NAC FORM	31	,	
10 CFR 30.	32.	33,	34.

APPLICATION FOR MATERIAL LICENSE

PLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:	IF YOU ARE LOCATED IN		
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY. NMS5 WASHINGTON, DC 2000	U.S. NUCLEAR REGULATORY COMMISSION, REGION III		
L OTHER PERSONS FILE APPLICATIONS AS FOLLOWS. IF YOU ARE CATED IN:	MATERIALE LICENSING SECTION 760 RODSEVELT ROAD OLEN ELLYN. IL 80137 ARKANBAB, COLORADO, IDAHO, KANBAB, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, BOUTH DAKOTA, TEXAB, UTAH, OR WYOMINU, SEND APPLICATIONS TO: U.S. NUCLEAR REGULATORY COMMISSION, REGION IV MATERIAL RADIATION PROTECTION SECTION 611 RYAN PLAZA DRIVE, BUITE 1000 ARLINGTON, TX 78011 ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSEESIONS IN THE PACIFIC, SEND APPLICATIONS TO: U.S. NUCLEAR REGULATORY COMMISSION, REGION V NUCLEAR MATERIALS BAFETY SECTION 1480 MARIA LANE, SUITE 210 WALNUT CREEK, CA BISSE		
INNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARVLAND. ISSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA. IODE ISLAND, OR VERMONT, SEND APPLICATIONS TO			
J.S. NUCLEAR REGULATORY COMMISSION, REGION I NUCLEAR MATERIALS BAFETY BECTION B DI PARK AVENUE (ING OF PRUSSIA, PA 19408			
ASAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, Erto Rico, South Carolina, tennessee, Virginia, Virgin Islands, or Ist Virginia, Bend Applications to			
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HIS IS AN APPLICATION FOR (Check appropriate (tem)	2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zo Code)		
A NEW LICENSE	Saginaw General Hospital		
C RENEWAL OF LICENSE NUMBER	1447 N. Harrison Street		
	Saginaw, MI 48602		
Duane Zenn (Medical Physics Consultants)	313-662-3197		
IMIT ITEMS & THROUGH 11 ON 8% + 11" PAPER. THE TYPE AND SCOPE OF INFORMATIC RADIOACTIVE MATERIAL	ON TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE		
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SAGINAW GENERAL HOSPITAL

21-00607-04

Item 5/6

Radioactive Material Use

Byproduct Material

Amount

As Needed

Material in 35.100

Material in 35.200 Material in 35.300 Material in 31.11 As Needed Uptake, delution, excretion studies As Needed Imaging and localization As Needed Radiopharmaceutical Therapy

In Vitro studies

Purpose Medical

Item 7	Radiation Safety F	Program		
Authorized Users	Material			
R.A. Siwik, M.D.	35.100,	35.200, 35.300	\$ 31.11	
Richard P. Heuschel	e, M.D. 35.100,	35.200, 35.300	\$ 31.11	
C.E. Mueller, M.D.	35.100, for	35.200, 35.300 therapy) & 31.	(lodine-13) /	as iodide
Gary Herzler, M.D.	35.100, mer dys	35.200, 35.300 at of hyperthyro sfunction) & 31	(Iodine-131) Didism & cardi .11	for treat- iac
John F. Cherry, M.I	. 35.100,	35.200 & 31.11		

William A.P. Supan, M.D. 35.100, 35.200 & 31.11

Radiation Safety Officer

C.E. Mueller, M.D.

SAGINAW GENERAL HOSPITAL

EQUIPMENT LIST

Gamma Cameras

- 1. General Electric Starcam model 46-34128666
- 2. General Electric 400A Tomographic Camera model 46-47503628
- 3. General Electric 400T model 46-403083P1

Dose Calibrator

Searle CRC-22NB

Survey Meters

- 1. Eberline model E-520 GM survey meter
- 2. Bicron surveyor model, serial number A159A

Xenon Delivery System

Pulmonex model 130500

Item 8.1

PERSONNEL TRAINING PROGRAM

All ancillary personnel whose duties will require them to work in the vicinity of radioactive materials will be instructed:

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

Ancillary personnel may include cleaning/housekeeping personnel, security, nurses, EKG technologists, etc.

Instruction will include the following subjects:

- 1. Applicable regulations and license conditions.
- 2. Areas where radioactive material is used or stored.
- Potential hazards associated with radioactive material in each area where the employees will work.
- 4. Appropriate radiation safety procedures.

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- 5. Licensee's in-house work rules.
- Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
- Appropriate response to emergencies or unsafe conditions.
- Worker's right to be informed of occupational radiation exposure a.d bioassay results.
- Locations where the licensee has posted or made available, notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions, as required by 10CFR19.

CONTROL NO 8619 0

Saginaw General Hospital

Facility Diagram



Item 9.2

CALIBRATION OF SURVEY INSTRUMENTS

All survey instruments will be calibrated and checked in accordance with 10CFR35.51. Survey instruments will be calibrated by: (1) the manufacturer; or (2) Medical Physics Consultants (NRC License No. 21-20153-01).

Item 9.3(1 of 3)

CALIBRATION OF DOSE CALIBRATOR

In accordance with 10CFR35.50

Testing Frequency and Tolerance

- a. Constancy: at least dally prior to the assay of patient doses +/- 10% tolerance
- b. Linearity: upon installation and at least quarterly thereafter +/- 10% tolerance
- c. Accuracy: upon installation and at least annually thereafter +/- 10% tolerance
- d. Geometry dependence: upon installation +/- 10% tolerance

Following repair or adjustment, the above tests will be repeated as appropriate.

Testing Methods

a. Constancy:

Source - 50 uCl or more of Cs-137

- Assay the source on the appropriate dose calibrator setting.
- Measure the background on the same setting, and subtract or confirm the proper operation of the automatic background subtraction circuit if it is used.
- Log in a book the background reading and the net activity of the source.
- Repeat the above procedure for a commonly used radioisotope setting.
- Write in the log book or post on the calibrator, action levels at which the individual performing the test will automatically notify the chief technologist or authorized user of suspected malfunction of the calibrator.

Page 2

- b. Linearity:
 - Source Tc-99m, activity at least as large as the maximum activity administered to a patient.
 - Decay Method
 - Assay the Tc-99m and subtract the background reading to obtain the net activity. Record the date, time, and net activity.
 - Repeat Step 1 three times daily at equally spaced intervals until the assayed activity is less than 10 uCl.
 - 3. Pick a reading (to be used as a standard) which is near to a millicurie value that is frequently used for patient doses. Backdecay this value to obtain calculated values for all readings prior to the standard reading. Decay the standard reading to obtain the calculated values for all readings taken after the standard reading.
 - Calculate the deviation of the measured values from the calculated values.
 - Shield Method

If the shield or sleeve method is used, the linearity test and initial calibration of the shields or sleeves will be performed in accordance with the manufacturer's instructions.

- c. Accuracy:
 - Sources Cs-137 dedicated source of at least 50 uCl <u>and</u>

Co-57 or Ba-133 dedicated source of at least 50 uCl

- 1. Assay the calibrated source on the appropriate setting.
- Remove the source from the calibrator and measure the background reading on the same setting.
- Subtract the background reading from the measured activity to obtain the net activity.
- Repeat this procedure for the other calibrated sources.

d. Geometry Dependence:

Source - Tc-99m between 1 and 10 mCi/ml Syringe method - for all licensees

- Draw 0.5 ml of Tc-99m liquid into a syringe of the size normally used for patient doses.
- Place the syringe in the dose calibrator in a reproducible geometry.
- 3. Assay the syringe. Record the measured value and the volume.

Item 9.3 cont.

- Draw an additional 0.5 ml of non-radioactive saline or water into the syringe. Special care must be taken that none of the original radioactive liquid is released from the syringe during this process.
- Assay and record the measured value and volume.
- Repeat this procedure until a volume of 2.0 ml has been assayed.
- Select as a standard the volume that is closest to that used most frequently for patient doses.
- Divide all measured values by the standard activity. The quotient is the volume correction factor.
- Vial method for facilities using generators or radiopharmaceutical kits (<u>in</u> <u>addition</u> to the above method).
 - Begin the test with 1 ml of Tc-99m in a vial of the size most frequently used for elutions and kits.
 - Assay the vial and record the measured value and the volume.
 - Add 2.0 ml of non-radioactive saline or water to the vial.
 - Assay and record the measured activity and volume.
 - Repeat this procedure until a 19 ml volume has been assayed.
 - Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits.
 - Divide all measured activities by the standard activity. This is the volume correction factor.

e. The Radiation Safety Officer must review and sign all of the above tests except the constancy tests.

Action Levels

Linearity or geometry errors in excess of 10% shall be mathematically corrected for in measurement of doses greater than 10 uCl.

Accuracy or constancy errors in excess of 10% shall be cause for repair or replacement of the dose calibrator.

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Item 9.4

PERSONNEL EXTERNAL EXPOSURE MONILORING PROGRAM

- The RSD or delegate will promptly review all film or TLD exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low.
- All individuals who are occupationally exposed to radiation on a regular basis and may receive greater than one-tenth the guarterly permissible limits will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis.
- All individuals who handle radioactive material on a regular basis will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.
- 4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for those patients.
- 5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

APPENDIX F

Model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority (See §§ 35.21, 35.22, and 35.23.)

You may use the following text as it appears here, saying on your application, "We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that was published in Appendix F to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own statement of authority, duties, administrative procedures, and delegation of authority. If you do so, you should consider for inclusion all the features in the model text and carefully review the requirements of §§ 35.22. Say on your application, "We will issue the Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that are appended as ATT 10.1," and append your charter and delegation.

MODEL CHARTER

Charge. The Committee shall:

- Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;
- Ensure that licensed material is used in compliance with NRC regulations and the institutional license;
- Ensure that the use of licensed material is consistent with the ALARA philosophy and program;
- Establish a table of investigational levels for individual occupational radiation exposures; and
- Identify program problems and solutions.

Responsibilities. The Committee shall:

- Be familiar with all pertinent NRC regulations, the license application, the license, and amendments;
- Review the training and experience of the proposed authorized users, the Radiation Safety Officer (RSO), and the teletherapy physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;
- Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the institution;

- Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures;
- Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;
- Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required in § 19.12 of 10 CFR Part 19;
- 7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system;
- Recommend remedial action to correct any deficiencies identified in the radiation safety program;
- Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken; and
- Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information

- The Committee shall meet as often as necessary to conduct its business but not less than once in each calendar guarter.
- 2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct members representatives from security, physical plant, housekeeping, and other departments. (Adjunct members should abstain from balloting on radiation safety technical questions such as Items 2 through 5 in the "Responsibilities" section above.)
- 3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.
- 4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

MODEL DELEGATION OF AUTHORITY

Memo To:	All Employees
From:	Chief Executive Officer
Subject:	Delegation of Authority

has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for maraging the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

The Radiation Safety Officer is also responsible for assisting the Radiation Safety Committee in the performance of its duties and serving as its secretary.

APPENDIX G

Model Program for Maintaining Occupational Radiation Exposure at Medical Institutions ALARA (See § 35.20.)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own ALARA program for NRC review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.20. Say on your application, "We have developed an ALARA program for your review that is appended as ATT 10.2," and append your program.

ALARA PROGRAM

Saginav General Hospital (Licensee's Name)

> 9-26-88 (Date)

- 1. Management Commitment
 - a. We, the management of this (medical facility, hospital, etc.), 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 instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and 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.

- 2. Radiation Safety Committee
 - a. Review of Proposed Users and Uses
 - (1) The RSC 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 RSC will review the efforts of the applicant to maintain exposure ALARA.
 - (3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.
 - b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

- The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
- (2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
- c. Review of ALARA Program
 - The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
 - (2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 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 (see Section 6 below for a discussion of investigational levels).*

^{*}The NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify investigations.

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Investigational Levels

		Investigational Levels (mrems per calendar quarter)	
		Level I	Level II
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 whole body*	750	2250

*Not normally applicable to medical use operations except those using significant quantities of beta-emitting isotopes.

(3) The RSC will evaluate our institution'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.

3. Radiation Safety Officer

- a. Annual and Quarterly Review
 - (1) <u>Annual review of the radiation safety program</u>. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
 - (2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.
 - (3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.
- b. Education Responsibilities for ALARA Program
 - 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, the RSC, and the RSO are committed to implementing the ALARA concept.
- c. 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.

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

- 4. Authorized Users
 - a. New Methods of Use Involving Potential Radiation Doses
 - The authorized user will consult with the RSO and/or RSC 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. Trial runs may be helpful.
 - 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.
- 5. 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 is not being promoted on the job.

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

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or 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 § 20.401 of 10 CFR Part 20. 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 of the reviews at the first RSC meeting 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 the Committee. The Committee 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 in the Committee minutes.

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 Form NRC-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

 Reestablishment of investigational levels to levels above those listed in Table 1.

In cases where a worker's or a 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. The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

7. Signature of Certifying Official*

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

Signature

Donald E. Juenemann Name (print or type)

President and C.E.O.

Title

*The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

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CONTROL NO. 8619 0

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

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.

RULES FOR THE SAFE USE OF RADIOPHARMACEUTICALS

- Wear laboratory coats or other protective clothing at all times in areas where radioactive materials used.
- Wear disposable gloves at all times while handling radioactive materials.
- Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low-background area.
- 4. Use syringe shields for routine preparation of patient dosages and administration of patients, except in those circumstances in which their use is contraindicated. In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose.
- 5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
- Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
- 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.
- Wear a finger exposure montior during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- 10. Never pipette by mouth.
- 11. Confine radioactive solutions in shielded containers that are clearly labeled with the isotope, the name of the compound, 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.
- 12. Assay each patient dose in the dose calibrator before administering it. Do not use a dose if it differs by more than 10 percent of the prescribed dose, except prescriptions of less than 10 uCi. Check the patient's name and I.D. number and the prescribed radionuclide, chemical form, and dosage before administering.

- Always keep radioactive material in shielded locations or containers.
- 14. Use a cart of wheelchair to move flood sources, syringes, waste, and other radioactive material.

EMERGENCY PROCEDURES

Minor Spills

- NOTIFY: Notify persons in the area 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 contaminated gloves and any other contaminated disposable material in the bag.
- SURVEY: Survey the area with a low-range, thin-end window GM survey meter. Check the area around the spill, hands, clothing, and shoes for contamination.
- REPORT: Report the incident to the Radiation Safety Officer who will supervise the cleanup of the spill and complete the Radioactive Spill Report.

Major Spills

- CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
- 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.
- SHIELD THE SOURCE: This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
- 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.
- REPORT: The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2.

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Item 10.6 Page 1 of 2

APPENDIX K

Model Guidance for Ordering and Receiving Radioactive Material (See §§ 30.51 and 20.205.)

You may use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may say on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of §§ 30.51 and 20.205. Say on your application, "We have developed a procedure for ordering and receiving radioactive material for your review that is appended as ATT 10.6," and append your procedure for ordering and receiving radioactive material.

MODEL GUIDANCE

- 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. For routinely used materials
 - Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.
 - (2) The above records will be checked to confirm that material received was ordered through proper channels.
 - b. For occasionally used materials (e.g., therapeutic dosages)
 - The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.
 - (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.
- For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.
- 4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

Item 10.6 Page 2 of 2

Sample Memorandum

MEMO TO: Chief of Security TRUM: Radiation Safety Officer SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room _____. Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that wither the driver nor the delivery vehicle is contaminated.

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

	Name	Home Telephone
Radiation Safety Officer:		
Chief of Nuclear Medicine:		
Chief Nuclear Medicine Technologist:		
Nuclear Medicine Technologist on call (call page operator at extension	_)	
Nuclear Medicine Physician on call (call page operator at extension		

OPENING RADIOACTIVE MATERIAL PACKAGES

We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2.

Page 1 of 2

APPENDIX L

Model Procedure for Safely Opening Packages Containing Radioactive Material (See §§ 35.23, 30.51, 20.203(f)(4), and 20.205.)

You may use the following model procedure for opening packages. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2."

If you develop your own package opening procedure for review, you should consider for inclusion all the features in the model. Say on your application, "We have developed a package opening procedure for your review that is appended as ATT 10.7," and append your package opening procedure.

MODEL PROCEDURE

- 1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraph 20.205(b) of 10 CFR Part 20 (e.g., more than 20 curies of Mo-99, Tc-99m, uncompressed Xe-133, or more than 3 curies of Xe-133, I-131, Cs-137, Ir-192, I-125, or more than 0.001 curie of Ra-226). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100 cm².
- For packages received under the specific license, the following procedure for opening each package will be followed:
 - a. Put on gloves to prevent hand contamination.
 - b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
 - c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSC. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface (see § 71.4 of 10 CFR Part 71); the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface. (See § 172.403 of 49 CFR Part 172.))
 - d. Open the package with the following precautionary steps:
 - (1) Remove the packing slip.

- (2) Open the outer package following the supplier's instructions, if provided.
- (3) Open the inner package and verify that the contents agree with the packing slip.
- (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
- (5) If anything is other than expected, stop and notify the RSO.
- e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. [The licensee should spc. fy in the procedure manual which instrument, for example, a thin-ene window GM survey meter, a NaI(T1) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.] Take precautions against the potential spread of contamination.
- Check the user request to ensure that the material received is the material that was ordered.
- g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.
 - (1) If contaminated, treat this material as radioactive waste.
 - (2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
- h. Make a record of the receipt.
- 3. For packages received under the general license in § 31.11, the following procedure for opening each package will be followed:
 - a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
 - b. Check to ensure that the material received is the material that was ordered.

See Exhibit 12 for a sample record form you may want to use.

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BYPRODUCT MATERIAL USE

Item 10.8

Unit Dose Records shall contain:

Radionuclide Chemical form or abbreviation Date of receipt Activity as recorded on the packing slip Supplier Lot or control number Administration data time and date of administration measured activity patient name and ID number Method of disposal and date Initials of person recording information

Item 10.9

Multidose Vial Records shall contain:

Radionuclide Chemical form or abbreviation Date of receipt or preparation Date, time, and activity of initial assay Supplier or kit manufacturer Administration data date and time dosage was drawn prescribed dosage calculated inverse concentration (cc/mCl) at drawing time calculated volume needed for prescribed dose measured activity patient name and ID number Method of disposal and date Initials of person recording information

Item 10.10

Molybdenum Concentration Records shall contain:

Date the generator was received Date and time of elution Measured Mo-99 activity in microcuries Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer Measured Tc-99m activity in millicuries Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and checkmark that ratio is less than that specified in 10 CFR 35.204 (a) Initials of the person who made the record

AREA SURVEY PROCEDURES

Surveys for contamination and ambient exposure rates will be performed in accordance with 10 CFR 35.70.

1. All areas where radiopharmaceuticals are eluted, prepared, and administered will be surveyed daily for ambient radiation exposure rates and weekly for removeable contamination. Special care will be taken to remove all paraphernalia from patient rooms where diagnostic administrations are occasionally made; and these rooms will not be surveyed.

2. All areas where radioactive materials are stored will be surveyed weekly for ambient radiation exposure rates and removeable contamination.

3. Laboratory areas where less than 200 uCl of by-product materials are used will be surveyed monthly for ambient radiation exposure rates and removeable 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 removeable 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 rates above the normal background reading for that area.

7. The trigger level for removeable contamination surveys will be the detection of values greater than three standard deviations above background values.

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

9. A record shall be kept of all survey results. The record will include:

- a. Location, date, and type of equipment used.
- b. Initials of the person conducting the survey.
- c. Drawing of the areas surveyed.
- d. Trigger levels keyed to the location on the drawing.
- e. Results keyed to the location on the drawing.
- Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.

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

PROCEDURES FOR AIR CONCENTRATION CONTROL OF XENON-133

Spent gas will be collected in a shielded trap. We will follow the procedures listed below for monitoring the trap effluent.

1. The trap effluent will be collected from the exhaust of the trapping system upon receipt and once each month in which the system is used.

2. The effluent will be collected from the trap during one patient study in a plastic bag.

3. The activity in the bag will be monitored by holding the bag against a camera which has been adjusted to detect Xe-133 and comparing its counts per minute (cr. to background cpm with no other activity in the area.

4. A record will be kept of the date, background cpm, and bag cpm.

5. An action level will be established based on the background cpm or a multiple of background. Significant increases in the bag cpm above normal, indicate that the trap is breaking down and will be replaced.

6. Manufacturer's directions will be followed for replacing the trap.

7. All rooms in which radioactive Xenon-133 gas studies are performed will be maintained at tem percent negative pressure.

8. Emergency procedures for the accidental release of Xenon-133 gas will be posted in the applicable imaging rooms.

SPILLED GAS CLEARANCE TIME (Item 10.13.4)

Because normal room ventilition is usually not sufficient to ensure timely clearance of spilled gas, the calculations described in Appendix 0.4 should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

If you will calculate spilled gas clearance times according to the following procedure, you may respond to Item 10.13.4 by saying, "We will calculate spilled gas clearance times according to the procedure that was published in Appendix 0.4 to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of § 35.205. Say on your application, "We have developed a procedure for calculating spilled gas clearance times that is appended as ATT 10.13.4," and append your procedure.

0.4 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

- 1. Collect the following data:
 - a. A, the highest activity of gas in a single container, in microcuries;
 - Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser value), in milliliters per minute;
 - c. Q, the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal air exhaust or a specially installed gas exhaust system;
 - d. C, the maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are $1 \times 10^{-5} \mu$ Ci/ml in restricted areas and $3 \times 10^{-7} \mu$ Ci/ml in unrestricted areas. For other gases, see Appendix B to 10 CFR Part 20; and
 - e. V, the volume of the room in milliliters.

0-4

- For each room make the following calculations:
 - a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
 - b. The evacuation time $t = \frac{-V}{O} \times \ln (C \times V/A)$.

Item 10.14 Page 1 of 3

APPENDIX P

Model Procedure for Radiation Safety During Iodine Therapy Over 30 Millicuries (See §§ 35.300, 35.75, and 20.105.)

You may use the following procedure for reducing worker and public dose during radiopharmaceutical therapy. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix P to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of §§ 19.12, 20.105, 35.75, and 35.300. Say on your application, "We have developed a procedure for radiation safety during therapeutic use of radiopharmaceuticals for your review that is appended as ATT 10.14," and append your procedure.

MODEL PROCEDURE

- The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.
- 2. Prepare the room for the procedure as follows:
 - a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, door knobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.
 - b. Prepare separate boxes for linen, disposable waste, and nondisposable contaminated items. Place a single large reclosable plastic bag in each box, or supply several small plastic bags.
 - c. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.
 - (1) Containers should be unbreakable and closable.
 - (2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.
 - (3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.
 - (4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately 3 mm of lead.)
 - (5) Supply a wide-mouth antisplash funnel.

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- d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.
- Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.
- 4. Supply the nurses with film badges, TLDs, or pocket ionization chambers.
- 5. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Iodine-131, Phosphorus-32, or Gold-198" (Exhibit 17), or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.
- Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.
- Only those persons needed for medical, safety, or training purposes should be present during the administration.
- 8. Mark a visitors', "safe line" on the floor with tape as far from the patient as possible.
- 9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in paragraph 20.105(b)). Record this and any other necessary information on the nursing instructions form or the nurses' dosimeter signout form. Post the room with a "Radioactive Materials" sign.
- 10. For patients treated with liquid or gelatin-capsuled I-131, 1 day after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Also consider a thyroid burden assay for patient care personnel 2 days after the administration. Make a record of the worker's name, amount of I-131 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden, and date.
- 11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.
- 12. Do not release any patient until either the exposure rate from the patient is less than 5 millirem per hour at 1 meter or the retained radioactivity is less than 30 millicuries (see § 35.75). If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

- Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.
 - a. Remove all absorbent paper, and place it in the appropriate container.
 - Transfer all containers to a decay-in-storage or decontamination area.
 - c. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm².
 - d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

Exhibit 18, "Radiation Safety Checklist for Iodine Therapy over 30 Millicuries," may also be helpful to you.

Item 11.1

WASTE DISPOSAL

Liquids and Games

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere.

- Disposal to the sanitary sewer will be made in accordance with 10CFR20.303. A record will be kept of the following: date, radionuclide, estimated activity released, and place where material was released.
- Permissible concentrations in effluents will be kept within the limits enumerated in Table II of Appendix B of 10CFR20. A record will be kept of the date, radionuclide, estimated activity released, estimated concentration, and vent site at which the material was released.

Decay-in-Storage

- Only material with a physical half-life of less than 65 days may be decayed in storage at the facility.
- 2. Material will be decayed for at least 10 half-lives.
- Prior to disposal as in-house waste, each container will be monitored as follows:
 - 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.
 - 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 radioactivity labels have been defaced.
- 4. Mo-99/Tc-99m generators will be held for at least 60 days before being dismantled. When dismantling generators, a low-range GM survey meter will be kept at the work area. The oldest generator will be dismantled first, working forward chronologically. Each individual column will be held in contact with a low-level survey instrument in a low background (less than 0.05 mR/hr) area. The generator date and disposal date will be logged in the disposal records. Radiation labels will be removed or defaced on the generator shield. Generators may also be returned to the manufacturer for disposal.

Unit Dose Waste

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