NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 11

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.

302225

Licensee	
1. Goshen General Hospital	In accordance with application dated January 9, 1997 3. License Number 13-18845-01 is amended in its entirety to read as follows:
2. 200 High Park Avenue Goshen, IN 46526	4. Expiration Date October 31, 2000
	5. Docket or Reference No. 030-14254

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. As needed (not to exceed 1 curie of I-131)
D. Any byproduct material identified in 10 CFR 35.500	D. Sealed sources identified in 10 CFR 35.500	D. As needed
E. Any byproduct material identified in 10 CFR 31.11	E. Prepackaged Kits	E. As needed

d1

COPY

SD

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
13-18845-01

Docket or Reference Number
030-14254

Amendment No. 11

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.

D. Medical use described in 10 CFR 35.500 in devices which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.

E. In vitro studies.

CONDITIONS

10. Location of Use: 200 High Park Avenue, Goshen, Indiana.

11. Radiation Safety Officer: John F. Maesaka, M.D.

12. Authorized Users:

A. G. Byington Pratt, M.D., for material in 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma).

B. John F. Maesaka, M.D., for material in 10 CFR 35.100, 35.200, 35.500, 31.11 and Iodine-131 for treatment of hyperthyroidism.

C. Richard F. Fox, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

13. In addition to the possession limits in Condition 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
13-18845-01

Docket or Reference Number
030-14254

Amendment No. 11

14. This license is based on the licensee's statements and representations listed below:

A. Applications dated May 30, 1990, August 2, 1993 and January 4, 1995; and

B. Letter received August 1, 1990.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 13 FEBRUARY 1997

By William P Reidbold
Nuclear Materials Licensing Branch, Region III

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 2B
Exp. Date: 20001031
Fee Comments:
Decom Fin Assur Reqd: N

R8

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: GOSHEN GENERAL HOSPITAL
   Received Date: 970121
   Docket No: 3014254
   Control No.: 302225
   License No.: 13-18845-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 440
   Check No.: 23084

3. COMMENTS

Signed D. Hersey
Date 1/29/97

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

1. Fee Category and Amount: (7C) 2B #440

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

3. OTHER

Signed SC
Date 1/29/97

FEB 10 1997

Log Jan. 10 III
Remitter
Check No. 23084
Amount #440
Fee Category (7C) 2B
Type of Fee Amend
Date Check Rec'd 1/28/97
Date Completed 1/29/97
By: SC

NRC FORM 313 (10-94)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

[redacted]

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-96
ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE ROAD
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

A
030-14254

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

___ A. NEW LICENSE
X B. AMENDMENT TO LICENSE NUMBER 13-18845-01
___ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

[redacted]

Goshen General Hospital
200 High Park Avenue
Goshen, IN 46526

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Same

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

David Close

TELEPHONE NUMBER 216-350-1242

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 7C

AMOUNT ENCLOSED $440.00

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
James O. Dague, President & CEO	James O. Dague	1/9/97

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
					Pm: 1-17-97
APPROVED BY				DATE	

RECEIVED
JAN 21 1997
REGION III

NRC FORM 313 (10-94)

30225 JAN 21 1997

The purpose of this amendment application is as follows:

1. We wish to name John F. Maesaka, M.D. as our Radiation Safety Officer. Dr. Maesaka is currently listed as an authorized user on our license.

2. We must delete David Barnes, M.D. from our license. Dr. Barnes passed away unexpectedly on [redacted] Dr. Maesaka has taken on the responsibilities of the RSO to assure continuity of the radiation safety program.

3. We wish to expand the authorizations for Dr. Maesaka to include the use of I-131 for treatment for hyperthyroidism. Dr. Maesaka has been involved with eleven hyperthyroid therapies under the supervision of Dr. Barnes from August 1993 through November 1996. Enclosed is documentation of these therapies. You will note Dr. Barnes has cosigned these forms along with Dr. Maesaka. Unfortunately, Dr. Barnes had not previously signed a preceptor form to document this supervision. As noted in our last Radiation Safety Committee meeting minutes (enclosed), we were just preparing to draft amendment documentation. We trust you appreciate the situation and will authorize Dr. Maesaka for these therapies.

Your prompt attention to this matter is appreciated.

Draft

GOSHEN GENERAL HOSPITAL

RADIATION SAFETY COMMITTEE MEETING

December 19,1996

PRESENT: Dr.Barnes,RSO; Staci Bobeck,Nursing; John Steele,Safety Officer; Charles Wilson,Administration; Lendel Burkey,Imaging Director; Greg Miller,CNMT

ABSENT: Claire Hochstedler,CNMT

I. Meeting was called to order at 9:07am by Greg Miller

II. The minutes were read and approved. Motion was made by John Steele and seconded by Charles Wilson.

III. Old Business

A. Code Brown

Discussion: Code procedures are being revised by the Hazardous Material Waste Subcommittee. Greg and Claire will participate in the revisions of Code Brown.

Follow-Up: None

B. 1500XP Acceptance

Discussion: NPC completed the acceptance testing on 10/31/96. Was found to be within the limits set by Picker International.

Follow-Up: None

C. In Service Fair

Discussion: The annual training for non-occupational personnel was held at the October,1996 Goshen General Hospital In Service Fair.

Follow-Up: None

IV. New Business

A. Report from NPC(David Close).

Discussion: Greg stated that Dave Close from NPC inspected the Nuclear Medicine Department,12/18/96. Everything was found to be in compliance and working well.

Follow-Up: None.

B. Revision of License

Discussion: Dave Close suggested that Dr.Fox and Dr.Pratt remain on the license until the end of March,1997, and then submit the letter to remove them stating due to retirement. This will allow for us to utilize them as fill in as needed until that time.

Follow-Up: Report at next meeting.

C. Cath Lab Policies

Discussion: Dave Close, reviewed the radiation policies for the cath lab and suggested some minor changes.(See attached paper). This includes implementing a declared pregnancy policy. Changes approved by committee.

Follow-Up:None.

D. Dr.Maesaka/Therapy doses of I-131

Discussion: Greg reported that Dr.John Maesaka has performed the required number of I-131 therapy doses under the supervision of Dr.Barnes, and is eligible to be placed on the license with an amendment. Motion was made and approved by the committee.

Follow-Up: Amendment to be made to license.

E. New Radiologist

Discussion; Dr.Barnes stated that a new radiologist will be joining the group in 1997. Will be added to the license after arriving in Goshen and documentation is received.

Follow-Up: New radiologist to be added to license after arrival in Goshen and documentation received.

F. Cath Lab Inspection

Discussion: Lendel reported the radiation safety inspection has been completed by a physicist. The label was fixed to the control panel.

Follow-Up: None.

V. Meeting was adjourned at 9:15am.

Gregory L Miller, CNMT

Gregory Miller,CNMT

Goshen General Hospital
Nursing Procedure Manual
Policy

Subject: Radiation Safety In The Cath Lab		**Approval Date:** 9/96	
Initiator: *Name:* Deb L. Kuitse *Title:* RN, IS Coordinator		**Approval:** *Name:* Colleen Trask *Title:* Director, Surgical Services	
Supersedes: Addendum S		**Review Date:** 12/94 **Revised Date:** 1/89, 7/91, 12/93	

Purpose: To outline the safety measures to be taken by staff participating in cath lab services.

Policy:

A. Non-essential persons leave the rooms when x-ray exposures are being made or fluoroscopy is being used.

B. The care group team moves as far away from the radiation field as is aseptically safe.

C. Cassette holding devices or appropriate leaded shields (aprons, glasses, gloves, thyroid shields) are used in or near the radiation field.

D. Females protect their reproductive organs from excessive exposure during child bearing years with proper shields and exposure not exceeding 0.5 Rems. (500 millirems) They may request a 2nd monitoring badge to wear on abdomen under the lead apron during a pregnancy. NCR recommends no more than 500 millirems of radiation during the entire pregnancy. Males use appropriate measures.

– OK

NRC

Implement declared pregnant radiation worker policy?

E. Monitoring badges are provided for any person desiring confirmation that rems/quarter is below the recommended level for safety.

1. Badge is placed on outside at neckline if an apron is worn.
2. Devices are sent in monthly for exposure readings.
3. Record of results are kept by the Director and a copy sent to Radiology.
4. A yearly report is received with a copy for each person wearing a badge.

F. Leaded devices are handled carefully and examined periodically to ascertain their effectiveness.

1. Aprons are hung and not folded, to prevent cracking.
2. Radiographic testing with documentation is done every 6 months to ascertain integrity of leaded devices. Results are in the PI manual.

G. Radiation safety is included in orientation and pregnant employees are reminded to stay away from field of exposure.

H. Any employee having additional questions beyond information already learned is encouraged to speak with the Radiation Safety Officer and/OR Surgical Services Director.

REVIEWED: 12/94
REVISED: 1/89, 7/91, 12/93

Draft

GOSHEN GENERAL HOSPITAL

RADIATION SAFETY COMMITTEE MEETING

December 24,1996

PRESENT: Dr.J.Maesaka; Charles Wilson,Administration; John Steele,Safety Officer; Pauline Arnold,Nursing; Lendel Burkey,Imaging Director; Greg Miller,CNMT.

ABSENT: Claire Hochstedler,CNMT; Staci Bobeck,Nursing.

I. Meeting was called to order by Greg Miller at 10:08am.

II. New RSO

Discussion: This emergency meeting was called to install Dr.John Maesaka as the new RSO to replace Dr.David Barnes due to his death on [redacted]. Motion was made by Charles Wilson and seconded by Greg Miller. Motion passed by the committee.

Follow-Up: None

III. Amendment to License

Discussion: An amendment is needed to place Dr.Maesaka on the license as RSO. Greg will start the paperwork to do this.

Follow-Up: Report at next meeting.

IV. RSO Training

Discussion: Training seminars are available for RSO's. Charles Wilson asked about dates for the seminars. Greg has information available regarding the seminars and will pass the information on to Dr. Maesaka. Dr.Maesaka said he has an interest in attending and would make arrangements for coverage in the department and also for call.

Follow-Up: None.

V. I-131 Thyroid Provider

Discussion: Dr.Maesaka stated that Dr.Fox is licensed for I-131 thyroid therapy. This will provide the coverage needed until Dr.Maesaka can be added to the license.

Follow-Up: None.

VI. Meeting adjourned at 10:15am.

Gregory L Miller, CNMT

Greg Miller,CNMT

[redacted] Goshen General HOSPITAL

NUCLEAR MEDICINE QUALITY MANAGEMENT FORM

(Therapeutic or Radioiodide Doses in Excess of 30 μCi)

Hospital Number: [redacted]

Patient Name: [redacted]

Location: Nuclear Medicine

Written Directive	Inpatient	Outpatient
Date		8-6-93
Radiopharmaceutical		I^{131}
Dose (millicurie)		10.34 mCi
Route of Administration		P.O.
Male ☐ Female ☒		
Pregnant?	Yes ☐ No ☐	Yes ☐ No ☒
Breast Feeding?	Yes ☐ No ☐	Yes ☐ No ☒
Signature (Authorized User)		[redacted]

Patient Confirmation	Check Two	Check Two
Name		[redacted]
Birthdate		4-11-21
Hospital I.D.		
Relative/Friend		
Wrist Band		
Before dosing, Confirm:		X
Followed Directive	Yes ☐ No ☐	Yes ☒ No ☐
After dosing, Confirm:		X
Radiopharmaceutical		I^{131}
Dose		10.34 mCi
Route of Administration		P.O
Signature		[redacted]
Date		8-6-93

PLACE LABELS HERE

Goshen HOSPITAL

NUCLEAR MEDICINE QUALITY MANAGEMENT FORM

(Therapeutic or Radioiodide Doses in Excess of 30 μCi)

Hospital Number: [redacted]

Patient Name: [redacted]

Location: Goshen GH Nuclear Medicine

Written Directive	Inpatient	Outpatient
Date		10-9-96
Radiopharmaceutical		131I Capsule [redacted] mCi
Dose (millicurie)		29.9 mC
Route of Administration		PO
Male ☒ Female ☐ Pregnant? Breast Feeding?	 Yes ☐ No ☐ Yes ☐ No ☐	 Yes ☐ No ☐ Yes ☐ No ☐
Signature (Authorized User)		John Macedia [signature]

Patient Confirmation	Check Two	Check Two
Name		[redacted]
Birthdate		2-9-63
Hospital I.D.		
Relative/Friend		
Wrist Band		

Before dosing, Confirm:		
Followed Directive	Yes ☐ No ☐	Yes ☐ No ☐

After dosing, Confirm:		
Radiopharmaceutical		I-131
Dose		29.0 mC
Route of Administration		PO
Signature		Gregory J Hill, CNMT
Date		10-10-96

[redacted]

PLACE LABELS HERE

Goshen HOSPITAL

NUCLEAR MEDICINE QUALITY MANAGEMENT FORM

(Therapeutic or Radioiodide Doses in Excess of 30 μCi)

Hospital Number: [redacted]

Patient Name: [redacted]

Location: Nuclear Medicine

Written Directive	Inpatient	Outpatient
Date		2/15/95
Radiopharmaceutical		^{131}I
Dose (millicurie)		9 mCi
Route of Administration		PO
Male☐ Female☑		
Pregnant?	Yes☐ No☐	Yes☐ No☑
Breast Feeding?	Yes☐ No☐	Yes☐ No☑
Signature (Authorized User)		[signature] John Marcella

Patient Confirmation	Check Two	Check Two
Name		[redacted]
Birthdate		✓ 8/31/60
Hospital I.D.		
Relative/Friend		
Wrist Band		

Before dosing, Confirm:		
Followed Directive	Yes☐ No☐	Yes☑ No☐

After dosing, Confirm:		
Radiopharmaceutical		^{131}I Cap
Dose		8.96 mCi
Route of Administration		PO
Signature		[signature]
Date		2-16-95

PLACE LABELS HERE [redacted]

Gasher HOSPITAL

NUCLEAR MEDICINE QUALITY MANAGEMENT FORM

(Therapeutic or Radioiodide Doses in Excess of 30 μCi)

Hospital Number: [redacted]

Patient Name: [redacted]

Location: Nuclear Medicine

Written Directive	Inpatient	Outpatient
Date		4-18-95
Radiopharmaceutical		131 I C.p
Dose (millicurie)		10 mCi
Route of Administration		PO
Male☐ Female☑		
Pregnant?	Yes☐ No☐	Yes☐ No☒
Breast Feeding?	Yes☐ No☐	Yes☐ No☒
Signature (Authorized User)		[signature]

Patient Confirmation	Check Two	Check Two
Name		[redacted]
Birthdate		✓ 8/31/66
Hospital I.D.		
Relative/Friend		
Wrist Band		

Before dosing, Confirm:		
Followed Directive	Yes☐ No☐	Yes☑ No☐

After dosing, Confirm:		
Radiopharmaceutical		131 I ~~10.40 mCi~~
Dose		10.40 mCi
Route of Administration		PO
Signature		[signature]
Date		4/18/95

PLACE LABELS HERE [redacted]

Goshen General HOSPITAL

NUCLEAR MEDICINE QUALITY MANAGEMENT FORM

(Therapeutic or Radioiodide Doses in Excess of 30 μCi)

Hospital Numbe [redacted]

Patient Name: [redacted]

Location: Goshen General Hospital 200 High Park Nuclear Medicine

Written Directive	Inpatient	Outpatient
Date		11-5-96
Radiopharmaceutical		131 I
Dose (millicurie)		29.9
Route of Administration		PO
Male☐ Female☒		
Pregnant?	Yes☐ No☐	Yes☐ No☒
Breast Feeding?	Yes☐ No☐	Yes☐ No☒
Signature (Authorized User)		[signature]

Patient Confirmation	Check Two	Check Two
Name		[redacted]
Birthdate		12-5-45
Hospital I.D.		
Relative/Friend		
Wrist Band		

Before dosing, Confirm:		
Followed Directive	Yes☐ No☐	Yes☑ No☐

After dosing, Confirm:		
Radiopharmaceutical		131 I Cap
Dose		28.7mCi
Route of Administration		PO
Signature		Gregory Hurst
Date		11-6-96

[redacted]

PLACE LABELS HERE

Goshen HOSPITAL

NUCLEAR MEDICINE QUALITY MANAGEMENT FORM

(Therapeutic or Radioiodide Doses in Excess of 30 μCi)

Hospital Number: [redacted]

Patient Name: [redacted]

Location: Nuclear Medicine Dept.

Written Directive	Inpatient	Outpatient
Date		9-11-96
Radiopharmaceutical		131 I Cap
Dose (millicurie)		10 mCi
Route of Administration		PO
Male ☐ Female ☒		
Pregnant?	Yes ☐ No ☐	Yes ☐ No ☒
Breast Feeding?	Yes ☐ No ☐	Yes ☐ No ☒
Signature (Authorized User)		[redacted]

Patient Confirmation	Check Two	Check Two
Name		[redacted]
Birthdate		9-3-45
Hospital I.D.		
Relative/Friend		
Wrist Band		
Before dosing, Confirm:		
Followed Directive	Yes ☐ No ☐	Yes ☑ No ☐
After dosing, Confirm:		
Radiopharmaceutical		131 I
Dose		9.91 mCi
Route of Administration		PO
Signature		[redacted]
Date		9-11-96

PLACE LABELS H[redacted]

Goshen HOSPITAL

NUCLEAR MEDICINE QUALITY MANAGEMENT FORM

(Therapeutic or Radioiodide Doses in Excess of 30 μCi)

Hospital Number: [redacted]

Patient Name: [redacted]

Location: Nuclear Medicine Dept

Written Directive	Inpatient	Outpatient
Date		10-17-96
Radiopharmaceutical		131 I Cap
Dose (millicurie)		29.9 mCi
Route of Administration		PO
Male ☒ Female ☐		
Pregnant?	Yes ☐ No ☐	~~Yes ☐~~ ~~No ☐~~
Breast Feeding?	Yes ☐ No ☐	~~Yes ☐~~ ~~No ☐~~
Signature (Authorized User)		John F Massaka, Brenda Brown

Patient Confirmation	Check Two	Check Two
Name		[redacted]
Birthdate		12-4-44
Hospital I.D.		
Relative/Friend		
Wrist Band		

Before dosing, Confirm:		
Followed Directive	Yes ☐ No ☐	Yes ☑ No ☐

After dosing, Confirm:		
Radiopharmaceutical		131 I Cap
Dose		29.4 mCi
Route of Administration		PO
Signature		Gregg J Mill
Date		10-18-96

PLACE LABELS HERE [redacted]

Goshen HOSPITAL

NUCLEAR MEDICINE QUALITY MANAGEMENT FORM

(Therapeutic or Radioiodide Doses in Excess of 30 μCi)

Hospital Number: [redacted]
Patient Name: [redacted]
Location: [redacted]

Written Directive	Inpatient	Outpatient
Date /		4-16-96
Radiopharmaceutical		^{131}I Capsule
Dose (millicurie)		29.5 mCi
Route of Administration		PO
Male☐ Female☑		
Pregnant?	Yes☐ No☐	Yes☐ No☑
Breast Feeding?	Yes☐ No☐	Yes☐ No☑
Signature (Authorized User)		John F. Morabito

Patient Confirmation	Check Two	Check Two
Name		[redacted]
Birthdate		12-2-20
Hospital I.D.		
Relative/Friend		
Wrist Band		
Before dosing, Confirm:		
Followed Directive	Yes☐ No☐	Yes☑ No☐
After dosing, Confirm:		
Radiopharmaceutical		^{131}I Tx
Dose		29.3 mCi
Route of Administration		PO
Signature		Gregg J Miller
Date		4-17-96

PLACE LABELS HERE [redacted]

Goshen HOSPITAL

NUCLEAR MEDICINE QUALITY MANAGEMENT FORM

(Therapeutic or Radioiodide Doses in Excess of 30 μCi)

Hospital Number: [redacted]
Patient Name: [redacted]
Location:

Written Directive	Inpatient		Outpatient	
Date			8-14-96	
Radiopharmaceutical			131I Cap	
Dose (millicurie)			29 mCi	
Route of Administration			PO	
Male☐ Female☒				
Pregnant?	Yes☐	No☐	Yes☐	No☒
Breast Feeding?	Yes☐	No☐	Yes☐	No☒
Signature (Authorized User)			[signature] [signature]	

Patient Confirmation	Check Two	Check Two
Name		✓
Birthdate		✓
Hospital I.D.		
Relative/Friend		
Wrist Band		

Before dosing, Confirm:				
Followed Directive	Yes☐	No☐	Yes☑	No☐

After dosing, Confirm:		
Radiopharmaceutical		131I (28.2 mCi)
Dose		28.2 mCi
Route of Administration		PO
Signature		[signature], CNMT
Date		8-15-96

PLACE LABELS HERE [redacted]

IODINE THERAPY CONSENT FORM

[redacted] _____

(Patient's Name) (Address)

certify that I agree to treatment of thyroid disorder by means of radioactive Iodine therapy. Alternative forms of therapy by medicine and surgery have been thoroughly discussed with me by a radiologist.

The risks and benefits of such therapy have been explained and I realize the potential of becoming hypothyroid because of this type of treatment and the possible need to take thyroid replacement therapy.

[redacted]

(Patient's Signature)

Date: 9-27-93

(Physician's Signature)

Goshen Gen HOSPITAL

NUCLEAR MEDICINE QUALITY MANAGEMENT FORM

(Therapeutic or Radioiodide Doses in Excess of 30 μCi)

Hospital Number: [redacted]

Patient Name: [redacted]

Location: Nuc Med

Written Directive	Inpatient	Outpatient
Date		9-27-93
Radiopharmaceutical		131 I
Dose (millicurie)		10.07 mCi
Route of Administration		PO
Male ☐ Female ☒		
Pregnant?	Yes ☐ No ☐	Yes ☐ No ☒
Breast Feeding?	Yes ☐ No ☐	Yes ☐ No ☒
Signature (Authorized User)		[signature]

Patient Confirmation	Check Two	Check Two
Name		[redacted]
Birthdate		11-30-47
Hospital I.D.		
Relative/Friend		
Wrist Band		
Before dosing, Confirm:		
Followed Directive	Yes ☐ No ☐	Yes ☒ No ☐
After dosing, Confirm:		
Radiopharmaceutical		✓ 131 I Cap
Dose		✓ 10.07 mCi
Route of Administration		✓ PO
Signature		[signature]
Date		9/27/93

PLACE LABELS HERE

Goshen HOSPITAL

NUCLEAR MEDICINE QUALITY MANAGEMENT FORM

(Therapeutic or Radioiodide Doses in Excess of 30 μCi)

Hospital Number: [redacted]

Patient Name: [redacted]

Location: GGH / Nuclear Medicine

Written Directive	Inpatient	Outpatient
Date		12-12-95
Radiopharmaceutical		131I Cap
Dose (millicurie)		151.2 μCi
Route of Administration		PO
Male☐ Female☒		
Pregnant?	Yes☐ No☐	Yes☐ No☒
Breast Feeding?	Yes☐ No☐	Yes☐ No☒
Signature (Authorized User)		John Macsata

Patient Confirmation	Check Two	Check Two
Name		[redacted]
Birthdate		6-11-54
Hospital I.D.		
Relative/Friend		
Wrist Band		

Before dosing, Confirm:		
Followed Directive	Yes☐ No☐	Yes☒ No☐

After dosing, Confirm:		
Radiopharmaceutical		131I Cap
Dose		151.2 μCi
Route of Administration		PO
Signature		Gregory J Mitt
Date		12-12-95

PLACE LABELS HERE

FEB 13 1997

James O. Dague
President and CEO
Goshen General Hospital
200 High Park Avenue
Goshen, In 46526

Dear Mr. Dague:

Enclosed is Amendment No. 11 to your NRC Material License No. 13-18845-01 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 regulation (10 CFR 30.36).

Also note, we have removed the license condition requiring decommissioning records because this requirement is in the regulations, and the license condition authorizing depleted uranium.

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).

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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,

W. P. Reichhold
Nuclear Materials Licensing Branch

License No.: 13-18845-01
Docket No.: 030-14254

Enclosure: Amendment No. 11

DOCUMENT NAME: M:\03014254.CL7
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OFFICE	DNMS/RIII									
NAME	WREICHHOLD:jaw									
DATE	02/ /97									

OFFICIAL RECORD COPY

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

January 23, 1997

John F. Maesaka, M.D.
Radiation Safety Officer
Goshen General Hospital
200 High Park Avenue
Goshen, IN 46526

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Application Dated 01/09/97)

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. 302225
License No. 13-18845-01