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FEB 21 1980

FCMLB:DJF
030-15104
(00415)

Medical Imaging Corporation
ATTN: Mr. Mark Peterson, Director
Nuclear Medicine
781 River Street
Haverhill, MA 01830

Gentlemen:

This is in reference to a telephone conversation on July 16, 1979 with Mr. Mark Peterson regarding a request to amend Material License No. 20-18449-01. I informed Mr. Peterson that in order to add Dr. Desmond Fitzgerald as an authorized user, additional information concerning his experience and training would be required, specifically:

1. Completion of Item 4, Supplement A to Form NRC-313M with a breakdown of hours spent in each field of training, and
2. Completion of Item 3, Supplement B to Form NRC-313M (preceptor statement) signed by Antonio Rodriguez-Antunez, M.D. This should include specific dates and total number of hours received in clinical radioisotopes training.

You are hereby notified that unless within thirty (30) days from the date of this notice we receive the additional information requested, we will consider your application as having been abandoned by you. This action is without prejudice to the resubmission of an application.

Please respond in duplicate and refer to Control No. 00415.

Sincerely,

William J. Walker, Jr., Ph.D.
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

8003110378
XA

XA Copy Has Been Sent to PDR

CRESS:WILL MC#8478: OFFICE		FCMLB	FCMLB		
Enclosures:		DJFoster:gtw	WJWalker		
SURNAME: Form NRC-313M		2/14/80	2/14/80		
DATE: 2. Appendix A to Regulatory Guide 10.8					



MEDICAL IMAGING CORPORATION

781 River Street Haverhill Massachusetts 01830

617 / 374-4344

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RECEIVED

IC 45

January 22, 1980

REG. SECTION

RECEIVED BY LFMB	
Date.	FEB 2 1980
Log.	FEB. 16 7 Amendment
By.	Brown
Orig. To.	
Action Compl.	2/8/80

U. S. Nuclear Regulatory Commission
 Radioisotope Licensing Branch
 Division of Fuel Cycle and
 Material Safety
 Washington, D.C. 20555

Attn: Michael A. Lamastra

Gentlemen:

Medical Imaging Corporation hereby requests an amendment to NRC Material License #20-18449-01 to allow a modification in the procedures to be followed in the preparation and handling of radiopharmaceuticals to be used at customer-hospitals. Experience in the operation to date has clearly indicated that the most practical means of obtaining the necessary Tc^{99m} pertechnatate is through the daily purchase of the required amount of "instant technetium" rather than the purchase of a generator. We therefore receive each morning a stock shipment of the order of 100 mCi of ^{99m}Tc pertechnatate, which is properly packaged in accordance with DOT regulations, and which is ideally shielded for our transport to the day's appointments. We then open this package and go through the necessary package checkout at the Haverhill headquarters, checking the activity present and the Mo-99 contamination in the Dose calibrator.

We now propose to take advantage of the manufacturers packaging and shielding and to minimize the probability of contamination (both pharmaceutically and radioactively) by transporting this bulk Tc-^{99m} container to the customer hospital for removal of individual patient doses as necessary. Although it is not usually mandatory to again check the calibration of individual patient doses extracted

Applicant	
Check No.	09992
Amount/Fee	840
Type of Fee	Amendment
Date Check Recd	FEB 8 1980
Received By	Brown

(7b)

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02658

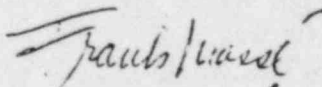
from a certified and prechecked container of instant technetium, we have devised a means of individual dose calibration using a Victoreen "Cutie Pie" ion chamber. By defining a reproducible geometry on the surface of the ion chamber in which to place the syringe containing the patient dose, we find that a 10 mCi dose yields a reading of 350 mr/hr, and that smaller or larger doses yield proportionate readings within an error of less than 5%. We plan to utilize this technique to check each patient dose.

The patient dose withdrawal and calibration will be done in the area designated by the customer/hospital for use by our operation (e.g. an empty patient room), and all waste materials will be returned to MIC headquarters as is currently the practice. A thorough survey of the area in which the dose is prepared and administered will be conducted with a thin-window G.M. survey meter, and the entire area is surveyed and left contamination-free at the end of each hospital visit. The multidose vial and all syringes are also returned to MIC headquarters at the end of the work day. As is currently the practice, vial and syringe shields and gloves are used throughout such procedures.

We feel strongly that the above proposed procedures will significantly improve both radiation safety and pharmaceutical safety for an operation such as ours without compromising patient dose calibration.

Please contact me at 617-245-6600 if you have any questions regarding this proposal. A check for \$40 covering the licensee fee for this request is enclosed.

Yours truly,



Frank Masse

Vice President Nuclear Division

FXM/jg
Enclosure

02658

DEC 31 1979

FCMLB:MAL
030-15104
(01890)

Medical Imaging Corporation
ATTN: Mr. Frank Masse
781 River Street
Haverhill, MA 01830

Gentlemen:

This is in reference to your request of November 6, 1979, to amend your Materials License No. 20-18449-01. In order to continue our review of your application, we need the following additional information:

OK

1. In order to list Arthur D. Burke, M.D. as an authorized user under your license No. 20-18449-01, please provide the following:
 - a. Evidence of 200 hours of training in basic radiological handling techniques as specified in Section 1.a. of Appendix A of Regulatory Guide 10.8. You should use Supplement A of Form NRC 313-M for this purpose.
 - b. The documentation of training and experience submitted for Dr. Burke indicates that a considerable amount of time has elapsed since his original training was obtained. If Dr. Burke has evidence of more recent training and experience or evidence of authorization to perform nuclear medicine procedures from the AEC/NRC or from an Agreement State, he should submit this information. Any additional timely training and experience should be documented on signed, completed preceptor statement (Form NRC-313M, Supplements A and B enclosed).

Evidence of certification by the American Board of Nuclear Medicine or certification by the American Board of Radiology in diagnostic radiology with special competence in nuclear radiology may be submitted in lieu of the above.

OK

2. In order to approve Dr. Robert Hannon as an onsite physician at Youville Hospital, we need evidence of 40 hours training in basic radiological handling techniques. You should use Supplement A, Form NRC-313M to supply this information.

Medical Imaging Corporation

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We will continue our review of your application upon receipt of this information. Please reply in duplicate and refer to Control No. 01890.

Sincerely,

Michael A. Lamastra
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosure: Form NRC-313M

St. Br. Dist.

CRESS
12/29/79
Lam 4/a

FCMLB *ML*
MALamastra:en
12/31/79