NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 57

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, 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.

Licensee	
1. Lahey Clinic Foundation	In accordance with the letter dated July 10, 1996,
2. 41 Mall Road Burlington, Massachusetts 01805	3. License Number 20-05766-02 is amended in its entirety to read as follows:
	4. Expiration Date September 30, 2005
	5. Docket or Reference No. 030-01879

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 except generators	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. 500 millicuries
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. 3000 millicuries
E. Any byproduct material identified in 10 CFR 31.11	E. Prepackaged Kits	E. 150 millicuries
F. Iridium 192	F. Sealed sources (Byk Mallinckrodt Model No. GM 212.03-000; RTS Technology Model 721; or RTS Technology Model 724)	F. 2 sources not to exceed 12 curies each
G. Cesium 137	G. Sealed sources	G. 201 millicuries
H. Cesium 137	H. Sealed sources (Technical Operations Model 773)	H. 200 millicuries
I. Depleted Uranium	I. Metal	I. 200 kilograms
J. Depleted Uranium	J. Metal	J. 10 kilograms
K. Depleted Uranium	K. Metal	K. 20 kilograms
L. Strontium 90	L. Sealed source (Nuclear Enterprise Model 2503/3)	L. 10 millicuries
M. Cesium 137	M. Sealed sources (International CIS Source Model No. CEA-ORIS-LAPIB Model 437-C)	M. Not to exceed 1870 curies per source and 3740 curies total

ML 10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
20-05766-02

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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. In vitro studies.
F. One source to be used in an Isotopen-Technik Dr. Sauerwein GmbH Gamma Med 12i HDR remote afterloading brachytherapy device for interstitial, intraluminal, and intracavitary radiotherapy in humans. One source in its shipping container for source replacement.
G. Non-human use. For calibrations and checking of instruments.
H. For use in a Nuclear Associates Instrument Calibrator Model 64-773 for calibrations and checking of licensee's survey instruments.
I. Shielding in a linear accelerator.
J. For use as beam absorbers.
K. Shielding in an Isotopen-Technik Dr. Sauerwein GmbH Gamma Med 12i HDR remote afterloading brachytherapy device.
L. Non-human use. For calibrations and checking of instruments.
M. In International CIS Device Model No. IBL-437-C Irradiator for the irradiation of biological materials except explosives, flammables, or corrosives.

CONDITIONS

10. A. Licensed material may be used at the licensee's facilities located at 41 and 45 Mall Road, Burlington, Massachusetts.

B. Licensed material in Items 6.A and 6.B., except gas, may be used at the licensee's facilities located at Lahey Clinic North, One Essex Drive, Peabody, Massachusetts and Medical Center at Symmes, Hospital Road, Arlington, Massachusetts.

11. The Radiation Safety Officer for this license is Herbert W. Mower, Sc.D.

12. The Medical Physicist for this license is Herbert W. Mower, Sc.D.

13. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
Vincent Agnello, M.D.	In vitro studies
J. Robert Cassady, M.D.	35.400; Iridium 192 in a high dose rate remote afterloading unit; Depleted uranium for use as stated in Subitem 9.K.
Lyubov Girschovich, M.D.	35.400; Iridium 192 in a high dose rate remote afterloading unit; Depleted uranium for use as stated in Subitem 9.K.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 20-05766-02

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Glenn A. Healey, M.D.	35.400; Iridium 192 in a high dose rate remote afterloading unit; Depleted uranium for use as stated in Subitem 9.K.
Glenn Knight, Ph.D.	In vitro studies
Sanford R. Kurtz, M.D.	In vitro studies; Cesium 137 for use as stated in Subitem 9.M.
Patricia Leasure, M.S.	In vitro studies
Theodore C.M. Lo, M.D.	35.400; Iridium 192 in a high dose rate remote afterloading unit; Depleted uranium for use as stated in Subitem 9.K.
Beverly A. Marotto	Cesium 137 for use as stated in Subitem 9.M.
Herbert W Mower, Sc.D.	In vitro studies; Cesium 137 for uses as stated in Subitems 9.G. and 9.H.; Depleted uranium for uses as stated in Subitems 9.I., 9.J., and 9.K.; Strontium 90 for use as stated in Subitem 9.L.
Lucia G. Palmer, M.D.	35.100; 35.200; 35.300
Francis J. Scholz, M.D.	35.100; 35.200
David W. Seldin, M.D.	35.100; 35.200; 35.300
Naimuddin Shaikh, Ph.D.	In vitro studies; Cesium 137 for uses as stated in Subitems 9.G. and 9.H.; Strontium 90 for use as stated in Subitem 9.L.
Kenneth A. Wright	In vitro studies; Cesium 137 for uses as stated in Subitems 9.G. and 9.H.; Depleted uranium for uses as stated in Subitems 9.I., 9.J., and 9.K.; Strontium 90 for use as stated in Subitem 9.L.
Carl T. Wrubel	Cesium 137 for use as stated in Subitem 9.M.

14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.

15. Notwithstanding the requirements of 10 CFR 35.400(d) and (g), the licensee may use iridium-192 as seeds encased in nylon ribbon and palladium-103 as a sealed source in seeds for topical, interstitial, and intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions to the extent that the instructions are not applicable to the type of use proposed by the licensee.

16. A. Access to the treatment room housing each high dose rate remote afterloading brachytherapy unit shall be controlled by a door at each entrance.

    B. Each entrance to the treatment 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 each entrance door to the treatment 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 unit 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.

17. Prior to initiation of a treatment program, and subsequent to each source exchange for each high dose rate remote afterloading brachytherapy unit, a radiation survey shall be made of:

    A. The 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 millirem per hour.

    B. All areas adjacent to the treatment room with the source in the exposed position. The survey shall clearly establish:

        (1) That radiation doses to occupationally exposed individuals do not exceed the limits specified in 10 CFR 20.1201(a), 20.1207 and 20.1208.

        (2) That radiation doses to individual members of the public do not exceed the limits specified in 10 CFR 20.1301(a).

18. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such service:

    A. Installation, and replacement of the sealed sources contained in each high dose rate remote afterloading brachytherapy unit.

    B. Maintenance or repair operations on any high dose rate remote afterloading brachytherapy unit and associated equipment 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.

19. In lieu of the source inventory described 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 high dose remote 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 survey instrument used, dose rate, 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).

20. 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, radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm 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).

21. 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.

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.

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

23. 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.

24. 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 35.59, 35.400 and 35.500 and every six months for all other sealed sources and devices.

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

26. The licensee shall not perform repairs or alterations of the irradiator in Subitem 9.M involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

27. The procedures contained in the manufacturer's instruction manual for the irradiator authorized by this license in Subitem 9.M 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 20-05766-02

Docket or Reference Number: 030-01879

Amendment No. 57

28. 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 received March 13, 1995
B Letter dated July 13, 1995
C. Letter dated July 27, 1995
D. Letter dated August 18, 1995 (Re: NRC Letter of June 30, 1995)
E. Letter dated September 8, 1995
F. Letter dated September 19, 1995
G. Letter dated September 27, 1995
H. Letter dated July 10, 1996

For the U.S. Nuclear Regulatory Commission

Date SEP 10 1996

By Original Signed By:
Michelle Beardsley

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

SEP 10 1996

Herbert Mower, Sc.D.
Radiation Safety Officer
Lahey Clinic Foundation
41 Mall Road
Burlington, MA 01805

Dear Dr. Mower:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the 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:

Michelle R. Beardsley
Division of Nuclear Materials Safety

License No. 20-05766-02
Docket No. 030-01879
Control No. 123449

Enclosure:
Amendment No. 57

DOCUMENT NAME: R:\WPS\MLTR\2005766.02
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					
NAME	Beardsley							
DATE	07/25/96		07/ /96		07/ /96		07/ /96	

OFFICIAL RECORD COPY **ML 10**

LAHEY HITCHCOCK CLINIC

JOHN A. LIBERTINO, M.D.
Chairman, Board of Governors
Massachusetts Region

030-01879

July 10, 1996

U. S. Nuclear Regulatory Commission, Region I
Nuclear Material Section B
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Re. NRC License #20-05766-02

To whom it may concern:

We wish to add to our license file the following two physicists, not named as medical physicists on our license, who can fulfill the duties of being the physicist physically present during HDR treatments.

The physicists are:

William A. Roventine, M.S.
Michael D. Rutstein, M.S.

Evidence of their qualifications and training are attached. Training was performed by Dr. Herbert W. Mower, a trainer for Barker + on the use of the GammaMed HDR Unit and the recognized "Medical Physicist" and "RSO" on our NRC license. Copies of the course outlines are attached.

If you have any questions, please feel free to contact Dr. Mower (617-273-8061), our Radiation Safety Officer.

Sincerely,

John Libertino M.D.

John A. Libertino, M.D.

JAL:mwl
Attachments

pc: Dr. Herbert W. Mower

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JUL 17 1996

Lahey Clinic Foundation ATT 7.1.

Training and Experience for Physicists Fulfilling the Duty of Being Physically Present During HDR Treatments

William A. Roventine, M.S.

TRAINING

Date	Hours	Trainer	Subjects
7/8/96	4.0	Mower	Introduction to HDR Afterloader Treatment Planning Radiation Safety Considerations Overview of Equipment Operation
7/9/96	4.0	Mower	Quality Assurance Day of Treatment Procedures Source Exchange

CERTIFIACTION

1976: American Board of Radiology: Radiological Physics
1991: American Board of Medical Physics: Radiation Oncology Physics
1971-1989: RSO in Rhode Island broad scope license 7B-026-01
Registered Physicist in Rhode Island (including teletherapy physics)

Lahey Clinic Foundation ATT 7.1.

Training and Experience for Physicists Fulfilling the Duty of Being Physically Present During HDR Treatments

Michael D. Rutstein, M.S.

TRAINING

Date	Hours	Trainer	Subjects
7/8/96	4.0	Mower	Introduction to HDR Afterloader Treatment Planning Radiation Safety Considerations Overview of Equipment Operation
7/9/96	4.0	Mower	Quality Assurance Day of Treatment Procedures Source Exchange
Jan. 1993	1 week		Nucletron training course for HDR

EXPERIENCE

4.5 hours of on-site experience with daily QA, patient calculations and verification, basic operation of the unit, calibration and monthly spot checks, and patient procedures with the Gammamed Unit.

Involved with treatment planning and treatment delivery of no less than twenty patients (approx.100 total treatments) with the Nucletron system.

CERTIFICATION

Teletherapy Physicist on NRC license 34-00746-03
Teletherapy Physicist on NRC license 34-01869-02
Authorized User for 10 CFR 35.400, Strontium-90 and Cesium-137 for instrument calibration on NRC license 34-00746-02

NRCLTR

LAHEY HITCHCOCK MEDICAL CENTER

Gammamed 12 i Training

INTRODUCTION TO GAMMAMED HDR AFTERLOADER

Date: 7-8-96 Preser tor: Herbert W. Mower, Sc.D.

Overview of GAMMAMED HDR Afterloader

- Theory
  - Use of Radioactive Source vs. External Beam
  - Use of HDR vs. LDR Brachytherapy
  - Use of Stepping Source to create desired isodoses
  - Use in conjunction with external beam
- Mechanics
  - Iridium-192 source / capsule / wire assenbly
  - Dummy source run to verify unobstructed path
  - Drive motors and feedback mechanism
  - Shielded safe for source when retracted
- Advantages
  - Faster treatment times
  - Excellent treatment control
  - Less staff exposure
  - Patient comfort
  - Outpatient treatments - convenience
  - Outpatient treatments - cost effective
- GAMMAMED
  - 30 years of HDR experience - the pioneers of HDR afterloading
  - Outstanding track record of Safety and Reliability

✓ Applicators and Applications

- General Principles
- Closed-end Catheters
- Distinction between Applicators and Catheters
- Marker Wires
- Gynecological Applications / Applicators
  - Descriptions
  - Method of use
- Bronchial Applicators
  - Descriptions
  - Methods of use
- Interstitial Applicators
  - Descriptons
  - Methods of use
- Intraoperative Applicators
- Other

Questions

LAHEY HITCHCOCK MEDICAL CENTER

Gammamed 12 i Training

TREATMENT PLANNING

Date: 7-8-96 Presentor: Herbert W. Mower, Sc.D.

Explanation of Main Menu
- Treatment Planning
- Patient Directory
- Treatment
- Configuration (view and set various options)

Entering Patient Date

Selecting Applicators
- Standard Applicators
  - Vaginal Cylinder
  - Fletcher Suit Applicator
- Free-definition Applicators
  - Bronchial Catheter
- Principles of deciding when to/not to Digitize

Methods of Optimization
- Predetermination of Source Times
- Optimization According to Predetermined Point Doses
- Optimization According to Doses

Defining Parameters
- Step Sizes
- Doses

Display of Data
- Changing Viewing Parameters
- Working with "Plane of Slice" Display
- 2-D Isodoses
- 3-D Menu
- Display of Dose Data

Output of Data

Transferring to GAMMAMED Treatment Software

Stored Plans - Adapting and Archiving

Digitizing Films

Special Programs

Practice

Questions

LAHEY HITCHCOCK MEDICAL CENTER

Gammamed 12 i Training

RADIATION SAFETY CONSIDERATIONS

Date: 7-8-96 Presentor: Herbert W. Mower, Sc.D.

- General Consideration
  - GAMMAMED unit must remain in designated room and area
  - Wall-mounted radiation monitor
    - Required
    - Operation
    - Remote
  - Survey meter
    - Required
    - Operation
    - Check
  - GAMMAMED built-in radiation monitor
  - Personnel dosimetry required

- Unit "OFF" Safety Considerations
  - Applicator / Source guide tube integrity
  - Decay factor verification
  - Pre-treatment dose verification
  - Post-treatment patient radiation survey
    - Patient
    - Applicators
    - Unit
  - Post-treatment source secured verification

- Unit "ON" Safety Considerations
  - Viewing with Camera during treatment
  - Emergency container near GAMMAMED unit
    - Long forceps
    - Cutters (caution - do NOT cut source)
    - Suture removal kit
  - Posted Emergency procedures
  - Interlocks and Treatment-in-Progress indicators

- EMERGENCY INTERVENTION PROCEDURES
  - Press "INTERRUPT" button on control unit
  - Press "EMERGENCY" button on control unit
  - Open treatment room door slightly (activates retract interlock)
  - Enter room and press EMERGENCY button on trolley
  - Turn Emergency Hand Crank
  - Remove applicator from patient, insert in emergency container
  - Evacuate patient, seal room, notify:
    - RSO
    - Physician
    - BARKER+

Practice sessions - each person to go through sequence

Questions

LAHEY HITCHCOCK MEDICAL CENTER

Gammamed 12 i Training

OVERVIEW OF EQUIPMENT OPERATION

Date: 7-8-96 Presentor: Herbert W. Mower, Sc.D.

GAMMAMED Treatment Unit (Trolley)
- Moving and handling
- Adjustable treatment head
- Treatment head key
- Brake mechanism
- Hand pendant
- Cable to Control Unit
- Emergency source container
- Emergency hand crank
- Channels / indexer - connections and special use channels (20-24)
- Connectors
- Fixed treatment length as safety feature (end test)
- Power requirements
- Battery operated trolley - continuous charge
- Keeping the GAMMAMED unit plugged in

GAMMAMED control unit
- Explanation of control buttons and lights
- Radiation indicator (audible and visible)
- Connectors on rear of control unit
- Use of control keys and interlocks to prevent simultaneous use of ????

Treatment Mode
- Patient ID
- Fraction #
- Offset (if any - beware MILLIMETERS)
- Nominal dwell times - decay factor
- Verification of overall treatment time
- Allowable step sizes (1-10 mm)
- Start
- Interrupt
- Emergency Stop
- Alarm and Error Codes

Simulations and Practice
- Powering up
- Attaching Source Guide Tubes / Applicators
- Error and Emergency conditions

Questions

LAHEY HITCHCOCK MEDICAL CENTER

Gammamed 12 i Training

QUALITY ASSURANCE

Date: 7-9-96 Presentor: Herbert W. Mower, Sc.D.

General Procedure of Source Exchange

Before each 'Treatment Day'
- Source stepping
  - Autoradiograph
  - Source Step Viewer
- Radiation warning lights
  - Gammamed control
  - Gammamed trolley
  - Door
- Check wall radiation monitor
- Viewing system (CCTV)
- Intercom
- Console interrupt and abort tests
- Decay verification

Monthly
- Battery check
- Source positioning accuracy checked
- Timer accuracy and linearity
- Measurement of source guide tubes / connectors
  - NRC verbal communication: "Not necessary for catheters."

Annual
- Inspection by manufacturer's rep
- PM / Service by manufacturer's rep

Calibrations
- At source replacement. Agreement to source provider within 5%
- Monthly check
- Electrometer or chamber used needs calibration every 2 years

Quality Management Program
- NRC required
- Agreement state will require
- Program outline
- Program updates
- Annual review of program

NRC Inspection
- Overview of what needed

Record keeping
- Quality Assurance Procedures Daily and Monthly
- Calibration records
- Maintenance

Annual Retraining

Questions

LAHEY HITCHCOCK MEDICAL CENTER

Gammamed 12 i Training

DAY OF TREATMENT

Date: 9-9-96

Presentor: Herbert W. Mower, Sc.D.

Daily QA

Placement of Applicators or Catheters

Simulation

Prescription

Plan

Verification of Plan

Transfer to Treatment

Verification of Intended Treatment

Presence of
- Authorized User
- Physicist or RSO
- (? - Nurse)

Treatment Delivery

Completion of Treatment

Survey of Patient, Applicators, Unit

Review of Treatment

Securing of Source and Room

Review of Sample Check Forms

Questions

LAHEY HITCHCOCK MEDICAL CENTER

Gammamed 12 i Training

SOURCE EXCHANGE

Date: 7-9-96 Presentor: Herbert W. Mower, Sc.D.

General Procedure of Source Exchange

Calibration data supplied with source
- NRC - "most" use manufacturer's activity
- Can use own measured activity

Discussion of 'Special Mode' in software

Measuring source activity
- Well chamber
- Ionization Chamber

Lab session on how to measure

Questions

NRC FORM 577
(1-95)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

LAHEY CLINIC FOUNDATION
ATTN: JOHN A. LIBERTINO, MD
41 MALL ROAD
BURLINGTON, MA 01805

TYPE OF ACTION

- ☐ NEW LICENSE
- ☐ RENEWAL OF LICENSE
- ☒ AMENDMENT TO LICENSE

REQUESTED DATE: 7-10-96

LICENSE NUMBER: 20-05766-02

CONTROL NUMBER: 123449

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	$	$	$ 440.00
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 440.00
PAYMENT RECEIVED	$ 0.00
AMOUNT DUE	$ 440.00

☒ Your request was received without the prescribed application fee.

☐ We received your Check No. _____ in the amount of $ _____. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

- ☐ We received your Check No. _____ in payment of the fee.
- ☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
- ☐ Your request was combined, prior to review, with your request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.

☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE -- LICENSE FEE ANALYST	LFDCB	LFDCB
BRENDA BROWN	BB BB 8/6/96	

Distribution: ROUTING File
MAF Correspondence FY
LFDCB Chief
LFDCB Analyst
Invoice File w/encl
LFDCB R/F
DAF R/F
DATE: 8-6-96

NRC FORM 577 (1-95)

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BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02230
STATUS CODE: 0
FEE CATEGORY: 7C 3E 2B
EXP. DATE: 20050930
FEE COMMENTS: 3E ADDED 11/17/95
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: LAHEY CLINIC FOUNDATION
RECEIVED DATE: 960717
DOCKET NO: 3001879
CONTROL NO.: 123449
LICENSE NO.: 20-05766-02
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: ---/---
CHECK NO.: ---/---

3. COMMENTS

SIGNED M. A. Perkins
DATE 7/12/96

1996 JUL 24 PM 3:58

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

1. FEE CATEGORY AND AMOUNT: 7C 3E 2B $440

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

3. OTHER ---

SIGNED SC
DATE 8/30/96

I (#6)

Log Aug L
Remitter
Check No. 77834
Amount $440
(L) 3E 2B
Amend
Date Check Rec'd
Date Completed 8/30/96
By SC