VOID SHEET

TO: License Fee Management Branch

FROM: RIII - _____

SUBJECT: VOIDED APPLICATION

Control Number: 302033

Applicant: MERIDIA HILLCREST HOSPITAL

License Number: 34-09739-01

Docket Number: 030-02791

Date Voided: 25 Nov. '96

Reason for Void: DEVICE REQUESTED HAS NOT BEEN APPROVED BY THE SEALED SOURCE & DEVICE REGISTRY. THEY MAY REAPPLY USING VOIDED CONTROL NUMBER

William P Kendall 25 Nov. '96
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

___ Refund Authorized and processed

✓ No Refund Due

___ Fee Exempt or Fee Not Required

Comments: _____ Log completed ✓

_____ Processed by: SAC 12/17/96

_____

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ML 30 SD

190062

57

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20040430
Fee Comments: CODE 23
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: MERIDIA HILLCREST HOSPITAL
   Received Date: 961108
   Docket No: 3002791
   Control No.: 302033
   License No.: 34-09739-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 440.00
   Check No.: ~~408142~~

3. COMMENTS

Signed Marcia Pearson
Date 11/13/96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered) 1_11

1. Fee Category and Amount: 7C $440

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

3. OTHER

Signed JC
Date 11/20/96

NOV 26 1996

Log NOV 8 III
Remitter
Check No. 408142
Amount $440
Fee Category 7C
Type of Fee AMD
Date Check Rec'd 11/19/96
Date Completed 11/20/96
By: JC

96 NOV -6 AM 6:1

MERIDIA
HILLCREST
HOSPITAL

October 25, 1996

US Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: License # 34-09739-01
Add 2.0 Ci Gd-153

Gentlemen:

This correspondence is to request authorization for the possession of 2.0 Curies of Gd-153 . A source up to 1000 mCi will be used for human use and installed in a Simultaneous Transmission-Emission Phantom (STEP) line source housing, purchased as an accessory on our Picker scintillation camera system.

The STEP line source holding device is being approved by the NRC. Application for a Device Registration has already been submitted by Picker International and clarifying information has been sent addressing questions on the original application. The Device Registration application is being processed under Assignment Number 96-83 and we have been advised approval of the application is eminent.

The Gd-153 line sources are provided by Isotope Products Laboratories (IPL), Burbank California under the following description: Model #HEGL -0061; Gd-153 Line Source per 3411 capsule, 800 millicurie (+/- 15%); Picker Specifications.

A possession limit of 2 Ci is requested for Gd-153 to facilitate source exchange or replacement. Spent sources will be disposed by return to the manufacturer following source exchange.

Authorization is also requested for use of Tc-99m in quantities of up to 600 mCi as sealed sources for human use which will be prepared on site. The sources will be fabricated using a fixture supplied by Picker as part of the STEP system package. Instructions will be followed as detailed in the STEP system operators guide supplied by Picker International. Depleted sources will be disposed by decay in storage and handled as radioactive waste as previously described in our byproduct materials license.

The appropriate amendment fee is enclosed. Thank you for your expeditious handling of this application.

Sincerely,

Erol Beytas, MD
Radiation Safety Officer
Meridia Hillcrest Hospital

6780 Mayfield Road
Mayfield Heights, Ohio 44124
(216) 449-4500

PM; 11-5-96

DEC 05 1996

Erol Beytas, M.D.
Radiation Safety Officer
Meridia Hillcrest Hospital
6780 Mayfield Road
Mayfield Heights, OH 44124

SUBJECT: VOID OF YOUR AMENDMENT REQUEST DATED OCTOBER 25, 1996

Dear Dr. Beytas:

We have voided your request for a Simultaneous Transmission-Emission Phantom (STEP) device at this time, because the specific device you requested has not been approved for use by the NRC. We voided your request without prejudice to resubmission.

As discussed with Mike Ballistrea by telephone on November 22, 1996, you may resubmit the same request within one year of the date of this letter. Information submitted should refer to VOIDED CONTROL NUMBER 302033 to avoid an additional fee.

The typical information needed to review a request for a STEP device includes the following:

1. A. The registry number of the device.
   B. The device model number.
   C. The gadolinium-153 source model number.
   D. The Isotope Product Code Model number.
   E. The maximum activity of the gadolinium-153 source.

2. Please clarify if you wish authorization for two gadolinium-153 sources so you can replace the source after it decays beyond its useful life.

3. Please specify which physicians you want authorized to use the device. The STEP device is used for diagnostic imaging purposes and its use is limited to physicians who are authorized for materials listed in 10 CFR 35.200.

The information needed to review the specific device you requested may vary from the above.

Also, we may need additional information depending upon the limitations and/or other considerations of use for the device.

302033

Please call me at (630) 829-9839 if you have any questions.

Sincerely,

Original Signed By
W. P. Reichhold
Nuclear Materials Licensing Branch

License No.: 34-09739-01
Docket No.: 030-02791

DOCUMENT NAME: M:\03002791.VD6

To receive a copy of this document, indicate in the box: "C" = Copy without enclosures "E" = Copy with enclosures "N" = No copy

OFFICE	DNMS/RIII C								
NAME	WREICHHOLD:jaw								
DATE	12/4/96								

OFFICIAL RECORD COPY

you with an additional statement reflecting those purposes.

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION 3
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

PHONE CONVERSATION RECORD

Jim Schepers
Chief Nuclear Medicine Technologist
Fisher-Titus Medical Center

Dear Mr. Schepers,

The following additional information is needed to complete the review of your request for a license amendment.

1. Please clarify the following information about the type of Transmission Line Source Housing you wish to use.

   A. The manufacturer of the device.
   B. The device Model.
   C. The gadolinium-153 source model.
   D. The Isotope Product Code Model.
   E. The maximum activity of the gadolinium-153 source.

Our files show that the following Transmission Line Source Housing has been approved.

Registry No. NR-104-D-101-S
Device Manufacturer: Picker International -Ohio Imaging
Device Model: STEP
Source Manufacturer: Isotope Products Laboratories
Source Model: 3409
Isotope Product Code: HEGL-0022
Maximum Activity for gadolinium-153: 86 millicuries

Please review your records and clarify it the above is the same device you wish added to your license. If the device you wish is not the same as in Registry No. NR-104-D-101-S , please provide as much information about the device as you can and confirm that the device was manufactured and distributed in accordance with a license issued pursuant to 10 CFR Parts 30 and 32.74.

2. Please clarify if you wish authorization for two gadolinium-153 sources so you can replace the source after it decays beyond its useful life.

3. Please clarify which physicians you want authorized to use the device. The STEP device is used for diagnostic imaging purposes and its use is limited to physicians who are authorized for materials listed in 10 CFR 35.200.

Please respond to the above within 15 days and refer to mail control 301266. Please call me at 708-829-9839 if you have any questions concerning the above.

Sincerely,

Bill Reichhold

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

November 14, 1996

Erol M. Beytas, M.D.
Radiation Safety Officer
Meridia Hillcrest Hospital
6780 Mayfield Road
Mayfield Heights, OH 44124

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 10/25/96)

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. 302033
License No. 34-09739-01