21-25968-01

VOID SHEET

TO: License Fee Management Branch

FROM: COLLEEN CASEY, NMLS, REGION III

SUBJECT: VOIDED APPLICATION

Control Number: 96293

Applicant: Atallah Heart Center

Date Voided: Dec. 22, 1994

Reason for Void: Licensee decided to merge the license locations into its other license - same owner, RSO, authorized user, etc. Action is voided prior to review, simultaneous with the merger into Rochester and the termination of the Atallah Heart Center license.

Colleen C Casey 12/22/94
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

☑ Refund Authorized and processed

☐ No Refund Due

☐ Fee Exempt or Fee Not Required

ML
30

Comments: _____

Log completed ☑

Processed by: SAC SD
2/1/95

240204
9502270293 941222
PDR ADOCK 03030794
C PDR

FEB 02 1994

Atallah Heart Center
ATTN: Deborah Arellano, R.T.
Radiation Safety Officer
P.O. Box 82177
Rochester, MI 48308

License No. 21-25968-01
Control No. 396293

Dear Ms. Arellano:

SUBJECT: LICENSE RENEWAL APPLICATION

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified and your license number.

Sincerely,

Original Signed By
Marianne Meenan, Chief
Nuclear Materials Support Section

RIII
Meenan/jaw
02/2/94

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02200
STATUS CODE: 2
FEE CATEGORY: 7C
EXP. DATE: 19940131
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   APPLICANT/LICENSEE: ATALLAH HEART CENTER
   RECEIVED DATE: 940114
   DOCKET NO: 3030794
   CONTROL NO.: 396293
   LICENSE NO.: 21-25968-01
   ACTION TYPE: RENEWAL

   Delinquent Fee

2. FEE ATTACHED
   AMOUNT: $1400.00
   CHECK NO.: 2041799

3. COMMENTS

SIGNED P. Outlaw
DATE 1-27-94

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1/1)

1. FEE CATEGORY AND AMOUNT: 7C $1400.00

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
   AMENDMENT ____
   RENEWAL ✓
   LICENSE ____

3. OTHER ____

SIGNED SC
DATE 1/27/94

RECEIVED
FEB 02 1994
REGION III

NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 8-31-87

APPLICATION FOR MATERIAL LICENSE

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.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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 JURISDICTION.

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 21-25968-01

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Atallah Heart Center
P.O. Box 82177
Rochester, Michigan 48307

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

See Attached "Locations of Use"

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION | TELEPHONE NUMBER

Thomas M. Kumpuris, M.S. Medical Physics Consultants, Inc. | 313 662-3197

SUBMIT ITEMS 5 THROUGH 11 ON 8½ 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. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND 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 7.C. | AMOUNT ENCLOSED $ 1400.00

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, 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.

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
X [signature]	Pierre C. Atallah M.D.	MD Owner	1/5/94

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K - $500K
- [ ] $500K - $750K
- [ ] $750K - 1M
- [ ] $1M - 3 $M
- [ ] $3 $M - 7M
- [ ] $7M - 10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Dollar and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial proprietary information furnished to the agency in confidence)

- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
Renewal	Jan 11 II	7C		SC

AMOUNT RECEIVED	CHECK NUMBER	DATE
$1400.00	0017391	1/24/94

PRIVACY ACT STATEMENT ON THE REVERSE

RECEIVED
JAN 14 1994
REGION III
JAN 1 [illegible]

CONTROL NO. 396293

LOCATIONS OF USE

Radioactive material will be received, possessed and used as noted above at the following locations:

Atallah Heart Center
P.O. Box 82177
Rochester, Michigan

620 address should be 610 Main.

53960 Van Dyke
Utica, Michigan

RADIOACTIVE MATERIAL AND USE

Item 5			Item 6
Byproduct Material	**Chem. & Phys. Form**	**Max. Possession Activity Limit**	**Purpose**
Material in 35.100	Any	As Needed	Uptake, Dilution,and Excretion Studies
Material in 35.200	Any (Excluding Xenon-133 & Generators)	As Needed	Imaging and Localization Studies

RADIATION SAFETY PROGRAM RESPONSIBILITY

Item 7.1

Authorized Users	Materials
Lawrence Wayburn, M.D.	35.100, 35.200

Training and experience for the above named individuals can be referenced under Material's License 21-26287-01.

Radiation Safety Officer

Item 7.2

Deborah Arellano, CNMT

Training and experience for the above named individual can be referenced in our original application.

PERSONNEL TRAINING PROGRAM

Item 8

All radiation workers and ancillary personnel whose duties will require them to work in the vicinity of radioactive materials will receive instruction. Documentation of the list of topics covered, the date of the instruction, and the names of those attending will be kept on hand for review.

Training Frequency

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or in the terms of the license.

Instruction Topics

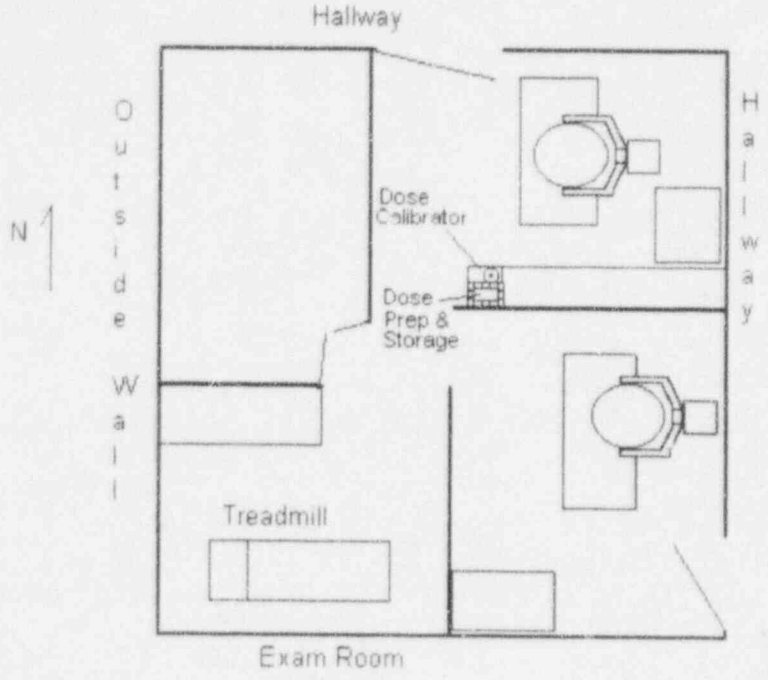
1. Applicable regulations and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. The licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
7. Appropriate response to emergencies or unsafe conditions.
8. The worker's right to be informed of occupational radiation exposure and bioassay results.

9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of the license and license conditions, as required by 10CFR19.

10. Quality Management Program - all policies and procedures.

FACILITY DIAGRAM

Item 9.1



EQUIPMENT LIST

Item 9.1 (Cont'd.)

Gamma Scintillation Camera

Ohio Nuclear	SFOV
MedX Ohio Nuclear	SFOV

Dose Calibrator

Capintec	CRC - 7

Survey Meters

Ludlum Model 3 GM Survey Meter, Side Window - Range (0-2000 mR/r)

Victoreen Model 498 GM Survey Meter, Side WindowRange (0 - 2000hr)

CALIBRATION OF SURVEY METERS

Item 10.2

All survey instruments will be calibrated and checked in accordance with 10 CFR 35.51.

Survey instruments will be calibrated by:

1. The manufacturer or
2. Medical Physics Consultants, Inc. (NRC License # 21-20153-01)

or

3. Any authorized user licensed to perform survey meter calibrations as a service.

CALIBRATION OF DOSE CALIBRATOR

Item 9.3

Test	Frequency	Tolerance
Constancy	Daily prior to patient dose assays	+/- 10%
Linearity	Installation, after repair, and quarterly	+/- 10%
Accuracy	Installation, after repair, and annually	+/- 10%
Geometry Dependence	Installation and following repair	+/- 10%

CONSTANCY testing will be performed using a long-lived reference source (e.g., Cesium-137) with activity greater than 50 microcuries. Zero or record the background reading on the appropriate setting. Assay the source for both the reference source setting and the most commonly used radiopharmaceutical settings. Record the readings and compare to the calculated values. The Radiation Safety Officer will be notified and the unit will be repaired or replaced if the constancy error exceeds 10 percent.

LINEARITY testing will be performed using a Technetium-99m source having activity at least as great as the maximum activity administered to patients. Testing will be conducted with the decay or the leaded-sleeve method over the entire range of administered activity.

Decay Method: Assay the source at approximately 0, 6, 24, 30, 48, etc. hours over the entire range of use(between the highest activity administered to patients and 10 uCi). Record the net activities, time, and date. Using a measured activity for reference which is closest to that which is commonly administered to patients, calculate the expected readings and compare to the measured readings. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the linearity error exceeds 10 percent over the range of use.

Item 9.3 Cont'd.

Sleeve Method. The sleeves will be calibrated at the time of an initial reading of a decay-method linearity test. Either the "Calicheck" or "Lineator" product will be used and the testing procedure will be performed according to the manufacturer's instructions. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the linearity error exceeds 10 percent over the range of use.

ACCURACY testing will be performed using Cesium-137 and Cobalt-57 or Barium-133 reference sources having NBS-traceable activities greater than 50 microcuries. The net measured activities will be compared to the calculated activities based on radioactive decay. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced if the accuracy error exceeds 10 percent.

GEOMETRY DEPENDENCE testing will be performed using a solution of technetium-99m having an activity concentration of 1-10 mCi/ml. If generators and/or radiopharmaceutical kits are normally used, both of the following tests will be performed.

Unit Dose users will assay 0.5 cc of the solution in a 3 cc plastic syringe. The solution in the syringe will then be diluted with water and assayed at incremental volumes of 1.0, 1.5, and 2.0 cc. Record all readings. Select a standard volume closest to that normally used for injections and divide the activity by the other measured activities. If any error exceeds 10 percent, correction factors will be applied to the appropriate volumes and a correction factor chart will be applied to the dose calibrator. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the geometry error exceeds 10 percent.

Generator/Kit users will assay 1.0 cc of the solution in a 30 cc glass vial. The solution in the vial will then be diluted with water and assayed at incremental volumes of 3, 5, 7, 9, 11, 13, 15, 17, and 19 cc. The assays should take place within 10 minutes. Record all readings. Select a standard volume closest to that normally used for mixing kits and divide the activity by the other measured activities. If any error exceeds 10 percent, correction factors will be applied to the appropriate volumes and a correction factor chart will be applied to the dose calibrator. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the geometry error exceeds 10 percent.

PERSONNEL MONITORING PROGRAM

Item 9.4

GENERAL PROGRAM DESCRIPTION

1. The RSO or delegate will promptly review all film or TLD exposure reports to look for workers or groups of workers whose reported exposures are unusual.

2. All individuals who are occupationally exposed to radiation and in compliance with 10 CFR 20.1502 will be issued a personnel monitor.

3. All individuals who handle radioactive material on a regular basis will be issued a film or TLD finger monitor.

4. The evaluation of possible exposure to those individuals not monitored is evaluated on a case by case basis. Whenever possible actual exposure data will be taken and evaluated for the potential to exceed the 10% limits of 10 CFR 20. If possible historical film badge data will be used in this analysis for comparison of similar job duties and exposure potential.

WEARING A PERSONNEL MONITOR

1. Whole body radiation monitor shall be worn on the anterior body surface at either the chest or collar level and always outside any shielding (if necessary).

2. Extremity radiation monitors, if necessary, shall be worn on the assigned extremity (left or right) and always facing the source of ionizing radiation.

PROPER USAGE OF RADIATION MONITORS

1. Each assigned monitor shall be worn as prescribed above at all times while handling and/or using ionizing radiation within the control of or on the premises of the licensee.

Item 9.4 Cont'd.

2. Assigned monitors shall be kept in areas within the licensees' control which are considered "low background" with respect to occupational sources of ionizing radiation during "off duty" hours i.e. lockers, desks, etc.. Monitor storage in a common low background area is encouraged if possible.

3. Assigned monitors should be protected whenever possible from excessive abuse and water such that each can be clearly identified for whom it is assigned. Abuse should not cause a spurious or inadvertent exposure or perceived exposure which was not truly received by the individual while performing assigned job functions.

4. Assigned monitors shall be returned to the RSO or designee on a monthly basis.

5. Any changes, additions, deletions, etc. with information provided to obtain these monitors shall be forwarded to the RSO or designee as soon as possible to maintain a current record.

6. At the cessation of employment it is the responsibility of the employee to return all issued monitors within their possession to the RSO or designee.

SUPPLIER

The present supplier for monthly personnel dosimetry services for this licensee is Landauer.

RADIATION SAFETY OFFICER

Item 10.0

The Radiation Safety Officer (RSO) shall:

1. Investigate overexposures, accidents spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, Misadministrations, and other deviations from the radiation safety practices approved by facility management and/or the Radiation Safety Committee, if applicable.

2. Establish, implement, and collect in a centralized location policies and procedures as follows:

   a. Authorization for the purchase of radioactive material.
   b. Receipt and opening of packages containing radioactive material.
   c. Storage of radioactive material.
   d. Inventory control of radioactive material.
   e. Safe use of radioactive material.
   f. Emergency procedures in the event of loss, theft, etc.
   g. Periodic radiation surveys
   h. Checks of radiation survey and other radiation safety instruments.
   i. Disposal of radioactive material.
   j. Personnel training of those who work in or frequent areas of radioactive material use or storage.

3. Maintain a record systems to include at least the following:

   a. All records, reports, written policies and procedures required by regulatory agencies concerning radioactive material.

   b. A copy of the regulations governing the possession, use and disposal of licensed material, such as Title 10 Code of Federal Regulations.

4. Review and sign the following radiation safety program records, if applicable.

   a. Sealed Source Inventories
   b. Sealed Source Leak Tests
   c. Dose Calibrator Linearity Tests
   d. Dose Calibrator Accuracy Tests
   e. Dose Calibrator Geometrical Variation Tests

Item 10.0 cont'd.

f. Misadministration documentation
g. Changes in the radiation safety program
h. Radiatic ' surveys of sealed source storage.

5. Inform facility management at least annually of the status of the licensed material program.

6. Establish in concert with the Radiation Safety Committee (RSC), if applicable, personnel exposure investigational levels as a part of the ALARA program and philosophy.

7. Approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management and the RSC, if applicable.

MAINTAINING OCCUPATIONAL RADIATION EXPOSURES ALARA

Item 10.1

This license is for a diagnostic imaging clinic and, therefore, is not required to have a Radiation Safety Committee. All pertinent responsibilities of the Radiation Safety Committee will be met by the Radiation Safety Officer with the assistance of the radiological physics consultants.

1. Management Commitment

a. We, the management of this medical facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and intructions to foster the ALARA concept within our facility. The organization will include a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

Item 10.1 Cont'd.

2. Radiation Safety Officer

a. Review of Proposed Users and Uses

(1) The RSO will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSO will review the efforts of the applicant to maintain exposures ALARA.

(3) The RSO will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

(1) The RSO will have the authority of enforcement of the ALARA concept.

(2) The management will support the RSO when it is necessary for the RSO to assert authority. If management has overruled the RSO, it will record the basis for its actions.

c. Review of ALARA Program

(1) The RSO will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSO will perform a quarterly review of occupational radiation exposure and survey records with particular attention to instances in which the investigational levels in Table I and/or action levels are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

(3) The RSO will conduct an annual review of the ALARA program.

Item 10.1 Cont'd.

TABLE I: INVESTIGATIONAL LEVELS

	Body Part Exposed	Level I (mrems per calendar quarter)	Level II (mrems per calendar quarter)
1.	Whole body; head and trunk; active blood forming organs; lens of eyes; or gonads.	125	375
2.	Hands and forearms; feet and ankles.	1875	5625
3.	Skin of the whole body.	750	2250

(3) The RSO will evaluate our clinic's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

d. Education Responsibilities for the ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, and the RSO are committed to implementing the ALARA concept.

e. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

Item 10.1 Cont'd.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

f. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

3. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO during the planning stage before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

4. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in recourses available if they feel that ALARA in not being promoted on the job.

Item 10.1 Cont'd.

5. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This facility hereby establishes investigational levels for occupational external radiation doses which, when exceeded will initiate review or investigation by the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by 10 CFR Part 20.401. The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

b. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results to management following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by management. The management will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review.

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's NRC Form-5 or its equivalent will be presented to management following completion of the investigation. The details of these reports will be filed by the RSO.

Item 10.1 Cont'd.

d. Re-establishment of investigational Levels to levels above those listed in Table 1.

In cases where a worker or group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented by the RSO.

6. Signature of Certifying Official

I hereby certify that this institution has implemented the ALARA Program set forth above.

Deborah A. Arellano
Signature

Deborah A Arellano
Name (Print or Type)

C.N.M.T., R.S.O
Title

PROCEDURE FOR LEAK TESTING SOURCES

Item 10.2

We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2.

Leak tests will be performed by:

1. Medical Physics Consultants, Inc. (NRC License No. 21-20153-01),

or

2. Anyone licensed by the NRC to perform leak testing as a service.

LABORATORY SAFETY RULES

Item 10.3

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Before leaving the area, monitor your hands and clothing for contamination in a low background area.

4. Use remote handling tools whenever possible to prevent direct handling of containers of radioactive materials.

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored.

6. Do not store food, drink, or personal effects in areas where radioactive material is used or stored.

7. Wear personnel monitoring devices (as prescribed by the RSO) at all times while in areas where radioactive materials are used or stored. Store personnel monitoring devices at the facility in a designated low-background area.

8. Wear extremity personnel monitoring devices during the preparation, assay, and injection of radiopharmaceuticals. Additionally these devices should be worn when holding patients during procedures.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Wipe test byproduct material storage, preparation and administration areas weekly for contamination. If necessary, decontaminate or secure the area.

Item 10.3 Cont'd.

12. With a radiation detection survey meter, survey the generator storage (if applicable), kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area.

13. Confine radioactive solutions in shielded containers that are clearly labeled with the isotope, compound name, and the date and time of receipt or preparation. Syringes and/or syringe shields shall be labeled with the radiopharmaceutical name or abbreviation contained within, type of study, or patient's name.

14. Always keep radioactive materials in shielded locations or containers.

15. Use syringe shields for routine preparation of multi-dose vials and in the administration of radiopharmaceuticals to patients.

16. Avoid splashing or forming an aerosol during dose preparation.

17. Assay each patient dose, except prescriptions of less than 10 uCi, in the dose calibrator prior to administration.

18. Always check the patient's name, ID., the prescribed radiopharmaceutical and dosage prior to administration.

19. When practical, use a cart to move large sources of radioactivity, such as flood sources, etc..

EMERGENCY PROCEDURES

Item 10.4

Minor Spills

1. NOTIFY: Notify persons nearby that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tools. Carefully fold the absorbent paper with the clean side out and insert in a plastic bag for transfer to a radioactive waste container. Also place the contaminated gloves and any other contaminated disposable material in the bag.

4. SURVEY: Survey the area with a low-range, GM survey meter. Check the area around the spill, hands, clothing, and shoes for contamination.

5. REPORT: Report the incident to the RSO.
   The RSO will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to ensure that the Report and Survey are completed properly.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

Item 10.4 Cont'd.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. NOTIFY: Notify the RSO immediately.

6. PERSONNEL DECONTAMINATION: Decontaminate personnel by removing contaminated clothing and flushing the contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination released by the perspiration.

7. REPORT: The RSO will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to see that the Report and Survey are completed properly.

PACKAGE ORDER AND RECEIPT PROCEDURES

Item 10.5

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

   a. Written records that identify the authorized user or department, isotope, chemical form, activity, supplier will be made.

   b. The above records will be checked to confirm that material received was ordered through proper channels.

3. For deliveries during normal working hours, packages are received in the hot lab.

4. If off duty deliveries are a necessity, Security will escort the carrier to the Nuclear Medicine Hot Lab. The carrier will then place the package within the Nuclear Medicine Hot Lab and re-lock all doors opened to gain access.

5. All packages containing radioactive material will be stored in a secured area to prevent unauthorized access to these items.

SAMPLE MEMORANDUM

TO: Security / Office Personnel
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Materials

When off duty deliveries are necessary the carrier should proceed to the front desk and obtain a key to the nuclear medicine department. The carrier will unlock the nuclear medicine department and the package will be left on the counter in the hot lab. The door to the department will then be relocked.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our Radiation Safety Officer, _____, at _____.

	Name	Home Phone
Radiation Safety Officer:	_____	_____
Chief Nuclear Medicine Tech:	_____	_____

PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Item 10.6

1. Put on gloves to prevent hand contamination.

2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop and notify the RSO.

3. Measure and record the exposure rate from the package at 1 meter and at the package surface. If the rate is greater than 10 mR/hr, stop and notify the RSO.

4. Measure and record the exposure rate on the surface of the package in the same orientation as the data taken in step 3 above. If greater than 200 mR/hr stop the procedure and notify the RSO.

5. Follow the steps listed below when opening the package.
   a. Remove the packing slip.
   b. Open the outer package following the supplier's instructions, if available.
   c. Open the inner package and verify that the contents agree with the packing slip.
   d. Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
   e. If anything unusual is noticed, stop and notify the RSO.

6. If there is any reason to suspect contamination, wipe the external surface of the final source container in compliance with 10 CFR 20 and remove the wipe sample to a low-background area. Assay the wipe with a thin-end window GM meter or a well counter to determine if there is any removable activity. If there is any contamination, notify the RSO.

7. Verify that the material received is the material ordered.

8. Monitor the packing material and the empty packages for contamination with a GM survey meter before discarding. If contaminated, treat as radioactive waste. If not contaminated, deface all radiation labels before discarding.

9. Record the receipt and all readings taken.

AREA SURVEY PROCEDURES
Item 10.7

1. Areas of radiopharmaceutical prep. & administration will be surveyed daily for ambient radiation exposure rates.

2. Areas of radiopharmaceutical storage and radiopharmaceutical waste storage will be surveyed weekly for ambient radiation exposure rates.

3. Areas of radiopharmaceutical prep, administration or waste storage will be wipe tested weekly for removable contamination.

4. Surveys for ambient exposure rates will be performed with a radiation detection survey instrument able to detect as low as 0.1 mR/hr.

5. Surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 dpm.

6. The trigger level for exposure rate surveys will be established by the Radiation Safety Officer in compliance with 10 CFR 35.70(d).

7. The trigger level for removable contamination surveys will be the detection of values equal to or less than the recommended levels in Table N-1 of the Regulatory Guide 10.8.
   Action Level: ^{99m}Tc or ^{201}Tl 2000 dpm/100 sq. cm.

8. Survey results greater than the trigger levels will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to ALARA levels on repeat surveys.

9. A record shall be kept of all survey results. These records will be retained for a period of three (3) years. The record will include:
   a. Location, date, and type of equipment used.
   b. Initials of the person conducting the survey.
   c. Drawing of the area surveyed.
   d. Trigger levels keyed to the location on the drawing.
   e. Results keyed to the location on the drawing.
   f. Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.

Item 10.7 Cont'd.

10. The RSO or their designate will review the survey results on a quarterly basis for conformance to certain action levels.

11. The method for determining the efficiency factor of each counting instrument used to detect contamination for wipe testing is as follows:

A = Calculated source activity of sample isotope in dpm
B = Measured source counts of sample isotope in cpm
C = Measured background counts in cpm
D = B - C (Net Counts in cpm)

$$\text{Efficiency Factor} = \frac{\text{Calculated Activity in dpm (A)}}{\text{Net Counts in cpm (D)}}$$

Wipe Sample-dpm = (Net Counts of Wipe Sample)(Efficiency Factor)

12. The RSO will be notified of all positive wipe test and ambient survey results.

AIR CONCENTRATION CONTROL

Item 10.8.1

We will not use radioactive gases at this facility.

WORKER DOSE FROM AEROSOLS

Item 10.8.2

We will collect spent aerosol in a single use shielded trap and therefore no effluent monitoring is needed.

PUBLIC DOSE FROM AIRBORNE EFFLUENTS

Item 10.8.3

We will not directly vent spent aerosols and gases to the atmosphere and, therefore, no effluent estimation is necessary

BYPRODUCT MATERIAL USAGE RECORDS

Item 10.9

Unit Dose Records - will contain:

1. Technical Data
   a. Radionuclide
   b. Chemical form or abbreviation
   c. Date of receipt
   d. Activity recorded on the packing slip
   e. Supplier
   f. Lot or serial number

2. Administrative Data
   a. Time and Date of Administration
   b. Measured activity
   c. Patient name and/or ID number
   d. Method of disposal
   e. Initials of person recording the information
   f. Date of disposal or return to supplier

Item 10.10

Multidose Vial Records - will contain:

1. Technical Data
   a. Radionuclide
   b. Chemical form or abbreviation
   c. Date of preparation
   d. Date, time, and activity of initial assay
   e. Supplier of kit manufacturer

2. Administrative Data
   a. Date and time dosage was drawn
   b. Prescribed dosage
   c. Calculated inverse concentration (cc/mCi) at drawing time
   d. Calculated volume needed for prescribed dose
   e. Measured activity
   f. Patient name and ID number
   g. Method of disposal and date
   h. Initials of person recording information

WASTE DISPOSAL

Item 11.1

LIQUIDS

1. Disposal to the sanitary sewer system will be made in accordance with 10 CFR 20.2003. A record will be kept of the following: date, radionuclide, estimated activity released, and place where material was released.

2. Permissible concentrations in effluents will be kept within the limits enumerated in Table 3 of Appendix B of 10 CFR 20.

3. Additionally, licensed commercial radioactive waste services such as ADCO may be used.

DECAY IN STORAGE

1. Only material with a physical half-life of less than 65 days may be decayed in storage at the facility.

2. Each container will be tagged to include:
   a. The date sealed or set into storage
   b. The longest-lived isotope in the container
   c. The initials of the person setting the waste for decay.

3. Material will be decayed for at least 10 half-lives.

4. Prior to disposal as in-house waste, each container will be monitored as follows:
   a. Low-range GM survey meter will be checked for proper operation.
   b. Waste will be monitored in a low level area.
   c. Any shielding around the container will be removed.
   d. All surfaces of each individual container will be monitored.
   e. Only those containers which cannot be distinguished from background levels will be disposed of after all radioactive labels have been defaced.
   f. The date on which the container was placed in storage will be recorded.
   g. The date of disposal will be recorded.
   h. The type of material will be recorded.

Item 11.1 Cont'd

UNIT DOSE WASTE

If a unit dose pharmacy is used, the materials supplied by them (e.g., syringes, needles, etc.) may be returned to the unit dose pharmacy in the original shipping container. Pertinent DOT regulations will be followed as specified by the unit dose pharmacy

QUALITY MANAGEMENT PROGRAM

Item 12

We confirm that this institution does not use any radioactive material which would cause the initiation of the Quality Management Program as described in 10 CFR 35.32. We therefore ask for an exemption from the Quality Management Program.

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

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

EMPLOYEE/VENDOR/PAYEE CODE: * _____

NAME: Ctallah Heart Center

ADDRESS: Attn: Dr Pierre C. Ctallah

ADDRESS: P.O. Box 82177

CITY: Rochester STATE: MI ZIP: 48308

TRANS CODE: PX TRANS TYPE: FE FUND: X5280

JOB CODE: _____ (FOR FE TRANS TYPE) REFUND AMOUNT: $1400.00

COMMENTS: Lic 21-25968-01 Rev Appl Rfnd
CK 17391

(limit comments to 40 characters, including spaces)

PREPARED BY: Shirley Crutchfield DATE: 2/2/95

AUTHORIZED BY: Cheryl Tubbs TITLE: Sys Inv Analyst

OFFICE: OCFO DATE: 2/10/95

ORIGINAL INVOICE #: _____ DATE PAID: _____ AMOUNT: $_____

REFUND ENTERED INTO COLLECT BY: _____

REFUND DETERMINED BY: _____ DATE: _____

PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION.

* AN ADDRESS MUST BE PROVIDED FOR VENDORS NOT FOUND ON THE VEND TABLE.

Ofc 11 III Rev TC #1400 17391

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