NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 75

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	In accordance with the letter dated June 4, 1996
1. New England Medical Center	3. License Number 20-03857-06 is amended in its entirety to read as follows:
2. 171 Harrison Avenue Boston, Massachusetts 02111	OFFICIAL RECORD COPY
	4. Expiration Date June 30, 2001
	5. Docket or Reference No. 030-01868

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. 3 curies
E. Any byproduct material identified in 10 CFR 35.500	E. Any diagnostic source identified in 10 CFR 35.500	E. 5 curies
F. Uranium depleted in Uranium 235	F. Cadmium plated metal	F. 300 kilograms
G. Any byproduct material with Atomic Numbers 3 through 83 and half-life of less than or equal to 120 days	G. Any	G. Not to exceed 500 millicuries of each radionuclide with a total possession limit of 20 curies
H. Hydrogen 3	H. Any	H. 1200 millicuries
I. Carbon 14	I. Any	I. 250 millicuries
J. Xenon 133	J. Any	J. 3 curies
K. Chlorine 36	K. Any	K. 5 millicuries
L. Calcium 45	L. Any	L. 45 millicuries
M. Nickel 63	M. Any	M. 3 millicuries
N. Zinc 65	N. Any	N. 5 millicuries
O. Cadmium 109	O. Any	O. 2 millicuries
P. Gadolinium 153	P. Any	P. 2 millicuries
Q. Any byproduct material with atomic numbers 3 through 83	Q. Sealed sources	Q. Not to exceed 1 curie per source and 20 curies total
R. Iridium 192	R. Sealed sources (BYK	R. Not to exceed 10 curies

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License Number: 20-03857-06

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	Mallinckrodt Model CI L BV)	per source and 20 curies total
S. Hydrogen 3	S. Neutron tubes	S. Not to exceed 14 curies each and 42 curies total
T. Any byproduct material with half-life less than 120 days	T. Activation products	T. As needed

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. Shielding in a linear accelerator.
G. through Q. Medical diagnosis, therapy and research in humans in accordance with any applicable Food and Drug Administration (FDA) requirements. Research and development as defined in Section 30.4 of 10 CFR Part 30, including animal studies and instrument calibration.
R. One source to be used in a Nucletron microSelectron High Dose Rate Afterloading Brachytherapy Device for interstitial, intracavitary, or bronchial treatment. One source in its shipping container to be in the possession of the licensee as necessary for replacement of the source in the irradiation device.
S. Sealed D-T neutron generator tubes to measure body fat in humans.
T. For possession incident to neutron capture therapy in humans only.

CONDITIONS

10. A. Licensed material listed in items 6.A. through 6.O. and item 6.R. may be used only at the licensee's facilities at 171 Harrison Avenue, 25 Bennet Street, 170 Morton Street, 75 Kneeland Street, State Laboratory Institute (Mass. DPH), 305 South Street, 20 Ash Street, and Lemuel Shattuck Hospital, and the USDA Northeastern Region Human Nutrition Research Center on Aging at Tufts University, all in Boston, Massachusetts.

B. Licensed material listed in item 6.Q. may be used only at the licensee's facilities at 750 Washington Street, Boston, Massachusetts.

C. Licensed material listed in item 6.P. may be used at the licensee's facilities listed in 10.A. and at the Massachusetts Institute of Technology Reactor Facility, 138 Albany Street, Cambridge, Massachusetts.

D. Licensed material listed in item 6.T. may be possessed as a result of boron neutron capture therapy on humans at the Massachusetts Institute of Technology Reactor Facility, 138 Albany Street, Cambridge, Massachusetts.

11. A. The use of licensed material in or on humans shall be by a physician as defined in Section 35.2 or 10 CFR Part 35.

B. Physicians designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR Part 35, Subpart J and shall be

designated by the Radiation Safety Committee. In addition, physicians designated to use licensed material in conjunction with boron neutron capture therapy on humans shall meet the requirements in the letter dated June 10, 1993. The licensee shall maintain records of individuals designated as users.

C. Medical Physicists designated to perform licensed activities in conjunction with the licensee's program for the High Dose Rate Remote Afterloading Brachytherapy Device shall meet the training criteria established in 10 CFR 35.961 and shall be designated by the Radiation Safety Committee. Physicists designated to perform licensed activities in conjunction with boron neutron capture therapy on humans shall meet the requirements in the letter dated June 10, 1993. The licensee shall maintain records of individuals designated as users.

D. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, F. X. Massé, C.H.P., Chairperson. The licensee shall maintain records of individuals designated as users.

E. The Radiation Safety Officer for this license is F. X. Massé, C.H.P.

12. 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 are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 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 3 months.

C. In the absence of a certificate from a transferor indicating that a 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 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. 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 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 I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source 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.

13. The licensee shall conduct a physical inventory every three (3) months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.57, 35.400 and 35.500 and every six (6) months for all other sources and/or devices.

14. 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 foil temperatures from exceeding that specified by the manufacturer.

15. Notwithstanding the requirements of 10 CFR 35.49(a)and (b), the licensee may use for medical use any byproduct material or reagent kit.

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

17. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash, provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as normal waste, radioactive waste shall be surveyed 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.

18. Experimental animals administered licensed materials or their products shall not be used for human consumption.

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

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SUPPLEMENTARY SHEET

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20. Pursuant to Sections 20.106(b) and 20.302 of 10 CFR part 20, the licensee is authorized to dispose of licensed material 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. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to 10 CFR 20.201 are made to determine that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in Appendix B, Table II, 10 CFR Part 20.

21. Notwithstanding the requirements of 10 CFR 35.404(a), the licensee may release from confinement for medical care patients treated with the COMS eye plaque in accordance with procedures described in the letter dated January 9, 1987.

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

23. For the purpose of boron neutron capture therapy of humans, the licensee shall interpret "prescribed dose" to mean the total maximum radiation dose to normal tissue and maximum radiation dose to normal tissue per fraction, as documented in the written directive.

24. For the purpose of boron neutron capture therapy for humans, "written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation at the Massachusetts Institute of Technology Medical Treatment Facility, containing the total maximum radiation dose to normal tissue, total radiation fluence, number of fractions, maximum radiation dose to normal tissue per fraction, radiation fluence per fraction, treatment site, and total treatment period.

25. For the purpose of boron neutron capture therapy for humans, the licensee shall interpret "recordable event" to mean:

    a. The administration of a radiation treatment without a written directive where the written directive is required and where treatment is appropriate;

    b. The administration of a radiation treatment where a written directive is required without the per treatment recording of administered radiation fluence and the maximum radiation dose to normal tissue in the appropriate record; or

    c. An administration error such that the calculated administered maximum dose to normal human tissue exceeds the prescribed dose by more than 10 percent of the prescribed dose.

26. For the purpose of boron neutron capture therapy for humans, "misadministration" shall mean:

    1) a radiation dose involving the wrong patient, wrong mode of treatment, or wrong treatment site; or

    2) a calculated administered total maximum radiation dose to normal tissue that exceeds the prescribed dose by more than 20 percent of the prescribed dose.

27. 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 1 meter from the surface of the main source safe shall not exceed 0.25 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).

28. 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.

29. 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.

30. For treatments using the High Dose Rate Afterloading Brachytherapy Device, 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).

31. For treatments using the High Dose Rate Afterloading Brachytherapy Device, in lieu of 10 CFR 35.404(a), radiation survey shall be made of the patient and the remote afterloading device with a portable radiation measurement survey instrument immediately after retracting the source from the patient into its shielded position in the remote afterloading device 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).

32. 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. Letter dated January 9, 1987
B. Letter dated May 24, 1988
C. Letter dated June 29, 1988
D. Letter dated October 21, 1988
E. Letter dated March 20, 1989
F. Letter dated April 12, 1989 with enclosure dated March 24, 1989
G. Letter dated October 19, 1989
H. Letter dated November 15, 1989
I. Letter dated June 5, 1990
J. Letter dated June 15, 1990
K. Letter dated June 22, 1990
L. Letter dated November 23, 1990
M. Letter dated June 21, 1990
N. Letter dated July 29, 1992
O. Letter dated June 10, 1993
P. Letter dated June 22, 1993
Q. Letter dated April 14, 1993
R. Letter dated July 9, 1993
S. Letter dated March 11, 1994
T. Letter dated June 4, 1996

For the U.S. Nuclear Regulatory Commission

ORIGINAL SIGNED BY:
THOMAS K. THOMPSON

Date AUG 1 3 1996

By _____

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

AUG 13 1996

Mary Schneider
Administrative Director of
Radiology
New England Medical Center
171 Harrison Avenue
Boston, Massachusetts 02111

Dear Ms. Schneider:

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:
THOMAS K. THOMPSON

Thomas K. Thompson, Sr. Health Physicist
Division of Nuclear Materials Safety

License No. 20-03857-06
Docket No. 030-01868
Control No. 123353

Enclosure:
Amendment No. 75

DOCUMENT NAME: R:\WPS\MLTR\L2003857.06
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	thompson TKT							
DATE	07/25/96		07/ /96		07/ /96		07/ /96	

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030-01868

New England Medical Center

June 4, 1996

License Number 20-03857-06

US Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia PA 19406

F.X. Massé, C.H.P., C.M.P.
Radiation Safety Officer

NEMC #787
750 Washington Street
Boston, Massachusetts 02111

Tel: (617) 636-6168
Fax: (617) 636-7777

Gentlemen:

New England Medical Center hereby requests amendment to license number 20-03857-06 authorizing the substitution of D-T neutron generator tubes manufactured by MF Physics Corporation, Colorado Springs CO, for those manufactured by Sandia Corporation for category Q purposes under our present license. All conditions of the current use of the Sandia sources will be followed in using the substitute sources.

The MF Physics Corporation units are devices that yield comparable neutron spectra and flux much more efficiently with lower ^{3}H content, and appear to be a significant improvement for our purposes. These units have been manufactured since 1962 and are registered as A-3043 sealed sources. These sources were recently approved for distribution under Colorado Registration number CO-1012-D-101-S (document attached). Although they are initially more expensive, they have a longer operating lifetime and should ultimately provide us with much greater stability and significantly lower operating cost per application. The ^{3}H content of these units is not expected to exceed 7.0 Ci each, hence the current possession limit will easily cover this substitution. If all works well and these units fulfill all needs, ultimate substitution of all the units on hand will allow a substantial decrease in activity in possession. As with our prior arrangement with Sandia, MF Physics Corporation agrees to accept the return of all used units for their recycling/disposal. It is our understanding that this device has been exempted from routine periodic leak testing and requires such testing only initially and prior to shipment for return. The sources will be contained in their sealed accelerator column while in our possession.

Enclosed is a check for $560 covering this amendment fee under category 7B of 10 CFR Part 170. Please don't hesitate to contact F.X. Massé at 617-253-9217 if further information is required.

Yours truly,

FXMasse

F.X. Massé, CHP, CMP

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123353

JUN 21 1996

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: CO-1012-D-101-S **DATE:** April 30, 1996

MODEL: A-3000 Series Neutron Generator Tubes;
Models A-3041, A-3043, A-3045, A-3062, A-3091 and A-3092

MANUFACTURER/DISTRIBUTOR:
MF Physics Corporation
5074 List Drive
Colorado Springs, CO 80919

SEALED SOURCE MODEL DESIGNATION:

Titanium Tritide plated on copper substrate manufactured by Martin Marietta Company to MF Physics Corporation specifications.

ISOTOPE:

Hydrogen 3

ACTIVITY:

Not to exceed 7 Curies (259 GBq)

LEAK TEST FREQUENCY: Not required

PRINCIPAL USE: (T)

Neutron tubes and neutron generators for use in neutron activation analysis, borehole logging, neutron radiography, explosive detection, transuranic waste characterization, mineral exploration, and classroom instruction.

CUSTOM SOURCE: _X_ YES ____ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: CO-1012-D-101-S DATE: April 30, 1996 Page 2 OF 7

DEVICE TYPE: Neutron tubes and neutron generators

DESCRIPTION:

MF Physics neutron generator tubes are used in conjunction with applicable accelerator heads to produce up to 1 x 10^{11} neutrons/second. When the neutron tubes are not operating, the deuterium and tritium sealed in the tubes reside in the reservoir and target and thus the tubes are essentially evacuated (a vacuum tube). Breakage of a bare tube has been estimated by the manufacturer to release only millicuries of tritium. Because the average energy of the beta emitted from H-3 is 18 keV, which is not energetic enough to penetrate any of the tube components, no beta radiation is emitted from a non-operating tube. Bremsstrahlung radiation was found to be non-detectable on the surface of a tube. When the tubes are operating, a current is passed through the reservoir element, driving out the tritium and deuterium which provides a change in the internal gas pressure (operating pressure about 0.000015 psi). A few kilovolts applied to the ion sources wil cause a Penning discharge to occur. An ion beam is extracted from the ion source, focused and then accelerated through an approximately 100 kV potential to the target. The interactions of beam ions with the target produce 14.3 MeV neutrons.

The accelerator heads consist of pressure housings, electrical connectors, high voltage sections and a neutron generator tube. The housings are fabricated of stainless steel and special high alloy metal depending on the application requirements for high pressure and high temperature. The accelerator heads are energized via high voltage power supply connections that produce voltages (100 kV) to accelerate the beam of ions within the neutron generator tube. The accelerator head volume is normally filled with sulfur hexafluoride which is used as an insulating gas (high voltage stand-off).

The housings of the accelerator heads are designed to contain any H-3 that may be present due to breakage of the tube. The accelerator heads are sealed and require special tools to open, preventing customer access to the tube.

The vacuum walls of the sealed tube are constructed from stainless steel, vacuum melt iron, copper, glass and ceramic. Laser welds, TIG welds and high temperature braze materials are

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: CO-1012-D-101-S DATE: April 30, 1996 Page 3 of 7

DEVICE TYPE: Neutron tubes and neutron generators

used in tube fabrication. All braze materials have melting points of 779 °C (1434 °F) or higher.

The reservoir element consists of a tungsten wire wrapped with zirconium. During tube processing, the reservoir element is loaded with deuterium. The H-3 targets are supplied through Martin Marietta Corp. of Largo, Florida. The targets consist of copper backing and a thin film of titanium tritide. The H-3 remains in the target as titanium tritide to a temperature of 500 °C (932 °F). The targets are ridgidly attached to target mounts within the acceleration lens of the tube.

The tubes are assembled, leak tested and then processed on a vacuum manifold. After processing the tubulation is pinch-welded and covered with epoxy. Before pinch-off, the tubes are wipe tested for H-3 contamination.

The A-210 laboratory neutron generator system includes a neutron tube and transformer assembly, a drive chassis and control chassis. These three components are interconnected through coaxial cables. The system also includes two commercial 0-600 Vdc power supplies. The system will produce a series of 14-MeV neutron pulses, 2.0 to 3.0 x 10^6 neutrons per pulse, at repetition rates up to 100 pulses per second. It is a device which has been incorporated into systems that monitor for diversion of special nuclear material at reactor facilities, and systems that detect and assay transuranic radionuclides for sorting nuclear waste containers.

The A-320 pulsed, borehole neutron generator is a 1 11/16 inch OD pulsed generator system specifically designed for downhole use in oil well logging and mineral exploration. The A-320 consists of an accelerator section and an electronic control unit. The two segments can be separated by up to four feet for insertion of user-supplied detector packages. The accelerator section contains a sealed neutron tube, high voltage power supply, power supply input transformer and ion source pulse transformer packaged in the 1 11/16 inch OD pressure housing.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: CO-1012-D-101-S DATE: April 30, 1996

DEVICE TYPE: Neutron tubes and neutron generators

MF Physics A-711 system is a general purpose contiuous yield neutron generator. It includes a portable control unit, a pressurized stainless steel accelerator cover, and a cooling source that uses tap water to cool the target and used Freon 113 to cool the ion source.

The A-801 pulsed, medium output neutron generator uses a mixed beam of deuterium and tritium ions colliding with the tritium-in-titanium target to extend the target life. The A-801 system consists of a portable accelerator assembly and a tabletop control console. The neutron generating tube and step-up transformer are contained within a stainless steel, pressurized accelerator assembly.

ANSI Classification for the neutron generator tubes have not been established. These tubes are identical to those previously manufactured by Kaman Sciences Corporation, and have been in use for many years without incidant related to loss of radioactive material.

LABELING: A. Each MF Physics Accelerator Head is labeled:

CAUTION
RADIATION
THIS EQUIPMENT PRODUCES
IONIZING RADIATION
WHEN ENERGIZED

-CAUTION-
THIS UNIT MUST BE PRESSURIZED
PSI OR BEFORE OPERA
TO
TIONAL USE.
UNIT MUST BE DEPRESSURIZED TO
5 PSI OR LESS PRIOR TO SHIPMENT
OR DISASSEMBLY

CAUTION
RADIOACTIVE
MATERIAL
ISOTOPE
AMOUNT
DATE

B. The outer container in which the tube is shipped is labeled in accordance with 49 CFR 173.424.

123353

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: CO-1012-D-101-S DATE: April 30, 1996 Page 5 OF 7

DEVICE TYPE: Neutron tubes and neutron generators

CONDITIONS OF NORMAL USE:

Tubes are not shipped to customers for their handling, installation or use. The system as shipped consists of an accelerator section, containing the neutron generator tube, and an electronics control unit.

For laboratory or above ground use, two basic types of shielding are described in Technical Bulletin No. 104 provided by MF Physics. These are shielded room/labrynth shielding with approximately 5 feet of concrete shielding, and pit or well installations in which the earth provides shielding. The design and use of shielding and interlocks is to be reviewed by the licensing authority.

The A-320 Neutron Generator well logging is designed for insertion into user supplied logging tool. The entire logging tool should be evaluated for down hole use by the appropriate licensing agency.

PROTOTYPE TESTING: Because of the construction materials, it is apparent that the neutron tubes could not be expected to withstand the ANSI tests for a regular device. Except for minor modifications these devices are the same as the Kaman Sciences Corporation neutron tubes which have been used for many years. All components are visually inspected and approved by trained staff prior to use. Each neutron tube is hand crafted and tested for proper operation prior to transfer to the user.

Prior to approval, the licensing authority should evaluate the use conditions to determine that these neutron tubes will withstand such conditions.

DIAGRAMS: Refer to Attachments 1, 2 and 3.

EXTERNAL RADIATION LEVELS:

No detectable Beta or Bremsstrahlung radiation was measured on contact with the non-operating neutron tubes.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: CO-1012-D-101-S DATE: April 30, 1996

DEVICE TYPE: Neutron tubes and neutron generators

Dose rates during operation (A-3041, A-3051, A-3062, A-3091 and A-3092):

167 Rem/hour at 5 cm
4.65 Rem/hour at 30 cm
0.42 Rem/hour at 100 cm

Dose rates during operation (A-3043 and A-3045)

41667 Rem/hour at 5 cm
1162 Rem/hour at 30 cm
104 Rem/hour at 100 cm

QUALITY ASSURANCE AND CONTROL:

An exhaustive Quality Assurance Program is carried out by the MF Physics Corporation which includes individual inspection and testing of components received, a series of vacuum checks on the containment system, verification of Tritium content, and weld inspection. The MF Physics Corporation Quality Assurance Policy and all quality assurance records are maintained by the Company for inspection.

LIMITATIONS AND OTHER CONSIDERATIONS OF USE:

This device shall be distributed to persons specifically licensed by the U.S. NRC or an Agreement State.

Each applicant must be considered on an individual basis, with Particular attention given to the following:

Training for authorized users.

Adequate shielding, such as described in th MF Physics Corporation Technical Bulletin No. 104, *Shielding Considerations as Applied to Fast-Neutron Generator Application*.

Handling, posting, and interlock or control procedures adequate for the use of this equipment generating 14.3 Mev neutrons and producing radiation levels to 41,667 Rem/hour.

FROM :

05/03/1996 07:05 303-782-5083 RAD.CONT.DIV.- CDPHE

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: CO-1012-D-101-S DATE: April 30, 1996

DEVICE TYPE: Neutron tubes and neutron generators

In instances when it it necessary to work in the proximity of the neutron generator soon after it has been operating care should be taken because of induced radiation in equipment on the generator or in samples or equipment in the vicinity of the generator. It will be necessary to monitor the generator and test samples before personnel are allowed to approach or work with this equipment.

Emergency procedures.

Fire protection considerations, since this device cannot be expected to withstand either a major fire or explosion.

The generator tube is replaced as a unit only by MF Physics technicians.

SAFETY ANALYSIS SUMMARY: Based upon our review of the information and the test data cited below, we conclude that the A-3000 Series Neutron Generator Tubes is acceptable for licensing purposes. The licensing authority must assure that personnel, equipment and facilities are adequate to assure continued integrity of the neutron generators.

REFERENCES:

A. Correspondence and attachments dated January 27, 1993; July 30, 1994; April 19, 1996; and April 23, 1996.

B. the *Quality Assurance Policy*, as revised August 1, 1994;

C. the MF Physics Technical Bulletin No. 104, *Shielding Considerations as Applied to Fast-Neutron Generator Application*; and

D. the Instruction Manuals for the Models A-210, A-320, A-711, and A-801 Neutron Generator Systems.

ISSUING AGENCY: Colorado Department of Public Health and Environment

DATE: April 30, 1996 REVIEWED BY: Charles E. Pattee

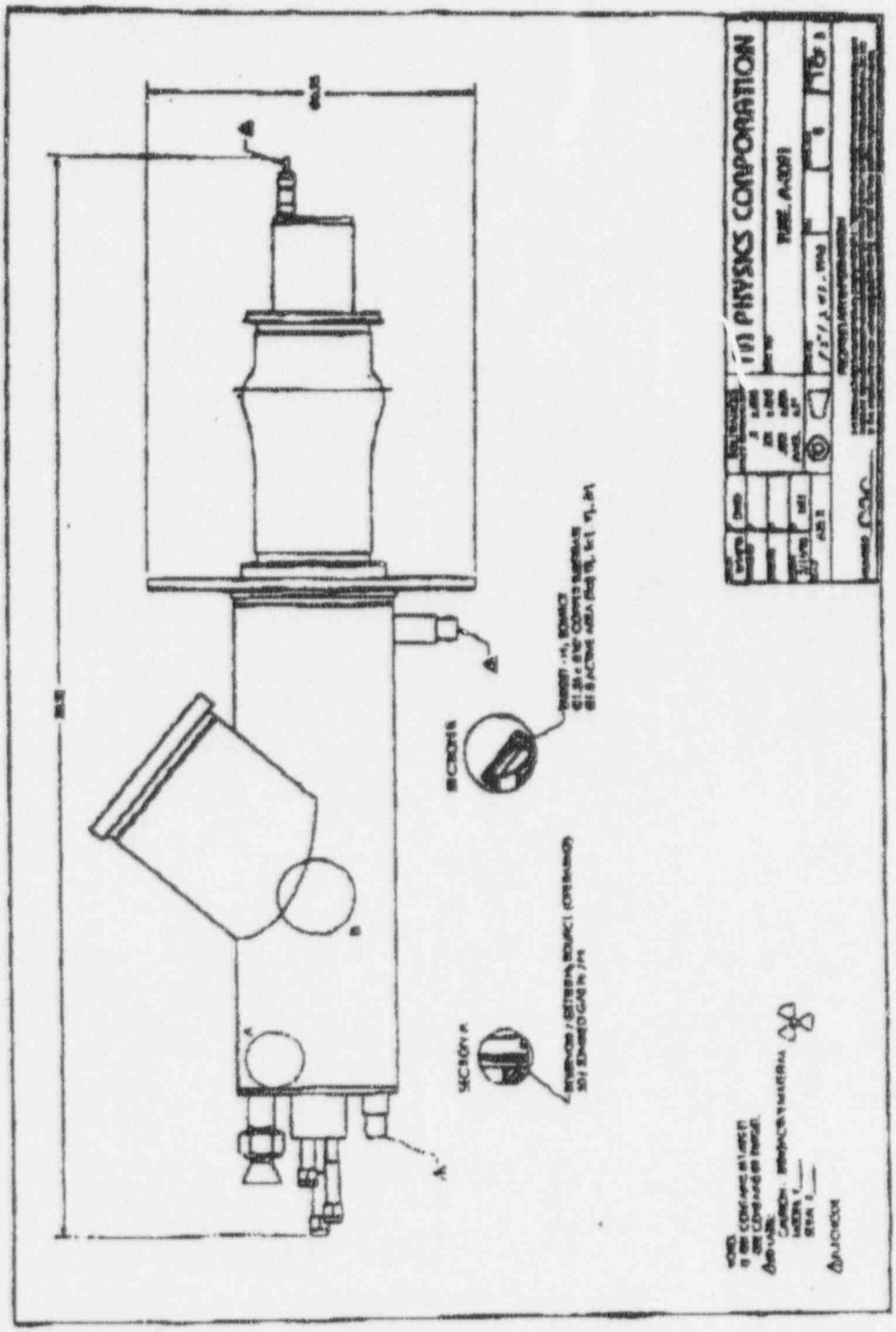
DATE: 5/3/96 CONCURRENCE: Elbert D. Thomas

FROM :

05/03/1996 07:05 303-782-5083 RAD.CONT.DIV. - CDPHE PAGE 09

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

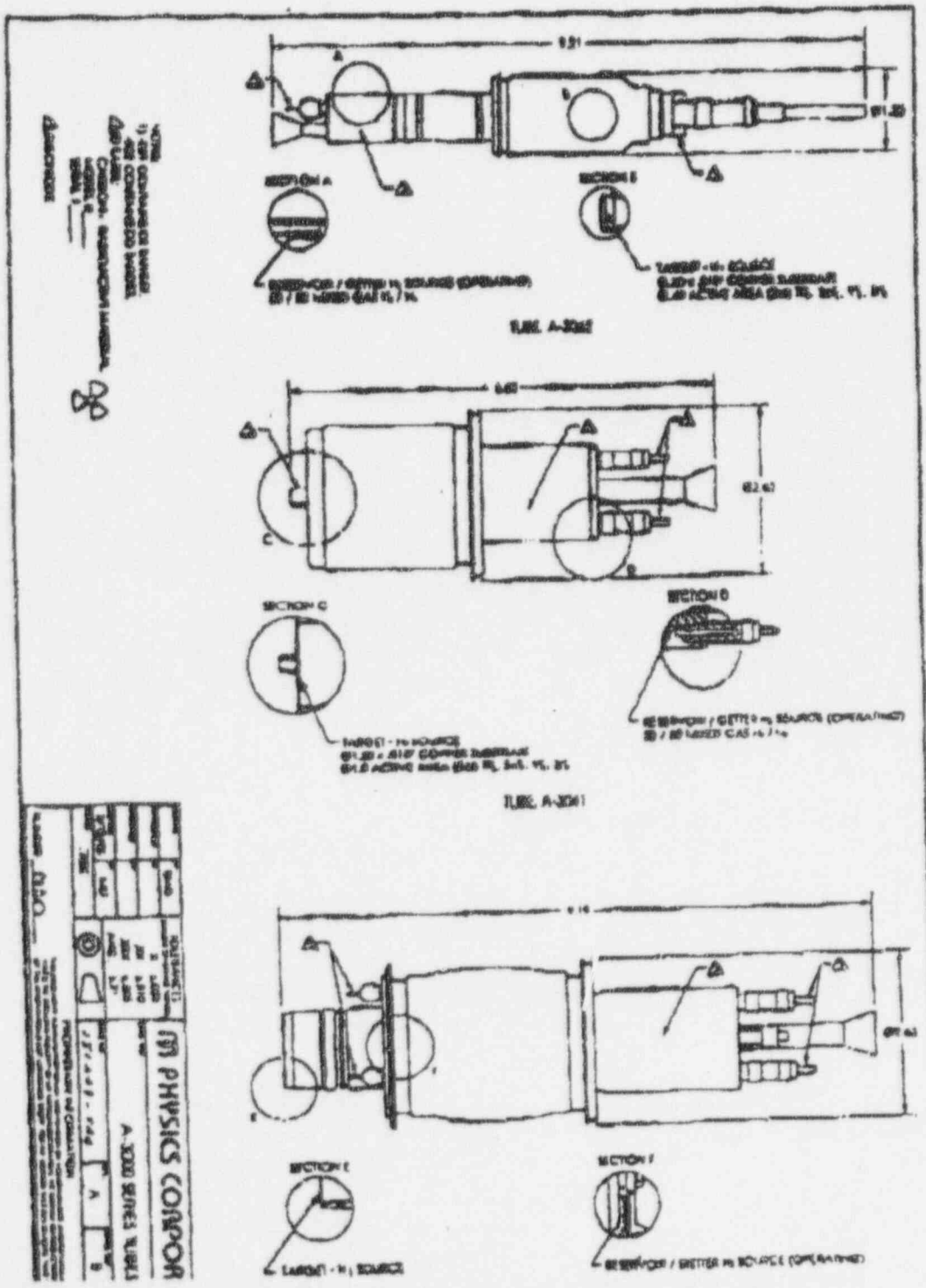
NO.: CO-1012-D-101-S **DATE:** April 30, 1996 **ATTACHMENT 1**

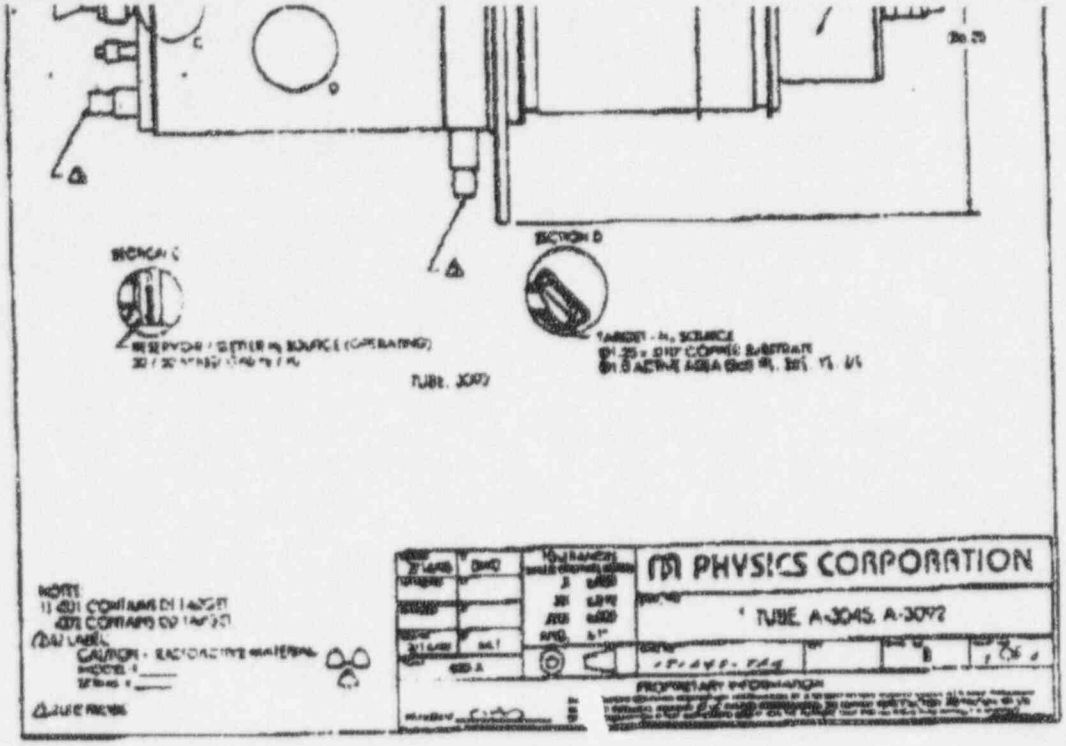


123353

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: CO-1012-D-101-S **DATE:** April 30, 1996 **ATTACHMENT 2**




SECTION C
SECTION D
TUBE, A-3045
PHYSICS CORPORATION
TUBE, A-3045, A-3072
PROPRIETARY INFORMATION

Jean Mayer
United States Department of Agriculture
Human Nutrition Research Center on Aging
At Tufts University

May 17, 1996

Thomas McMahon, RSO
NEMC Hospital
Box 787
171 Harrison Avenue,
Boston, Massachusetts 02111

Re: A-325 neutron generator, A-3043 neutron tube

Dear Mr. McMahon:

I talked today with Dr. J. Reichardt of MF Physics Corporation regarding our question with the neutron tube replacement process. He assured me that on-site replacement is not necessary and it is not dictated by the State license. The statement on the Registry document regarding replacement of the tube by an MF Physics technician only refers to the actual opening of the sealed accelerator column, which is kept pressurized in dielectric material. We plan to ship the whole column to MF Physics every time we need replacement of the tube. Shipping regulations and labeling are described on the license. This method of replacement is the safest and perfectly acceptable to us.

Joseph Kehayias

Joseph J. Kehayias, Ph.D.
Chief, Body Composition Laboratory
(617) 556-3162

file:lmcmaho3

711 Washington Street
Boston, Massachusetts 02111
FAX: 617-556-3344

123353

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

NEW ENGLAND MEDICAL CENTER
ATTN: F. X. MASSE
CHP, CMP
750 WASHINGTON STREET
BOSTON, MA 02111

*EFFECTIVE DATE FOR THE NEW FEE WAS 6/11/96. YOUR REQUEST WAS RECEIVED 6/21/96, THEREFORE, THE NEW FEE IS APPROPRIATE.

TYPE OF ACTION

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

REQUESTED DATE: 6-4-96

LICENSE NUMBER: 20-03857-06

CONTROL NUMBER: 123353

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
7B	$	$	$ 580.00
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 580.00
PAYMENT RECEIVED	$ 560.00
AMOUNT DUE	$ 20.00

☒ Your request was received without the prescribed application fee.

☒ We received your Check No. 232029 in the amount of $ 560.00. 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 7/8/96	

Distribution: Awaiting File
MAF Correspondence ✓
LFDCB Chief
LFDCB Analyst
Invoice File w/encl
LFDCB R/F (✓)
DAF R/F
DATE: 7-8-96

NRC FORM 577 (1-95)

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 2B
EXP. DATE: 20010630
FEE COMMENTS: 7B OK 6/88
DECOM FIN ASSUR REQD: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: NEW ENGLAND MEDICAL CENTER
RECEIVED DATE: 960621
DOCKET NO: 3001868
CONTROL NO.: 123353
LICENSE NO.: 20-03857-06
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: #560.00
CHECK NO.: 232029

3. COMMENTS

SIGNED Rebecca J. Brown
DATE 6/26/96

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

1. FEE CATEGORY AND AMOUNT: (7B) 2B $580

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

3. OTHER ---

SIGNED ---
DATE ---

I (94

Log July 1
Plantitle
Check No 00232029 / 102482
Amount $560 / $20
Fee Category (7B) 2B
Type of Fee AMD
Date Check Rec'd 8/9/96
Date Completed
By BR

07 for 8/9/96

67:1 - TAC PAM