VOID SHEET

TO: License Fee Management Branch

FROM: RIII - James R. Mullauer

SUBJECT: VOIDED APPLICATION

Control Number: 305159

Applicant: Mercy Medical Center

License Number: 34-01954-01

Docket Number: 030-02694

Date Voided: 5/25/99

Reason for Void: No changes are being made to the license dispite the change of ownership, therefore, no amendment is necessary.

Jim Mullauer 5/25/99
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: 030-18 Log completed √

Processed by: SAC 6/1/99

9906100101 990525
PDR ADOCK 03002694
C PDR

ML30
JAW

R4

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: 20041031
Fee Comments: CODE 21
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: MERCY MEDICAL CENTER
   Received Date: 19990416
   Docket No: 3002694
   Control No.: 305159
   License No.: 34-01954-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 0
   Check No.: ---

3. COMMENTS

Signed D. Hersey
Date 4-30-99

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone has been entered /)

1. Fee Category and Amount: 7C 2B FEE NOT REQUIRED

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

3. OTHER ---

Signed SC
Date 4/22/99

Log APR B III
Remitter
Check No.
Amount
Fee Category 7C 2B
Type of Fee AMD
Date Check Rec'd 4/22/99
Date Completed 4/22/99
By: SC

MERCY MEDICAL CENTER
A Ministry of the Sisters of Charity of St. Augustine

DIAGNOSTIC RADIOLOGISTS
D. W. Spriggs, M.D., F.A.C.R., Chairman
D. H. Bang, M.D.
T. J. Barbush, M.D.
L. A. Cawthon, M.D.
M. DeGalan, M.D., Ph.D.
B. McNulty, M.D.
W. D. Murphy, M.D.
D. L. Pretorius, M.D.
J. N. Rauchenstein, M.D.
R. E. Reaven, M.D.

Department of Radiology
ADMINISTRATIVE DIRECTOR
S. L. Spearing, R.T. (R)

RADIATION ONCOLOGISTS
C. V. Rozenbom, M.D., Director
M. R. Puterbaugh, M.D.
P. A. Schneider, M.D.
P. B. Hardin, M.D.

RADIATION BIOPHYSICISTS
D. E. Starchman, Ph.D., F.A.C.R.
W. R. Hedrick, Ph.D.
L. Milavickas, Ph.D.
P. R. Diltz, Ph.D.
D. L. Hykes, Ph.D.
P. N. Shaheen, M.S.
M. Lafont, M.MSC.

April 12, 1999

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

Dear Sir:

This constitutes notification that Mercy Medical Center, Canton, Ohio is entering into a new partnership with University Hospitals Health System of Cleveland, Ohio. (NRC Byproduct Material License No. 34-01954-01). In accordance with NRC Information Notice No. 89-25, the following information is provided:

a. The name of the organization (Mercy Medical Center) is not changed. The date of this partnership change is not known but you will be advised as it becomes available.

b. Personnel and individual qualifications listed under the current license will remain unchanged.

c. Mercy Medical Center will remain in business as a health care facility, providing the same services that are currently licensed by the NRC.

d. Mercy Medical Center will remain in business at its current location and operations pertinent to NRC licensing requirements will remain unchanged.

e. No changes will occur in the use, possession, or storage of licensed materials.

f. All surveillance items and records including radioactive material inventory and accountability requirements (calibrations, leak tests, and surveys) will be current at the time of transfer. All surveillance items and records are current.

Chg. of Ownership
FEE NOT REQUIRED

Pm: 4-13-99

RECEIVED
APR 16 1999
REGION III

1320 Mercy Drive, NW, Canton, OH 44708 330-489-1067 Fax 33[illegible]

30515?

g. Studies using licensed material are ongoing at Mercy Medical Center. Area surveys including monitoring for contamination are conducted as required. No areas of contamination have been identified.

h. No areas of contamination have been identified. Past activities of Mercy Medical Center have been conducted with no cost incurred for decontamination. This is anticipated to continue.

j. CSA and UHHS have agreed to the establishment of this partnership.

k. The Partnership agrees to abide by all constraints, conditions, requirements, representations and commitments stated in the existing license.

Sincerely,
MERCY MEDICAL CENTER

Jeffrey L. Smith
Vice President

JRS:kb

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

MAY 25 1999

Jeffrey L. Smith
Vice President
Mercy Medical Center
1320 Mercy Drive, NW
Canton, OH 44708

Dear Mr. Smith:

This refers to your letter dated April 12, 1999, and letter dated May 20, 1999, from Harlin Adelman, Assistant General Counsel, University Hospitals Health System, requesting NRC consent to the proposed change of ownership of Mercy Medical Center, NRC License No. 34-01954-01. Based upon our review of the information you provided, the NRC consents to the change of ownership.

In addition, we have determined that the transaction as described in these letters does not require an amendment to the existing license.

If you have any questions or require clarification on any of the information stated above, you may contact us at 630-829-9873.

Sincerely,

James R. Mullauer, M.H.S.
Health Physicist
Materials Licensing Branch

License No. 34-01954-01
Docket No. 030-02694

cc: Harlin Adelman
Assistant General Counsel
University Hospitals Health System
W.O. Walker Center
10524 Euclid Avenue
Cleveland, OH 44106-2205

305159

University Hospitals Health System

University Hospitals of Cleveland

Via FederalExpress

May 20, 1999

United States Nuclear Regulatory Commission
ATTN: Susan Greene
Materials Licensing Section
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Ms. Greene:

Enclosed please find an executed copy of the Nuclear Regulatory Commission Information Notice 89-25 for Mercy Medical Center, 1320 Mercy Drive, NW, Canton, OH 44708.

Please call me at (216) 983-1053 if you have any questions. Thank you for your prompt attention to this matter.

Very truly yours,

Harlin Adelman
Assistant General Counsel

HGA/dem
F:\hadelman\nrc – mercy.doc

Enclosure

Pm; 5-21-99

Law Department W.O. Walker Center 10524 Euclid Avenue Cleveland, Ohio 44106-2205 Phone 216-983-1050 FAX 216-983-1057

University Hospitals of Cleveland is the Primary Affiliate of Case Western Reserve University

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

NRC INFORMATION NOTICE 89-25

INFORMATION NEEDED FOR CHANGE OF OWNERSHIP APPLICATION

The applicant, CSAHS/UHHS-Canton, Inc., an Ohio non-profit corporation (the "Transferee"), hereby provides the following information to the Nuclear Regulatory Commission ("NRC") with respect to the change of ownership of Mercy Medical Center:

(1) NAME OF LICENSED ORGANIZATION: The name of the licensed organization will be Mercy Medical Center (the "Hospital").

(2) LICENSE CONTACT AND TELEPHONE NUMBER: The new license contact and telephone number to facilitate communications is:

Jeffrey L. Smith, Vice President
330-489-1067

(3) CHANGES IN PERSONNEL: The Transferee is an Ohio non-profit corporation, the two sole members of which are the Sisters of Charity of St. Augustine Health System, an Ohio non-profit corporation ("CSAHS"), and University Hospitals Health System, Inc., an Ohio non-profit corporation ("UHHS"). A list of the trustees and officers of the Transferee is included herewith as ***Exhibits "A"*** and ***"B,"*** respectively.

There are currently no changes planned in Hospital personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in the most recent license application as responsible for radiation safety or use of licensed materials.

(4) TRANSFEROR: The transferor, Columbia-CSA/HS Greater Canton Area Healthcare System, L.P., an Ohio limited partnership (the "Transferor"), will not remain in non-licensed business without the license.

(5) TRANSACTION DESCRIPTION: The transaction is structured as an asset purchase agreement between the Transferor and the Transferee. The Transferor is composed of two general partners, CSAHS and Columbia/HCA Healthcare Corporation of Northern Ohio, Inc., an Ohio corporation ("Columbia"). As indicated above, the Transferee is an Ohio non-profit corporation, the two sole members of which are CSAHS and UHHS.

(6) PLANNED CHANGES-OPERATING OR EMERGENCY PROCEDURES: Except as noted above, there are currently no changes planned in organization, location, facility, equipment or procedures with respect to licensed activities.

(7) PLANNED CHANGES-LICENSED MATERIALS: Except as noted above, there are currently no changes planned in use, possession, location, or storage of the licensed materials.

(8) PLANNED CHANGES-LICENSE AMENDMENT: Except as noted above, there are currently no changes planned in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without the change of ownership.

(9) SURVEILLANCE REQUIREMENTS AND RECORDS: It is anticipated that all surveillance items and records will be current at the time of transfer (which is currently expected to occur on or before May 31, 1999). A description of the status of all surveillance requirements and records is provided as ***Exhibit "C"***.

(10) RECORDS: All records concerning the safe and effective decommissioning of the facility, pursuant to 10 C.F.R. §§ 30.35(g), 40.36(f), 70.25(g), and 72.30(d); public dose; and waste disposal by release to sewers, incineration, radioactive materials spills, and on-site burials, will be transferred to the Transferee at the time of the closing, which is currently expected to occur on or before May 31, 1999.

(11) FACILITY STATUS: There is currently no contamination at the facility.

(12) DECONTAMINATION PLANS: There is currently no contamination at the facility.

(13) COVENANTS OF THE PARTIES: The Transferee hereby agrees to abide to all commitments and representations previously made to the NRC by the Transferor.

There is currently no contamination at the facility.

There are currently no open inspection items.

(14) DOCUMENTATION: By execution of this document, the Transferor and Transferee hereby agree to the change in ownership and control of the licensed material and activity, and the conditions of the transfer as set forth herein. A copy of the bill of sale will be forwarded to the NRC upon closing as evidence of the transaction.

As indicated above, there are currently no open inspection items.

(15) COMMITMENT OF THE TRANSFEREE: The Transferee will abide all constraints, conditions, requirements, representations, and commitments identified in the existing license.

TRANSFEROR

COLUMBIA-CSA/HS GREATER CANTON AREA HEALTHCARE SYSTEM, L.P.

BY: Norman W. Wenger
PRINTED: Norman W. Wenger
TITLE: President & CEO
DATE: 5/18/99

TRANSFEREE

CSAHS/UHHS-CANTON, INC.

BY: James J. McMonagle
PRINTED: James J. McMonagle
TITLE: Sec'y
DATE: 5/17/99

NUCLEAR MEDICINE INSPECTION RECORD
RADIATION ONCOLOGY INSPECTION RECORD
OHIO DEPARTMENT OF HEALTH
BUREAU OF RADIATION PROTECTION

License No. 02120770009

Licensee (Name & Address)
Mercy Medical Center
1320 Mercy Drive, NW
Canton, Ohio 44708
Licensee Contact: Wayne R. Hedrick, Ph.D. Telephone No. 330-489-1067
R.S.O.: Mark R. DeGalan, M.D., Ph.D.
Licensed Material: Co-57, Tl-201,Ga-67,In-111, I-123, Pd-103, Ra-226, F-18

Date of Last Inspection: None
Date of This Inspection: February 16, 1999

Type of Inspection:
( ) Announced
(x) Routine
(x) Initial
(x) Unannounced
( ) Special

Justification for change in normal inspection frequency: None.

Summary of Findings and Actions:

( ) No violations cited
(x) Issue/s of noncompliance
( ) Follow-up on previous violations

Inspector (s): Robert Reid Date 2/25/99
Nuclear Materials Inspector

Approved: Date 2/25/99
Mark Light, Nuclear Materials
Nuclear Materials Inspection and Licensing
Supervisor

Marcia Howard Date 3/1/99
Marcia Howard, Program Administrator
Nuclear Materials Safety Program

Survey Instrument/s - Ohio Department of Health

INSTRUMENTATION	SERIAL #	CALIBRATION DATE
Ludlum Model 12	18359	2/26/98
Model 44-7 front end probe	PR 9556	2/26/98

PART I - LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; and orders.)

None

2. INCIDENT/EVENT HISTORY:
(List any incidents, recordable events, or misadministrations reported to the Ohio Department of Health since the last inspection. Citing indicates that event logs or licensing files have no evidence of any incidents or events since the last inspection.)

None

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organization; authorities and responsibilities; authorized locations of use; type, quantity and frequency of radioactive material use; staff size; mobile nuclear medicine service; limited distribution of pharmaceuticals; PET; and research involving human subjects.)

Management Organization, Nuclear Medicine

Norm Wengerd, President & Chief Executive Officer
↓
Jeff Smith, Vice President
↓
Stephen Spearing – Mark R. DeGalan, M.D., Ph.D., RSO
– Wayne Hedrick, Ph.D., Medical Physicist
↓
Ronda Mottice, Senior Licensed Nuclear Medicine Technologist
↕
Lisa Borello, Licensed Nuclear Medicine Technologist
Chryzanne Gadza-Grimm, Licensed Nuclear Medicine Technologist
Mike Freeman, Licensed Nuclear Medicine Technologist
Heidi Kins, Licensed Nuclear Medicine Technologist
Eric Schockling, Licensed Nuclear Medicine Technologist

Authorized Users Nuclear Medicine	Material and Use
Dae Hyun Bang, M.D.	10 CFR 35.100 and 35.200
Thomas J. Barbush, M.D.	10 CFR 35.100 and 35.200
Thomas W. Crosby, M.D.	10 CFR 35.100 and 35.200
Laura Cawthon, M.D.	10 CFR 35.100 and 35.200
Mark R. DeGalan, M.D., Ph.D.	10 CFR 35.100 and 35.200
Neil Goldberg, M.D.	10 CFR 35.100 and 35.200
Todd L. Johnson, M.D.	10 CFR 35.200 Cardiovascular
Mohamad S. Kassir, M.D.	10 CFR 35.100 and 35.200 Cardiovascular
William D. Murphy, M.D.	10 CFR 35.100 and 35.200
Diane Pretorius, M.D.	10 CFR 35.100 and 35.200
John N. Rauchenstein, M.D.	10 CFR 35.100 and 35.200
Robert E. Reaven, M.D.	10 CFR 35.100 and 35.200
Patricia J. Rubin, M.D.	10 CFR 35.100 and 35.200
George Q. Seese, M.D.	10 CFR 35.200 Cardiovascular

Management Organization, Radiation Oncology

Norm Wengerd, President & Chief Executive Officer

|

Jeff Smith, Vice President

|

Stephen Spearing - Mark R. DeGalan, M.D., Ph.D., RSO

- Wayne Hedrick, Ph.D., Medical Physicist

- Mike LaFont, Medical Physicist

Authorized Users Radiation Oncology

Carlos V.Rozenbom, M.D.	10 CFR 35.400
Peter B. Hardin, M.D.	10 CFR 35.400

The Radiation Safety Officer (RSO) oversee's the radiation safety program and is involved in the day-to-day operations of the program. The Nuclear Medicine Technologists and Radiation Therapists normally perform the day-to-day operations which the RSO reviews periodically.

Nuclear Medicine, Mercy Medical Center

Mercy Medical Center is a 350 bed Level 2 Trauma community hospital located in Canton, Ohio. 50% of the licensee's ownership is through Columbia Health Care and 50% ownership through Charity of St. Augustine. The licensee performed in the month of January, 1998, 1066 diagnostic and therapy procedures which included 257 Tc-99m Cardiolite® myocardial perfusion rest and stress studies, 257 Tc-99m Cardiolite® myocardial perfusion wall motion studies, 251 Tc-99m Cardiolite® myocardial perfusion with ejection, 74 Tc-99m MDP bone and 3-phase studies, 10 gated heart pool procedures (MUGAs®), 110 lung ventilation/perfusion (VQ) scans, 21 I-123 NaI uptake & scans, 23 Tc-99m IDA studies, 11 renograms, 1 liver/spleen scan, 6 Ga-67 citrate scans, 15 hepatobiliary exams, 13 I-123 NaI thyroid uptake and scans, 4 In-111 DTPA

cisternograms, and 3 Testicular scans. Radiopharmaceutical therapy procedures in January 1999 included 8 I-131 NaI hyperthyroid doses, no I-131 NaI thyroid ablation doses, and no Sr-89 chloride doses for palliation of bone metastases. The Nuclear Medicine facility does not have a fume hood and the I-131 NaI is ordered in capsule form. Dosages are delivered via courier from Mallinckrodt and Syncor radiopharmacies. The facility does not receive Mo-99/Tc-99m generators.

Radiation Oncology, Mercy Medical Center

The licensee is licensed to perform I-125 and Pd-103 permanent seed implants for prostate carcinomas. To date, 3 I-125 seed implants have been performed at Mercy Medical Center. The licensee performs Ra-226 temporary implants with needles and tubes for cervical and vaginal carcinomas.

2. MANAGEMENT OVERSIGHT:
(Management support to radiation safety; Radiation Safety Officer; and program audits, including ALARA reviews.)

The licensee is a community hospital located in Canton metropolitan area. The licensee has a radiation safety committee that meets quarterly. An annual ALARA review is performed. The ALARA report of January 11, 1999 was reviewed. The inspector reviewed selected RSC records from August 18, 1997, through November 3, 1998. The facility was found to comply with required administrative policy and procedures, record keeping, training and radiation protection documentation. The licensee has a Quality Management Program (QMP) for both Nuclear Medicine and Radiation Oncology therapeutic procedures. Audits are conducted periodically and annually by the licensee's Medical Physicist (Wayne Hedrick, Ph.D.) and include, but not limited to, dosimetry records and NRC and ODH regulations. The RSC reviews the Medical Physicist's audits. The inspectors reviewed the Medical Physicist's audits from January 14, 1998 through January 11, 1999. The ODH inspectors reviewed the January 14, 1998, and the January 7, 1999, QMP reports. Written directives for I-125 permanent implant surgery (2) and Ra-226 temporary implant surgery (3) were found to comply with 10 CFR 35.32 and Regulatory Guide 8.33 requirements.

Within areas inspected, no citations of ODH requirements were identified.

3. FACILITIES:
(Facilities as described; uses; control of access; and engineering controls.)

Nuclear Medicine Facility, Mercy Medical Center

The Nuclear Medicine facility is located on the first floor of the main hospital.The Nuclear Cardiology lab is located on the third floor of the main hospital. The licensee has one hot lab. The hot lab (first floor of main Nuclear Medicine Division) is locked when licensee personnel are away from the lab. A shielded decay-in-storage area, a waste storage area, dose calibrator, L block and prep area are located within the hot lab. The Nuclear Medicine facility has four gamma cameras, an uptake area, injection area, an office, a computer processing area, and a waiting area. Unit dosages and multidose vials are delivered via courier to the hot lab.

Radiation Oncology Facility, Mercy Medical Center

The licensee has a brachytherapy storage area located on the ground floor of the main hospital within the Radiation Oncology Division. The seeds (I-125 & future Pd-103) are stored in the manufacturer's container in the Radiation Oncology storage room. The I-125 & future Pd-103 seed implants are performed in the facility's Cystoroom, OR # 7. The patient is taken to the ambulatory care recovery room (ACU) post implant. Patients that are hospitalized are housed in a private end room on the seventh floor. The Pd-103 implants are permanent and the patient will be released according to 10 CFR 35.75 and U.S.N.R.C. Regulatory Guide 8.39 requirements. The implant team consists of the Authorized User, Medical Physicist, Anaesthesiologist, Urologist and Oncology Nurse. Approximately 60 - 100 seeds are utilized per implantation (~1mCi/seed of Pd-103). The OR is equipped with a cystoscope, ultrasound and fluoroscope instrumentation and a x-ray machine. The ultrasound device is used for determining implantation of the seeds after determination of the size and shape of the prostate. The Cystoscope can determine if any stray seeds are found in the bladder or ureter by the Urologist.
Ra-226 temporary implantation is performed in the patient's room. The room is a private end room on the seventh floor. Adjacent rooms and upper and lower levels bordering the room are monitored.Two lower bed shields around the patient affords the licensee's staff adequate protection. Prior to release the patient is surveyed to ensure that no needles or tubes have been inadvertently left within the patient.

Within the areas inspected, no citations of ODH requirements were identified.

4. EQUIPMENT AND INSTRUMENTATION:
(Dose calibrator; instrumentation for assaying alpha- and beta- radionuclides; generators; syringes and vials; survey instruments; Part 21 procedures; and special equipment and instrumentation.)

Nuclear Medicine Facility,

The licensee possesses four gamma cameras: (Nuclear Cardiology Division - 3rd floor - one ADAC Vertex SPECT dual head camera), (Nuclear Medicine Division - 1st floor - one ADAC Vertex SPECTdual head camera, one portable Ohio Nuclear 420, and one Siemens LFOV nonSPECT head camera). A Capintec CRC-15 dose calibrator is used to assay patient dose in the hot lab. A CRC-10 dose calibrator is maintained for back-up. A Canberra NaI(Tl) probe and well counter system is located in the laboratory for smear wipes was calibrated on August 4, 1998. The efficiency of the well is 77%. The energy resolution for the uptake probe and well counter measured in July 1998 was 8% and 7%, respectively. Constancy, linearity and accuracy checks are performed on the Capintec CRC-15 dose calibrator at the proper levels (daily, quarterly and annually respectively). The inspector had the licensee confirm the constancy test on the day of the inspection using the licensee's check source. The constancy check was within normal operational parameters and matched the licensee's earlier test results that day (I-123 & Tl-201). The inspectors viewed a selected sample of the constancy (January 1998 through February 16, 1999), linearity (October 13, 1997 through January 25, 1999) and accuracy (January 13, 1998 - January 28, 1999) test records and did not identify any abnormal or unusual test results. The geometry was last performed on September 26, 1995, and was found to be within limits. The accuracy and linearity checks are current on the back-up CRC-10 dose calibrator. The geometry was performed on January 13, 1997. 5 GM survey meters were inspected at the facility: a Ludlum Model 2 survey meter, calibrated 10/12/98, a Picker CDV-700 survey meter,

serial # 1170141, calibrated on 7/1/98, a Ludlum Model 14C, serial # 92267, calibrated 11/10/98, a Ludlum Model 19A NaI, calibrated 7/1/98, and a Kiethley 36105 Digital Ionization, calibrated 10/12/98.

Radiation Oncology Facility, Mercy Medical Center

The Radiation Oncology facility at Mercy Medical Center located on the ground floor of the main hospital houses a Radiation Oncology storage area. Two survey meters were inspected at the facility: a Keithley Model 36105, calibrated 10/12/98, is located in the Nuclear Medicine Laboratory and is used for monitoring in the operating room, and a Ludlum Model 3 survey meter, serial # 36437, calibrated 7/1/98, is used for surveying for patient release criteria per 10 CFR 35.75(a). The licensee measures the exposure rate at one meter for implant therapy as described in U.S.N.R.C. Regulatory Guide 8.39.

Within the areas inspected, no citations of ODH requirements were identified.

5. MATERIAL USE, CONTROL, AND TRANSFER:
(Materials and uses authorized; use of radiopharmaceuticals; security and control of licensed materials; and procedures for receipt and transfer of licensed material.)

Nuclear Medicine Facility, Mercy Medical Center

Safety precautions using licensed materials include, but are not limited to, gloves, lab coats, syringe shields and surveys of the area and personnel. Manipulation of diagnostic and therapeutic quantities of liquid material is through sealed systems such as vial or syringe. Licensed material is delivered to the licensee via courier from Mallinckrodt and Syncor radiopharmacies and locked in the hot lab upon arrival. Mo-99 breakthrough and Al concentration tests are performed by Mallinckrodt and Syncor Radiopharmacies as required by the N.R.C. and F.D.A. respectively. The licensee's storage of waste is contained in the hot lab and under lock and key when personnel are not present. The hot lab is locked at all times while personnel are not present. Area monitoring threshold limits for restricted areas are 0.06 - 10.0 mR/hr in the Nuclear Medicine facility.

Radiation Oncology Facility, Mercy Medical Center

Therapy seeds will be delivered to the Radiation Oncology Division for package monitoring and wipes and will be secured in the Radiation Oncology storage area. The Radiation Oncology storage area is locked at all times while personnel are not present.

The licensee implemented procedures regarding the receipt and transfer of licensed material. All wipe tests and surveys are performed as required and the licensee possesses instrumentation sensitive enough to detect its established threshold limit of 200 dpm/100 cm^2 in the restricted and unrestricted areas. A random review of records for package surveys for the period 1998 -1999 indicated that no abnormal radiation levels were identified. All radioactive waste is held for a minimum of 10 physical half-lives of the longest lived radionuclide in the waste sample as required.

Within the areas inspected, no citations of ODH requirements were identified.

6. RADIOPHARMACEUTICAL THERAPY AND BRACHYTHERAPY:
(Safety precautions; surveys; and release criteria of patients and rooms.)

The licensee performs I-131 sodium iodide for hyperthyroidism, I-131 sodium iodide for thyroid ablation, and Sr-89 chloride radiopharmaceutical therapy for palliation of bone metastases (35.300 procedures). The licensee presently performs brachytherapy (35.400 procedures) with I-125 and seeds for prostate carcinoma. Safety precautions, training, applicable surveys, policies and procedures, written directive, QMP and release criteria were reviewed by the inspector for Pd-103 permanent implant seed brachytherapy. The licensee performs Ra-226 temporary implants for cervical and vaginal carcinoma. Safety precautions, training, applicable surveys, policies and procedures, written directive, QMP and release criteria were reviewed by the inspector for Ra-226 temporary implant brachytherapy.

Within the areas inspected, no citations of ODH requirements were identified.

7. QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS:
(QMP - written directive, implementation, reviews, and records; misadministrations - identification, notifications, reports, and records.)

The licensee performs an audit annually and has not identified any recordable events or misadministrations with NARM materials. The inspectors reviewed the written directive, implementation of the QMP, safety precautions, surveys, needle and tube accountability, training, and release of the Ra-226 temporary implant patient.
The inspectors reviewed the written directive, implementation of the QMP, safety precautions, surveys, seed accountability, training, and release criteria of the I-125 and future Pd-103 permanent implant patient.
The ODH inspectors reviewed 2 I-125 and 3 Ra-226 written directives from 1998 - 1999. The following policies and procedures were reviewed: 1) authorized user date & sign the written directive prior to administration, 2) verify by more than one method the identity of the patient named in the written directive, 3) specific details of the treatment plan - radioisotope, number of sources, source strengths are confirmed to verify agreement with the written directive & plan of treatment, 4) AU or qualified person under the supervision of an AU verify that the radioisotope, number of sources, source strengths, loading sequence of sources are in agreement with written directive and plan of treatment, 5) procedure for using radiographs or other comparable images to verify the position of the sources and calculating total dose, 6) after implantation, procedure for AU to promptly record the actual number of radioactive sources implanted and sign or initial the patient's chart or appropriate record, 7) procedure to check the dose calculations before the total prescribed dose has been administered, 8) procedure to have AU date & sign a written record in patient's chart or in another appropriate record that includes radioisotope, treatment site, & total dose.
The above specific policies and procedures ensure the objectives of 10 CFR 35.32 and Regulatory Guide 8.33 section 3.2 regarding Quality Management Programs specific to the modality of Brachytherapy. Upon review of the 2 I-125 and 3 Ra-226 written directives and the accompany patient charts, the ODH inspectors determined that the licensee achieved U.S.N.R.C. and ODH regulatory compliance.

Within the areas inspected, no citations of ODH requirements were identified.

8. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:
(Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; records; and public doses.)

Nuclear Medicine Facility, Mercy Medical Center

The licensee conducts surveys to ensure radiation levels and contamination do not exceed ODH limits. Surveys are conducted at the end of the day in areas where licensed materials are routinely used. The trigger limits for daily GM surveys are 0.06 - 10 mR/hr in restricted areas in Nuclear Medicine.

Sealed sources are leak tested every six months by Wayne Hedrick, Medical Physicist. Leak test records for the period (January 14, 1998 through January 7, 1999) indicated that no leakage in excess of .005 microcuries {185 Bq} was identified. Inventories of sealed sources for the period (October 2, 1997 through January 28, 1999) indicated location, activity, and RSO signature as required. Pd-103 seeds from Theragenics need not be wipe tested by the licensee.

All individuals handling licensed material use gloves, lab coats, TLD badges, whole body badges, and syringe shields. A review of the licensee's surveys, evaluations and records indicate that public doses are below the ODH limits as delineated in 3701-39-021 and referenced in 10 CFR 20.

Radiation Oncology Facility, Mercy Medical Center

The licensee conducts surveys to ensure radiation levels and contamination do not exceed ODH limits. Sealed sources are leak tested every six months by Mike LaFont, Medical Physicist. Leak test records for the period (March 6, 1997 through October 30, 1998) indicated that no leakage in excess of .005 microcuries {185 Bq} was identified. Inventories of sealed sources for the period (December, 1997 through February 16, 1999) indicated location, activity, and RSO signature as required. The storage safe housed 32 Ra-226 needles and tubes. The total activity is 290 millicuries (mg). Type of sources include 5 mg needles (8 sources), 10 mg needles (20 sources), 10 mg tubes (2 sources), and 15 mg tubes (2 sources). The inspectors had the Medical Physicist open the safe and viewed a compartment of the storage safe from behind the L Block that housed Ra-226 needles that matched the inventory log. The inspectors viewed the survey records performed by Medical Physicist. With the safe closed, the highest reading was in front of the L Block - 17 mR/hr. 1 meter above the safe registered 1 mR/hr. The hallway and mechanical areas surrounding the source storage area was background (0.1 mR/hr). Storage behind the safe surveyed 3 mR/hr. Lead bricks surrounded the storage safe. The inspectors recorded 0.1 mR/hr at the doorway to the source storage room.
One issue of noncompliance was recorded by the ODH inspectors. The licensee had not performed the required leak test on the 28 Ra-226 therapy needles and 4 Ra-226 therapy tubes. The sources were leak tested on October 9, 1997 and October 30, 1998. The licensee shall test the sources for leakage at intervals not to exceed six months. This is an issue of noncompliance of the Ohio Administrative Code 3701-39-021 as delineated in 10 CFR 35.59(b)(2) which states:

> *Test the source for leakage at intervals not to exceed six months or at intervals approved by the Commission or an Agreement State and described in the label*

or brochure that accompanies the source.

Within inspected areas, one citation of ODH requirements were identified.

9. TRAINING AND INSTRUCTIONS TO WORKERS:
(Interviews and observations of routine work; staff knowledge of all routine activities; Part 20 requirements; therapy training and postulated; emergency situations; and supervision by authorized users.)

Nuclear Medicine Facility, Mercy Medical Center

Interviews with staff indicate all appropriate radiation safety precautions have been implemented. The licensee's staff were aware of normal operational and emergency procedures as described by the licensee's policy and procedure manual. Authorized users are available to the technologists who administer licensed material. Training for the technologists who administer licensed material is documented in staff meetings and records. Records show that staff has taken Radiation safety and protection training sessions accredited by the Ohio Department of Health for state licensure. All Nuclear Medicine Technologists (6) at the facility are licensed by the Ohio Department of Health. Training is also provided to non-occupational personnel. Annual housekeeping training was performed.

TRAINING AND TOPIC	1998 - 1999
Annual Radiation Safety In-service Nuclear Medicine Technologists	1/13/1999
Annual Radiation Safety In-service Housekeeping	1/20/99
HAZMAT training (every 2 years)	11/97

Radiation Oncology Facility, Flower Hospital

The licensee's staff were aware of normal operational and emergency procedures as described by the licensee's policy and procedure manual. The Authorized Users administer the licensed material (I-125 and future Pd-103) in the form of seeds to the prostate carcinoma patient and Ra-226 needles and tubes to the cervical and vaginal carcinoma patient.

TRAINING AND TOPIC	1998 - 1999
Brachytherapy Implants (I-125 & Pd-103) Ra-226 temporary implants Housekeeping	1/20/99

Within inspected areas, no citations of ODH requirements were identified.

10. RADIATION PROTECTION:
(Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose records; and patient release.)

Nuclear Medicine Facility, Mercy Medical Center

The licensee's dosimetry program consists of monthly extremity TLD and whole body film badges which are purchased and processed by Landauer. The inspector reviewed dosimetry records from 1/98 to 12/98. Investigational Level I whole body limit is 125 mrem and Investigational Level II whole body limit is 375 mrem. No individual exceeded Investigational Level 2. The highest recorded whole body dose for 1998 is 340 mrem and highest TLD was 390 mrem.

Radiation Oncolgy Facility, Mercy Medical Center

The inspector reviewed the Policies and Procedures for brachytherapy. All personnel who handle brachytherapy sources are monitored with a body and extremity dosimeter.

YEAR	Investigational Level I	Investigational Level II
Whole body badge	125 mrem	375 mrem
TLD ring badge	1250 mrem	3750 mrem

YEAR	Whole Body Badge	TLD Ring Badge
1998	710 mrem	5130 mrem

PERSONNEL	DATE OF DECLARED PREGNANCY	WHOLE BODY AND TLD READING
none	N/A	N/A

Within inspect..1 areas, no citations of ODH requirements were identified.

11. RADIOACTIVE WASTE MANAGEMENT:
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment incinerators, hoods, vents and compactors; EPA referral form; and records.)

Nuclear Medicine Facility, Mercy Medical Center

The licensee disposes of used licensed material by decay-in-storage. The waste is surveyed in a low background area in the hot lab and then disposed of as biohazard waste. A record is made of the date of disposal, period of decay, mR/hr reading at time of disposal, bkg reading, and name of surveyor at the time of disposal. This facility also sends spent and unused radiopharmaceutical doses (limited quantity shipments - 49 CFR 173.421) back to Mallinckrodt and Syncor Radiopharmacies after proper wipes and surveys are performed (6600 cpm/300 cm^2 and <0.5 mR/hr @ surface). The licensee does not dispose of radioactive materials via incineration or sanitary sewer.

The outpatient radiopharmacetical therapy patient (35.300) is sent home with an instruction sheet that conforms to U.S.N.R.C. Regulatory Guide 8.39, if the dose exceeds Table 2 levels.

Radiation Oncology Facility, Mercy Medical Center

Pd-103 seeds (if ordered) from Theragenics and I-125 seeds from Amersham/Mediphysics are stored in the Radiation Oncology storage room on the ground floor of the main hospital in the Radiation Oncology Division. Unused seeds are returned to the storage room in the original maufacturer container and are held for decay-in-storage. Ra-226 needles and tubes 290 mg (32 sources) are stored in the storage safe in the Radiation Oncology Division. The storage room is locked when licensee personnel are away from the lab.

The outpatient brachytherapy patient (35.400) is sent home with an instruction sheet that conforms to U.S.N.R.C. Regulatory Guide 8.39, if the dose exceeds Table 2 levels.

Within areas inspected, no violations of ODH requirements were identified.

12. DECOMMISSIONING:
(Records of radiological conditions; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements.)

The licensee is not required to post financial assurance for decommissioning, however, the licensee maintains all records of surveys, inventories and leak tests for future decommissioning purposes.

Within areas inspected, no citations of ODH requirements were notified.

13. TRANSPORTATION:
(Quantities and types of licensed material shipped; packaging design requirements; HAZMAT communication procedures; unit dose return; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports.)

The licensee receives unit doses from Mallinckrodt and Syncor Radiopharmacies. All unused doses are decayed-in-storage and returned as limited quantities (49 CFR 173.421). The licensee performs the appropriate wipe tests and surveys of all packages when they are received within three hours (surface, 1 meter and external smear wipes 6,600dpm/300 cm^2) and when they are returned to Mallinckrodt and Syncor Radiopharmacies (6600 cpm/300 cm^2 and <0.5 mR/hr @ surface). The Nuclear Medicine Technologist demonstrated appropriate package surveys and wipe tests to the ODH inspector.

The licensee surveys and smear wipes the incoming packages of brachytherapy implant seeds in the Radiation Oncology facility. The seeds in the manufacturer's container will be stored in the brachytherapy storage room until utilized in prostate cancer surgery by an Authorized User. A utilization log (date out, date in, # seeds, signature) is kept in the brachytherapy storage room.

Within areas inspected, no citations of ODH requirements were identified.

14. NOTIFICATIONS AND REPORTS:
(Theft; loss; incidents; overexposures; change in RSO, authorized user, or nuclear pharmacist; and radiation exposure reports to individuals.)

The licensee has not experienced any fires, explosions, fatalities, lost/stolen/missing radioactive materials or misadministrations in the past year. According to the Nuclear Medicine Technologists and Medical Physicists, the licensee has not experienced any incidents that would require a planned special

exposure (PSE).

Within areas inspected, no citations of ODH requirements were identified.

15. POSTING AND LABELING:
(Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material.)

Nuclear Medicine Facility, Mercy Medical Center

All pertinent and required postings were posted as per NRC and ODH requirements. The storage area was posted. At the time of this inspection the hot laboratory was posted with a '*Caution Radioactive Materials*' sign. The state license was posted. Appropriate '*Ohio Department of Health Notice To Employees*' forms were posted on the department bulletin board.

Radiation Oncology Facility, Mercy Medical Center

All pertinent and required postings were posted as per NRC and ODH requirements. The storage area was posted.

Within areas inspected, no citations of ODH requirements were identified.

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date.)

Nuclear Medicine Facility, Mercy Medical Center

Trigger limits for GM surveys in restricted areas and unrestricted areas are established. Radiation levels in the unrestricted areas outside the hot lab were <0.02mR/hr. The inspectors performed a radiation survey in and around the hot lab and identified radiation levels < 0.7 mR/hr. The inspectors recorded the following survey levels in each respective area: ADAC Vertex SPECT Nuclear Cardiology room - 0.01 mR/hr, ADAC Vertex Nuclear Medicine room - 0.01 mR/hr, Siemens nonSPECT room - 0.02 mR/hr. The Ohio Department of Health inspector witnessed the Nuclear Medicine Technologist perform the constancy test on the Capintec CRC-15R dose calibrator. Witnessed values matched recorded values on all appropriate settings (Tl-201 & I-123).

The inspector witnessed the Nuclear Medicine Technologist perform package surveys and the performance of smear wipes. The package survey met the Ohio Department of Health's regulations. Appropriate attire (lab coat, gloves, syringe shield, TLD, body badge) was worn by the Nuclear Medicine Technologists and proper handling and disposal of spent needles and syringes were observed.

Radiation Oncology Facility, Mercy Medical Center

The inspectors had the Medical Physicist open the safe and viewed a compartment of the storage safe from behind the L Block that housed Ra-226 needles that matched the inventory log. The inspectors

viewed the survey records performed by Medical Physicist. With the safe closed, the highest reading was in front of the L Block - 17 mR/hr. 1 meter above the safe registered 1 mR/hr. The hallway and mechanical areas surrounding the source storage area was background (0.1 mR/hr). Storage behind the safe surveyed 3 mR/hr. Lead bricks surrounded the storage safe. The inspectors recorded 0.1 mR/hr at the doorway to the source storage room.

Within the areas inspected, no citations of ODH requirements were identified.

17. ISSUES OF NONCOMPLIANCE, NON-CITED ISSUES OF NONCOMPLIANCE AND OTHER SAFETY ISSUES:

(State requirement and how and when licensee violated the requirement. For NCVs, indicate why the Issue of Noncompliance was not cited. Attach copies of all licensee documents needed to support Issues of Noncompliance.)

Within the areas inspected, one citation of ODH requirements was identified:

The licensee had not performed the required leak test on the 28 Ra-226 therapy needles and 4 Ra-226 therapy tubes. The sources were leak tested on October 9, 1997 and October 30, 1998. The licensee shall test the sources for leakage at intervals not to exceed six months. This is an issue of noncompliance of the Ohio Administrative Code 3701-39-021 as delineated in 10 CFR 35.59(b)(2) which states:

> *Test the source for leakage at intervals not to exceed six months or at intervals approved by the Commission or an Agreement State and described in the label or brochure that accompanies the source.*

18. PERSONNEL CONTACTED:

(Identify licensee personnel contacted during the inspection [including those individuals contacted by telephone]).

#^Wayne Hedrick, Ph.D., Medical Physicist
#^*Stephen Spearing, Administrative Services
*Jeff Smith, Vice President
#^*Ronda Mottice, Senior Licensed Nuclear Medicine Technologist
^*Mike LaFont, Medical Physicist
^Chryzanne Gadza-Grimm, Licensed Nuclear Medicine Technologist

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting
+ Individual not present at entrance or exit
^ Individual contacted during inspection

19. PERFORMANCE EVALUATION FACTORS:

A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight	( ) Y (X) N
B.	RSO too busy with other assignments	( ) Y (X) N
C.	Insufficient staffing	( ) Y (X) N

D.	RSC fails to meet or functions inadequately	( ) N/A ( ) Y (X) N
E.	Inadequate consulting services or inadequate audits conducted	( ) N/A ( ) Y (X) N

Remarks (consider the above assessment and/or other pertinent PEFs with regard to the licensee's oversight of the radiation safety program):

Senior management adequately supports the radiation safety program at the Nuclear Medicine and Radiation Oncology facilities.