NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 20

MATERIALS LICENSE

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.

Licensee	
1. Syncor Corporation	In accordance with letter dated July 22, 1992 3. License number 34-19607-01MD is amended in its entirety to read as follows:
2. 300 Forest Avenue Dayton, Ohio 45405	4. Expiration date July 31, 1996
	5. Docket or Reference No 030-15204

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. Molybdenum-99	A. Any Molybdenum-99/technetium-99m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.73 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	A. 50 curies
B. Any byproduct material listed in Paragraph 31.11(a)	B. Prepackaged in vitro diagnostic test kits	B. 50 millicuries total possession limit
C. Any byproduct material authorized under Paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or Paragraph 35.57(a) of 10 CFR Part 35 (effective April 1, 1987)	C. Any sealed source listed in Paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or Paragraph 35.57(a) of 10 CFR Part 35 (effective April 1, 1987) that has	C. 50 millicuries total for all sources authorized under Subitem 6.C.

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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
	been manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations.	
D. Xenon-133	D. Unit dose containers of gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	D. 10 curies
E. Iodine-131	E. Any form listed in Groups I through V of Schedule A, Section 35...0, 35.200, 35.300 of 35.100 of 10 CFR Part 35 (superseded) of Sections 35.100, 35.200, 35.300 of 10 CFR Part 35 (effective April 1, 1987	E. 990 millicuries

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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
F. Technetium-99m	F. Any form listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Sections 35.100 and 35.200 of 10 CFR Part 35 (effective April 1, 1987)	F. 50 curies
G. Any byproduct material, except iodine-131 and technetium-99m, listed in Group I of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.100 of 10 CFR Part 35 (effective April 1, 1987	G. Any form listed in Group I of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.100 of 10 CFR Part 35 (effective April 1, 1987)	G. 50 millicuries total possession limit
H. Any byproduct material, except iodine-131 and technetium-99m, listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.200 of 10 CFR Part 35 (effective April 1, 1987)	H. Any form listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.200 of 10 CFR Part 35 (effective April 1, 1987	H. 100 millicuries total possession limit
I. Any byproduct material, except iodine-131, listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.300 of 10 CFR Part 35 (effective (April 1, 1987)	I. Any form listed in Group IV of Schedule A Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.300 of 10 CFR Part 35 (effective April 1, 1987)	I. 100 millicuries total possession limit

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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
J. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.400 of 10 CFR Part 35 (effective April 1, 1987)	J. Any sealed source that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State, pursuant to equivalent State regulations	J. 500 millicuries
K. Gadolinium-153	K. Sealed source (Gulf Nuclear Model GDI, Amersham Model GDC-CYI and New England Nuclear Models 430 or 431)	K. No single source to exceed 1.5 curies, 4.5 curies total
L. Iodine-125	L. Sealed source (Amersham Model IMC-P2, and AECL Models C-324 or C-325)	L. No single source to exceed 800 millicuries, 1.0 curies total
M. Uranium (depleted in the isotope Uranium 235)	M. Metal encased in stainless steel	M. 100 kilograms

9. Authorized Use:

A. Production of technetium-99m pertechnetate. Redistribution of unused generators to authorized recipients in accordance with statements, representations and procedures contained in application dated October 15, 1990.

B. Redistribution to general and specific licensees in accordance with statements, representations and procedures contained in application dated October 15, 1990.

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9. (Continued)

C. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to Section 32.74 of 10 CFR Part 32, the licensee is authorized to redistribute sources to persons licensed pursuant to Section 35.14 and 35.100 of 10 CFR Part 35 (superseded) or Section 35.57(a) of 10 CFR Part 35 (effective April 1, 1987) or under equivalent licenses of Agreement States.

D. Distribution to authorized recipients.

E. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Compounding of iodine-131 capsules and distribution of these capsules to authorized recipients in accordance with the statements, representations and procedures contained in application dated October 15, 1990.

F. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium-99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals.

G. through I. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

J. through L. Redistribution of sealed sources as received from the manufacturer in the manufacturer's original packaging and shielding and accompanied by the manufacturer's approved instructions to authorized recipients for use and storage.

M. Shielding of Molybdenum-99/technetium-99m generators.

Pursuant to 10 CFR, Parts 32.72, 32.73, 32.74 and not withstanding 10 CFR 32.72(a)(2), the licensee is authorized to distribute the byproduct material described in Items 6 and 7 and prepared in accordance with license Conditions 16., 18., and 22. of this license to persons licensed in accordance with Sections 35.14 and 35.100 of 10 CFR Part 35 (superseded) or Sections 35.100, 35.200, 35.300, 35.400, and 35.500 of 10 CFR Part 35 (effective April 1, 1987), or under equivalent Agreement State licenses, for Groups or Sections indicated below:

A. Unused molybdenum-99/technetium-99m generators may be redistributed to persons licensed pursuant to Group III or Section 10 CFR 35.200.

D. Gas or gas in saline may be distributed to persons licensed pursuant to 10 CFR 35.200 (effective April 1, 1987).

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9. (Continued)

E. through I. Any form listed in each group, Groups I, II, III and IV of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or authorized by Sections 35.100, 35.200 and 35.300 (effective April 1, 1987), may be distributed to persons licensed pursuant to that Group or Section.

J. through L. Sealed sources may be redistributed to persons licensed pursuant to Group VI of Sections 35.400 and 35.500 (effective April 1, 1987).

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 300 Forest Avenue, Dayton, Ohio and 8561 Gander Creek Drive, Miamisburg, Ohio.

11. A. Licensed material shall be used by, or under the supervision of, individuals who are specifically named as users in Condition 12.A. of License Number 34-16654-01MD. The licensee shall verify that each individual selected as a user is specifically named in Condition 12.A. of License Number 34-16654-01MD and, for this purpose, shall maintain for inspection by the Commission copies of License Number 34-16654-01MD.

B. At lease one individual named in Condition 11.A. shall be physically present at the authorized place of use when ever licensed material is being used.

C. The Radiation Protection Officer for the activities authorized by this license is Gregory G. Korte, R.Ph.

★ ★ ★ ★ ★

12. A. (1) The source(s) specified in Item(s) 7.C, J through L shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

(2) 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 material or 10 microcuries or less of alpha emitting material.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

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12. (Continued)

C. 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, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A 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, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source 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.

D. 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. Sealed sources containing licensed material shall not be opened or removed from their respective source holders by the licensee.

14. 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 2 years from the date of each inventory.

15. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

16. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:

(i) Repackaged from prepared radiopharmaceuticals that are the subject of an FDA-approved "New Drug Application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or

(ii) Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which FDA has accepted an IND.

B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or reagent kits for which FDA has accepted an IND shall be dispensed and/or distributed:

(i) In accordance with the directions provided by the sponsor of the IND, and

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16. (Continued)

(ii) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

The licensee shall inform in writing each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

17. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in its application dated October 15, 1990.

18. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit; or not withstanding 10 CFR 32.72(a)(2), the licensee may prepare radiopharmaceuticals in accordance with the specific departures authorized in license Condition 17. of License Number 34-16654-01MD, provided that the licensee has all current specific departure directions and equipment required by License Condition 17. of License Number 34-16654-01MD and they are available for inspection by the commission.

19. Reagent kits may be redistributed to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35, or under equivalent licenses of Agreement States, for Group III.

20. Any proposed changes in packaging, shielding or labeling shall be submitted for review to the U.S. Nuclear Regulatory Commission, Region III, Materials Licensing Section, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

21. The licensee shall maintain records of information important to safe and effective decommissioning at 300 Forest Avenue, Dayton, Ohio per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

22. Not withstanding 10 CFR 32.72(a)(2), the licensee may make departures to prepared iodine 131 (as sodium iodide) therapy dose radiopharmaceuticals, provided that the departures are made in accordance with License Condition 24 of License Number 34-16654-01MD and that the licensee has all current specific departure directions and required equipment and they are available for inspection.

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23. 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 October 15, 1990; and

B. Letters dated September 26, 1988, January 24, 1989 and July 10, 1991, July 30, 1991, August 12, 1991, August 26, 1991 (with attachments contained in License No. 34-16654-01MD, letter dated April 4, 1991), May 3, 1992, May 27, 1992, June 29, 1992 and July 22, 1992.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date September 10, 1992

By _____
Materials Licensing Section, Region III

COPY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

SEP 11 1992

Syncor Corporation
ATTN: Jeffrey S. Mueller, M.S.
Department of:
Program Manager, Quality & Regulatory
300 Forest Avenue
Dayton, OH 45405

License No 34-19007-01MD

TO THE LICENSEE:

Enclosed is NRC license or license amendment which you requested.

You are encouraged to carefully review your license or amendment upon receipt as special conditions may have been added to ensure that the changes requested meet NRC requirements.

Any future correspondence relating to your license should specifically reference your license number to expedite your inquiry.

Should you have any questions regarding your new license or amendment or require clarification, please contact the Materials Licensing Section at (708) 790-5625.

Materials Licensing Section

Enclosures: As stated

syncor®

July 22, 1992

John Madera
Materials Licensing Section
U.S. NUCLEAR REGULATORY COMMISSION
799 Roosevelt Road
Glen Ellyn, IL 60137

Re: **AMENDMENT REQUEST for LICENSE #34-19007-01MD, DAYTON, OH**

Mr. Madera:

Syncor International Corporation requests that the Nuclear Regulatory Commission amend the above referenced license to permit upgrades to our current iodine-131 air sampling equipment and procedures as described below:

EQUIPMENT

1. Vacuum pump with air flow gauge (rotameter).

   Because we will operate our air sampling equipment continually, evaluation of the effluent concentration will be done every 7 days.

2. Appropriate teflon (or equivalent material) tubing.

3. Tandem carbon cartridge holders.

4. Two (2) TEDA-impregnated carbon cartridges.

5. Scintillation counting assembly and NIST Ba-133 cartridge standard.

6. All fittings in sampling system are stainless steel.

Log Aug 3 III
Remitter
Check No. 316559 $460
Amount
Fee Category 3C amd
Type of Fee
Date Check Rec'd. 7/30
Date Completed 8/12
By

An open-face tandem cartridge holder in the breathing zone in front of the I-131 glove box-type fume hood will sample the restricted area I-131 concentration; an in-line tandem cartridge holder will sample the fume hood exhaust for the I-131 concentration in effluent to unrestricted areas.

Innovators in high-tech pharmacy services

Syncor International Corporation • 20001 Prairie Street • Chatsworth, California 91311-6127
(818) 886-7400 • FAX 886-6028 • Telex MCI 67-18642 Syncor CHATS

Pm 7/24/92

Each of the two cartridge holders will hold two TEDA-impregnated carbon cartridges, 2.25" in diameter and 1" thick (HI-Q Environmental Products Co., San Diego, CA, 619/549-2820, Catalog #TC-12) with no pre-filter. The manufacturer's stated efficiency factor for these cartridges is 99% at 10 liters per minute (0.35 CFM) for worst case, i.e., for methyl iodide (Methyl iodide has the poorest retention efficiencies of organic iodides and other iodine species. Since our radioiodine is not in the form of methyl iodide, our retention efficiency will be >99%.).

A calibrated, NIST-traceable barium-133 (0.5 uCi in carbon cartridge, Isotope Product Laboratories, Burbank, CA, 818/843-7000, Catalog #EG-133 CH) source will be used to simulate I-131 for calibrating the single channel analyzer (SCA) counting system. The Ba-133 source is in a cartridge of the same dimensions as the sample cartridges to emulate the sample counting geometry. This barium-133 standard will be placed on a 1" scintillation probe/SCA in the same geometrical configuration as the sample cartridges will be counted. The SCA's analyzer transmission will be set between 300 keV and 430 keV (or in equivalent channels if an MCA is used), and the instrument will be peaked to obtain the maximum count rate for the standard. The standard will be counted for a minimum of 10,000 net CPM to insure an accuracy of 2% at 95% confidence level, i.e., two (2) standard deviations. This calibration will be performed each time the sample cartridge is counted and the activity of the standard in net CPM will be used in the determination of sample cartridge iodine-131 activity. An LLD and an MDA will be determined for the Ba-133 standard.

We will modify our current software program to allow entry of the correction factor into the equation for calculating iodine-131 activity. The equipment will be checked prior to use (every 7 days) with the Barium-133 standard to ensure accuracy of the system.

The tandem cartridge holders will be used to evaluate a second, in line carbon cartridge each week for breakthrough of the initial cartridge. The breakthrough carbon cartridge will be counted and exchanged every 30 days.

The air flow measuring rotameters will be calibrated annually using a mass flow calibrator which is also calibrated annually for NIST traceability.

I-131 AIR MONITORING PROCEDURES

The following procedure is to be used with a Syncor Form RS-55, or an equivalent form.

1. Mount the air sampling apparatus in a manner which will ensure that effluents being released to both restricted and unrestricted areas will be sampled. Sampling must be done in the exhaust vent pipe on the down stream side of any additional cartridges. Be sure that the standard laboratory fume hood sash opening is closed as far as possible so that the face velocity across the fume hood opening is increased. This decreases the amount of volatile I-131 that will escape into the restricted area.

2. The initial carbon cartridge will be counted and exchanged every 7 days. The breakthrough carbon cartridge will be counted and exchanged every 30 days.

3. To obtain the data necessary to determine the activity in the cartridge:

   (a) Put on disposable gloves.

   (b) Calibrate the counting system by placing the barium-133 cartridge standard directly on the scintillation probe housing. Set the analyzer transmission with the lower discriminator at 300 keV and the upper discriminator at 430 keV and peak the instrument by adjusting the high voltage potentiometer or gain control. Obtain a count on the standard. Remove the standard and obtain a background count. Record the background and standard counts on RS-55 form or enter this data into the RS-55 computer program .

   (c) Place the cartridge on the scintillation probe in the same geometrical configuration as the standard source; and,

   (d) Obtain a count on it. Make sure that an efficiency factor (F_e) for the barium-133 standard has been calculated for the analyzer setting in (b) above.

   (e) Record the Ba-133 count on Form RS-55 or enter this data into the RS-55 computer program.

4. Record the sampling pump air flow in ml from measured flow of vacuum pump.

5. Record uCi quantity of barium-133 standard.

INSTALLATION OF CARTRIDGE AIR MONITORING SYSTEM

1. Cartridge Holder #1 will be mounted on the OUTSIDE of the I-131 glove box-type fume hood above the area where an individual would be working. This cartridge monitors the air in a RESTRICTED area at the level of the operators breathing zone.

2. Cartridge Holder #2 will be an in-line cartridge with the sampling probe mounted in the vent stack. This cartridge monitors the air to the UNRESTRICTED area, i.e., the air being vented to the environment.

CARBON CARTRIDGE TECHNICAL DATA

(HI-Q Environmental Products Company*, Catalog #TC-12 Cartridges)

Iodide Retention Efficiency	>98% at 10 liters/minute for methyl iodide, ASTM D3803, Method A, 1979 Procedure.
Physical Description	2.25" diameter, 1" thick, high density polypropylene (plastic)
Raw Material	Coconut Shell Carbon
Surface Area	1200-1300 m^2/gm, typical
Activation Method	High Temperature Steam
Particle Type	Natural Grain
Carbon Adsorptive Properties	ASTM-D3467 (Carbon Tetrachloride Activity = 40%)
Particle Size	ASTM-D2862 (8-16 mesh)
Impregnant	Triethylene Diamine (Tertiary Amines) 4-5%

(* HI-Q Environmental Products, San Diego, CA, 619/549-2820)

If you require additional information, please contact me at 818/886-7400 (X-4457).

Sincerely,

SYNCOR INTERNATIONAL CORPORATION

Jeffrey S. Mueller

Jeffrey S. Mueller, M.S.
Program Manager
Quality & Regulatory

Enclosure: $460.00 Amendment Fee

cc: Frank Comer, Program Director, Regulatory Compliance
Greg Corte, Manager, Location #23
License File

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02500
STATUS CODE: 0
FEE CATEGORY: 3C
EXP. DATE: 19960731
FEE COMMENTS:
DECOM FIN ASSUR READY R

LICENSE FEE TRANSMITTAL

A. REGION III

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: SYNCOR CORP.
RECEIVED DATE: 920727
DOCKET NO: 3015204
CONTROL NO.: 393758
LICENSE NO.: 34-19007-01MD
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: $460.00
CHECK NO.: 816559

3. COMMENTS

SIGNED P. Lacroff
DATE 7-29-92

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

1. FEE CATEGORY AND AMOUNT: 3C $460

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ✓
RENEWAL
LICENSE

3. OTHER

SIGNED Rita Jacques
DATE 8/13/92