

MATERIALS LICENSE

Amendment No. 33

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 letter dated November 15, 1996, and letter received January 16, 1997	
1. Henry Ford Wyandotte Hospital		3. License Number 21-12930-01 is amended in its entirety to read as follows:	
2. 2333 Biddle Avenue Wyandotte, MI 48192		4. Expiration Date May 31, 2005	
		5. Docket or Reference No. 030-02140	
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. 1 curie	
9. Authorized Use:			
A. Medical use described in 10 CFR 35.100.			
B. Medical use described in 10 CFR 35.200.			
C. Medical use described in 10 CFR 35.300.			

CONDITIONS

10. Location of Use: 2333 Biddle Avenue, Wyandotte, Michigan.
11. Radiation Safety Officer: Piyush Pandya

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

21-12930-01

Docket or Reference Number

030-02140

Amendment No. 33

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 UsersMaterial and Use

- | | |
|--------------------------|----------------------------------|
| A. T. G. McDonald, M.D. | 10 CFR 35.100, 35.200 and 35.300 |
| B. K. D. Bartold, M.D. | 10 CFR 35.100, 35.200 and 35.300 |
| C. Sharon Helmer, M.D. | 10 CFR 35.100, 35.200 and 35.300 |
| D. Sophia Roumanis, M.D. | 10 CFR 35.100, 35.200 and 35.300 |
| E. Jerry W. Drake, M.D. | 10 CFR 35.100, 35.200 and 35.300 |
13. The Radiation Safety Committee will review the justification for and must approve or disapprove all revisions of investigational radiation dose levels in the ALARA program.
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. Application dated October 14, 1994; and
- B. Letter dated April 10, 1995 (excluding 1 microcurie of molybdenum-99 per millicurie of technetium-99m ratio).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 29 JANUARY 1997By William P. Reinhold
Nuclear Materials Licensing Branch, Region III

COPY

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

Program Code: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20050531
Fee Comments: NOT EX 12/28/87
Decom Fin Assur Req'd: N

57

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: WYANDOTTE HOSPITAL & MEDICAL CTR.
Received Date: 961127
Docket No: 3002140
Control No.: 302087
License No.: 21-12930-01
Action Type: Amendment

2. FEE ATTACHED

Amount: 440
Check No.: 22887

3. COMMENTS

Signed D. Hersey
Date 12-3-96

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

1. Fee Category and Amount: 7C \$440

2. Correct Fee Paid. Application may be processed for:

Amendment ☒
Renewal ☐
License ☐

3. OTHER

Signed SC
Date 12/9/96

1996 DEC -9 PM 2:16

Log	<u>Dec 3 1996</u>
Remitter	
Check No.	<u>111881</u>
Amount	<u>\$440</u>
Fee Category	<u>7C</u>
Type of Fee	<u>ADD</u>
Date Check Rec'd	<u>12/9/96</u>
Date Completed	<u>12/9/96</u>
By	<u>SC</u>



HENRY FORD WYANDOTTE HOSPITAL

2333 Biddle Avenue
Wyandotte, MI 48192
(313) 284-2400

November 15, 1996

Federal Express

Mr. John Madera
Section Chief
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

**RE: Amendment Request: Wyandotte Hospital and Medical Center NRC
License Number 21-12930-1**

Dear Mr. Madera:

Effective at the close of business on December 31, 1996, Wyandotte Hospital and Medical Center (assumed name: Henry Ford Wyandotte Hospital), will be changing Radiation Safety Officers. The Wyandotte diagnostic imaging program and the radiation safety program will continue to operate in the same manner, under the same authority. However, Piyush Pandya will become the new Radiation Safety Officer at the Wyandotte facility while Jay Pockyarath, the present Radiation Safety officer, will remain a member of administration on the Radiation Safety Committee.

Mr. Piyush Pandya meets the requirements of 10 CFR 35.900(b) 1 and 2. His qualifications are as follows:

- He has been a nuclear medicine technologist at Wyandotte Hospital and Medical Center since December, 1981.
- His training for nuclear medicine technology included at least 200 hours of classroom and laboratory training. Certificates of Nuclear Medicine Technology graduate study and American Registry of Radiological Technologists Nuclear Medicine certification (registry) are enclosed.

RECEIVED

NOV 27 1996

REGION III

302087

Pm: 11-26-96

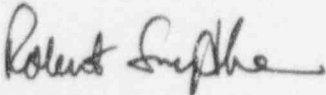
NOV 27 1996

Mr. John Madera
November 15, 1996
Page 2 of 2

- He has been working closely with the current RSO regarding the duties and responsibilities of the RSO for the last 3 years and routinely attends the Radiation Safety Committee meetings.
- He has attended a refresher course in radiation safety offered by Engelhardt and Associates Inc. on July 29-31, 1996. Certificates of completion are enclosed.

We are informing you of this change in order to expedite this amendment to our NRC license. Please feel free to contact me at (313) 246-6004 or our consulting Physicist, Neil Keller at (313) 662-3197 if you have any questions.

Very truly yours,



Robert C. Smythe
Chief Operating Officer

attachment / CHECK FOR \$440⁰⁰

cc: Jay Pockyarath

Certificate of Completion

awarded to

Piyush Pandya

for participation in a radiation safety training course

Given by Engelhardt & Associates, Inc.

July 29-31, 1996

Orlando, FL

Susan J. Engelhardt
Susan J. Engelhardt, M.S.

Ralph Grunewald
Ralph Grunewald, Ph.D.

Dee Kaiser
Dee Ann Kaiser, M.S.

Judith Grunewald
Judith Grunewald, R.N., M.S.

THE AMERICAN REGISTRY OF RADIOLOGIC TECHNOLOGISTS

Representative of
The American College of Radiology and
The American Society of Radiologic Technologists

HEREBY CERTIFIES THAT

Hiyush G. Pandya

has pursued an approved educational program in Nuclear Medicine Technology, has met certain standards and qualifications and has passed the examinations conducted under authority of this Registry, and is thus qualified as a

Registered Technologist

Nuclear Medicine Technology

and by virtue of this certificate is authorized to use the title Registered Technologist and its abbreviation R.T. (N) (ARRT) as long as this certificate is in force as is indicated by the current date appearing on the seal hereon attached.

Ralph W Coates, RT (R) (ARRT)
PRESIDENT

B. R. Vallins, RT (R) (ARRT)
SECRETARY

154371

1979

Detroit General Hospital

School of Nuclear Medical Technology

This is to certify that

Dipush G. Pandya

has satisfactorily completed
an approved course of graduate study in

Nuclear Medical Technology

Date June 30, 1979

Administrator

Director

JAN 30 1997

Robert C. Smythe
Chief Operating Officer
Henry Ford Wyandotte Hospital
2333 Biddle Avenue
Wyandotte, MI 48192

Dear Mr. Smythe:

Enclosed is Amendment No. 33 to your NRC Material License No. 21-12930-01 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 we have extended the expiration date of the license for five years in accordance with the regulations (10 CFR 30.36).

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 licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

302087

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 Policy and Procedures for NRC Enforcement Actions. Since serious consequences

R. Smythe

-3-

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
W. P. Reichhold
Nuclear Materials Licensing Branch

License No.: 21-12930-01
Docket No.: 030-02140

Enclosure: Amendment No. 33

DOCUMENT NAME: M:\03002140.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 <i>WR</i>								
NAME	WREICHOLD:jaw								
DATE	01/21/97								

OFFICIAL RECORD COPY



HENRY FORD WYANDOTTE HOSPITAL

2335 Biddle Avenue
Wyandotte, MI 48192
(313) 264-2400

January 14, 1996

ATTN: Bill Reichold
Materials and Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: Control No. 302087
Amendment request
Wyandotte Hospital and Medical Center
License No. 21-12930-01

Dear Mr. Reichold:

This letter is a response to your letter January 3, 1997 requesting additional information about our name change and changing the Radiation Safety Officer.

1. Clarification of 200 hours and laboratory training for Piyush Pandya:

* Mr. Pandya graduated from a certified nuclear medicine technology program in 1979. This program included one full year of didactic lectures. Please reference the enclosed transcripts and certificate of graduation. The Certificates of Nuclear Medicine Technology and American Registry of Radiological Technologists Nuclear Medicine certification (registry) were previously enclosed and are again submitted for your review.

* Mr. Pandya has recently taken a Radiation Safety training course from Englehardt and Associates, Inc. The 3 day curriculum included basic physics, radiation protection, radiation biology, radiation safety, radiation waste management, and NRC regulations review. Please see the attached Certificate of Completion.

RECEIVED
JAN 16 1997
REGION III

JAN 16 1997



HENRY FORD WYANDOTTE HOSPITAL

2333 Biddle Avenue
Wyandotte, MI 48192
(313) 284-2400

2. Please clarify Piyush Pandya has completed one year of full time experience as a radiation safety technologist under the radiation safety officer.

* Mr. Pandya has been a nuclear medicine technologist at this facility since December, 1981. He has also been a member of the radiation safety committee for the past 3 years. During this time he has worked under the supervision of the current radiation safety officer, Jay Pockyarath, regarding issues of radiation safety and protection in nuclear medicine.

3. The name of our organization from Wyandotte Hospital and Medical Center to Henry Ford Wyandotte Hospital was not an ownership change. During the time the facility was called Wyandotte Hospital and Medical Center it was a member of the Henry Ford Health System.

Please contact us at 313-284-2400 x 2272 if you have any questions.

Sincerely,

Jay R. Pockyarath
Jay Pockyarath
Radiation Safety Officer

Detroit General Hospital

School of Nuclear Medical Technology

This is to certify that

Wynish G. Davis

has satisfactorily completed
an approved course of graduate study in

Nuclear Medical Technology

Date June 30, 1979

[Signature]
Administrator

[Signature]
Director

CONVERSATION RECORD

|TIME

|DATE

Morning 3 January 1997

☐ VISIT☐ CONFERENCE

TELEPHONE

IN COMING

☒ OUTGOING

NAME OF PERSON(S) CONTACTED

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

Piyush Pandya, Nuclear Medicine Tech. Wyandotte Hospital (313) 284-2400

SUBJECT

Additional/clarification of information

SUMMARY

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

1. Please clarify if the 200 hours of classroom and laboratory training received by Piyush Pandya included the following:
 - a. Radiation physics and instrumentation
 - b. Radiation protection
 - c. Mathematics pertaining to the use and measurement of radioactivity
 - d. Radiation biology
 - e. Radiopharmaceutical chemistry
2. Please clarify if Piyush Pandya has completed one year of full time experience as a radiation safety technologist under the supervision of the Radiation Safety Officer.
3. Please clarify if the hospital's name has changed to Henry Ford Wyandotte Hospital or if the hospital has had an ownership change. If the hospital has had an ownership change, please answer the questions in Attachment 1.

ACTION REQUIRED

Phone call.

NAME OF PERSON DOCUMENTING CONVERSATION
DATE

Bill Reichhold

SIGNATURE

Bill Reichhold

| 3 Jan. 1997



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

December 3, 1996

Piyush Pandya
Radiation Safety Officer
Wyandotte Hospital & Medical Center
Department of Nuclear Medicine
2333 Biddle Avenue
Wyandotte, MI 48192

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 11/15/96)

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 ☒ 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. 302087
License No. 21-12930-01