

MATERIALS LICENSE

Amendment No. 02

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.

ORIGINAL RECORD COPY

Licensee

1. Nycomed Incorporated
2. P.O. Box 6630
466 Devon Park Drive
Wayne, Pennsylvania 19087-8630

In accordance with the letter dated
January 22, 1997,3. License Number 37-30243-01 is amended
in its entirety to read as follows:

4. Expiration Date October 31, 2000

5. Docket or
Reference No. 030-339386. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This License

- A. Hydrogen 3
- B. Carbon 14
- C. Phosphorus 32
- D. Phosphorus 33
- E. Sulfur 35
- F. Potassium 42
- G. Chromium 51
- H. Manganese 54
- I. Iron 59
- J. Rubidium 86
- K. Yttrium 90
- L. Technetium 99m
- M. Technetium 99
- N. Iodine 125
- O. Iodine 131
- P. Barium 133
- Q. Gadolinium 153
- R. Ytterbium 169

- A. Any
- B. Any
- C. Any
- D. Any
- E. Any
- F. Any
- G. Any
- H. Any
- I. Any
- J. Any
- K. Any
- L. Any
- M. Any
- N. Any
- O. Any
- P. Any
- Q. Any
- R. Any

- A. 300 millicuries
- B. 200 millicuries
- C. 65 millicuries
- D. 40 millicuries
- E. 50 millicuries
- F. 20 millicuries
- G. 20 millicuries
- H. 25 millicuries
- I. 50 millicuries
- J. 20 millicuries
- K. 20 millicuries
- L. 60 millicuries
- M. 20 millicuries
- N. 40 millicuries
- O. 30 millicuries
- P. 20 millicuries
- Q. 50 millicuries
- R. 20 millicuries

9. Authorized use

- A. through R. Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. A. Licensed material may be used only at the licensee's facilities located at 466 Devon Park Drive, Wayne, Pennsylvania.

100011



ML 10

9706160015 970207
PDR ADOCK 03033938
C PDR

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

37-30243-01

Docket or Reference Number

030-33938

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11. A. Licensed material listed in Items 6.A. through 6.R. shall be used by, or under the supervision of Christopher D. V. Black, Ph.D.; Vinay C. Desai, Ph.D.; Judith A. Johnson, M.S.; Lewis B. Kinter, Ph.D. or Dennis K. Fujii, Ph.D.
- B. Licensed material listed in Items 6.A. and 6.B. shall be used by, or under the supervision of Charles D. Kennedy, Jr.
- C. The Radiation Safety Officer for this license is Christopher D. V. Black, Ph.D.
12. 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.
13. Licensed material shall not be used in or on human beings.
14. 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.
- 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.

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- 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: Chief, Nuclear Materials Safety Branch, 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.
- 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.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. 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.
17. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.
18. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.
19. 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.
20. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
21. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

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22. 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:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
 - B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument 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 such 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.
23. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
24. 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 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 August 11, 1995
 - B. Letter dated September 22, 1995
 - C. Letter dated September 5, 1996
 - D. Letter dated September 25, 1996
 - E. Letter dated January 22, 1997

Date FEB - 7 1997

For the U.S. Nuclear Regulatory Commission

ORIGINAL SIGNED BY:

PENNY A. LANZISERA

By

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

FEB - 7 1997

Thomas F. Keelty
Assistant Director of Operations
Nycomed Incorporated
P.O. Box 6630
466 Devon Park Drive
Wayne, PA 19087-8630

Dear Mr. Keelty:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:
PENNY A. LANZISERA

Penny Lanzisera
Division of Nuclear Materials Safety

License No. 37-30243-01
Docket No. 030-33938
Control No. 124149

Enclosure:
Amendment No. 02

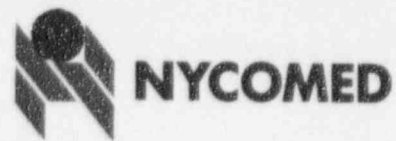
DOCUMENT NAME: R:\WPS\MLTR\L3730243.01

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	CNMS/RI	<input checked="" type="checkbox"/> N	DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	Lanzisera <i>PL</i>						
DATE	01/31/97	01/ /97	01/ /97	01/ /97	01/ /97		

OFFICIAL RECORD COPY

ML 10



January 22, 1997

Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

030-33938

Gentlemen,

This is to request that the Nycomed Inc. NRC License 37-30243-01, be amended as follows:

- a. Add the following nuclides in any chemical form as follows:

^{90}Y 20mCi

^{99}Tc 20 mCi

These nuclides will be used in research and development activities as described in the License Application dated August 11, 1995. In addition, the ^{90}Y will be used in radiotherapy to treat animal models of human diseases. The addition of these nuclide does not require an increase in the financial assurance for decommissioning.

- b. Modify the current areas within the facility where radioactive materials will be used and stored to include all laboratory spaces on the first floor of the facility.

These facilities consist of new modern labs with durable, easily cleaned floor and work surfaces with proper ventilation. All materials and equipment as described in the License Application dated August 11, 1995 will be available for use in each of these areas. Labeling and monitoring will be performed in accordance with 10 CFR 20 and NRC License 37-30243-01.

Enclosed is a check for \$610.00 for the license amendment fee. If you require any additional information in support of this request, please contact me at (610)225-4174.

Sincerely,

Thomas F. Keelty
Assistant Director of Operations

1 2 4 1 4 9

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620
STATUS CODE: 0
FEE CATEGORY: 3M
EXP. DATE: 20001031
FEE COMMENTS: _____
DECOM FIN ASSUR REQD: Y
.....

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: NYCOMED INCORPORATED
RECEIVED DATE: 970123
DOCKET NO: 3033938
CONTROL NO.: 124149
LICENSE NO.: 37-30243-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: \$ 610.00
CHECK NO.: 41476

3. COMMENTS

SIGNED

DATE

M. A. Perkin
1/24/97

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED Y)

1. FEE CATEGORY AND AMOUNT: 3M 8610

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT _____
RENEWAL _____
LICENSE _____

3. OTHER _____

SIGNED

DATE

I (97)

Log	<u>9152</u>
Remitter	
Check No.	<u>41476</u>
Amount	<u>\$ 610</u>
Fee Category	<u>3M</u>
Type of Fee	<u>AM</u>
Date Check Rec'd	<u>2/4/97</u>
Date Completed	<u>6B</u>
By:	