VOID SHEET

TO: License Fee Management Branch

FROM: RIII - COLLEEN CASEY

SUBJECT: VOIDED APPLICATION

Control Number: 399909

Applicant: MISSOURI REHABILITATION CENTER

License Number: 24-18732-01

Docket Number: 030-14103

Date Voided: 7/12/96

Reason for Void: Licensee requested termination of the license. Action was voided prior to review.

Colleen C. Casey 7/12/96
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

✓ Refund Authorized and processed

___ No Refund Due

___ Fee Exempt or Fee Not Required

Comments: _____

Log completed ✓

Processed by: SAC 8/26/96

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02121
STATUS CODE: 2
FEE CATEGORY: 7C
EXP. DATE: 19950630
FEE COMMENTS: MOBILE NUC MED SUB TO
DECOM FIN ASSUR REQD: N

1996 FEB 15 AM 11:08

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MISSOURI REHABILITATION CENTER
RECEIVED DATE: 960207
DOCKET NO: 3014103
CONTROL NO.: 399909
LICENSE NO.: 24-18732-01
ACTION TYPE: AMENDMENT

56

2. FEE ATTACHED
AMOUNT: 500
CHECK NO.: 110567

3. COMMENTS

SIGNED D. Hersey
DATE 2-15-96

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 JC
DATE 2/15/96

Log Feb 8 III
Remitter
Check No. 110567
Amount $500 ($430)
Fee Category 7C
Type of Fee AMD
Date Check Rec'd 2/15/96
Date Completed
By: JC

RECEIVED
FEB 28 1996
REGION III

DIVISION OF ACCOUNTING AND FINANCE
REQUEST FOR REFUND TO EMPLOYEE/VENDOR

THE EMPLOYEE/VENDOR IDENTIFIED BELOW HAS OVERPAID THE NUCLEAR REGULATORY COMMISSION FOR GOODS AND/OR SERVICES PROVIDED AND IS DUE A REFUND

EMPLOYEE/VENDOR/PAYEE CODE: _____

NAME: Springfield Clinic

ADDRESS: Attn: Sister Mary Katheryn Slaughter, RN

ADDRESS: 1235 E. Cherokee

CITY: Springfield STATE: MO ZIP: 65804

TRANS CODE: PX

TRANS TYPE: FE	FUND: X5280	JOB CODE:	AMOUNT: $70.00
TRANS TYPE: IR	FUND: R1435	JOB CODE: INTR	AMOUNT:
TRANS TYPE: IR	FUND: R1099	JOB CODE: ADCH	AMOUNT:
TRANS TYPE: IR	FUND: R1099	JOB CODE: FINE	AMOUNT:

TOTAL REFUND AMOUNT: $70

COMMENTS: Lic 24-18732-01 1/31/96 AMD Rqst CK. 110567

(limit comments to 40 characters, including spaces)

PREPARED BY: Shirley Crutchfield DATE: February 20, 1996

AUTHORIZED BY: [signature] DATE: 2/21/96

ORIGINAL INV. NO: _____ DATE PAID: _____ AMOUNT: _____

REFUND ENTERED INTO COLLECT BY: _____

REFUND DETERMINED BY: _____ DATE: _____

PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION

Feb BIII 7C ($430) 110567 $500 AMD 399909

Springfield Clinic
A Division of St. John's Health System, Inc.

Debra M. Barnhart, M.P.H.
Vice President

January 31, 1995

Licensing Division
Nuclear Regulatory Commission
801 Warrenville Road
Lisle, IL 60532-4351

RE: By-product Materials License Number 24-18732-01

Dear Sir:

Please amend the above by-product materials license as noted below:

We wish to add to our by-product use the therapeutic administration of I-131 for hyperthyroidism limited to doses under 30 mCi. In this end, we have enclosed the following:

1. The documents necessary to qualify Dr. Michael R. Fancher as an authorized user for material in 10 CFR 35.300 limited to I-131 for hyperthyroidism. This includes his original preceptorship form from Oakwood Hospital showing his experience with 31 cases in 1987. In addition, as second preceptor statement, supplement B showing involvement with two additional cases in 1996 as the past training was not within the five year limit.

2. We have enclosed our Quality Management program to be added to the terms of our license.

3. Please amend our authorized use list to include 10.CFR 35.300 limited to hyperthyroidism. We will use unit doses in capsule form only.

4. A check for $500.

Sincerely,

Debra Barnhart

Debra M. Barnhart
Vice President

DMB:kdk

Enc.

1900 S. National, Suite 3650, North Wing • Springfield, Missouri 65804 • 417-841-3516 • FAX 417-841-3520

Springfield Clinic
Smith-Glynn-Callaway Branch

A Division of St. John's Health System, Inc.

Department of Nuclear Medicine

STATEMENT OF AUTHORIZATION

The policies and procedures of this Quality Management Program have been developed by Springfield Clinic Smith-Glynn-Callaway Branch, a division of St. John's Health System, Inc. in accordance with the requirements of 10CFR part 35.32 of the Nuclear Regulatory Commission and form an addition to the Clinic's By-Products Materials License Number 24-26278-01.

The following members of the Radiation Safety Committee have reviewed and approved this program:

Don Myers — 1/30/96
Radiation Safety Officer — *Date*

Debra M. Barnhart — 1/29/96
Representative of Clinic Administration — *Date*

Carolyn Baker — 1-31-96
Nuclear Medicine Supervisor — *Date*

Springfield Clinic
A Division of St. John's Health System, Inc.
Smith-Glynn-Callaway Branch

01/29/96

TO WHOM IT MAY CONCERN:

I have recently participated in two cases for the treatment of hyperthyroidism with Iodine-131. For these cases, I precepted with Steven Long, MD at St. John's Regional Health Center in Springfield, Missouri. These were "refresher" cases which are in addition to the 31 cases I was involved in during residency training from 1984 through 1987 at Oakwood Hospital in Dearborn, Michigan (see enclosed preceptor statement from St. John's Regional Health Center and from Oakwood Hospital).

I witnessed the two recent cases with Dr. Steven Long from beginning to end, that is, from the evaluation of the patients' laboratory testing as well as review of the thyroid uptake and imaging as well as witnessing the discussion of Dr. Long with the patients in regards to their disease state, possible complications, and expectations. I also witnessed the administration of the radioisotope to the patient in the nuclear department at St. John's Regional Health Center. One of the recent cases involved a patient with toxic multinodular goiter. The other case involved a young woman whose thyroid was relatively radioresistant and who had severe Grave's disease with exophthalmus and who was being treated for the third time.

I will be happy to provide any additional information in regards to past and recent training as it applies to radioiodine treatment for hyperthyroidism if requested.

Sincerely,

Michael R. Fancher

Michael R. Fancher, MD
Radiologist

djd/01/29/96 2:49 P

NRC-313M-SUPPLEMENT B

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. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME
Michael Riley Fancher, M.D.

STREET ADDRESS
2200 Varney

CITY | STATE | ZIP CODE
Neosho | MO | 64850

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope 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 in duplicate on separate sheet.) D
I-123 I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	210	Thyroid Uptake
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES (Tc-99m)	87	Renal, renogram, cystogram
	IN VITRO STUDIES		
OTHER	Ga-67; In-111 WCB labeling	91	Abscess, tumor; abscess localization
Tc-99m MAA I-125	DETECTION OF THROMBOSIS	195	Venogram and lung scan
I-123 I-131	THYROID IMAGING	220	Thyroid Scan (I-123) & Total Body Imaging(I-1
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
In-DTPA Yb-169	CISTERNOGRAPHY	9	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	260	Lung Ventilation Study
OTHER	angiogram	11	
Tc-99m	BRAIN IMAGING	151	
	CARDIAC IMAGING	1047	MUGA, myocardial and Tl-201
	THYROID IMAGING Tc 99m	3	
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	819	Including hepatobiliary
	LUNG IMAGING	534	
	BONE IMAGING	1099	
OTHER	Testicular; GI Bleed; Parathyroid; 31; 22; 2; 1; 2; 9 Joint Scan; Parathyroid Meckel's		

AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Michael Riley Fancher, M.D.	MI, MO

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Diagnostic Radiology passed written portion 10/86 oral section to be repeated 5/88		

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Oakwood Hopsital Dearborn, MI July 1983 - June 1987	100	5
b. RADIATION PROTECTION	"	30	5
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	20	5
d. RADIATION BIOLOGY	"	20	5
e. RADIOPHARMACEUTICAL CHEMISTRY	"	30	5

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
67Ga	5mCi	Oakwood Hospital	July 1983-June 1987	Gallium Scan
111 In	.5	Oakwood Hospital	July 1983-June 1987	Cisternogram & WBC label
123 I	.4	Oakwood Hospital	July 1983-June 1987	Thyroid Scan in
131 I	150	Oakwood Hospital	July 1983-June 1987	Therapy
32 P	5	Oakwood Hospital	July 1983-June 1987	Therapy
99m Tc	20	Oakwood Hospital	July 1983-June 1987	Bone,liver,RBC labeling,
201 TI	2	Oakwood Hospital	July 1983-June 1987	Thallium Scan venogram
133 Xe	15	Oakwood Hospital	July 1983-June 1987	Ventilation Scan

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 (Sodium)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	5	
P-32 (Colloidal)	INTRACAVITARY TREATMENT	0	
I-131	TREATMENT OF THYROID CARCINOMA	5	
	TREATMENT OF HYPERTHYROIDISM	31	
Au-198	INTRACAVITARY TREATMENT	0	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	0	
	INTRACAVITARY TREATMENT	0	
I-125 or Ir-192	INTERSTITIAL TREATMENT	0	
Co-60 or Cs-137	TELETHERAPY TREATMENT	0	
Sr-90	TREATMENT OF EYE DISEASE	0	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	5	
Sn-113/ In-113m	GENERATOR	0	
Tc-99m	REAGENT KITS	5	
Other	I 131 - total body	10	
	Therapy Eval	16	

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

September 1984 — September 1985 — October 1986
October 1984 — November 1985 — May 1987 — Total Hours = 1200
April 1985 — September 1986

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

a. NAME OF SUPERVISOR: Reza Abghari, M.D.

b. NAME OF INSTITUTION: Oakwood Hospital

c. MAILING ADDRESS: 18101 Oakwood Blvd., P.O. Box 2500

d. CITY: Dearborn, MI 48123-2500

5. MATERIALS LICENSE NUMBER(S): 21-04515-01

6. PRECEPTOR'S SIGNATURE: R. Abghari

7. PRECEPTOR'S NAME (Please type or print): Reza Abghari, M.D.

8. DATE: June 30, 1987

PROPOSED PHYSICIAN USER

Michael Riley Fancher, 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		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM	2	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

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

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
St. John's Regional Health Center	1/25/96	1
St. John's Regional Health Center	1/29/96	1

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

a. NAME OF SUPERVISOR: Stephen Long M.D.

b. NAME OF INSTITUTION: St. John's Regional Health Center

c. MAILING ADDRESS: 1235 E. Cherokee, Springfield, MO 65804

d. CITY

5. MATERIALS LICENSE NUMBER(S): 24-00866-02

6. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME (Please type or print): Stephen Long, M.D.

8. DATE: 1/29/96

SPRINGFIELD CLINIC
POLICY & PROCEDURE GUIDELINES

DEPARTMENT: NUCLEAR MEDICINE **PROCEDURE NO.:** 5681.3290

DATE: January 17, 1996 **PAGE:** 1 of 1

APPROVED BY: Debra M Barnhart **DISTRIBUTION:** _____

APPROVED BY: _____

SUBJECT: RECORD OF ADMINISTERED DOSAGE (Re: 10CFR part 35.32 (d)(2))

I. STATEMENT OF POLICY:

A. A record of the administered dosage will be maintained for a minimum of three (3) years.

II. PROCEDURE:

A. An authorized user or a qualified person working under the supervision of an authorized user, after administering I-131 capsules greater than 30 uCi, will complete and sign a written record to document information pertaining to the administered dosage. This record will contain administered dose, patient name, patient chart number, method of dual identification, method of confirmation of non-pregnancy (*if appropriate*), time of administration, and the name of the technologist or physician who administered the dose.

B. This record will be maintained for a minimum of three (3) years.

C. The form we intend to use is attached.

I-131 ADMINISTRATION FOR HYPERTHYROID THERAPY

PHYSICIAN DIRECTIVE

Patient Name: _____

DOB: _____ Secondary ID: _____

SSN, Chart #, Ins. Card, etc.

Prescribed I-131 Activity _____ mCi capsule given orally.

Is confirmation required that the patient is not pregnant? Yes No

_____ _____

Authorized User *Date*

PATIENT IDENTIFICATION

Patient Name: _____

DOB: _____ Secondary ID: _____

SSN, Chart #, Ins. Card, etc.

Method of Non-Pregnancy Confirmation _____

(attach form if applicable) _____

Technologist or Physician *Date* *Time*

Dose Assay:

I-131 Activity _____ mCi in capsule form given orally (within 10% of prescribed).

Dose Assayed by _____

Date *Time*

Dose Administered by _____

Date *Time*

QUALITY MANAGEMENT REVIEW

Is written directive complete? Yes No Correct? Yes No

Is secondary ID complete? Yes No Correct? Yes No

Difference in prescribed and administered dose. _____ MCI _____ %

Is the difference within +/- 10% limit? Yes No

Reviewed by _____

Date *Time*

#5681.3290

SPRINGFIELD CLINIC
POLICY & PROCEDURE GUIDELINES

DEPARTMENT: NUCLEAR MEDICINE **PROCEDURE NO.:** 5681.3260

DATE: January 17, 1996 **PAGE:** 1 of 1

APPROVED BY: Debra M Barnhart **DISTRIBUTION:** _____

APPROVED BY: _____

SUBJECT: PATIENT IDENTIFICATION (Required by 10CFR part 35.32 (a)(2))

I. STATEMENT OF POLICY:

A. Before administering any radionuclide therapy or other I-131 sodium iodide greater than 30 uCi, the identity of the patient named in the written directive will be verified by at least two (2) methods.

II. PROCEDURE:

A. The procedure used to identify the patient is to ask the patient's name and confirm it and then ask and compare at least one of the following:

1. Birth Date
2. Address
3. Social Security Number
4. Signature
5. Name on Patient's I.D. Card
6. Insurance Card
7. Driver's License.

B. If the patient is not able to respond with their name, two other methods will be used.

SPRINGFIELD CLINIC
POLICY & PROCEDURE GUIDELINES

DEPARTMENT: NUCLEAR MEDICINE **PROCEDURE NO.:** 5681.3260

DATE: January 17, 1996 **PAGE:** 1 of 1

APPROVED BY: Debra M. Barnhart **DISTRIBUTION:** _____

APPROVED BY: Don Weyeard

SUBJECT: PATIENT IDENTIFICATION (Required by 10CFR part 35.32 (a)(2))

I. STATEMENT OF POLICY:

A. Before administering any readionuclide therapy or other I-131 sodium iodide greater than 30 uCi, the identity of the patient named in the written directive will be verified by at least two (2) methods.

II. PROCEDURE:

A. The procedure used to identify the patient is to ask the patient's name and confirm it and then ask and compare at least one of the following:

1. Birth Date
2. Address
3. Social Security Number
4. Signature
5. Name on Patient's I.D. Card
6. Insurance Card
7. Driver's License.

B. If the patient is not able to respond with their name, two other methods will be used.

SPRINGFIELD CLINIC
POLICY & PROCEDURE GUIDELINES

DEPARTMENT: NUCLEAR MEDICINE **PROCEDURE NO.:** 5681.3235

DATE: January 17, 1996 **PAGE:** 1 of 1

APPROVED BY: Debra M. Barnhart **DISTRIBUTION:** _____

APPROVED BY: Don Myeard

SUBJECT: ORAL DIRECTIVES and REVISIONS to WRITTEN DIRECTIVES

I. STATEMENT OF POLICY:

A. The policy contained in the footnote to 10CFR part 35.32 (a)(1) will be implemented.

II. PROCEDURE:

A. "If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

B. "Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

C. "If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's records and a written directive is prepared within 24 hours of the oral directive."

SPRINGFIELD CLINIC
POLICY & PROCEDURE GUIDELINES

DEPARTMENT: NUCLEAR MEDICINE **PROCEDURE NO.:** 5681.3395

DATE: January 17, 1996 **PAGE:** 1 of 1

APPROVED BY: Debra M Barnhart **DISTRIBUTION:** _____

APPROVED BY: [signature]

SUBJECT: VERIFICATION OF TREATMENT (Re: 10CFR part 35.32 (a)(4))

I. STATEMENT OF POLICY:

A. Procedures shall be implemented to verify specific details of administration of I-131 sodium iodide (*greater than 30 uCi*) in accordance with the written directive. The radiopharmaceutical, dosage, and route of administration shall be confirmed by the person administering the I-131 to verify agreement with the written directive.

II. PROCEDURE:

A. The I-131 capsule will be assayed in the dose calibrator. The measured activity will then be compared with the prescribed dosage in the written directive. The measured dose must be within ±10% of the prescribed dose or, for doses under 150 uCi, within 15 uCi of the prescribed dose.

B. The radiopharmaceutical, measured dose, time of administration, and technologist administering the dose will be recorded.

C. These records will be kept for a minimum of three (3) years.

SPRINGFIELD CLINIC
POLICY & PROCEDURE GUIDELINES

DEPARTMENT: NUCLEAR MEDICINE **PROCEDURE NO.:** 5681.3300

DATE: January 17, 1996 **PAGE:** 1 of 2

APPROVED BY: Debra M Barnhart **DISTRIBUTION:** _____

APPROVED BY: Don Meyer

SUBJECT: REVIEW of the RADIOPHARMACEUTICAL QUALITY MANAGEMENT PROGRAM (Re: 10CFR part 35.32 (b)(1,2))

I. STATEMENT OF POLICY:

A. The Quality Management Program (**QMP**) will be reviewed at least annually.

II. PROCEDURE:

A. The QMP review will include all patient administrations of I-131 sodium iodide greater than 30 uCi and all other therapeutic administrations, all recordable events, and all misadministrations and will be conducted at least annually.

B. The review will include the following for each patient:

1. Comparison of the prescribed and the administered dose to determine if the administered was within ±10% of the prescribed.

2. If the dose was not within ±10% of the prescribed, it will be determined if a recordable event or misadministration occurred.

3. Was the route of administration as prescribed?

4. Was the patient properly identified?

C. If any deviations from the written directive occurred, the cause of the deviation and future preventative action will be reviewed.

D. Whenever possible the persons conducting the review will not review their own work. If this is not possible, then two people will work as a team to conduct the review. The Radiation Safety Committee will review the findings of the periodic reviews during the annual ALARA review to ensure the effectiveness of the QMP.

E. After each annual review, the QMP will be reevaluated to determine whether changes need to be made to make the program more effective. If no deficiencies are found, the program will be considered effective. If deficiencies are found, the policies and/or procedures will be revised to prevent recurrence of the problems.

F. Additional personnel training or increased supervisory participation may be implemented.

G. Corrective action will be implemented within a reasonable time after the deficiency is identified.

H. The program review will be documented and available for regulatory inspection. These records will be kept for a minimum of three years.

SPRINGFIELD CLIN[illegible]
POLICY & PROCEDURE GUIDELINES

DEPARTMENT: NUCLEAR MEDICINE **PROCEDURE NO.:** 5681.3435

DATE: January 17, 1996 **PAGE:** 1 of 1

APPROVED BY: Debra M. Barnhart **DISTRIBUTION:** _____

APPROVED BY: [signature]

SUBJECT: WRITTEN DIRECTIVE (Required by 10CFR part 35.32 (a)(1))

I. STATEMENT OF POLICY:

A. This Clinic will require a written directive for each patient who receives I-131 sodium iodide in quantities greater than 30 microcuries. This directive will be signed and dated by an authorized user prior to administration to that specific patient.

II. PROCEDURE:

A. The referring physician will write a prescription for each specific patient for every therapy administration.

1. The order must contain:
   a) Patient's Name
   b) Patient's Chart Number
   c) Patient's Age
   d) Pertinent Clinical Information
   e) Physician's Name and Signature
   f) Date.

B. An authorized user shall review the referring physician's order and clinical information. Should any questions arise, the authorized user will contact the referring physician for clarification.

C. An authorized user shall determine the prescribed dosage to be administered. This dosage, the date, the patient's name, method of identification and the authorized user's signature must be recorded on a written directive.

D. The written directive will accompany the patient requisition and be present when the technologist orders and measures the dose.

E. Prior to administration, the technologist will identify the patient by the name and other identification noted on the written directive. Administration will proceed according to the written directive.

F. The written directive will be kept available for audit for a minimum of three (3) years.

SPRINGFIELD CLINIC
POLICY & PROCEDURE GUIDELINES

DEPARTMENT: NUCLEAR MEDICINE **PROCEDURE NO.:** 5681.3335

DATE: January 17, 1996 **PAGE:** 1 of 1

APPROVED BY: Debra M Barnhart **DISTRIBUTION:** _____

APPROVED BY: Ron Weyeart

SUBJECT: SEEKING GUIDANCE on the WRITTEN DIRECTIVE, (Re: 10CFR part 35.32, Regulatory Position 1)

I. STATEMENT OF POLICY:

A. Any technologist carrying out orders of a written directive must seek guidance if they do not understand every detail of the procedure.

II. PROCEDURE:

A. Any technologist carrying out a written directive or administering any radiopharmaceutical should ask their supervisor or authorized user for instructions if they do not fully understand the details of the procedure.

B. The technologist should not proceed to administer any dose of radioactive material if any questions remain concerning the dose or the procedure.

C. The Clinic Administration will provide adequate time to correctly perform the procedures, to seek guidance if needed, and to keep appropriate records.

SPRINGFIELD CLINIC
POLICY & PROCEDURE GUIDELINES

DEPARTMENT: NUCLEAR MEDICINE **PROCEDURE NO.:** 5681.3295

DATE: January 19, 1996 **PAGE:** 1 of 1

APPROVED BY: Debra M Barghaus **DISTRIBUTION:** _____

APPROVED BY: Jon Meyers

SUBJECT: RESPONSE to a RECORDABLE EVENT (Re: 10CFR part 35.32 (c))

I. STATEMENT OF POLICY:

A. The clinic will evaluate and respond, within 30 days after the discovery of a recordable event, to each recordable event by:

1. Assembling the relevant facts, including the cause.
2. Identifying what, if any, corrective action is required to prevent recurrence.
3. Retaining a record, in auditable form, for three (3) years, of the relevant facts and what corrective action, if any, was taken.

II. PROCEDURE:

A. Upon discovery of a recordable event, the technologist must notify his/her supervisor or an authorized user. Within 30 days of the discovery, an investigation will be performed. The relevant facts, including the cause, will be assembled. The proper corrective action, if any, will be determined and measures will be taken to prevent recurrence, if necessary. Records of the above mentioned information will be kept for at least three (3) years for review by regulatory agencies.

SPRINGFIELD CLINIC
POLICY & PROCEDURE GUIDELINES

DEPARTMENT: NUCLEAR MEDICINE **PROCEDURE NO.:** 5681.3205

DATE: January 19, 1996 **PAGE:** 1 of 1

APPROVED BY: Debra M Barnhart **DISTRIBUTION:** _____

APPROVED BY: Tom Weyeart

SUBJECT: MODIFICATIONS to the QUALITY MANAGEMENT PROGRAM (QMP) (Re: 10CFR part 35.32 (e))

I. STATEMENT OF POLICY:

A. The Clinic will notify the NRC of any modification to the QMP within 30 days after the modification has been made.

II. PROCEDURE:

When any modification is made to the QMP, the NRC will be notified in writing within 30 days after the implementation of the modification. Any pertinent change in recording methods or modifications of the QMP forms will be included in the notification to the NRC.

DIVISION OF ACCOUNTING AND FINANCE
REQUEST FOR REFUND TO EMPLOYEE/VENDOR

THE EMPLOYEE/VENDOR IDENTIFIED BELOW HAS OVERPAID THE NUCLEAR REGULATORY COMMISSION FOR GOODS AND/OR SERVICES PROVIDED AND IS DUE A REFUND

EMPLOYEE/VENDOR/PAYEE CODE: _____

NAME: Springfield Clinic

ADDRESS: Attn. Debra M. Barnhart, Vice President

ADDRESS: 1900 S. National Suite 3650 North Wing

CITY: Springfield STATE: MO ZIP: 65804

TRANS CODE: PX

TRANS TYPE: FE	FUND: X5280	JOB CODE: _____	AMOUNT: $430.00
TRANS TYPE: IR	FUND: R1435	JOB CODE: INTR	AMOUNT: _____
TRANS TYPE: IR	FUND: R1099	JOB CODE: ADCH	AMOUNT: _____
TRANS TYPE: IR	FUND: R1099	JOB CODE: FINE	AMOUNT: _____

TOTAL REFUND AMOUNT: $430.00

COMMENTS: Lic 24-18732-01/CK 110567/RFND 7/31/95 Reg

(Limit comments to 40 characters, including spaces)

PREPARED BY: Shirley Crutchfield DATE: August 28, 1996

AUTHORIZED BY: [signature] DATE: 8/28/96

ORIGINAL INV. NO: _____ DATE PAID: _____ AMOUNT: _____

REFUND ENTERED INTO COLLECT BY: _____

REFUND DETERMINED BY: _____ DATE: _____

Feb 8 III
CK. 110567 $500
Refund #70 2/21/96
TC AmD #430

PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION

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