NRC FORM 374 (7-94) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 67

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.

302066

Licensee	
1. Cleveland Clinic Foundation ATTN: Director Radiation Safety, W1B 2. 9500 Euclid Avenue Cleveland, OH 44195	In accordance with letter dated November 13, 1996 3. License Number 34-00466-01 is amended in its entirety to read as follows: 4. Expiration Date December 31, 2001 5. Docket or Reference No. 030-02649

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. As needed
E. Any byproduct material identified in 10 CFR 35.500	E. Sealed sources identified in 10 CFR 35.500	E. 5 curies
F. Any byproduct material with Atomic Numbers between 1 through 83 except as specified below	F. Any	F. 1 millicurie of each radionuclide with total possession not to exceed 50 millicuries
G. Hydrogen-3	G. Any	G. 400 millicuries
H. Carbon-14	H. Any	H. 40 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
I. Phosphorus-32	I. Any	I. 300 millicuries
J. Sulfur-35	J. Any	J. 500 millicuries
K. Calcium-45	K. Any	K. 10 millicuries
L. Chromium-51	L. Any	L. 200 millicuries
M. Iron-55	M. Any	M. 5 millicuries
N. Iron-59	N. Any	N. 5 millicuries
O. Strontium-85	O. Any	O. 5 millicuries
P. Strontium-90	P. Any	P. 0.01 millicuries
Q. Technetium-99m	Q. Any	Q. 100 millicuries
R. Iodine-125	R. Any	R. 500 millicuries
S. Iodine-129	S. Any	S. 0.01 millicuries
T. Iodine-131	T. Any	T. 100 millicuries
U. Cerium-141	U. Any	U. 25 millicuries
V. Selenium-75	V. Any	V. 10 millicuries
W. Phosphorus-33	W. Any	W. 100 millicuries
X. Rubidium-86	X. Any	X. 10 millicuries
Y. Niobium-95	Y. Any	Y. 25 millicuries
Z. Ruthenium-103	Z. Any	Z. 25 millicuries
AA. Rhenium-186	AA. Any	AA. 100 millicuries
BB. Rhenium-188	BB. Any	BB. 200 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
CC. Iridium-192	CC. Sealed source (Model CIL BV Byk Mallinckrodt)	CC. 21 curies total (2 sources not to exceed 10 curies each)
DD. Cesium-137	DD. Sealed source (Model 6810 J.L. Shepherd & Assoc.)	DD. 2 sources 4000 curies each not to exceed 8000 curies
EE. Cesium-137	EE. Sealed source (Model ISO-1000 AECL)	EE. 2 sources 720 curies each not to exceed 1440 curies
FF. Cesium-137	FF. Sealed source (Model 773 or equiv. Victoreen TECh/Ops)	FF. 2 sources 165 millicuries not to exceed 330 millicuries
GG. Any byproduct material identified in 10 CFR 31.11	GG. Prepackaged Kits	GG. As needed
HH. Yttrium-90	HH. Any	HH. 100 millicuries
II. Rhenium-188 and contaminants resulting from neutron activation	II. Solid Wire Source	II. 3 wires not to exceed 200 millicuries each. Total possession not to exceed 600 millicuries.
JJ. Rhenium-186/Rhenium-188	JJ. Solid Wire Source	JJ. 10 wires not to exceed 50 millicuries of Rhenium-186 and 100 millicuries of Rhenium-188. Total possession not to exceed 500 millicuries of Rhenium-186 and 1 curie of Rhenium-188.

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9. Authorized Use:

A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.

B. Any imaging and localization procedure approved in 10 CFR 35.200.

C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.

D. Any brachytherapy procedure approved in 10 CFR 35.400.

E. Medical use of sealed sources included in 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

F. through BB. and HH. Research and development as defined in Section 30.4 of 10 CFR Part 30, Instrument calibration, and animal studies.

CC. One source to be used in a Nucletron Micro-Selectron - HDR remote after loading brachytherapy irradiator for interstitial, intracavitary, or bronchial therapy and non-clinical radiobiology studies in non-humans. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

DD. One source to be used in J. L. Shepherd and Associates Mark I series, Submodel No. 25 irradiator for the irradiation of animals and materials (excluding highly flammable or explosive materials), and one source in it's shipping container in possession of the licensee as necessary for replacement of the source in the irradiator unit only.

EE. One source to be used in AECL Gamma Cell 1000A irradiator for the irradiation of blood, blood components, biological samples and materials, excluding flammable and explosive materials. one source in its shipping container in possession of the licensee as necessary to the replacement of the source in the irradiator unit only.

FF. To be used in Victoreen Model 64-773 Gamma Survey instrument calibrator for calibration of survey instruments and ionization chambers.

GG. For in vitro testing.

II. and JJ. For research and development as defined in 30.4, 10 CFR Part 30, limited to in vitro studies.

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CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, Ohio. Licensed material may also be received at the Cleveland Clinic Foundation loading dock, 2045 E. 90th St., Cleveland, Ohio.

11. The Radiation Safety Officer for this license is Xiaowei Zhu.

12. A. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.

B. Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

C. Notwithstanding Condition 12.B., licensed material in Subitem 6.CC. shall be used by physicians who meet the training criteria established in 10 CFR 35, Subpart J, Section 35.940 as designated by the licensee's Radiation Safety Committee.

D. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee, Guy M. Chisolm, III, Ph.D., Chairperson. The licensee shall maintain records of individuals designated as users.

E. Dr. Donald R. Neumann shall be the Radiation Safety Committee Chairperson, effective January 1, 1996.

13. In addition to the possession limits in Item 8, the license 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.

14. 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 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. 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.

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, 801 Warrenville Road, Lisle, IL 60532-4351, 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.

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.

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15. Pursuant to 10 CFR 40, "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.

16. The licensee shall conduct a physical inventory every three months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 10 CFR 35.400 and 10 CFR 35.500 and every six months for all other sources and/or devices. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the information required in 10 CFR 35.59(g).

17. 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 temperature from exceeding that specified by the manufacturer and approved by NRC.

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

18. 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.

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 65 days and sulfur-35 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 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. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

D. 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.

21. Radioactive waste identified in Condition 20. shall not be retained for a period longer than five years. Other radioactive waste shall not be retained for longer than 2 years.

22. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.

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 not acquire licensed material in a sealed source or device that contains a sealed source unless the source or device has been registered with the U. S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

25. 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."

26. In addition to the possession limits in condition 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

27. The licensee shall maintain records of information to safe and effective decommissioning at 9500 Euclid Avenue, Cleveland, Ohio per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

28. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to conform that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

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29. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:

A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each remote afterloading brachytherapy procedure.

B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr (μSieverts/hr), time, date and name of the individual making the survey.

D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

30. Prior to initiation of a treatment program, and subsequent to each source exchange using the Nucletron device remote afterloading brachytherapy devices, 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 10 centimeters from the surface of the main source safe shall not exceed 1 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 (10 CFR 20.1201).

(b) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b) (10 CFR 20.1301).

31. The following shall be performed only by manufacturer's representatives or 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 afterloading brachytherapy device(s).

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B. Any maintenance or repair operations on the remote afterloading brachytherapy unit(s) listed in Item 9., Subitem(s) involving work on the source safe, the source drive 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.

32. A. Access to the rooms housing the afterloading brachytherapy device 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 each day of use.

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.

33. 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 Nucletron after loading brachytherapy unit(s).

B. Any maintenance or repair operations on the Nucletron after loading brachytherapy unit(s) listed in Item 9. Subitem Y. 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.

34. For each J. L. Shepherd and Associates, Mark I Cesium-137 Irradiator installed and used, the licensee shall:

A. Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and

B. 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

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C. Have room monitors installed that will:

(i) Operate at all times when the irradiator is in use; and

(ii) Activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and

(iii) Detect any radiation leaking from the irradiator door; and

(iv) Be visible to the irradiator user when he is next to the irradiator; and

D. If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:

(i) Determine the radiation level at the irradiation door when the door is closed; and

(ii) Check for any increase in radiation levels each time the irradiator door is opened.

E. Immediately stop the use of the irradiator and notify the NRC, Region III Material Licensing, by telephone if abnormal levels of radiation or any malfunction of the irradiator is detected; and

F. Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

35. The procedures contained in the instruction manual for the Model Mark I device shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

36. Types and associated frequencies, as well as action levels for bioassays of Iodine-131, and Iodine-125 will be as outlined in Regulatory Guide 8.20, Revision 1, September 1979.

37. Pursuant to 10 CFR 20.1302(c) and 10 CFR 2002, the licensee is authorized to dispose of carbon-14 and hydrogen-3 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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38. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing carbon-14 and hydrogen-3 as ordinary waste in a landfill provided the concentration of the radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than one-tenth of the value in Table II, Column 2, 10 CFR Part 20, Appendix B.

39. 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 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 June 24, 1986, September 18, 1991, February 26, 1992 (except all references to Mobile Nuclear Medicine Scanning Unit), March 27, 1995 and November 3, 1995 (with attachments - excluding financial assurance); August 9, 1996 (with attached letter dated August 6, 1996); and

B. Letters dated November 2, 1981, October 22, 1987, February 29, 1988, February 14, 1992, May 12, 1992, June 18, 1992, June 19, 1992, June 26, 1992, and December 8, 1992, November 12, 1993 (except Item 10.16.2 (Bioassay Program), July 5, 1994, August 30, 1994, February 27, 1996, June 11, 1996 (excluding Item 7-7.1), June 27, 1996, September 3, 1996, and November 13, 1996 (with attachments).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 12/4/96

By Kevin A. Null
Nuclear Materials Licensing Branch, Region III

R2

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02110
Status Code: 0
Fee Category: 7B 3E 2B
Exp. Date: 20020630
Fee Comments: CODE 23
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: CLEVELAND CLINIC FOUNDATION
   Received Date: 961115
   Docket No: 3002649
   Control No.: 302066
   License No.: 34-00466-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: X
   Check No.: X

X ADDL INFO
301427-R2

3. COMMENTS

Signed D. Hersey
Date 11-22-96

1996 NOV 27 AM 8:49

B. LICENSE FEE MANAGEMENT BRANCH (Check when all necessary information has been entered /__/)

1. Fee Category and Amount: FEE NOT REQUIRED 301427

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed SC
Date 11/29/96

DEC 0 2 1996

RECEIVED BY LFDCB
Date Nov. 27 1996
Log Nov 11 III
By SC
Date Completed 11/29/96

THE CLEVELAND CLINIC FOUNDATION

A National Referral Center An International Health Resource

Radiation Safety / QQ10
216/444-6645

Mr. Kevin Null
Nuclear Materials Licensing Branch
U.S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60532-4351

November 13, 1996
Please expedite !!!
NRC License 34-00466-01

Dear Mr. Null,

The relocation of brachytherapy sources to the new source storage room was completed. As requested by your July 24, 1996 letter, we are submitting the results of the survey conducted in and around the new storage room (G70-58) and the survey data of the old source storage room (M2-165) for your review. As we discussed last week, I would like to request an expeditious review and approval of the request for the demolition of the old source storage room (M2-165). The old source room (M2-165) will be demolished for a renovation project at the Cleveland Clinic, pending your approval.

I. Survey in and around new storage room (G70-58)

On October 25, 1996, the Cs-137 source storage safe in M2-165 was relocated to G70-58 as planned. Upon the placement of the sources in the new location (G70-58), an integrity survey was performed in and around the new storage location. The exposure levels are less than what were predicted by shielding assumptions and calculations. Additional 1.5 inch lead bricks (1.8 TVL) were placed on the storage table to further reduce radiation exposure in the surrounding areas. Please review the results of the area surveys (Attachment 1- Survey around the new storage room, Attachment 2 - Survey in the new storage room). The instruments used for the surveys were: Keithly Model 36150 ion chamber, and Ludlum Model 9 ion chamber.

II. Survey of the old source storage room (M2-165)

After all sources were removed, Radiation Safety performed a thorough meter survey and wipe test through out the old source storage room (M2-165). No reading above background (0.03 mR/hr) was found. No removable contamination was found in the room. Each wipe covered a area of approximately 100 cm^2. The survey meters used for the survey were: Ludlum Model 2 with 44-9 probe(GM) and Ludlum Model 3 with 44-9 probe (GM). The instruments used for evaluating the wipe tests were: a Beckman 4000, for Gamma radiation and a Packard 2000 LSC, for beta radiation. Both instruments have the capability of detecting 220 dpm removable contamination for possible radionuclides stored in the old source storage room. Please review the Attachment 3 - Survey Old source storage Room - M2-165 for more information.

Continuation of 30427
FEE NOT REQUIRED

RECEIVED
NOV 15 1996
REGION III

PM: 11-14-96

9500 Euclid Avenue, Cleveland, Ohio 44195

302066
NOV 15 1996

III. About the items removed from the old source room

During the survey of M2-165, we found eleven (11) inactive Iridium-192 (Ir-192, halflife:74 days) seeds. However, we detected 0.10 uCi to 0.18 uCi of Coblt-60 (Co-60, half-life: 30 years) in each inactive seed. According to the brachytherapy source manufacturer, Co-60 was one of contaminants from activation of the stainless steel in which the Ir-192 seeds were encapsulated. The Ir-192 seeds were used at least five years ago, because the Ir-192 component of the seeds has decayed and Radiation Oncology has not used the same manufacturer for Ir-192 seeds since October 1991. The current manufacturer, who has supplied Ir-192 seeds in the last five years indicates that their Ir-192 seeds have no Co-60 contaminant because of a different process that is employed in the manufacturing of the seeds. Also a review of the Ir-192 source inventory records from 1991 to present did not indicate any discrepancy.

We also removed three (3) old radium ovarian/rectal applicators and one (1) shelf from a cabinet in the room. The applicators and shelf have non-removable contamination of Pb-210, a radium decay product (Attachment 4 - Radium Decay Series). The contact readings from the applicators were less than 0.8 mR/hr with Ludlum Model 3 with 44-9 (GM) probe. A used lead shield (L-block) was also removed from the room. Non-removable contamination was found on the lead shield, with a contact reading of 0.4 mR/hr with the Ludlum (GM) probe. Two lead bricks, which might have been used for radium source storage in the past, have removable contamination of Pb-210, the removable contamination from Q-tips used for wiping was less than 0.07 μCi. An EG&G Ortec 916A multi-channel analyzer (MCA) was used to identify the radionuclides. All above items have been removed from the old source storage room (M2-165), and transferred to the Radiation Safety Office (QQ1-06) for evaluation and future disposal.

If any additional information is needed, please do not hesitate to contact me at (216)-444-6645 or by e-mail at ZHUX@CESMTP.CCF.ORG. Thank you for your timely assistance in these matters.

Sincerely,

Xiaowei Zhu, M.S., DABMP
Radiation Safety Officer

Attachment 1 - Survey around new storage room G70-58
1.A Table

Assumptions for one manipulation are six (6) Cs-137 sources, each source handling ten (10) seconds, and activity per source: 52.2 mCi.

The measurement were taken with the one 52.2 mCi source in the out position for one minute exposure.

Location	Use	Distance (meters)	Dose for one manipulation (mR)-calculated**	Dose for one manipulation (mR)-measured without 1.5 " Pb	Dose for one manipulation (mR)-measured with 1.5" Pb*
North	Hallway	1.68	0.7	0.086	0.007
West	Desk counter	1.22	1.3	0.009	0.007
South	Shower/pt.Rm	0.76	3.4	0.454/0.305	0.001
East	Corridor	2.29	0.4	0.010	0.010
(G80) Ceiling	Storage	3.23	0.2	0.007	0.007
(G60) Floor	Hallway	2.71	0.3	0.009	0.009

* 1.5 inch Pb bricks are placed on south and north sides of the table to further reduce radiation exposure to surrounding areas.

** June 11, 1996 NRC Amendment, Attachment 9.B

Attachment 1 - Survey around new source storage room

1.B. Diagram

NOTES:

& FRAME, SAVE FOR REUSE.

NEW 3' X 8'H. DOOR & FRAME.

(3) CLOSE OFF EXIST. OPENING WITH DRYWALL ON STUDS.

(4) G7-58: PAINT ALL WALLS, REWORK EXISTING VINYL BASE TO MATCH, REWORK EXISTING CEILING TILE AS NEEDED, REWORK SHEET VINYL FLOORING IF NEEDED.
G7-90: PAINT ALL DAMAGED AREAS TO MATCH, REWORK EXISTING BASE AND SHEET VINYL TO MATCH.

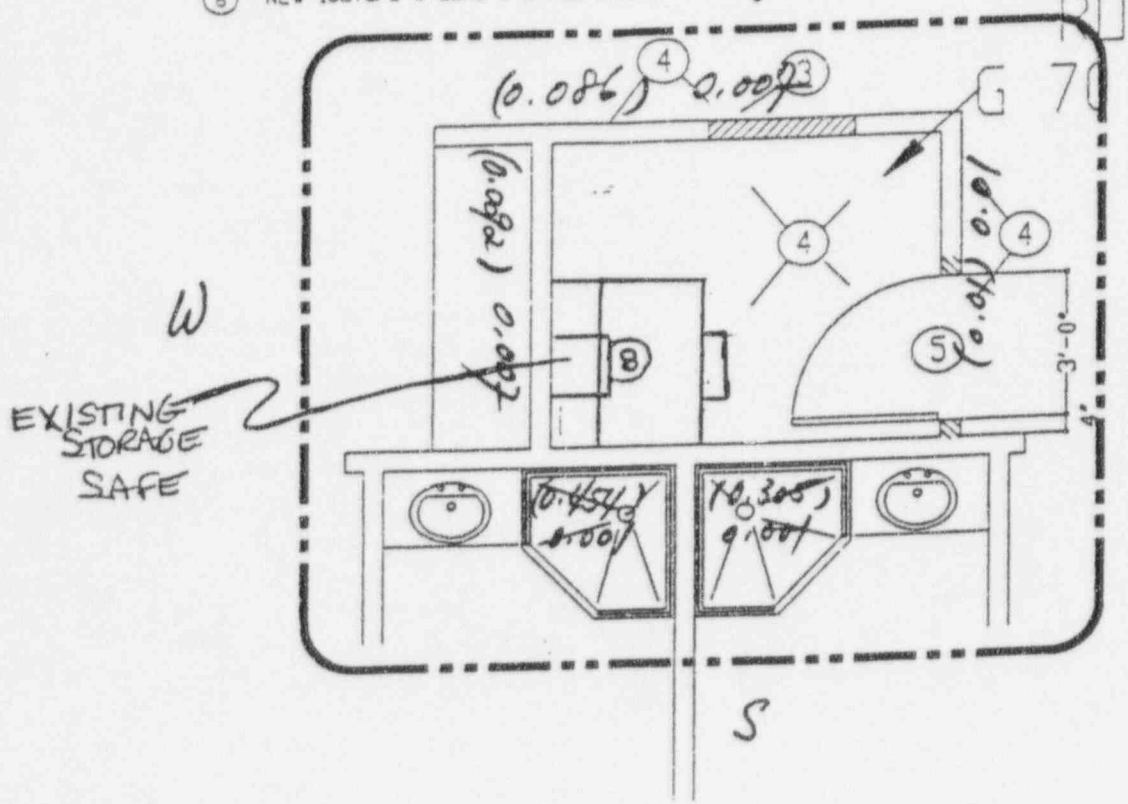
(5) RELOCATE EXISTING REUSED DOOR & FRAME AS SHOWN. SEE D5/A1.1
CHANGE EXISTING PASSAGE HARDWARE TO TYPE RECOMMENDED BY RADIATION SAFETY DEPARTMENT.

(6) RELOCATE LIGHT SWITCH AS SHOWN.

(7) EXISTING CEILING FIXTURES, TILE, & GRID REMAIN UNCHANGED.

(8) NEW ISOTOPE & LEAD STORAGE CABINET

ISOTOPE STORAGE ROOM G 70 0058



Survey Instrument: Ker. Mk 6
Cal'd date: 9/16/96

REMODELING PLAN
@ 1/4" = 1'-0"

N

( )- in mR/manipulation, before 1.5" lead bricks are placed

-in mR/manipulation, after 1.5" lead bricks are placed

CONTINUOUS METAL RUNNER @ FLOOR

downstairs G60: 0.0073 mR/manipulation

upstairs G80: 0.0086 mR/manipulation

Survey performed by: [illegible] KZ, DWB, [illegible] on 10/25/96

2 1/2" x 3 5/8" METAL STUDS

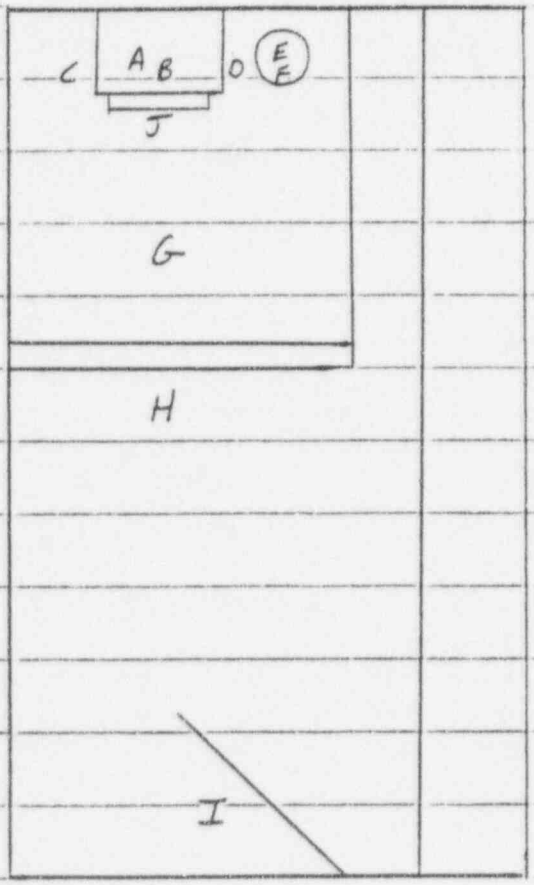
Attachment 2 - Survey in the storage room (G70-58)

G70-58 10/28/96

by: T. Cam

Meter: Ludlum 9 (RS#5)

BKG: < 0.2 mR/hr Calib date: 5/21/96 perf ✓: OK



	mR/hr
A. 1 Ft above Cs safe	≤ 0.2
B. @ contact w/ top of Cs safe	≤ 0.2
C. Left side Cs safe	≤ 0.2
D. Right side Cs safe	≤ 0.2
E. 1 Ft. above Spare Safe	≤ 0.2
F. @ contact w/top Spare safe	≤ 0.2
G. Work Area (centered)	≤ 0.2
H. Behind L block	≤ 0.2
I. @ doorway to room	≤ 0.2
J. @ contact w/Cs safe door	3.2

Room monitor Functioning, alarm @ ≈ 3600 cpm

performance ✓ - 20×10^3 cpm w/ 10 μCi Cs_{137} (AS #2)

This is the initial survey of this room G70-58.

All sources present at time of survey. Area monitor installed & Functioning properly. Proper signage on door to room & inside room.

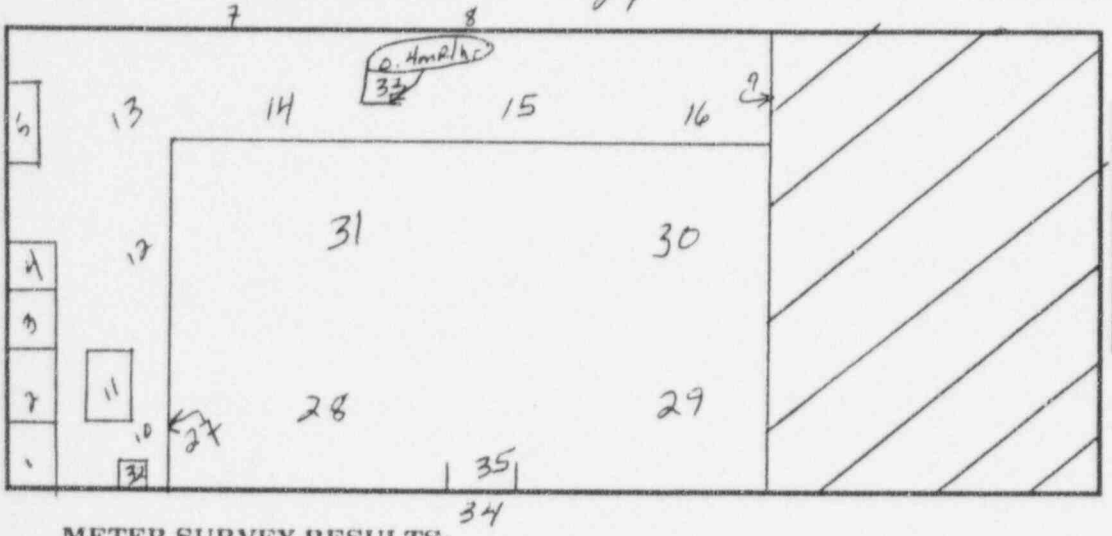
The Cleveland Clinic Foundation — Attachment 3 - Survey old source storage room (M2-165)

Survey Report - Radionuclide Use Area

(Source) storage
Old Brachytherapy Room

Location M2-165 Survey Date Oct 29 1996 By: Troy Adams / Xiaowei (Winnie) Zhu

Authorized User Radiation Oncology Radionuclides Used



Legend:
RW = Rad Waste
RS = Rad Sink
RSA = Rad Storage Area
FH = Fume Hood
RR = Rad Refrigerator

Drawers	
17	21
18	22
19	23
20	24
	25
	26

METER SURVEY RESULTS:

Instrument Used Ludlum 2 RS#10 GM / Ludlum 3 RS#11 GM Calibration Date 8-22-96 / 1-29-96 Op. Check OK / OK

Background ≤ 0.03mR/hr (for both GM's)

Summary of Results Area surveyed is ≤ 0.03mR/hr, except where indicated above.
F-33 (L-Block) was removed from M2-165 & placed in room QQ1-06 due to the 0.4mR/hr contact (surface) measurement. TLA 11-8-1996.

Trigger Levels - - - Restricted Area = 1.0 mR/hr, Unrestricted Area = 0.1 mR/hr

WIPE TEST RESULTS:

Instrument Beckman γ/β- / Packard 2k Efficiency 76% γ / 37% β-

#	Location	dpm γ	dpm β-	#	Location	dpm γ	dpm β-	#	Location	dpm γ	dpm β-
1	Shelf	00	00	11	Sink	00	00	21	Drawer	00	00
2		11	00	12	Counter top	17	00	22		00	00
3		00	00	13		01	00	23		14	00
4		00	00	14		00	00	24		00	00
5		00	00	15		00	00	25		00	00
6	Wall	00	00	16		00	00	26		00	00
7		00	00	17	Drawer	00	00	27	Floor under sink	00	00
8		00	00	18		00	00	28	Floor	09	00
9		00	00	19		00	00	29		00	00
10	Counter top	00	00	20		00	00	30		00	00

Trigger Levels - - Restricted Area = 2000 dpm per 100 cm^2, Unrestricted Area = 200 dpm per 100 cm^2

SUMMARY OF FINDINGS:

X no significant contamination levels/ meter readings

____ other

T L Adams / X. Zhu — Surveyor

Oct 29, 1996 — Date

RS 10/92

WIPE TEST RESULTS - - CONT.

Radiation Oncology
by Winnie Zhu / Troy Adams
Oct 29 1996

(2)

α β

#	Location	dpm		#	Location	dpm	#	Location	dpm
31	Floor	00	00						
32	Phone	04	00						
33	L-Block	00	00						
34	Outside door on floor	00	00						
35	Door	03	00						
36	BKG 189cpm / 38cpm								

Attachment 4 - Radium Decay Series

Ref: Introduction to Health Physics
by H. Cember

TABLE 4.3. URANIUM SERIES ($4n + 2$)

Nuclide	Half-life	Energy, MeV		
		Alpha[a]	Beta	Gamma (photons/trans.)[b]
$^{238}_{92}U$	4.51×10^9 y	4.18		
$^{234}_{90}Th(UX_1)$	24.10 d		0.193, 0.103	0.092(0.04)
$^{234m}_{91}Pa(UX_2)$	1.175 m		2.31	0.063(0.03) 1.0(0.015);
$^{234}_{91}Pa(UZ)$	6.66 h		0.5	0.76(0.0063), I.T.
$^{234}_{92}U(UII)$	2.48×10^5 y	4.763		Many weak
$^{230}_{90}Th(I_0)$	8.0×10^4 y	4.685		
$^{226}_{88}Ra$	1,622 y	4.777		0.068(0.0059)
$^{222}_{86}Em(Rn)$	3.825 d	5.486		
$^{218}_{84}Po(RaA)$	3.05 m	5.998 (99.978%)[c]	Energy not known (0.022%)[c]	0.51 (very weak)
$^{218}_{85}At(RaA')$	2 s	6.63 (99.9%)[c]	Energy not known (0.1%)[c]	0.186(0.030)
$^{218}_{86}Em(RaA'')$	0.019 s	7.127		
$^{214}_{82}Pb(RaB)$	26.8 m		0.65	0.352(0.036) 0.295(0.020) 0.242(0.07)
$^{214}_{83}Bi(RaC)$	19.7 m	5.505 (0.04%)[c]	1.65, 3.7 (99.96%)[c]	0.609(0.295) 1.12(0.131)
$^{214}_{84}Po(RaC')$	1.64×10^{-4} s	7.680		
$^{210}_{81}Tl(RaC'')$	1.32 m		1.96	2.36(1) 0.783(1) 0.297(1)
$^{210}_{82}Pb(RaD)$	19.4 y		0.017	0.0467(0.045)
$^{210}_{83}Bi(RaE)$	5.00 d		1.17	
$^{210}_{84}Po(RaF)$	138.40 d	5.298		
$^{206}_{82}Pb(RaG)$	Stable			0.802(0.000012)

[a],[b],[c] See footnotes under Table 4.1.

DEC 05 1996

Xiaowei Zhu, M.S., DABMP
Radiation Safety Officer
The Cleveland Clinic Foundation
Radiation Safety, W18
9500 Euclid Avenue
Cleveland, OH 44195

Dear Ms. Zhu:

Enclosed is Amendment No. 67 to your NRC Material License No. 34-00466-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

In accordance with survey results of your old brachytherapy source storage area submitted with letter dated November 13, 1996, we hereby authorize the release of that room for unrestricted use.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

302066

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;

   b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;

   c. Change Radiation Safety Officers;

   d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   f. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements,

prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Kevin G. Null
Nuclear Materials Licensing Branch

License No.: 34-00466-01
Docket No.: 030-02649

Enclosure: Amendment No. 67

DOCUMENT NAME: M:\03002649.CL6

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

November 27, 1996

Xiadwei Zhu, M.S.
Radiation Safety Officer
Cleveland Clinic Foundation
Radiation Safety Office, W-18
9500 Euclid Avenue
Cleveland, OH 44195

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 11/13/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

___ New License X Amendment ___ Renewal
___ Termination ___ Auth User (Amendment not required)
___ Other_____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302066
License No. 34-00466-01