NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE ____ OF ____ PAGES

CORRECTED COPY

MATERIALS LICENSE

Amendment No. 81

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.

OFFICIAL RECORD COPY

Licensee	
1. Department of Health and Human Services National Institutes of Health 2. 31 Center Drive, MSC 2260 Bethesda, Maryland 20892-2260	In accordance with the application dated April 26, 1995, 3. License number 19-00296-10 is amended in its entirety to read as follows: 4. Expiration date June 30, 2002 5. Docket or Reference No 030-01786

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 with atomic number 1 through 83	A. Any	A. Not to exceed 1 curie per radionuclide and 75 curies total
B. Hydrogen 3	B. Any	B. 150 curies
C. Carbon 14	C. Any	C. 3 curies
D. Phosphorus 32	D. Any	D. 4 curies
E. Sulfur 35	E. Any	E. 8 curies
F. Chromium 51	F. Any	F. 2 curies
G. Krypton 85	G. Any	G. 7 curies
H. Molybdenum 99	H. Any	H. 20 curies
I. Technetium 99m	I. Any	I. 20 curies
J. Bismuth 213	J. Any	J. 50 millicuries
K. Iodine 131	K. Any	K. 4 curies
L. Iodine 129	L. Any	L. 50 microcuries
M. Iodine 125	M. Any	M. 2 curies
N. Xenon 133	N. Any	N. 2 curies
O. Iridium 192	O. Any	O. 2 curies
P. Gadolinium 153	P. Any	P. 2 curies

ML 10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 19-00296-10
Docket or Reference number: 030-01786
Amendment No. 81

CORRECTED COPY

(6., 7., & 8. continued)

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
Q. Americium 241	Q. Sealed sources (Amersham Model AMC.24)	Q. 28 millicuries
R. Depleted Uranium	R. Metal	R. 600 kilograms
S. Californium 252	S. Foil	S. 250 microcuries
T. Any byproduct, source, or special nuclear material with atomic number 1 through 99	T. Any	T. Not to exceed 0.1 microcurie per gram and 3 curies total

9. Authorized use

A. through P. Medical diagnosis, therapy and research in humans in accordance with any applicable Food and Drug Administration (FDA) requirements. Research and development as defined in 10 CFR Part 30.4, including animal studies, student instruction and In-Vitro studies. Instrument calibration.

Q. For use in a medical scintillation gamma camera as a dual isotope motion correction detector.

R. Shielding in a linear accelerator.

S. For use in fission recoil ionization mass spectrometers.

T. Incidental contaminants in processed radioactive waste returned for interim storage.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

CORRECTED COPY

License number: 19-00296-10

Docket or Reference number: 030-01786

Amendment No. 81

(Continued) CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at the grounds and buildings under the control of the National Institutes of Health.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, Lance A. Liotta, M.D., Ph.D., Chairman.

B. Use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.

C. Individuals designated in writing to work as authorized users or authorized nuclear pharmacists, as defined in 10 CFR 35.2, shall meet the training and experience criteria established in 10 CFR Part 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee. Exceptions may be made on a case-by case basis in accordance with the procedures described in the letter dated April 26, 1995.

D. The Radiation Safety Officer for this license is Robert A. Zoon.

12. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

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 three months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 19-00296-10

Docket or Reference number: 030-01786

CORRECTED COPY

Amendment No. 81

(12. Continued) CONDITIONS

E. Sealed sources and detector cells 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 transfer 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 test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. 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 or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Director, Division of Nuclear Materials Safety, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

13. The licensee shall conduct a physical inventory every three months to account for all sealed sources and devices containing licensed material received and possessed pursuant to 10 CFR 35.57, 35.400 and 35.500 and every six months for all other sealed sources and devices.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 19-00296-10

Docket or Reference number: 030-01786

CORRECTED COPY

Amendment No. 81

(Continued) CONDITIONS

14. Notwithstanding the requirements of 10 CFR 35.92(a), the licensee may hold any radioactive material authorized by this license with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided the licensee stores the material for decay in accordance with all other requirements of 10 CFR 35.92.

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

16 A. 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 temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

18. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
19-00296-10
Docket or Reference number
030-01786

CORRECTED COPY

Amendment No. 81

(Continued) CONDITIONS

19. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material at a single location 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.

20. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

21. Notwithstanding the requirements of 10 CFR 35.49(a), 35.100, 35.200, 35.300, 35.400 and 35.500 the licensee may use for medical use any byproduct material. The licensee shall possess and use byproduct material for medical use in accordance with the prescriptive and performance criteria in the other sections of 10 CFR Part 35. This does not relieve the licensee from complying with applicable U.S. Food and Drug Administration (FDA) and other Federal and State requirements.

22. Notwithstanding the requirements of 10 CFR 35.315(a)(4), the licensee may use the alternate method for determining the dose rate in areas contigious to the current therapy room as described in the letter dated March 5, 1996. Dose rates in contigious areas will be remeasured and documented following structural modification, reconfiguration or relocation of the current therapy room.

23. Notwithstanding the requirements of 10 CFR 35.51(a)(3), the licensee may record the apparent exposure rate from a single dedicated check source located in a centralized location upon receipt of calibrated ionization chamber type survey instruments from the calibration laboratory. The dedicated check source used for this procedure shall become the dedicated check source for the survey instrument.

24. Notwithstanding the requirements of 10 CFR 35.315(a)(7), the licensee may reassign a patient room to another radiopharmaceutical therapy patient when removable contamination is less than 2000 disintegrations per minute per 100 square centimeters, and in accordance with other procedures described in the application dated April 26, 1995 except Attachment 10.7, under "Release of Patient From Radiation Safety Isolation Procedures", paragraph 5, third sentence.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 19-00296-10

Docket or Reference number: 030-01786

CORRECTED COPY

Amendment No. 81

(Continued) CONDITIONS

25. The licensee shall conduct refresher training as described in Item 8, page 8-3 of application dated April 26, 1995 on an annual basis.

26. 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. 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 April 26, 1995 except: Attachment 10.2, page 6; Item 4, paragraph 1; Attachment 10.7, under "Release of Patient From Radiation Safety Isolation Procedures", paragraph 5, third sentence, last paragraph, fifth line
B. Letter dated October 3, 1995
C. Letter dated November 17, 1995
D. Letter dated November 29, 1995
E. Letter dated December 19, 1995
F. Letter dated March 5, 1996 except Item 18, page 18 and Item 7, page 9, paragraphs under "Refresher Training Change"
G. Letter dated April 19, 1996
H. Letter dated April 25, 1996
I. Letter dated February 25, 1997

For the U.S. Nuclear Regulatory Commission

Date JUN 27 1997

By ORIGINAL SIGNED BY: THOMAS K. THOMPSON

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

JUN 27 1997

License No. 19-00296-10
Docket No. 030-01786
Control No. 121698

Robert A. Zoon, ME, MS
Radiation Safety Officer
Department of Health and Human Services
National Institute of Health
31 Center Drive, MSC 2260
Bethesda, MD 20892-2260

Dear Mr. Zoon:

Enclosed is the Corrected Copy of Amendment No. 81 for License No. 19-00296-10. in accordance with your letter dated June 18, 1997 and a telephone conversation with Thomas K. Thompson of my staff on June 19, 1997 we have made the following corrections:

- We increased the Iodine 129 possession limit to 50 microcuries.
- We removed Radium 224, Radium 225, and Actinium 225 from your license.
- We have changed your authorization for Gadolinium 153 to read any form with a total quantity of 2 curies.
- Condition 10 of your license has been modified to clarify that licensed materials may be used at your facilities under the control of the National Institute of Health but not limited to the location in Bethesda, Maryland.
- We have removed the redundant decay in storage condition from your license.
- We have corrected the typographical errors that you identified in Conditions 26 and 27 (now 25 and 26) of your license.

We apologize for any inconvenience these errors or misunderstandings may have caused.

OFFICIAL RECORD COPY ML 10

Sincerely,

ORIGINAL SIGNED BY:
MOHAMED M. SHANBAKY

Mohamed Shanbaky, Chief
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

License No. 19-00296-10
Docket No. 030-01786
Control No. 121698

Enclosure:
Corrected Copy of Amendment No. 81

DOCUMENT NAME: R:\WPS\MLTRL190.10
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	N				
NAME	thompson TAT		shanbaky MMS					
DATE	06/26/97		06/27/97		06/ /97		06/ /97	

OFFICIAL RECORD COPY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

June 18, 1997

Dr. Mohammed Shanbaky, Chief
Nuclear Materials Safety Branch I
Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Dr. Shanbaky:

Thank you for your letter of June 16, 1997 renewing the NIH Broad/Medical License No 19-00296-10 for another five years. I am disappointed that certain of the conditions which have been a part of the NIH license for many years were not continued; we will be communicating with your office in the near future regarding these issues.

I reviewed the license conditions very carefully upon receipt. Since it had been over two years since our initial reapplication package was submitted I wanted to make certain that essential requirements within Sections 6, 7, 8, & 9 were as requested or as subsequently amended during your review. It has come to my attention that the following items should be changed or deleted for the reasons given:

Item	Action	Reason
L. Iodine 129	Increase to 50 µCi	A typographical error occurred in the possession limit table (Item 5 in our application); 0.00005 Ci is 50 µCi; not 5 µCi.
P. Radium 224	Delete condition	Radium 224 is a naturally occurring radioactive material and possession is not subject to NRC regulation or licensing.
Q. Radium 225	Delete condition	Radium 225 is a naturally occurring radioactive material and possession is not subject to NRC regulation or licensing.
R. Actinium 225	Delete condition	Actinium 225 is a naturally occurring radioactive material and possession is not subject to NRC regulation or licensing.

121698

ML 10

OFFICIAL RECORD COPY

JUN 19 1997

W. Gadolinium 153	Modify Gd-153 possession limit to 2 Ci total, any form; delete 9.W. Authorized Use	This was discussed with your licensing staff recently while NIH obtained a second set of gadolinium 153 sources for SPECT cameras; as a broad licensee it was deemed unnecessary to specify the "authorized use" since 9 A., etc. already specified "medical diagnosis."

In addition to the above, it appears that Condition 15 merely duplicates Condition 14. I request that, for simplicity and clarity that Condition 15 be deleted. Also, it is my opinion that in Condition 26 your intent is that "The *licensee* shall..." not "The *license* shall.." Finally, Condition 27, citing the correspondence between NIH and the NRC during the review process, has lettered both the December 19, 1995 and the March 5, 1996 correspondence as item "E."

Thank you for your prompt attention to these corrections. Should you require discussion about these items, please contact me at 301-496-2254.

Sincerely

Robert A. Zoon

Robert A. Zoon, M.E., M.S.
Radiation Safety Officer, NIH

cc: Dr. Gottesman, DDIR, NIH
Dr. Wyatt, ADIR, NIH
Dr. Liotta, Chair, RSC, NIH
Dr. McKinney, Director, DS, ORS