NRC FORM 374 (7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 01

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.

302413

Licensee	
1. Midwest Imaging Diagnostic, Inc., Ltd. (MIDI)	In accordance with letter dated March 11, 1997
2. 111 Wellington Place Cincinnati, OH 45219	3. License Number 34-26753-01 is amended in its entirety to read as follows:
	4. Expiration Date October 31, 2001
	5. Docket or Reference No. 030-34230

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, xenon-133, and aerosols)	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300 (limited to iodine-131 for hyperthyroidism and cardiac dysfunction)	C. Not to exceed 1 curie

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200 (except generators, xenon-133, and aerosols).

C. Medical use described in 10 CFR 35.300 (limited to iodine-131 for hyperthyroidism and cardiac dysfunction).

239035

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
34-26753-01

Docket or Reference Number
030-34230

Amendment No. 01

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 111 Wellington Place, Cincinnati, Ohio.

11. Radiation Safety Officer: Harold T. Pretorius, M.D., Ph.D.

12. 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
A. Harold T. Pretorius, M.D., Ph.D.	10 CFR 35.100, 35.200 (except generators, xenon-133, and aerosols) and 35.300 (limited to iodine-131 for hyperthyroidism and cardiac dysfunction)

13. 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) for establishing decommissioning financial assurance.

14. 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. Letter received October 10, 1996; and

B. Letter dated March 11, 1997 (excluding the Quality Management Program).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 11 1997

By Charles F. Gill
Materials Licensing Branch, Region III

COPY

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02200
Status Code: 0
Fee Category: 7C
Exp. Date: 20011031
Fee Comments:
Decom Fin Assur Reqd: N

S8

97 MAR 18 PM 1:04

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: MIDWEST IMAGING DIAGNOSTIC/INC/LTD.
   Received Date: 970312
   Docket No: 3034230
   Control No.: 302413
   License No.: 34-26753-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 430
   Check No.: 1245

3. COMMENTS

Signed D. Hersey
Date 3-17-97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / ✓)

1. Fee Category and Amount: 7C #430

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

3. OTHER

Signed DC
Date 4/15/97

APR 25 1997

Log Mail Room
Remitter
Check No. 1245 / 5015
Amount #430 / #10
Fee Category 7C AMD
Type of Fee
Date Check Rec'd 3/18/97
Date Completed 4/15/97
By: DC

Midwest Isotope Diagnostics Imaging
111 Wellington Place Suite G-4
Cincinnati OH 45219
Tel 513 621 4003
Fax 513 621 4005

US NRC Region III
801 Warrenville Rd
Lisle IL 60532-4351

Attn. Material Licensing

Re: NRC License # 34-26753-01 11-Mar-97

Dear NRC Specialist

This is to request an amendment to the above referenced license to include byproducts use for therapy as specified in Section 35.300, subpart F.

Enclosed are the proposed Quality Management Program according to section 35.32 which will be implemented at our site in order to control and administer therapeutic doses of I-131 less than 30 mCi and license amendment fee in amount of $430, as specified in section 170.31.

Please, refer to Application for Material License submitted to and approved by your office earlier for detailed description of our facility and radiation safety procedures.

Sincerely

H.T.Pretorius, MD, Ph.D.
Medical Director and RSO

RECEIVED
MAR 1 2 1997
REGION III
30243
MAR 1 2 1997

Pm; 3-11-97

Midwest Isotope Diagnostics Imaging
111 Wellington Place, Suite G-4
Cincinnati, OH 45219

QUALITY MANAGEMENT PROGRAM

This QMP is applicable for the radiopharmaceuticals (r/p) I^{131} > 30 μCi and will be implemented as follows:

A/ Prior to therapy dose administration, a physicians written directive, showing the patients name, radiopharmaceutical type and amount (activity), date & time and route of administration must be issued. It must also be signed by the physician.

B/ The purchase of r/p from a vendor for therapeutic purposes will be documented on the form (*see attachment*) **Radiopharmaceutical Therapy Prescription and Patient Record**. This form is the Physicians Written Directive so it will also be used for the following items.

C/ Before administration the patient shall be identified by any two methods per following:

i The patient shall be asked to say or spell his/her name;
ii The patient shall be asked to state his/her birth date;
iii The patient shall be asked to state his/her social security number;
iv The patient shall be asked to state his/her address;
v The patient shall be asked for identification, e.g. drivers license, etc.;
vi For patients unable to respond, an accompanying relative/friend may attest to the patients identity. Record name & relation-ship of same.

D/ (a) Before dose is administered, the technologist will check that the dosage he/she prepared is in accordance with the "*Physician Written Directive/Prescription* as stipulated on the **Radiopharmaceutical Therapy Prescription and Patient Record** form.

(b) If the written directive is unclear or ambiguous, then clarification from the prescribing physician will be sought prior to radiopharmaceutical administration.

(c) Upon administration of the radiopharmaceutical dose the remainder of the form **Radiopharmaceutical Therapy Prescription and Patient Record** will be completed. This should assure that the correct type & amount of radiopharmaceutical was administered.

(d) The technologist will also complete the **Quality Management Monitor** (see enclosed) for every patient who receives a therapy dose. This will be kept in the patient chart at all times.

E/ In an emergency, when a patients well being could be jeopardized, an oral directive or oral directive revising an existing written directive will be acceptable, where the said instructions will be recorded in the patients chart immediately. A written directive of the revised instructions will be issued signed & dated within 24 hours of the oral directives.

F/ All unintended deviations from a written directive shall be identified and evaluated. Unintended deviations include incidents, recordable events, misadministration, and patient illness possibilities.

(a) As soon as a technologist, or anyone else, recognizes an unintended deviation(s), he/she must immediately report the problem to the supervisor who will them apprise the situation. The medical physicist must be consulted also. In the case of a mis-adminitration, a written report will be generated that includes:

- The licensees name;
- The prescribing physicians name;
- Description of the event;
- Why the event occurred;
- The effect on the patient;
- Corrective action/s taken;
- Whether or not patient notified & why and by whom;
- When the referring physician is notified.

} **This report will be kept for at least five years.**

(b) Unintended deviations from the written directive including recordable events, mis-administrations, etc., shall be evaluated within 30 days after the discovery of such. A meeting will be held with the department supervisor, a medical physicist, the prescribing physician and the technologist involved. All relevant facts will be assembled including the cause and identifying what, if any, corrective action/s is required to prevent a recurrence. A record will be kept of this meeting and its findings for three years.

G/ The findings in the monthly audits will be presented at the quarterly Radiation Safety Committee meeting, as a means to evaluate the effectiveness of the QMP program. If problems exist with he QMP program, the committee will address them. Modifications to the QMP program will be submitted to the NRC within 30 days after the modifications have been made.

(a) A "Quality Management Audit", of the program, will be performed monthly. All patient therapy administration forms will be reviewed in this audit to determine that the written directives are followed. The audit will be performed by the department supervisor and reviewed by a Medical Physicist on a quarterly basis. Copies of these monthly audits shall be retained for three years.

H/ The completed **Radiopharmaceutical Therapy Prescription and Patient Record** form along with a copy of the dose calibrator activity printout shall be retained for three years after the date of administration.

I/ There will be an annual review of our QMP program conducted by the authorized user, medical physicist & administration. Additionally they will also review randomly selected patient administrations as per following criteria-- minimum of 20% of cases if >100 patients, 20 cases if between 20 - 100 patients, and all cases if < 20 patients.

J/ Training will be provided at orientation, and annually thereafter, to all individuals working with any radioactive (NARM or by-product) materials. Particular emphasis will be given to the various forms included with this **QMP program**. Such documentation will be maintained on file.

Midwest Isotope Diagnostics Imaging

111 Wellington Place, Suite G-4
Cincinnati, OH 45219

Radiopharmaceutical Therapy Prescription and Patient Record

For I^{131} > 30 µCi

Patient Name: _____ ; Social Security #: _____
Patient Address: _____
Patient Diagnosis: _____

Physician Written Directive/Prescription

Radiopharmaceutical: _____ ; Amount: _____ mCi
Route of administration: _____

Physician signature: _____ ; Date: _____ ; Time: _____

Revisions (If any):
MUST BE DATED/SIGNED:

Vendor Order Record

Radiopharmaceutical: _____ ; Amount: _____ mCi
Date of order: _____ ; Ordering technologist: _____

Administration Record

How patient identified: DL / DOB / SS# / Name (as applicable) Other

Pregnancy check: **(if applicable)**
Date tested: _____

Radiopharmaceutical: _____ ;Route of administration: _____

Assay #1: _____ mCi by _____

Dose Administered: _____ mCi **Is this within 10%? Y / N**
Date: _____ ; Time: _____ If no, explain _____

Administering Physician Signature: _____
Date: _____ ; Time: _____

ATTACH A COPY OF THE DOSE CALIBRATOR RECORD ADMINISTRATION SHEET

Midwest Isotope Diagnostics Imaging

111 Wellington Place, Suite G-4
Cincinnati, OH 45219

Radiopharmaceutical Misadministration Record

Authorized User _____

Referring physician _____

Patient name _____

Date when the event occurred _____

Description of the event _____

_____

_____

Why the event occurred _____

_____

The effect on the patient _____

Corrective action/s taken _____

_____

_____

Whether or not patient notified
& why and by whom _____

Whether or not Referring
physician is notified
& why and by whom _____

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

MIDWEST ISOTOPE DIAGNOSTICS IMAGING
ATTN: H. T. PRETORIUS, M.D., PH.D
MEDICAL DIRECTOR & RADIATION
SAFETY OFFICER
111 WELLINGTON PLACE SUITE G-4
CINCINNATI, OH 45219

TYPE OF ACTION

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

REQUESTED DATE: 3-11-97

LICENSE NUMBER: 34-26753-01

CONTROL NUMBER: 302413

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	$ 430.00
AMOUNT DUE	$ 10.00

☐ Your request was received without the prescribed application fee.

☒ We received your Check No. 1245 in the amount of $ 430.00. 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
SHIRLEY CRUTCHFIELD	SC 3/18/97	

Distribution: OC/DAF/RF
Pending Fee File OC/DAF/SF (LF-3 2 7)
LFARB R/F (2) Region 2

DATE: Mar. 18, 1997

JUN 11 1997

Harold T. Pretorius, M.D., Ph.D.
Radiation Safety Officer
Midwest Imaging Diagnostic, Inc., Ltd.
111 Wellington Place
Cincinnati, OH 45219

Dear Dr. Pretorius:

Enclosed is Amendment No. 01 to your NRC Material License No. 34-26753-01 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.

Please note that License Condition No. 14 excludes reference to changes made in your Quality Management Program (QMP). In effect, excluding the Quality Management Program from the license allows you the flexibility to make changes to it without obtaining prior NRC approval. When modifications are made to your QMP program, you are required to submit the modified program to this office within 30 days after the modification is made, as required by 10 CFR 35.32(e). It appears that your QMP addresses the requirements of 10 CFR 35.32; however, the adequacy of your QMP will be reviewed during your next NRC inspection.

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 mailing address listed on the license changes. (No fee is required if the location of byproduct material remains the same.)

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 Statement of Policy and Procedure 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
Charles F. Gill
Nuclear Materials Licensing Branch

License No.: 34-26753-01
Docket No.: 030-34230

Enclosure: Amendment No. 01

DOCUMENT NAME: M:\03034230.CL7
To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII							
NAME	CFGILL:jaw							
DATE	06/11/97							

OFFICIAL RECORD COPY

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

March 17, 1997

Harold T. Pretorius, M.D.
Radiation Safety Officer
Midwest Imaging Diagnostic, Inc., Ltd.
111 Wellington Place
Cincinnati, OH 45219

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 03/11/97)

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. 302413
License No. 34-26753-01