration.

E. For use in [ ] for medical and radiobiological research.

F. For use in an [ ] for biomedical research.

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- G. To be used in samples. Ex 2 for the irradiation of medical and biological
- H. To be used in samples. Ex 2 for the irradiation of medical and biological
- I. To be used for automatic attenuation correction on gamma cameras.
- J. To be used in a irradiation of medical and biological samples. Ex 2 for the
- K. One source for medical use, as permitted by 10 CFR 35.600, in a One source (not to exceed while stored pending installation in a shipping container for source replacement. The source may also be used for physics calibrations and intercomparison studies. Ex 2

CONDITIONS

- 10. A. Licensed material shall be used only at the licensee's facilities located at the Mayo Clinic Rochester campus, Rochester, Minnesota.
- B. Licensed material in 10 CFR 35.100, 35.200 (excluding Xenon-133 and generators), 35.500, and Iodine-131 for treatment of hyperthyroidism and cardiac dysfunction may be used at temporary job sites of medical care facilities anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.
- C. Licensed material listed in Subitem K. may be used and stored at the Charlton or Eisenberg buildings located on the Mayo Foundation campus, Rochester, Minnesota.
- 11. The Radiation Safety Officer for the activities authorized by this license is Richard J. Vetter, Ph.D.
- 12.A. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.
  - B. Individuals designated to work as authorized users, authorized nuclear pharmacists, or authorized medical physicists, as defined in 10 CFR 35.2, shall meet the training, experience and recentness of training criteria established in 10 CFR Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee.
  - C. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee, Michael Haddock, M.D., Chairperson. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

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13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material, and shall further restrict the possession of unsealed licensed material to less than  $10^5$  times the applicable limits in Appendix C of 10 CFR 20, as specified in 10 CFR 30.35(d).
14. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- 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. Sealed sources need not be leak tested if:
- (i) they contain only hydrogen 3;
  - (ii) they contain only radioactive gas;
  - (iii) the half-life of the isotope is 30 days or less;
  - (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.
- E. 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, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532-4352, 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.

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- 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.
15. Detector cells containing a titanium tritide foil or a scandium 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 U.S. Nuclear Regulatory Commission.
16. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade.
17. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
18. Pursuant to 10 CFR Part 20, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material.
19. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
20. 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:
- Radioactive waste to be disposed in this manner shall be held for decay a minimum of 10 half-lives.
  - 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.
  - Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
  - 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.
21. 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, 10 CFR Part 20.

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22. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with Atomic Nos. 1 through 83, except as identified below, as ordinary waste in a landfill, provided that the concentration of radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than the values of Table II, Column 2, 10 CFR Part 20, Appendix B. For hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver-108m, niobium-94, iodine-129, technetium-99 and thallium-204, the concentration can be no greater than one-tenth of the value in Table II, Column 2, 10 CFR Part 20, Appendix B. If more than one radionuclide is present in the ash, then the sum of fractions rule applies.
23. Experimental animals administered licensed materials or their products shall not be used for human consumption.
24. 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"
25. This license does not authorize commercial distribution of licensed material.
26. 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 service.
27. For each irradiator installed and used, the licensee shall:
- Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and
  - Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and
  - Have room monitors installed that will:
    - Operate at all times when the irradiator is in use; and
    - Activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and
    - Detect any radiation leaking from the irradiator door; and
    - Be visible to the irradiator user when he is next to the irradiator; or
  - If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:
    - Determine the radiation level at the irradiation door when the door is closed; and
    - Check for any increase in radiation levels each time the irradiator door is opened.