MATERIALS LICENSE

Amendment No. 10

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Environmental Protection Agency National Health and Environmental Effect Research Laboratory, 2. Mid-Continent Ecology Division NHEERL MED-Duluth 6201 Congdon Boulevard Duluth, MN 55804	In accordance with letter dated June 28, 1996 3. License Number 22-13390-01 is amended in its entirety as follows: 4. Expiration Date March 31, 2003 5. Docket or Reference No. 030-05046

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Hydrogen-3	A. Any	A. 100 millicuries
B. Carbon-14	B. Any	B. 80 millicuries
C. Cadmium-109	C. Any	C. 1.0 millicuries
D. Mercury-203	D. Any	D. 1.0 millicuries
E. Hydrogen-3	E. Foil sources (which have been elevated and approved by the NRC or an Agreement State)	E. No single source to exceed 250 millicuries. Total possession not to exceed 500 millicuries
F. Nickel-63	F. Foil sources (which have been evaluated and approved by the NRC or an Agreement State)	F. No single source to exceed 15 millicuries. Total possession not to exceed 450 millicuries
G. Iodine-125	G. In-vitro test kits.	G. 5.0 millicuries total, not to exceed 40 microcuries per kit.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 22-13390-01
Docket or Reference Number: 030-05046
Amendment No. 10

9. Authorized Use:

A. through D. and G. To be used in laboratory studies.

E. through F. To be used in gas chromatographs for sample analysis.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 6201 Congdon Blvd. Duluth, Minnesota.

11. A. Licensed material except subitem 6.G. shall be used by, or under the supervision of, Gary E. Glass, James M. McKim, Allan R. Batterman, Rodney Johnson, Patricia K. Schmieder, Steven Bradbury, Michael Sierszen, Joseph E. Tietge or Douglas Lothenbach.

B. Licensed material listed in subitems 6.E. and 6.F. may also be used, or under the supervision of, Michael L. Knuth.

C. Radiation Safety Officer: Allan R. Batterman

D. Licensed material listed in subitem 6.G. shall be used by Mumtaz Pasha.

12. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.

13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

14. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

15. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the quantities and kinds of byproduct material, manufacturer's name and model numbers, location of the sources and/or devices, and the date of the inventory.

16. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), the licensee is hereby authorized to label detector cells, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 22-13390-01
Docket or Reference Number: 030-05046
Amendment No. 10

17. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

18. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by U.S. Nuclear Regulatory Commission.

    B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

19. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

    B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

    D. Sealed sources need not be leak tested if:

    (i) they contain only hydrogen-3; or

    (ii) they contain only a radioactive gas; or

    (iii) the half-life of the isotope is 30 days or less; or

    (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

    (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
22-13390-01

Docket or Reference Number
030-05046

Amendment No. 10

E. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

F. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to Perform such services.

20. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated February 5, 1993; and

B. Letters dated March 3, 1988, June 28, 1996, and March 3, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date March 17, 1997

By Evelyn R. Gibson
Nuclear Materials Licensing Branch, Region III

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620
STATUS CODE: 0
FEE CATEGORY: EX 3M
EXP. DATE: 20030331
FEE COMMENTS: 170.11(A)(5)
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: ENVIRONMENTAL PROTECTION AGENCY
RECEIVED DATE: 960702
DOCKET NO: 3005046
CONTROL NO.: 301566
LICENSE NO.: 22-13390-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: ~~*~~
CHECK NO.: ~~*~~

* addl info
398925 - 56

3. COMMENTS

SIGNED D. Hersey
DATE ~~4-12-96~~

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

1. FEE CATEGORY AND AMOUNT: _____

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

3. OTHER _____
_____

SIGNED _____
DATE _____

FEE EXEMPT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HEALTH AND ENVIRONMENTAL EFFECTS
RESEARCH LABORATORY
MID-CONTINENT ECOLOGY DIVISION
6201 CONGDON BOULEVARD • DULUTH, MN 55804- 2595

June 28, 1996

Nuclear Regulatory Commission
Region III
ATTN:Colleen C. Casey
Nuclear Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

OFFICE OF
RESEARCH AND DEVELOPMENT

Dear Ms. Casey:

Enclosed are materials which address your concerns on the amendment to License No. 22-13390-01; Docket No. 030-05046, these materials address only the I^{125} research. The other issues will be dealt with separately.

In the enclosed documents, we attempt to address all your questions with detailed explanations. If certain issues require additional clarification please notify our Radiation Safety Officer, Allan R. Batterman. Thank-you for your time and effort in reviewing these materials.

Sincerely,

Steven F. Hedtke,
Acting Director

Attachments (3)

1. I^{125} Safety Summary
2. I^{125} Research Workplan Summary
3. Summary of Researchers Technical Training and Experience

cc: Allan R. Batterman

FEE EXEMPT

301566

1. MED-Duluth I^{125} SAFETY SUMMARY

I^{125} LABORATORY RADIOIMMUNOASSAY STUDIES will follow guidelines described in depth in MED's "The Radiation Safety, Operational Procedures Manual". The manual was revised and edited by Allan R. Batterman and reviewed by the Radiation Safety Committee and approved by the Director on November 30, 1995 for the Mid-continent Ecology Division, National Health and Environmental Effects Research Laboratory, Office of Research and Development, U.S. Environmental Protection Agency.

A. GENERAL RULES

The purpose of these guidelines is to provide a safe working environment for occupationally exposed workers, the public at large, and the environment (avoid contamination of equipment and facilities).

All persons who are permitted as specified by the facilities license to work with radioactive materials shall be aware of the procedures specified and be trained in matters of radiation safety. Employees working with radioisotopes shall read and comply with the information in 10 CFR 20 and 10 CFR 30.

B. LABORATORY RULES

The use of good laboratory procedures is greatly facilitated by having the proper tools/ supplies at hand; before any work begins the Principal Investigator and the Radiation Safety Officer must:

1. Discuss with the employee(s) the work to be done and the necessary safety precautions in accordance with 10 CFR 20;

2. Outline in the research work plan the procedure for each job (make the amount of detail commensurate with the hazard);

3. Have the laboratory stocked with suitable gloves, lab coats, warning tags and labels, wipes, appropriate survey/counting instruments, forms for necessary records, plastic bags and tape for waste disposal absorbent paper, etc.

4. Have available, and use when appropriate, shielding, remote handling devices, automatic pipettes or dispensers, tongs, etc., for the manipulation and transfer of radioactive material and a lockable storage area for radioactive materials.

5. Conduct "dry runs" to ensure that all personnel know the procedures to be carried out and to work out the process to ensure that all supplies and equipment are readily available and in suffucient quantity to eliminate the need to have to stop procedures before completion. These "dry-runs" contribute to developing laboratory practices that eliminate extended exposures and the spread of

contaminationand ensure that needed supplies and equipment are readily available in a confined area.

C. SPECIAL REQUIREMENTS FOR CERTAIN RADIOISOTOPES

1. Shielding Requirements: X or gamma ray sources(e.g., ^{125}I, ^{51}Cr, ^{131}I) - lead or other high Z shielding. Contact the RSO for appropriate type and thickness of shielding.

2. Film badges an d TLD ring dosimeters may be required for certain radiation sources (e.g. P^{32}). Also, bioassay monitoring (e.g., urine analysis for tritium, thyroid count for iodine) may be required. Contact the RSO for assistance in determining if monitoring is necessary.

3. Portable radiation monitoring instruments - Users of certain gamma sources are required to have a portable survey instrument in the laboratory use area. Contact the RSO for assistance in ordering approved instruments.

4. Volatility considerations: Research procedures which result in airborne releases of radioactive material must be confined to a properly designed hood and maintained within a closed system. A "dry-run" under the supervision of the RSO is required prior to initial use of radioactive materials in such a procedure.

5. All Radioisotope users must maintain quarterly report records and radioisotope receipts, waste disposal, and laboratory contamination surveys. Radioisotope purchase orders must be placed through the Health and Safety Program Manager and the RSO.

6. Radioisotope users must call the RSO to schedule radioactive waste pick-up.

D. MARKING AND LABELING

Rooms, areas and equipment where radioactive materials are used or stored shall be clearly marked with appropriately worded and designated standard radiation warning signs when required under the conditions set forth in the study. The sign must bear the three-bladed radioactive caution symbol (magenta or purple on yellow background).

E. PERSONNEL MONITORING

All persons who enter a restricted area shall wear appropriate personnel monitoring devices to ascertain the extent of any radiation exposures.. The RSO shall be responsible for obtaining, distributing, and collecting these devices.

F. CONDUCTING LABORATORY SURVEYS FOR MONITORING OF CONTAMINATION

The purpose of conducting laboratory swipe surveys is two-fold. Surveys are used to measure any potential removable contamination from laboratory work surfaces and to evaluate the potential exposure level to workers in the work area. Each laboratory using radioactive materials (except those with sealed sources such as ^{63}Ni EC Detectors) will be surveyed on a routine basis, in the case of I^{125} this will be after each operation or on a daily bases whichever is less frequent. The areas to be surveyed include appropriate benchtops, fume hoods, storage and waste disposal areas. The method to evaluate surface-contamination is to wipe a 100cm^2 area with a small piece of filter paper. Radioactivity on the filter paper is determined by gamma counting. The Pac Swipe Counter can be used for immediate routine checks (after each operation or daily) but should not be used for quarterly monitoring (use the gamma counter for this monitoring).

A diagram of the laboratory must be obtained prior to conducting the survey. Each laboratory diagram will illustrate the designated swipe survey areas and their associated i.d. number. Using disposable gloves, swipe a 100 cm^2 area with the Whatman #1, 2.5 cm filter paper. Place the paper into a prelabeled scintillation vial containing general purpose liquid scintillation cocktail. Place a minimum of 1 blank filter paper swipe (paper which does not contact any swipe areas) per laboratory or per designated sample site within a laboratory into a vial to establish a background level of radioactivity. Count all swipe samples on a liquid scintillation counter with the proper calibration procedure. For rapid analytical workup, check results using the same swipe procedures however check the swipes using the Pac Swipe Counter. Record all results on a Swipe Test Form, send the original to the RSO and maintain a copy for your files. Areas with removable contamination greater than 3 times the background level will be decontaminated and resurveyed until the levels are acceptable. Decontamination procedures are described in this manual and are available from the RSO.

I. RADIOACTIVE WASTE DISPOSAL

All radioactive waste must be placed in approved radioactive waste containers. Consider the wastes to be radioactive if, upon survey with a radiation monitor, the activity appears to be at least three times the normal background activity at that time.

Radioactive fish carcass and waste -

1. Do not place fish or any part of the carcass containing radioisotopes in laboratory radioactive waste containers. Serious odor problems will result.

2. Place the fish and/or any part of the carcass in a double plastic bag. Label the bag and list the radioisotopes and activity of each radioisotope (in millicuries) contained in the fish.

3. Temporarily store the waste in a radioisotope freezer or refrigerator in the laboratory or the Toxic Substances Control Room to prevent biodegradation until pick-up.

4. Vials or test tubes which contain small amounts of tissue or blood products may require special preparation prior to disposal. Contact the RSO for instructions.

5. When surveying equipment and lab benchs for beta and gamma emitters, the acceptable contamination levels are as follows: average 5000dpm/100cm^2, maximum 15,000dpm/100cm^2, removable 1000dpm/100cm^2. Half-life of I^{125} is 60.2 days, therefore 7 half-lifes is 1.15 years (421 days). NOTE: For the I^{125} study currently being considered the amounts of waste being generated will be held for decay (7 half-lifes) before disposal.

6. To request pick-up of radioactive biological wastes, contact the RSO.

J. EMERGENCY PROCEDURES

The most practical plan for handling radiation emergencies requires adequate training of persons who might become involved. Correct decisions are made when common sense is applied to a special problem. The primary consideration in an emergency is the PREVENTION OF INJURY TO HUMANS. The secondary consideration is the salvage of facilities and equipment. Persons discovering or involved in an emergency shall immediately notify trained personnel. Notification shall be made in the following order:

A. Radiation Safety Officer or his alternate.

B. Health and Safety Program Manager or a member of the Radiation Safety Committee or the Health and Safety Committee.

C. Local physician or contract clinic.

D. NRC Regional Office for Emergency Assistance. While awaiting the summoned assistance, steps shall be taken to control and contain the radioactive material. Emergencies include uncontrolled contamination, lost source(s), large exposures to radiation, or any other situations or circumstances which could possibly lead to contamination or radiation exposure. All personal injuries or radiochemical spills, no matter how slight, shall be monitored to determine if contamination has occurred. Three portable radiation instruments are available from the RSO.

2. I^{125} Research Workplan Summary

Introduction:

The Gamma Coat [I^{125}] Radioimmunoassay Kit for hormones will be purchased from a commercial source (INCSTAR). These kits will be used for in vitro quantitative determinations of hormones in the serum of fish and amphibians. No human serum will be used in any of the above assays. The analysis of hormones using these kits will involve handling of I^{125}. The total isotopic content of these kits will never exceed 40 uCi. These kits involved very little handling of radioactive material, the reagent is preprepared and therefore no measuring, weighing or dilution of the radiotracer is needed.

Principles of the Method:

The GammaCoat Radioimmunoassay is a competitive binding assay which is preformed entirely within a tube coated with the antigen specific antibody. During incubation, the free antigen and the [I^{125}] labeled antigen competes with the binding sites on the antibody. After incubation, the tubes are decanted into a container and counted.

Reagents:

1. [I^{125}] tracer, 1-5 vials. Each vial contains approximately 7uCi (259kBq) tracer and less than 1 ug of antigen per ml.

2. Anti-T4 Coated Tubes: Polypropylene (12X75 mm) coated with rabbit anti-antigen serum.

3. Incubation Buffers

4. Antigen Standards

Assay Procedure:

The assay procedure involves the preparation of a standard curve from which unknown free hormone level of the samples is interpolated.

1. Label 20 Gamma Coat tubes in duplicate.

2. Add to the appropriate duplicate tubes:

    a. 50 ul of standard for standard tubes
    b. 50 ul of fish or amphibian serum sample for sample tubes
    c. 50 ul of [I^{125}] labeled antigen to all tubes

3. Add 1.0 ml of incubation buffer to all tubes. Gently vortex each tube at low speed.

4. Incubate for 1 hour in a 37°C water bath.

5. Decant or aspirate all tubes into waste container.

6. Count all tubes in a gamma counter for 1 minute with the window suitably adjusted for I^{125}.

Precautionary measures for reagents containing Iodine^{125}

Appropriate precautions, good laboratory and record keeping practices will be used in the storage, handling and disposal of this material. All procedures explained in NRC Guidance and "The Radiation Safety, Operational Procedures Manual" of the laboratory will be followed. Storage of these materials will be limited to designated areas. Access to radioactive materials will be limited to authorized personnel only.

3. SUMMARY OF THE RESEARCHERS TECHNICAL TRAINING AND EXPERIENCE

Mumtaz Pasha has had experience in Quantative Chemistry and Radioimmunoassay Work that has developed her abilities to work with radiotracer analysis. The Radiation Safety Officer (RSO) will work closely with her in planning, conducting, and surveying the I^{125} work, probably the first several months. He will conduct Dry-Run Surveys during this entire period. Once her confidence is apparent and the RSO has certified her abilities in radioimmunoassay work he will then make only periodic spot checks. However, during this entire series of I^{125} planned radioimmunoassay tests we will require the swipe surveys and these will be monitored and approval received from the RSO before the next immunoassay can be conducted.

Following is Supplement A which lists the actual experience of Mumtaz Pasha.

Supplement A — **U.S. Nuclear Regulatory Commission**

TRAINING AND EXPERIENCE OF AUTHORIZED USER

1. NAME OF PROPOSED AUTHORIZED USER:	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
MUMTAZ S. PASHA	

3. CERTIFICATION

SPECIALITY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED
A	B	C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB TRAINING
a. RADIATION PHYSICS AND INSTRUMENTATION	---	NONE	NONE
b. RADIATION PROTECTION	EPA MED RADIATION SAFETY TRAINING/U OF M SERIES	4	NONE
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	EPA MED RADIATION SAFETY TRAINING/U OF M SERIES	4	NONE
d. RADIATION BIOLOGY	---	NONE	NONE
e. RADIOPHARMACEUTICAL CHEMISTRY	UNIVERSITY OF MINNESOTA, MINNEAPOLIS, JUNE 1991 SYNTHESIS OF RADIOACTIVE COMPOUND	---	40

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

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
H^3	1-5 mCi	EPA-MED RESEARCH LAB	500	RADIOIMMUNOASSAY INCLUDE', DILUTION OF RADIOISOTOPE STOCK SOLUTION, MEASURING AND COUNTING USING SCINTILLATION COUNTER

MAR 17 1997

Steven F. Hedtke
Acting Director
Environmental Protection Agency
National Health and Environmental
Effect Research Laboratory,
Mid-Continent Ecology Division
NHEERL MED-Duluth
6201 Congdon Boulevard
Duluth, MN 55804

Dear Mr. Hedtke:

Enclosed is Amendment No. 10 to your NRC Material License No. 220-13390-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

301566

b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

d. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Evelyn Matson
Nuclear Materials Licensing Branch

License No.: 22-13390-01
Docket No.: 030-05046

Enclosure: Amendment No. 10

DOCUMENT NAME: M:\03005046.CL7

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	N							
NAME	EMATSON:jaw								
DATE	03/17/97								

OFFICIAL RECORD COPY

FAX TRANSMISSION

USEPA, NHEERL, MED-D
6201 Congdon Boulevard
Duluth, MN 55804
218-720-5733
Fax: 218-720-5703

To:	Evelyn Matson	**Date:**	March 3, 1997
Fax #:	630-515-1259	**Pages:**	16, including this cover sheet.
From:	Allan R. Batterman		
Subject:	NRC License Amendment, Control No. 301566		

COMMENTS:

Following is our response to your request of February 19, 1997. I will be in my office all week do not hesitate to call if you have additional questions.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HEALTH AND ENVIRONMENTAL EFFECTS
RESEARCH LABORATORY
MID-CONTINENT ECOLOGY DIVISION
6201 CONGDON BOULEVARD • DULUTH, MN 55804-2595

March 3, 1997

Nuclear Regulatory Commission
Region III, Nuclear Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351
ATTN:Evelyn R. Matson

OFFICE OF
RESEARCH AND DEVELOPMENT

RE: Revisions to I^{123} Safety Summary and Research Plan Received 2/19/97

Dear Ms. Matson:

Enclosed are materials which address your concerns on the amendment to License No. 22-13390-01; Docket No. 030-05046, Control No. 301566; these materials address only the I^{125} research.

In the enclosed documents, we attempt to address all your questions, which were asked in the FAXed correspondence of February 19, 1997 with detailed explanations. The requested additional input is found in *italics* The deleted materials are ~~lined-out~~ in the attached summaries. Mumtaz Pasha will be the sole user of I^{125}. If any issues require further clarification, please notify our Radiation Safety Officer, Allan R. Batterman. Thank you for your time and effort in reviewing these materials. Other actions that were originally addressed in this Amendament Request have been dropped from our request.

Sincerely,

Steven F. Hedtke,
Acting Director

Attachments (5)

1. I^{123} Safety Summary (Revised)
2. I^{123} Research Workplan Summary (Revised)
3. Summary of Researchers Technical Training and Experience
4. Model Procedures for Area Surveys
5. Model Proceduresfor waste Disposal

cc: Allan R. Batterman

1. MED-Duluth I^{125} *RADIOIMMUNOASSAY* SAFETY SUMMARY

I^{125} LABORATORY RADIOIMMUNOASSAY STUDIES will follow guidelines described in depth in MED's "The Radiation Safety, Operational Procedures Manual". The manual was revised and edited by Allan R. Batterman, reviewed by the Radiation Safety Committee and approved by the Division Director on November 30, 1995 for the Mid-Continent Ecology Division, National Health and Environmental Effects Research Laboratory, Office of Research and Development, U.S. Environmental Protection Agency. *It follows all applicable NRC regulations and includes all items listed in #4 of your February 19, 1997 correspondance.*

A. GENERAL RULES

The purpose of these guidelines is to provide a safe working environment for occupationally exposed workers, the public at large, and the environment (avoid contamination of equipment and facilities).

All persons who are permitted as specified by the facilities license to work with radioactive materials shall be aware of the procedures specified and be trained in matters of radiation safety. Employees working with radioisotopes shall read and comply with the information in 10 CFR 20 and 10 CFR 30.

B. LABORATORY RULES

The use of good laboratory procedures is greatly facilitated by having the proper tools/ supplies at hand; before any work begins the Principal Investigator and the Radiation Safety Officer must:

1. Discuss with the employee(s) the work to be done and the necessary safety precautions in accordance with 10 CFR 20;

2. Outline in the research work plan the procedure for each job (make the amount of detail commensurate with the hazard);

3. Have the laboratory stocked with suitable gloves, lab coats, warning tags and la els, wipes, appropriate survey/counting instruments, forms for necessary records, plastic bags and tape for waste disposal absorbent paper, etc. *And be assured that the employee knows when to use the supplies provided, i.e., when handling the radioisotope*

4. Have available, and use when appropriate, shielding, remote handling devices, automatic pipettes or dispensers, tongs, etc., for the manipulation and transfer of radioactive material and a lockable storage area for radioactive materials. *In this I^{125} project the activities used should not require use of the above mentioned items except for controlled storage of the I^{125}.*

5. Conduct "dry runs" to ensure that all personnel know the procedures to be carried out and to work out the process to ensure that all supplies and equipment are readily available and in suffucient quantity to eliminate the need to have to stop procedures before completion. These "dry-runs" contribute to developing laboratory practices that eliminate extended exposures and the spread of contamination and ensure that needed supplies and equipment are readily available in a confined area.

C. SPECIAL REQUIREMENTS FOR CERTAIN RADIOISOTOPES

1. Shielding Requirements: X or gamma ray sources(e.g., ^{125}I, ^{51}Cr, ^{131}I) - lead or other high Z shielding. Contact the RSO for appropriate type and thickness of shielding. *Not needed in <u>this</u> I^{125} Radioimmunoassay study, activity of radioisotope is low enough to not require shielding.*

2. Film badges and TLD ring dosimeters may be required for certain radiation sources (e.g. P^{32}) Also, bioassay monitoring (e.g., urine analysis for tritium, thyroid count for iodine) may be required. Contact the RSO for assistance in determining if monitoring is necessary. *Not needed in <u>this</u> I^{125} Radioimmunoassay study.*

3. Portable radiation monitoring instruments - Users of certain gamma sources are required to have a portable survey instrument in the laboratory use area. Contact the RSO for assistance in ordering approved instruments. *The instrument to be used in this radioimmunoassay study is a Research products International Corp. Model SD10, Rad Monitor, (seeattachment) it will be calibrated for I^{125} detection by the manufacturer and after the initial purchase calibration will be done by Isotronics Labs, 312 Bramble Lane, Schaumburg, Il 60193 other similar qualified Calibration Laboratory. We will request that they use the NRC model procedures or whatever is authorized on their license.*

4. Volatility considerations: Research procedures which result in airborne releases of radioactive material must be confined to a properly designed hood and maintained within a closed system. A "dry-run" under the supervision of the RSO is required prior to initial use of radioactive materials in such a procedure. *This will not be a problem in <u>this</u> radioimmunoassay study.*

5. All Radioisotope users must maintain quarterly report records and radioisotope receipts, waste disposal, and laboratory contamination surveys. Radioisotope purchase orders must be placed through the Health and Safety Program Manager and the RSO. *We will establish and implement the model procedures for area surveys that were published in Appendix N to Regulatory Guide 10.8, Revision 2 as well as use the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2 (see attachment).*

6. Radioisotope users must call the RSO to schedule radioactive waste pick-up, *it will be held for decay-in-storage, DIS.*

D. MARKING AND LABELING

Rooms, areas and equipment where radioactive materials are used or stored shall be clearly marked with appropriately worded and designated standard radiation warning signs when required under the conditions set forth in the study. The sign must bear the three-bladed radioactive caution symbol (magenta or purple on yellow background).

E. PERSONNEL MONITORING

All persons who enter a restricted area shall wear appropriate personnel monitoring devices to ascertain the extent of any radiation exposures.. The RSO shall be responsible for obtaining, distributing, and collecting these devices. *Not needed in the presently planned I^{125} radioimmunoassay study.*

F. CONDUCTING LABORATORY SURVEYS FOR MONITORING OF CONTAMINATION

The purpose of conducting laboratory swipe surveys is two-fold. Surveys are used to measure any potential removable contamination from laboratory work surfaces and to evaluate the potential exposure level to workers in the work area. Each laboratory using radioactive materials ~~(except those with sealed sources such as ^{63}Ni EC Detectors)~~ will be surveyed on a routine basis, in the case of I^{125} this will be after each operation or ~~on a daily bases whichever is less frequent~~ *monthly*. The areas to be surveyed include appropriate benchtops, fume hoods, storage and waste disposal areas. ~~The method to evaluate surface contamination is to wipe a 100cm^2 area with~~ a small piece of filter paper. ~~Radioactivity on the filter paper is determined by gamma counting. The Pac Swipe Counter can be used for immediate routine checks (after each operation or daily) but she did not be used for quarterly monitoring (use the gamma counter for this monitoring).~~ *We will establish and implement the model procedures for an area survey that were published in Appendix N of Regulatory Guide 10.8, Revision 2 (see attached).*

~~A diagram of the laboratory must be obtained prior to conducting the survey. Each laboratory diagram will illustrate the designated swipe survey areas and their associated i.d. number. Using disposable gloves, swipe a 100 cm² area with the Whatman #1, 2.5 cm filter paper. Place the paper into a prelabeled scintillation vial containing general purpose liquid scintillation cocktail. Place a minimum of 1 blank filter paper swipe (paper which does not contact any swipe areas) per laboratory or per designated sample site within a laboratory into a vial to establish a background level of radioactivity. Count all swipe samples on a liquid scintillation counter with the proper calibration procedure. For rapid analytical workup, check results using the same swipe procedures however check the swipes using the Pac-Swipe Counter. Record all results on a Swipe Test Form, send the original to the RSO and maintain a copy~~ for your files. Areas with removable contamination greater than ~~3 times the background level~~ *200 dpm/100cm²* will be decontaminated and resurveyed until the levels are acceptable. Decontamination procedures are described in ~~this~~ *the MED* manual and are available from the RSO.

I. RADIOACTIVE WASTE DISPOSAL

All radioactive waste must be placed in approved radioactive waste containers. Consider the wastes to be radioactive if, upon survey with a radiation monitor, the activity appears to be ~~at least three times the normal background activity at that time~~ *greater than 200 dpm/100 cm²*.

Radioactive fish carcass and waste -

1. Do not place fish or any part of the carcass containing radioisotopes in laboratory radioactive waste containers. Serious odor problems will result.

2. Place the fish and/or any part of the carcass in a double plastic bag. Label the bag and list the radioisotopes and activity of each radioisotope (in millicuries) contained in the fish

3. Temporarily store the waste in a radioisotope freezer or refrigerator in the laboratory or the Toxic Substances Control Room to prevent biodegradation until pick-up.

4. Vials or test tubes which contain small amounts of tissue or blood products may require special preparation prior to disposal. Contact the RSO for instructions.

5. When surveying equipment and lab benchs for ~~beta and gamma emitters~~ *I^{125} contamination* the acceptable contamination levels are ~~as follows: average 5000dpm/100cm², maximum 15,000dpm/100cm², removable 1000dpm/100cm²~~ : *less than 200 dpm/100cm²*. Half-life of I^{125} is 60.2 days, therefore ~~7~~ *10* half-lifes is ~~1.15~~ *1.65* years (~~421~~ *600* days). NOTE: For the I^{125} study currently being considered the amounts of waste being generated will be held for decay (*7 10* half-lifes) before disposal.

6. To request pick-up of radioactive biological wastes, contact the RSO.

J. EMERGENCY PROCEDURES

The most practical plan for handling radiation emergencies requires adequate training of persons who might become involved. Correct decisions are made when common sense is applied to a special problem. The primary consideration in an emergency is the PREVENTION OF INJURY TO HUMANS. The secondary consideration is the salvage of facilities and equipment. Persons discovering or involved in an emergency shall immediately notify trained personnel. Notification shall be made in the following order:

A. Radiation Safety Officer or his alternate.

B. Health and Safety Program Manager or a member of the Radiation Safety Committee or the Health and Safety Committee.

C. Local physician or contract clinic.

D. NRC Regional Office for Emergency Assistance. While awaiting the summoned assistance, steps shall be taken to control and contain the radioactive material. Emergencies include uncontrolled contamination, lost source(s), large exposures to radiation, or any other situations or circumstances which could possibly lead to contamination or radiation exposure. All personal injuries or radiochemical spills, no matter how slight, shall be monitored to determine if contamination has occurred. Three portable radiation instruments are available from the RSO.

2. I^{125} Research Workplan Summary

Introduction:

The Gamma Coat [I^{125}] Radioimmunoassay Kit for hormones will be purchased from a commercial source (INCSTAR). These kits will be used for in vitro quantitative determinations of hormones in the serum of fish and amphibians. No human serum will be used in any of the above assays. The analysis of hormones using these kits will involve handling of I^{125}. The total isotopic content of these kits will never exceed 40 uCi. These kits involved very little handling of radioactive material, the reagent is preprepared and therefore no measuring, weighing or dilution of the radiotracer is needed. *The total I^{125} isotopic amount on-site at any time will not exceed 5 mCi (stock, in-use, and awaiting decay(DIS)).*

Principles of the Method:

The GammaCoat Radioimmunoassay is a competitive binding assay which is performed entirely within a tube coated with the antigen specific antibody. During incubation, the free antigen and the [I^{125}] labeled antigen competes with the binding sites on the antibody. After incubation, the tubes are decanted into a container and counted.

Reagents:

1. [I^{125}] tracer, 1-5 vials. Each vial contains approximately 7uCi (259kBq) tracer and less than 1 ug of antigen per ml.

2. Anti-T4 Coated Tubes: Polypropylene (12X75 mm) coated with rabbit anti-antigen serum.

3. Incubation Buffers

4. Antigen Standards

Assay Procedure:

The assay procedure involves the preparation of a standard curve from which unknown free hormone level of the samples is interpolated.

1. Label 20 Gamma Coat tubes in duplicate.

2. Add to the appropriate duplicate tubes:

   a. 50 ul of standard for standard tubes
   b. 50 ul of fish or amphibian serum sample for sample tubes
   c. 50 ul of [I^{125}] labeled antigen to all tubes

3. Add 1.0 ml of incubation buffer to all tubes. Gently vortex each tube at low speed.

4. Incubate for 1 hour in a 37°C water bath.

5. Decant or aspirate all tubes into waste container.

6. Count all tubes in a gamma counter for 1 minute with the window suitably adjusted for I^{125}.

Precautionary measures for reagents containing Iodine^{125}

Appropriate precautions, good laboratory and recordkeeping practices will be used in the storage, handling and disposal of this material. All procedures explained in NRC Guidance and "The Radiation Safety, Operational Procedures Manual" of the laboratory will be followed. Storage of these materials will be limited to designated areas. Access to radioactive materials will be limited to authorized personnel only.

3. SUMMARY OF THE RESEARCHERS TECHNICAL TRAINING AND EXPERIENCE

Mumtaz Pasha has had experience in Quantative Chemistry and Radioimmunoassay Work that has developed her abilities to work with radiotracer analysis. The Radiation Safety Officer (RSO) will work closely with her in planning, conducting, and surveying the I^{125} work, probably the first several months. He will conduct Dry Run Surveys during this entire period. Once her confidence is apparent and the RSO has certified her abilities in radioimmunoassay work he will then make only periodic spot checks. However, during this entire series of I^{125} planned radioimmunoassay tests we will require the swipe surveys and these will be monitored and approval received from the RSO before the next immunoassay can be conducted.

Following is Supplement A which lists the actual experience of Mumtaz Pasha, *the only user of Iodine* ^{125}.

Supplement A — **U.S. Nuclear Regulatory Commission**

TRAINING AND EXPERIENCE OF AUTHORIZED USER

1. NAME OF PROPOSED AUTHORIZED USER: MUMTAZ S. PASHA			2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
3. CERTIFICATION			
SPECIALITY BOARD A	CATEGORY B		MONTH AND YEAR CERTIFIED C
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES			
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB TRAINING
a. RADIATION PHYSICS AND INSTRUMENTATION	-------	NONE	NONE
b. RADIATION PROTECTION	EPA MED RADIATION SAFETY TRAINING/U OF M SERIES	4	NONE
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	EPA MED RADIATION SAFETY TRAINING/U OF M SERIES	4	NONE
d. RADIATION BIOLOGY	-------	NONE	NONE
e. RADIOPHARMACEUTICAL CHEMISTRY	UNIVERSITY OF MINNESOTA, MINNEAPOLIS, JUNE 1991 SYNTHESIS OF RADIOACTIVE COMPOUND	-------	40
5. EXPERIENCE WITH RADIATION (Actual Use of Radioisotopes or Equivalent Experience)			
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
I^{125}	1.5 mCi	EPA-MED RESEARCH LAB	900	RADIOIMMUNOASSAY INCLUDES, DILUTION OF RADIOISOTOPE STOCK SOLUTION, MEASURING AND COUNTING USING SCINTILLATION COUNTER.

APPENDIX N

Model Procedure for Area Surveys
(See § 35.70.)

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

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 § 35.70. Say on your application, "We have developed survey procedures for your review that are appended as ATT 10.12," and append your survey procedures.

MODEL PROCEDURE

Ambient Dose Rate Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.

   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.

   d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.

3. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:

   a. The date, area surveyed, and equipment used.

   b. The name or initials of the person who made the survey.

   c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO. (Recommended removable surface contamination action levels are published in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions." See Regulatory Guide 8.23 or Table N-1 below for guidance in establishing your action levels.)

   d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm^2, as appropriate.

   e. Actions taken in the case of excessive dose rates or contamination and followup survey information.

2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

The following information is not part of the model procedure.

See Exhibit 16 for a sample record form.

Table N-1

Recommended Action Levels in dpm/100 cm^2 for Surface Contamination by Radiopharmaceuticals

		P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1.	Unrestricted areas, personal clothing	200	2,000
2.	Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

APPENDIX R

Model Procedure for Waste Disposal
(See §§ 20.301, 20.303, 20.306, and 35.92.)

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R 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 general guidance and models and carefully review the requirements of §§ 20.301, 20.303, 20.306, and 35.92. Say on your application, "We have developed a procedure for waste disposal for your review that is appended as ATT 11.1," and attach your procedure.

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta (see paragraph 20.303(d)) and generally licensed in vitro kit exemptions (see paragraph 31.11(f)), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See paragraphs 30.51(a) and 20.401(c)(3).)

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in § 20.303. Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see paragraph 20.303(d).) Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 millicurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (§ 20.306). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material for at least 10 half-lives.

4. Prior to disposal as in-house waste, monitor each container as follows:

   a. Check your radiation detection survey meter for proper operation;

   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

   c. Remove any shielding from around the container;

   d. Monitor all surfaces of each individual container;

e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed pursuant to § 31.11 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

FAXED 3/3/97 alb

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HEALTH AND ENVIRONMENTAL EFFECTS
RESEARCH LABORATORY
MID-CONTINENT ECOLOGY DIVISION
6201 CONGDON BOULEVARD • DULUTH, MN 55804- 2595

March 3, 1997

Nuclear Regulatory Commission
Region III, Nuclear Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351
ATTN:Evelyn R. Matson

OFFICE OF
RESEARCH AND DEVELOPMENT

RE: Revisions to I^{125} Safety Summary and Research Plan Received 2/19/97

Dear Ms. Matson:

Enclosed are materials which address your concerns on the amendment to License No. 22-13390-01; Docket No. 030-05046, Control No. 301566; these materials address only the I^{125} research.

In the enclosed documents, we attempt to address all your questions, which were asked in the FAXed correspondence of February 19, 1997 with detailed explanations. The requested additional input is found in *italics*. The deleted materials are ~~lined-out~~ in the attached summaries. Mumtaz Pasha will be the sole user of I^{125}. If any issues require further clarification, please notify our Radiation Safety Officer, Allan R. Batterman. Thank you for your time and effort in reviewing these materials. Other actions that were originally addressed in this Amendament Request have been dropped from our request.

Sincerely,

Steven F. Hedtke,
Acting Director

Attachments (5)

1. I^{125} Safety Summary (Revised)
2. I^{125} Research Workplan Summary (Revised)
3. Summary of Researchers Technical Training and Experience
4. Model Procedures for Area Surveys
5. Model Proceduresfor waste Disposal

cc: Allan R. Batterman

RECEIVED
MAR 0 6 1997
REGION III

MAR 0 6 1997

FAX TRANSMISSION

USEPA, NHEERL, MED-D
6201 Congdon Boulevard
Duluth, MN 55804
218-720-5733
Fax: 218-720-5703

To:	Evelyn Matson	**Date:**	March 3, 1997
Fax #:	630-515-1259	**Pages:**	16, including this cover sheet.
From:	Allan R. Batterman		
Subject:	NRC License Amendment, Control No. 301566		

COMMENTS:

Following is our response to your request of February 19, 1997. I will be in my office all week do not hesitate to call if you have additional questions.

1. MED-Duluth I^{125} *RADIOIOMMUNOASSAY* SAFETY SUMMARY

I^{125} LABORATORY RADIOIMMUNOASSAY STUDIES will follow guidelines described in depth in MED's "The Radiation Safety, Operational Procedures Manual". The manual was revised and edited by Allan R. Batterman, reviewed by the Radiation Safety Committee and approved by the Division Director on November 30, 1995 for the Mid-Continent Ecology Division, National Health and Environmental Effects Research Laboratory, Office of Research and Development, U.S. Environmental Protection Agency. *It follows all applicable NRC regulations and includes all items listed in #4 of your February 19, 1997 correspondance.*

A. GENERAL RULES

The purpose of these guidelines is to provide a safe working environment for occupationally exposed workers, the public at large, and the environment (avoid contamination of equipment and facilities).

All persons who are permitted as specified by the facilities license to work with radioactive materials shall be aware of the procedures specified and be trained in matters of radiation safety. Employees working with radioisotopes shall read and comply with the information in 10 CFR 20 and 10 CFR 30.

B. LABORATORY RULES

The use of good laboratory procedures is greatly facilitated by having the proper tools/ supplies at hand; before any work begins the Principal Investigator and the Radiation Safety Officer must:

1. Discuss with the employee(s) the work to be done and the necessary safety precautions in accordance with 10 CFR 20;

2. Outline in the research work plan the procedure for each job (make the amount of detail commensurate with the hazard);

3. Have the laboratory stocked with suitable gloves, lab coats, warning tags and labels, wipes, appropriate survey/counting instruments, forms for necessary records, plastic bags and tape for waste disposal absorbent paper, etc. *And be assured that the employee knows when to use the supplies provided, i.e., when handling the radiooisotope*

4. Have available, and use when appropriate, shielding, remote handling devices, automatic pipettes or dispensers, tongs, etc., for the manipulation and transfer of radioactive material and a lockable storage area for radioactive materials. *In this I^{125} project the activities used should not require use of the above mentioned items except for controlled storage of the I^{125}.*

5. Conduct "dry runs" to ensure that all personnel know the procedures to be carried out and to work out the process to ensure that all supplies and equipment are readily available and in suffucient quantity to eliminate the need to have to stop procedures before completion. These "dry-runs" contribute to developing laboratory practices that eliminate extended exposures and the spread of contamination and ensure that needed supplies and equipment are readily available in a confined area.

C. SPECIAL REQUIREMENTS FOR CERTAIN RADIOISOTOPES

1. Shielding Requirements: X or gamma ray sources(e.g., ^{125}I, ^{51}Cr, ^{131}I) - lead or other high Z shielding. Contact the RSO for appropriate type and thickness of shielding. *Not needed in <u>this</u> I^{125} Radioiommunoassay study, activity of radioisotope is low enough to not require shielding.*

2. Film badges and TLD ring dosimeters may be required for certain radiation sources (e.g. P^{32}). Also, bioassay monitoring (e.g., urine analysis for tritium, thyroid count for iodine) may be required. Contact the RSO for assistance in determining if monitoring is necessary. *Not needed in <u>this</u> I^{125} Radioiommunoassay study.*

3. Portable radiation monitoring instruments - Users of certain gamma sources are required to have a portable survey instrument in the laboratory use area. Contact the RSO for assistance in ordering approved instruments. *The instrument to be used in this radioioummnoassay study is a Research products International Corp. Model SD10, Rad Monitor, (seeattachment) it will be calibrated for I^{125} detection by the manufacturer and after the initial purchase calibration will be done by Isotronics Labs, 312 Bramble Lane, Schaumburg, Il 60193 other similar qualified Calibration Laboratory. We will request that they use the NRC model procedures or whatever is authorized on their license.*

4. Volatility considerations: Research procedures which result in airborne releases of radioactive material must be confined to a properly designed hood and maintained within a closed system. A "dry-run" under the supervision of the RSO is required prior to initial use of radioactive materials in such a procedure. *This will not be a problem in <u>this</u> radioiommunoassay study.*

5. All Radioisotope users must maintain quarterly report records and radioisotope receipts, waste disposal, and laboratory contamination surveys. Radioisotope purchase orders must be placed through the Health and Safety Program Manager and the RSO. *We will establish and implement the model procedures for area surveys that were published in Appendix N to Regulatory Guide 10.8, Revision 2 as well as use the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2 (see attachment).*

6. Radioisotope users must call the RSO to schedule radioactive waste pick-up, *it will be held for decay-in-storage,DIS.*

D. MARKING AND LABELING

Rooms, areas and equipment where radioactive materials are used or stored shall be clearly marked with appropriately worded and designated standard radiation warning signs when required under the conditions set forth in the study. The sign must bear the three-bladed radioactive caution symbol (magenta or purple on yellow background).

E. PERSONNEL MONITORING

All persons who enter a restricted area shall wear appropriate personnel monitoring devices to ascertain the extent of any radiation exposures.. The RSO shall be responsible for obtaining, distributing, and collecting these devices. *Not needed in the presently planned I^{125} radioioammunoassay study.*

F. CONDUCTING LABORATORY SURVEYS FOR MONITORING OF CONTAMINATION

The purpose of conducting laboratory swipe surveys is two-fold. Surveys are used to measure any potential removable contamination from laboratory work surfaces and to evaluate the potential exposure level to workers in the work area. Each laboratory using radioactive materials ~~(except those with sealed sources such as ^{63}Ni EC Detectors)~~ will be surveyed on a routine basis, in the case of I^{125} this will be after each operation or ~~on a daily bases whichever is less frequent~~ *monthly*. The areas to be surveyed include appropriate benchtops, fume hoods, storage and waste disposal areas. ~~The method to evaluate surface contamination is to wipe a 100cm^2 area with a small piece of filter paper. Radioactivity on the filter paper is determined by gamma counting. The Pac Swipe Counter can be used for immediate routine checks (after each operation or daily) but should not be used for quarterly monitoring (use the gamma counter for this monitoring).~~ *We will establish and implement the model procedures for an area survey that were published in Appendix N of Regulatory Guide 10.8, Revision 2 (see attached).*

~~A diagram of the laboratory must be obtained prior to conducting the survey. Each laboratory diagram will illustrate the designated swipe survey areas and their associated i.d. number. Using disposable gloves, swipe a 100 cm² area with the Whatman #1, 2.5 cm filter paper. Place the paper into a prelabeled scintillation vial containing general purpose liquid scintillation cocktail. Place a minimum of 1 blank filter paper swipe (paper which does not contact any swipe areas) per laboratory or per designated sample site within a laboratory into a vial to establish a background level of radioactivity. Count all swipe samples on a liquid scintillation counter with the proper calibration procedure. For rapid analytical workup, check results using the same swipe procedures however check the swipes using the Pac Swipe Counter. Record all results on a Swipe Test Form, send the original to the RSO and maintain a copy for your files.~~ Areas with removable contamination greater than ~~3 times the background level~~ *200 dpm/100cm²* will be decontaminated and resurveyed until the levels are acceptable. Decontamination procedures are described in ~~this~~ *the MED* manual and are available from the RSO.

I. RADIOACTIVE WASTE DISPOSAL

All radioactive waste must be placed in approved radioactive waste containers. Consider the wastes to be radioactive if, upon survey with a radiation monitor, the activity appears to be ~~at least three times the normal background activity at that time~~ *greater than 200 dpm/100 cm².*

Radioactive fish carcass and waste -

1. Do not place fish or any part of the carcass containing radioisotopes in laboratory radioactive waste containers. Serious odor problems will result.

2. Place the fish and/or any part of the carcass in a double plastic bag. Label the bag and list the radioisotopes and activity of each radioisotope (in millicuries) contained in the fish.

3. Temporarily store the waste in a radioisotope freezer or refrigerator in the laboratory or the Toxic Substances Control Room to prevent biodegradation until pick-up.

4. Vials or test tubes which contain small amounts of tissue or blood products may require special preparation prior to disposal. Contact the RSO for instructions.

5. When surveying equipment and lab benchs for ~~beta and gamma emitters~~ *I^{125} contamination* the acceptable contamination levels are ~~as follows: average 5000dpm/100cm², maximum 15,000dpm/100cm², removable 1000dpm/100cm²~~ *: less than 200 dpm/100cm².* Half-life of I^{125} is 60.2 days, therefore ~~7~~ *10* half-lifes is ~~1.15~~ *1.65* years (~~421~~ *600* days). NOTE: For the I^{125} study currently being considered the amounts of waste being generated will be held for decay (~~7~~ *10* half-lifes) before disposal.

6. To request pick-up of radioactive biological wastes, contact the RSO.

J. EMERGENCY PROCEDURES

The most practical plan for handling radiation emergencies requires adequate training of persons who might become involved. Correct decisions are made when common sense is applied to a special problem. The primary consideration in an emergency is the PREVENTION OF INJURY TO HUMANS. The secondary consideration is the salvage of facilities and equipment. Persons discovering or involved in an emergency shall immediately notify trained personnel. Notification shall be made in the following order:

A. Radiation Safety Officer or his alternate.

B. Health and Safety Program Manager or a member of the Radiation Safety Committee or the Health and Safety Committee.

C. Local physician or contract clinic.

D. NRC Regional Office for Emergency Assistance. While awaiting the summoned assistance, steps shall be taken to control and contain the radioactive material. Emergencies include uncontrolled contamination, lost source(s), large exposures to radiation, or any other situations or circumstances which could possibly lead to contamination or radiation exposure. All personal injuries or radiochemical spills, no matter how slight, shall be monitored to determine if contamination has occurred. Three portable radiation instruments are available from the RSO.

2. I^{125} Research Workplan Summary

Introduction:

The Gamma Coat [I^{125}] Radioimmunoassay Kit for hormones will be purchased from a commercial source (INCSTAR). These kits will be used for in vitro quantitative determinations of hormones in the serum of fish and amphibians. No human serum will be used in any of the above assays. The analysis of hormones using these kits will involve handling of I^{125}. The total isotopic content of these kits will never exceed 40 uCi. These kits involved very little handling of radioactive material, the reagent is preprepared and therefore no measuring, weighing or dilution of the radiotracer is needed. *The total I^{125} isotopic amount on-site at any time will not exceed 5 mCi (stock, in-use, and awaiting decay(DIS)).*

Principles of the Method:

The GammaCoat Radioimmunoassay is a competitive binding assay which is performed entirely within a tube coated with the antigen specific antibody. During incubation, the free antigen and the [I^{125}] labeled antigen competes with the binding sites on the antibody. After incubation, the tubes are decanted into a container and counted.

Reagents:

1. [I^{125}] tracer, 1-5 vials. Each vial contains approximately 7uCi (259kBq) tracer and less than 1 ug of antigen per ml.

2. Anti-T4 Coated Tubes: Polypropylene (12X75 mm) coated with rabbit anti-antigen serum.

3. Incubation Buffers

4. Antigen Standards

Assay Procedure:

The assay procedure involves the preparation of a standard curve from which unknown free hormone level of the samples is interpolated.

1. Label 20 Gamma Coat tubes in duplicate.

2. Add to the appropriate duplicate tubes:

    a. 50 ul of standard for standard tubes
    b. 50 ul of fish or amphibian serum sample for sample tubes
    c. 50 ul of [I^{125}] labeled antigen to all tubes

3. Add 1.0 ml of incubation buffer to all tubes. Gently vortex each tube at low speed.

4. Incubate for 1 hour in a 37°C water bath.

5. Decant or aspirate all tubes into waste container.

6. Count all tubes in a gamma counter for 1 minute with the window suitably adjusted for I^{125}.

Precautionary measures for reagents containing Iodine^{125}

Appropriate precautions, good laboratory and recordkeeping practices will be used in the storage, handling and disposal of this material. All procedures explained in NRC Guidance and "The Radiation Safety, Operational Procedures Manual" of the laboratory will be followed. Storage of these materials will be limited to designated areas. Access to radioactive materials will be limited to authorized personnel only.

3. SUMMARY OF THE RESEARCHERS TECHNICAL TRAINING AND EXPERIENCE

Mumtaz Pasha has had experience in Quantative Chemistry and Radioimmunoassay Work that has developed her abilities to work with radiotracer analysis. The Radiation Safety Officer (RSO) will work closely with her in planning, conducting, and surveying the I^{125} work, probably the first several months. He will conduct Dry-Run Surveys during this entire period. Once her confidence is apparent and the RSO has certified her abilities in radioimmunoassay work he will then make only periodic spot checks. However, during this entire series of I^{125} planned radioimmunoassay tests we will require the swipe surveys and these will be monitored and approval received from the RSO before the next immunoassay can be conducted.

Following is Supplement A which lists the actual experience of Mumtaz Pasha, *the only user of Iodine* ^{125}.

Supplement A — **U.S. Nuclear Regulatory Commission**

TRAINING AND EXPERIENCE OF AUTHORIZED USER

1. NAME OF PROPOSED AUTHORIZED USER: MUMTAZ S. PASHA			2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
3. CERTIFICATION			
SPECIALITY BOARD A	CATEGORY B		MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES			
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB TRAINING
a.RADIATION PHYSICS AND INSTRUMENTATION	--------	NONE	NONE
b. RADIATION PROTECTION	EPA MED RADIATION SAFETY TRAINING/U OF M SERIES	4	NONE
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	EPA MED RADIATION SAFETY TRAINING/U OF M SERIES	4	NONE
d. RADIATION BIOLOGY	-------	NONE	NONE
e. RADIOPHARMACEUTICAL CHEMISTRY	UNIVERSITY OF MINNESOTA, MINNEAPOLIS, JUNE 1991 SYNTHESIS OF RADIOACTIVE COMPOUND	---------	40

5. EXPERIENCE WITH RADIATION (Actual Use of Radioisotopes or Equivalent Experience)				
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
H^3	1-5 mCi	EPA-MED RESEARCH LAB	500	RADIOIMMUNOASSAY INCLUDES, DILUTION OF RADIOISOTOPE STOCK SOLUTION, MEASURING AND COUNTING USING SCINTILLATION COUNTER

APPENDIX N

Model Procedure for Area Surveys
(See § 35.70.)

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

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 § 35.70. Say on your application, "We have developed survey procedures for your review that are appended as ATT 10.12," and append your survey procedures.

MODEL PROCEDURE

Ambient Dose Rate Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.

   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.

   d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.

3. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:

   a. The date, area surveyed, and equipment used.

   b. The name or initials of the person who made the survey.

   c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO. (Recommended removable surface contamination action levels are published in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions." See Regulatory Guide 8.23 or Table N-1 below for guidance in establishing your action levels.)

   d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm^2, as appropriate.

   e. Actions taken in the case of excessive dose rates or contamination and followup survey information.

2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

The following information is not part of the model procedure.

See Exhibit 16 for a sample record form.

Table N-1

Recommended Action Levels in dpm/100 cm^2 for Surface Contamination by Radiopharmaceuticals

		P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1.	Unrestricted areas, personal clothing	200	2,000
2.	Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

APPENDIX R

Model Procedure for Waste Disposal
(See §§ 20.301, 20.303, 20.306, and 35.92.)

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R 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 general guidance and models and carefully review the requirements of §§ 20.301, 20.303, 20.306, and 35.92. Say on your application, "We have developed a procedure for waste disposal for your review that is appended as ATT 11.1," and attach your procedure.

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta (see paragraph 20.303(d)) and generally licensed in vitro kit exemptions (see paragraph 31.11(f)), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See paragraphs 30.51(a) and 20.401(c)(3).)

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in § 20.303. Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see paragraph 20.303(d).) Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 millicurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (§ 20.306). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material for at least 10 half-lives.

4. Prior to disposal as in-house waste, monitor each container as follows:

   a. Check your radiation detection survey meter for proper operation;

   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

   c. Remove any shielding from around the container;

   d. Monitor all surfaces of each individual container;

e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed pursuant to § 31.11 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
CONVERSATION RECORD

(X) TELEPHONE (X) OUTGOING ( ) INCOMING ( ) CONVERSATION TIME: DATE: 2/19/97

NAME OF PERSON(S) CONTACTED: ORGANIZATION: TELEPHONE NO.:

Allan Batterman
EPA
218-720-5733

SUBJECT:

Amendment request letter dated June 28, 1996
License No. 22-13390-01
control No. 301566

SUMMARY:

The NRC needs that following additional information:

1. Specify the total possession limit for I-125. Consider amount in use and amounts in waste storage. We had discussed 5 millicuries or less.

2. Specify who will be using the I-125 kits. Will M. Pasha be the only user? Provide the training and experience of others who will be handling I-125.

3. Modify your training program to state that radiation workers (technologists, authorized users, etc.) will be instructed in accordance with the model training program described in Appendix A (attached) of Regulatory Guide 10.8 or submit an equivalent training program.

4. Please state that personnel will abide by the following laboratory rules when handling radioactive materials:

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

   b. Wear disposable gloves at all times while handling licensed materials.

   c. For high energy beta or gamma emitters, either after each procedure or before leaving the area, monitor your hands for contamination in low-background area.

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

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

   f. Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored.

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

   h. Never pipette by mouth.

I. Confine radioactive solutions in clearly labeled containers.

j. Secure all licensed material when not under the constant surveillance and immediate control of the authorized users.

5. Your procedures state that surveys for removable I-125 contamination will be conducted after each procedure or daily which ever is less frequent. Since it is not always clear when a single procedure starts or ends, please state that removable contamination wipe tests be conducted at the following intervals:

A. For ambient dose rate surveys, in lab areas where less than 200 microcuries are used, stored as waste or stored as stock solutions, survey monthly with a radiation detection survey meter.

B. For ambient dose rate surveys, in areas using or storing greater than 200 microcuries, survey weekly.

C. For removable contamination wipe testing, in lab areas, waste storage areas, and stock storage areas, where less than 200 microcuries are used at a time, survey monthly for removable contamination.

D. For removable contamination wipe tests, in areas where greater than 200 microcuries will be used or stored, survey weekly.

6. Regarding decontamination action levels, your letter under Item F. states decontamination will be conducted if areas exceed three times background. Also, Item I, 5. describes action levels of 5000 dpm\pm, 15,000 dpm and 1000 dpm. Please clarify. These levels seem higher than necessary. We recommend action levels for clean up as stated in Reg. Guide 10.8, Appendix N, Table N-3. If you agree to accept these levels you may state that you will adopt the action levels for decontamination as described in Table N-1 of Regulatory Guide 10.8.

7. State that you will have a radiation detection survey instrument with a thin sodium iodide crystal detector probe to detect iodine-125 contamination. Provide the manufacturer and model number of the instrument that will be used for this purpose. Possession of such a meter is necessary for surveying work areas and waste prior to disposal of contaminated waste after decay.

8. Radiation Detection Survey Instrument:

A. Please state that your survey meter will be calibrated once every 12 months.
B. Describe how the meter will be calibrated. If it will be calibrated by a contractor service, you only need to specify the name of the firm. However, you must assure that the firm will calibrate the instrument in accordance with the procedures contained in Appendix B to Reg. Guide 10.8 (attached). You may elect to calibrate your survey meter yourself. If so, please submit procedures equivalent to those described in Reg. Guide 10.8, Appendix B.(attached).

9. Regarding personnel monitoring, describe how you will determine if personnel monitoring will be required in accordance with 10 CFR 20.1502. If you state quantities of iodine-125 handled at one time will not exceed 40 micorcuries per kit, then you do not need to describe the use of personnel monitoring because it will not likely exceed the limits describe in 10 CFR 20.1502.

10. Modify your procedures for disposal of iodine-125 waste by decay-in-storage. State that you will:

a. hold the radioactive waste in storage for at least 10 half-lives,

b. survey the waste in a low background area with a low-level survey meter with all the shielding removed,

c. not dispose of the waste as normal trash unless the radiation level is at background,

d. remove or deface the radioactive material labels or otherwise indicate that containers no longer hold radioactive materials, and

e. maintain records of these waste disposal surveys including the date the material was placed into storage, the radionuclide, the date of final disposal and the radiation levels measured on the date of final disposal, identification of the survey meter used and it's date of calibration. You may state that you will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R (attached) to Regulatory Guide 10.8, Revision 2 .

Attachments:

1. Appendix A, Model training program, RG 10.8.
2. 10 CFR Part 19
3. Appendix B, Calibration of Instruments, RG 10.8
4. Appendix N, Model Procedures for Area Surveys, RG 10.8
5. Appendix R, Model Procedure for Waste Disposal, RG 10.8

ACTION REQUIRED:

Please respond in writing within 15 days, provide two copies of your response and refer to Control No. 301566.

ACTION TAKEN:

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE | DATE

Evelyn R. Matson
630-829-9822

TRANSMIT CONFIRMATION REPORT

NO.	:	005
RECEIVER	:	218 720 5703
TRANSMITTER	:	US NRC REG III
DATE	:	FEB 19'97 16:24
DURATION	:	08'04
MODE	:	STD
PAGES	:	15
RESULT	:	OK

FAX TRANSMISSION

U.S. NUCLEAR REGULATORY COMMISSION
801 WARRENVILLE ROAD
LISLE, IL 60532
630-829-9822
FAX: 630-515-1259

To:	Allan Batterman-EPA	**Date:**	February 19, 1997
Fax #:	218-720-5703	**Pages:**	15, including this cover sheet.
From:	Evelyn R. Matson		
Subject:	amendment to License No. 22-13390-01		

COMMENTS:

Attached is a record of the additional information needed by NRC with some model radiation safety procedures.

Please call me if you have questions about what is acceptable.

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
CONVERSATION RECORD

(X) TELEPHONE (X) OUTGOING ( ) INCOMING ( ) CONVERSATION TIME: DATE: 2/19/97

NAME OF PERSON(S) CONTACTED: ORGANIZATION: TELEPHONE NO.:
Allan Batterman
EPA
218-720-5733
Fax 218-720-5703

SUBJECT:
Amendment request letter dated June 28, 1996
License No. 22-13390-01
control No. 301566

SUMMARY:

The NRC needs that following additional information:

1. Specify the total possession limit for I-125. Consider amount in use and amounts in waste storage. We had discussed 5 millicuries or less.

2. Specify who will be using the I-125 kits. Will M. Pasha be the only user? Provide the training and experience of others who will be handling I-125.

3. Modify your training program to state that radiation workers (technologists, authorized users, etc.) will be instructed in accordance with the model training program described in Appendix A (attached) of Regulatory Guide 10.8 or submit an equivalent training program. only one user

4. Please state that personnel will abide by the following laboratory rules when handling radioactive materials:

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

   b. Wear disposable gloves at all times while handling licensed materials.

   c. For high energy beta or gamma emitters, either after each procedure or before leaving the area, monitor your hands for contamination in low-background area.

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

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

   f. Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored.

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

   h. Never pipette by mouth.

14 pages

I. Confine radioactive solutions in clearly labeled containers.

j. Secure all licensed material when not under the constant surveillance and immediate control of the authorized users.

5. Your procedures state that surveys for removable I-125 contamination will be conducted after each procedure or daily which ever is less frequent. Since it is not always clear when a single procedure starts or ends, please state that removable contamination wipe tests be conducted at the following intervals:

A. For ambient dose rate surveys, in lab areas where less than 200 microcuries are used, stored as waste or stored as stock solutions, survey monthly with a radiation detection survey meter.

B. For ambient dose rate surveys, in areas using or storing greater than 200 microcuries, survey weekly.

C. For removable contamination wipe testing, in lab areas, waste storage areas, and stock storage areas, where less than 200 microcuries are used at a time, survey monthly for removable contamination.

D. For removable contamination wipe tests, in areas where greater than 200 microcuries will be used or stored, survey weekly.

6. Regarding decontamination action levels, your letter under Item F. states decontamination will be conducted if areas exceed three times background. Also, Item I, 5. describes action levels of 5000 dpm\pm, 15,000 dpm and 1000 dpm. Please clarify. These levels seem higher than necessary. We recommend action levels for clean up as stated in Reg. Guide 10.8, Appendix N, Table N-3. If you agree to accept these levels you may state that you will adopt the action levels for decontamination as described in Table N-1 of Regulatory Guide 10.8.

7. State that you will have a radiation detection survey instrument with a thin sodium iodide crystal detector probe to detect iodine-125 contamination. Provide the manufacturer and model number of the instrument that will be used for this purpose. Possession of such a meter is necessary for surveying work areas and waste prior to disposal of contaminated waste after decay.

8. Radiation Detection Survey Instrument:

A. Please state that your survey meter will be calibrated once every 12 months.
B. Describe how the meter will be calibrated. If it will be calibrated by a contractor service, you only need to specify the name of the firm. However, you must assure that the firm will calibrate the instrument in accordance with the procedures contained in Appendix B to Reg. Guide 10.8 (attached). You may elect to calibrate your survey meter yourself. If so, please submit procedures equivalent to those described in Reg. Guide 10.8, Appendix B.(attached).

9. Regarding personnel monitoring, describe how you will determine if personnel monitoring will be required in accordance with 10 CFR 20.1502. If you state quantities of iodine-125 handled at one time will not exceed 40 micorcuries per kit, then you do not need to describe the use of personnel monitoring because it will not likely exceed the limits describe in 10 CFR 20.1502.

10. Modify your procedures for disposal of iodine-125 waste by decay-in-storage. State that you will:

a. hold the radioactive waste in storage for at least 10 half-lives,

b. survey the waste in [redacted]w background area with a low-level su[redacted] meter with all the shielding removed,

c. not dispose of the waste as normal trash unless the radiation level is at background,

d. remove or deface the radioactive material labels or otherwise indicate that containers no longer hold radioactive materials, and

e. maintain records of these waste disposal surveys including the date the material was placed into storage, the radionuclide, the date of final disposal and the radiation levels measured on the date of final disposal, identification of the survey meter used and it's date of calibration. You may state that you will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R (attached) to Regulatory Guide 10.8, Revision 2 .

Attachments:

1. Appendix A, Model training program, RG 10.8.
2. 10 CFR Part 19
3. Appendix B, Calibration of Instruments, RG 10.8
4. Appendix N, Model Procedures for Area Surveys, RG 10.8
5. Appendix R, Model Procedure for Waste Disposal, RG 10.8

ACTION REQUIRED:

Please respond in writing within 15 days, provide two copies of your response and refer to Control No. 301566.

ACTION TAKEN:

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE | DATE

Evelyn R. Matson
630-829-9822

Evelyn R Matson 7/19/97

APPENDIX A

Model Training Program
(See §§ 19.12 and 35.21)

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2, and have appended a table ATT 8.1 that identifies the groups of workers who will receive training and the method and frequency of training." You may use lectures, video-taped presentations, or demonstrations, for example, as methods of training.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of § 19.12. Say on your application, "We have developed a training program for your review that is appended as ATT 8.1." Be sure to include the table that identifies groups of workers, the method of their training, and the frequency of training.

It may not be assumed that safety instruction has been adequately covered by prior occupational training, board certification, etc. Site-specific training should be provided for all workers. Ancillary personnel (e.g., nursing, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. All training should be tailored to meet the needs of the individuals in attendance. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel will be instructed:

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 the terms of the license.

Instruction for individuals in attendance will include the following subjects:

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. 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. 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 pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

10. Question and answer period.

APPENDIX B

Model Procedure for Calibrating Survey Instruments
(See § 35.51.)

You or your contractor may use the following guidance to calibrate survey instruments. If you, or the contractor, follow all the guidance, you may say on your application, "We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2."

If your procedure does not follow 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 § 35.51. Say on your application, "We have developed a survey instrument calibration procedure for your review that is appended as ATT 9.2," and append your survey instrument calibration procedure.

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing.")

MODEL PROCEDURE

1. The source must be approximately a point source.

2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.

4. The source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cs-137 or 21 millicuries of Co-60.

5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.

6. A record must be made of each survey meter calibration.

7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.

8. Three kinds of scales are frequently used on survey meters:

   a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.

   b. Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

   c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

9. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.

10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.

11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:

   a. The owner or user of the instrument;

   b. A description of the instrument that includes manufacturer, model number, serial number, and type of detector;

   c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;

   d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;

   e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);

   f. The angle between the radiation flux field and the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument);

   g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;

h. The apparent exposure rate from the check source; and

i. The name of the person who performed the calibration and the date on which the calibration was performed.

12. The following information will be attached to the instrument as a calibration sticker or tag:

a. The source that was used to calibrate the instrument;

b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);

c. For each scale or decade, one of the following as appropriate:

(1) The average correction factor,

(2) A graph or graphs from which the correction factor for each scale or decade may be deduced, or

(3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;

d. The angle between the radiation flux and the detector during the calibration; and

e. The apparent exposure rate from the check source.

Note: One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

See Exhibit 7 for a form you may want to use.

APPENDIX N

Model Procedure for Area Surveys
(See § 35.70.)

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

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 § 35.70. Say on your application, "We have developed survey procedures for your review that are appended as ATT 10.12," and append your survey procedures.

MODEL PROCEDURE

Ambient Dose Rate Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.

   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.

   d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.

3. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:

   a. The date, area surveyed, and equipment used.

   b. The name or initials of the person who made the survey.

   c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO. (Recommended removable surface contamination action levels are published in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions." See Regulatory Guide 8.23 or Table N-1 below for guidance in establishing your action levels.)

   d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm^2, as appropriate.

   e. Actions taken in the case of excessive dose rates or contamination and followup survey information.

2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

The following information is not part of the model procedure.

See Exhibit 16 for a sample record form.

Table N-1

Recommended Action Levels in dpm/100 cm^2 for Surface Contamination by Radiopharmaceuticals

		P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1.	Unrestricted areas, personal clothing	200	2,000
2.	Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

APPENDIX R

Model Procedure for Waste Disposal
(See §§ 20.301, 20.303, 20.306, and 35.92.)

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R 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 general guidance and models and carefully review the requirements of §§ 20.301, 20.303, 20.306, and 35.92. Say on your application, "We have developed a procedure for waste disposal for your review that is appended as ATT 11.1," and attach your procedure.

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta (see paragraph 20.303(d)) and generally licensed in vitro kit exemptions (see paragraph 31.11(f)), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See paragraphs 30.51(a) and 20.401(c)(3).)

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in § 20.303. Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see paragraph 20.303(d).) Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 millicurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (§ 20.306). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material for at least 10 half-lives.

4. Prior to disposal as in-house waste, monitor each container as follows:

   a. Check your radiation detection survey meter for proper operation;

   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

   c. Remove any shielding from around the container;

   d. Monitor all surfaces of each individual container;

e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed pursuant to § 31.11 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

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

July 23, 1996

Allan R. Batterman
Radiation Safety Officer
Environmental Protection Agency
National Health & Environmental
Effect Research Laboratory
6201 Congdon Blvd.
Duluth, MN 55804

SUBJECT: ACKNOWLEDGEMENTOF CORRESPONDENCE (Corrected)
(Letter Dated June 28, 1996)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

_ New License ✓ Amendment _ Renewal
_ Termination _ Auth User (Amendment not required) _ QMP Revision
_ Other _____.

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information, technical issues that require additional information, or policy/technical issues that require coordination with headquarters or other NRC regional offices.

It appears that your request is routine (see 1-3 below, as applicable) and complete.

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (708) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301566
License No. 22-13390-01

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

JUL 12 1996

Allan R. Batterman
Radiation Safety Officer
Environmental Protection Agency
National Hhealth & Environmental
Effect Research Labortory
6201 Congdon Blvd.
Duluth, MN 55804

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(X Letter Dated June 28, 1996)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

X New License _ Amendment _ Renewal
_ Termination _ Auth User (Amendment not required) _ QMP Revision
_ Other _____.

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information, technical issues that require additional information, or policy/technical issues that require coordination with headquarters or other NRC regional offices.

It appears that your request is routine (see 1-3 below, as applicable) and complete.

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (708) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301566
License No. 22-13390-1