MATERIALS LICENSE

Amendment No. 15

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.

301818

Licensee	
1. Defiance Hospital, Inc.	In accordance with letter dated August 27, 1996 3. License Number 34-15654-01 is amended in its entirety to read as follows:
2. 1206 East Second Street Defiance, OH 43512	4. Expiration Date July 31, 2000
	5. Docket or Reference No. 030-09534

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

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

CONDITIONS

10. Location of Use: 1206 East Second Street, Defiance, Ohio.

11. Radiation Safety Officer: John P. Ewonus, D.O.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
34-15654-01

Docket or Reference Number
030-09534

Amendment No. 15

12. Authorized Users:

A. J. A. Mitchell, M.D., for material in 10 CFR 35.100 and 35.200.

B. S. T. Pinsky, M.D., for material in 10 CFR 35.100 and 35.200.

C. R. E. Meyers, M.D., for material in 10 CFR 35.100 and 35.200.

D. G. B. Glasberg, M.D., for material in 10 CFR 35.100 and 35.200.

E. P. M. Royen, M.D., for material in 10 CFR 35.100 and 35.200.

F. D. E. Hoover, M.D., for material in 10 CFR 35.100 and 35.200.

G. M. F. Fadell, M.D., for material in 10 CFR 35.100 and 35.200.

H. S. E. Gordon, M.D., for material in 10 CFR 35.100 and 35.200.

I. S. L. Mayers, M.D., for material in 10 CFR 35.100 and 35.200.

J. R. W. Siders, M.D., for material in 10 CFR 35.100 and 35.200.

K. R. B. Doerfler, M.D., for material in 10 CFR 35.100 and 35.200.

L. T. T. Loh, M.D., for material in 10 CFR 35.100 and 35.200.

M. S. S. Manion, M.D., for material in 10 CFR 35.100 and 35.200.

N. John P. Ewonus, D.O., for material in 10 CFR 35.100 and 35.200.

O. Thomas J. Zekan, M.D., for material in 10 CFR 35.100 and 35.200 (excluding generators).

13. Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material in the molybdenum-99/technetium-99m generators authorized by this license.

14. The licensee shall maintain records of information important to safe and effective decommissioning at the address in Condition 10. per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 34-15654-01

Docket or Reference Number 030-09534

Amendment No. 15

15. 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 April 5, 1990; and

B. Letter dated May 24, 1990 (with attachments) and June 25, 1990 (with attachments).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date November 25, 1996

By Heidi Walton
Nuclear Materials Licensing Branch, Region III

COPY

SS
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BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02121
Status Code: 0
Fee Category: 7C 2B
Exp. Date: 20000731
Fee Comments:
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: DEFIANCE HOSPITAL
   Received Date: 960910
   Docket No: 3009534
   Control No.: 301818
   License No.: 34-15654-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 440
   Check No.: 109660

3. COMMENTS

Signed D. Hersey
Date 9-17-96

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 AC
Date 9/17/96

SEP 23 1996

Log Sep 6 III
Remitter
Check No. 109660
Amount $440
Fee Category 7C
Type of Fee AMD
Date Check Rec'd 9/16/96
Date Completed 9/17/96
By AC

Defiance Hospital

August 27, 1996

U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: License No. 34-15654-01

Gentlemen:

We are requesting an amendment to our current U.S. Nuclear Regulatory Commission Materials License. Please note that this information was originally submitted with our license renewal in June of 1995, which was recently extended for 5 years.

Please add Dr. Thomas J. Zekan, M.D. to the list of authorized users for material groups 35.100 and 35.200.

Attached you will find supplements A and B indicating Dr. Zekan's training and experience and preceptor's statement.

Dr. Zekan is in full clinical practice and maintains continuing medical education in accordance with ACR guidelines.

Enclosed you will find our amendment fee of $440.00.

If you have any questions, please feel free to contact us.

Sincerely,

Terry L. Jacobs

Terry L. Jacobs
Director of Radiology

RECEIVED
SEP 10 1996
REGION III

PM 9/6/96

1206 East Second Street - Defiance, Ohio 43512 - 419/783-6955 - Fax 419/783-6967

301818

EXHIBIT 2

SUPPLEMENT A

SUPPLEMENT — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
Thomas James Zekan, MD	OHIO

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: CLOCK HOURS IN LECTURE OR LABORATORY	TYPE AND LENGTH OF TRAINING: CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	The Ohio State University Medical Center Columbus, OH 7/91-6/95		
b. RADIATION PROTECTION	The Ohio State University Medical Center Columbus, OH 7/91-6/95		
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	The Ohio State University Medical Center Columbus, OH 7/91-6/95		
d. RADIATION BIOLOGY	The Ohio State University Medical Center Columbus, OH 7/91-6/95		
e. RADIOPHARMACEUTICAL CHEMISTRY	The Ohio State University Medical Center Columbus, OH 7/91-6/95		

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
I-131	300 mCi	The Ohio State University Medical Center		Diagnostic
I-123				
Tc-99m	800 mCi			Diagnostic
In-111	500 micro Ci			
Thalium	3 mCi			
Ga-67	12 mCi			

EXHIBIT 3

SUPPLEMENT B

SUPPLEMENT — U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME: Thomas James Zekan, M.D.

STREET ADDRESS: 1206 E. 2nd Street

CITY: Defiance | STATE: OH | ZIP CODE: 43512

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1. Supervised examination of patients to determine the suitability for radiotherapeutic diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted on duplicate or separate sheets.) D
	Thyroid scan	150	
	Thyroid uptake	150	
	Lung perfusion scan	200	
	Xenon ventilation study	30	
	Aerosol ventilation scan	200	
	Renal flow scan	150	
	Brain scan	50	
	Liver/spleen scan	50	
	Bone scan	500	
	Gastroesophageal study	100	
	LeVeen shunt study	5	
	Cystogram	5	
	Dacryocystogram	—	
	Cardiac perfusion scan.	500	
	Cardiac stress ventriculogram	500	
	Cardiac rest ventriculogram	500	
	Gallium scan	50	

PROPOSED PHYSICIAN USER

Thomas James Zeko, M.D.

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	0	
P-32 (Colloidal)	INTRACAVITARY TREATMENT	0	
I-131	TREATMENT OF THYROID CARCINOMA	15	
	TREATMENT OF HYPERTHYROIDISM	20	
Au-198	INTRACAVITARY TREATMENT	0	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	0	
	INTRACAVITARY TREATMENT	0	
I-125 or I-192	INTERSTITIAL TREATMENT	0	
Co-60 or Cs-137	TELETHERAPY TREATMENT	0	
Sr-90	TREATMENT OF EYE DISEASE	0	
	RADIOPHARMACEUTICAL PREPARATION	0	
Mo-99/ Tc-99m	GENERATOR	101	
Sn-113/ In-113m	GENERATOR	0	
Tc-99m	REAGENT KITS	[illegible]	
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
The Ohio State University Medical Ctr.	7/1-7/20/91 11/1-11/30/91 11/22/93-12/19/93 8/29/94-9/25/94 & 5/8/95-6/4/95	

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR: John O. Olsen, M.D.

b. NAME OF INSTITUTION: 450 W. 10th Avenue

c. MAILING ADDRESS: Columbus, OH 43210

d. CITY

e. MATERIALS LICENSE NUMBER(S): 34-00293-01

5. PRECEPTOR'S SIGNATURE: John O. Olsen, M.D.

6. PRECEPTOR'S NAME (Please type or print): John O. Olsen, M.D.

7. DATE: 7/[illegible]/95

NOV 26 1996

Terry L. Jacobs
Director of Radiology
Defiance Hospital, Inc.
1206 East Second Street
Defiance, OH 43512

Dear Mr. Jacobs:

Enclosed is Amendment No. 15 to your NRC Material License No. 34-15654-01 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 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).

301818

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

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
Gidget Watson
Nuclear Materials Licensing Branch

License No.: 34-15654-01
Docket No.: 030-09534

Enclosure: Amendment No. 15

DOCUMENT NAME: M:\03009534.CL6

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	GWATSON:jaw									
DATE	11/25/96									

OFFICIAL RECORD COPY

CONVERSATION RECORD

TIME | DATE 11/20/96

O VISIT O CONFERENCE X TELEPHONE

X INCOMING
O OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT | ORGANIZATION (OFFICE, DEPT.ETC.) | TELEPHONE NO.
Terry Jacobs, Dir. of Radiology | Deiance Hospital | 419/783-6955

SUBJECT
License No. 34-15654-01

SUMMARY
I requested the following additional information in regards to amendment request dated 8/27/96:

The number of clock hours obtained in accordance with 35.920 (b1), (b2) and (b3).

Mr. Jacobs stated that he would forward the information ASAP.

ACTION REQUIRED

Michael Watson | SIGNATURE | 11/20/96
NAME OF PERSON DOCUMENTING CONVERSATION | DATE

ACTION TAKEN

SIGNATURE | TITLE | DATE

Ms. Gidget Watson
U.S. NRC
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Ms. Watson:

I hereby certify that Dr. Thomas J. Zekan meets the requirements set forth in the United States Nuclear Regulatory Commission's Rules and Regulations part 35, subsection 35.920. Dr. Zekan has completed at least 200 hours of classroom and laboratory training in the areas identified in section (b1), 500 hours of supervised work experience under supervision of an authorized user in the areas identified in section (b2) and 500 hours of supervised clinical experience under the supervision of an authorized user in the areas identified in section (b3).

The training and experience indicated above was obtained under the supervision of

John O. Olson, M.D.
450 W. 10th Avenue
Columbus, OH 43210
Materials License Number 34-00293-01

Signature John Olson Date Nov 22, 1996

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

September 11, 1996

John P. Ewonus, D.O.
Radiation Safety Officer
Defiance Hospital
1206 E. Second Street
Defiance, OH 43512

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 08/27/96)

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. 301818
License No. 34-15654-01