Department of Biological Sciences
(215) 895-2624

ms

2862

drexel university · philadelphia 19104 · 215-895-2000

October 10, 1979

Mr. Michael Lamastra
Radioisotopes Licensing Branch
Division of Fuel Cycle and Material Safety
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Lamastra:

Submitted herewith are changes and additions requested in our license application for byproduct and special nuclear material (Control No. 99067).

Thank you for the assistance provided by your office in helping us prepare an appropriate document.

Sincerely,

Keith P. West

Keith P. West
Professor Biological Sciences
Radiation Safety Officer

KPW/jew

"OFFICIAL RECORD COPY"

ML10

(Reference your letter 030-15139, May 31, 1979)

2. a. Sealed sources

(1) Depth density gauge Model MC
Campbell Pacific Nuclear Corp.

CPN-131 Cs-137 10 mCi
CPN-131 Am-241 50 mCi

(2) Gas chromatograph Model óAM
Shimadzu Scientific Instruments
ECD-6 Ni-63 10 mCi

(3) United States Nuclear Corp.
Type 375 Cs-137 100 mCi

(4) United States Radium Corp.
Varian Aerograph Model 02-104
Titanium tritide foil Model LAB-508-1
H-3 250 mCi

(5) United States Nuclear Corp.
Encapsulation No. 375 or 378
Co-60 1 mCi
Encapsulation No. 325
TI-204 1 mCi

(6) United States Radium Corp.
No. LAB-204-1A
Am-241 156 uCi

(7) ORTEC Plated sources Model No. AM-10
Am-241 6 sources of 0.1 uCi each

(8) General Radioisotope Processing Corp.
Plated sources Cat. No. 97
Ac-227 2 sources of 0.1 uCi each

(9) Tracerlab Corp. Model THA
Electroplated source on platinum foil
mounted on an aluminum disk.
Th-228 5 uCi

(10) Nuclear Chicago depth density gauge Model P-20
Cs-137 11 uCi

2. b. (Reference 6 (b) on form NRC 313)

Change hydrogen-3 from 100,000 to 21,000 mCi (20 curies of this amount is to cover possession of four tritiated zirconium targets of five curies each for Texas Nuclear Corp. neutron generator Model 9591).

Change sulfur-35 from 100 to 200 mCi

Change total possession limit from 107 to 21.7 curies.

3. Duties and responsibilities of the radiation safety officer.

a. To act as chairman of the radiation safety committee and to supervise its functioning in providing for the establishment of a safe radiation program.

b. To ensure compliance with regulations to the extent that radioactive material is used by or under the direct supervision of approved individuals.

c. To conduct radiation monitoring and contamination surveillance of all laboratories using or storing radioactive materials.

d. To maintain an inventory control and ensure that adequate security is provided for radioactive materials.

e. To ensure that personnel monitoring is accomplished when appropriate.

f. To approve radiological purchase specifications

g. To establish timely leak test and calibration schedules.

h. To ensure the generation of appropriate reports and data retention.

i. To supervise the waste management program.

j. To conduct periodic reviews of the terms and conditions of the license to ensure compliance with requirements.

4. Bioassay Procedures.

Bioassy procedures will be carried out, when required, during the use of tritium (urine analysis) and radioactive iodine (thyroid scans) according to criteria outlined in NRC document "Guidelines for Bioassay Requirements for Tritium" dated October 19, 1977, and regulatory Guide 8.20 "Applications of Bioassay for I-125 and I-131." Equipment used will be a Nuclear Chicago Mark I Liquid Scintillation System (Model 6860) and Baird Atomic Scaler Model 146 with NaI crystal scintillation detector Model 919820.

5. Instructions for use of phosphorus-32

Since P-32 is a relatively high energy beta emitter (E_{max}=1.710 Mev), the following procedures should be followed when using millicurie quantities of this radionuclide to promote safety and protect the health of the individual worker.

a. Wear protective clothing (laboratory coat or apron) and wear disposable gloves while handling the material. If a potential exists for splashing, wear protective goggles.

b. Wear a personnel dosimeter (film badge or TLD) at the chest or waist level. Wear a ring TLD to determine dose to the hand while pipetting or otherwise handling P-32 on a regular basis.

c. Use shielding to protect the body. Clear plastic panels one-half inch thick provide see-through capability and good trunk of the body protection.

d. Monitor hands and clothing for the presence of contamination after each procedure and before leaving the work area.

e. Use pipet controllers when transferring liquids and never pipet by mouth.

f. Always transport the radioactive material in a shielded and covered container.

g. Identify the immediate work area with a "Radiation Area" sign and keep unauthorized personnel out of the area.

h. Provide for locked storage of the radioactive material and identify with a "Radioactive Material" sign. Place an appropriate label on the container indicating the quantity of P-32 (curiage) and the reference date for that quantity.

i. Provide for safe, locked storage of waste to await natural decay. (At least ten half lives or until background levels are reached.) Do not dispose of waste in public sewers except as provided in 10 CFR Part 20 section 20.303.

6. Radiation Safety Committee

a. Criteria to be followed in approving new users of byproduct material.

(1) The new user will be any individual who actually uses or immediately supervises the use of byproduct material.

(2) The person must have a bachelor's degree in the biological or physical sciences, or engineering, or have equivalent training and experience.

(3) The person must have at least forty hours of training and experience in the safe handling of radioactive materials and in the characteristics of ionizing radiation, units of radiation quantities and dose, radiation detection instrumentation and biological effects of exposure to radiation appropriate to the type and form of byproduct material to be used.

(4) The person must also have established for his proposed operation appropriate controls, including record keeping, for his obtaining byproduct material, surveying during possession, disposing of the material properly, accounting for specific quantities involved, and providing for management review to assure safe operation.

b. Criteria for approving laboratories using or storing radioactive material.

(1) Consideration will be given to the kind of radionuclide requested (beta emitter, gamma emitter, etc.) its physical and chemical form (volatility etc., effecting its potential for dispersal), and the quantity (curiage) desired.

(2) Security of material in use and of stored material must be sufficient to prevent unauthorized removal from the area.

(3) Shielding must be provided and exposure times adjusted to reduce personnel exposure to as low a level as reasonably achievable and in no case to exceed levels established in 10 CFR Part 20 Section 20.101.

(4) Work areas must be designed to minimize contamination and reduce spread of radioactive material. Depending on nature of material identified in (1) above, fume hood or glove box operation may be required.

(5) Appropriate signs and symbols must be displayed to notify personnel of the presence of radioactive material.

c. Criteria for requiring surveys.

(1) Surveys will be conducted monthly for laboratories using less than 100 uCi of radioactive material.

(2) Laboratories using 100 uCi or more of radioactive material will be surveyed weekly.

(3) Surveys will consist of:
(a) Measurement of radiation levels with a survey meter capable of detecting 0.1 mRem/hr.
(b) Wipe tests to determine contamination level at a sensitivity capability of 100 dpm per 100 cm^2.

(4) Permanent records will be kept of all survey results. (See attached form.)

(5) Area will be cleaned if the contamination level exceeds 100 dpm per 100 cm^2.

d. Add to the membership of the Radiation Safety Committee as a management representative:
Mr. Harold M. Myres
Vice-President and Treasurer
Drexel University

7. Receipt of radioactive material.
Radioactive material will be delivered to the Receiving Department in building 16. Receiving department personnel will place the package in a remote lockable area and will call the Radiation Safety Officer (X 2625 or 2635). The RSO or his assistant will monitor the package at the receiving area in accordance with 10 CFR Part 20 Section 20.205 and authorize its delivery to the user.
Packages delivered during off duty hours will be receipted for by the security guard on duty and placed in the receiving room. If package and contents sppear to be damaged, he will call the RSO (215-353-0346).

Radiation levels in the receiving area (an unrestricted area) must not exceed levels which could produce an exposure dose greater than 2 mRem/hr for a person continually present in the area or a seven consecutive day dose of 100 mRem.

8. Procedures for examining and opening incoming packages in accordance with 10 CFR Part 20 Section 20.205.

a. Wear gloves during the opening process.
b. Visually inspect for signs of damage.
c. Monitor package surface for removable contamination.
d. Open the package carefully and monitor the packing material for contamination.
e. If any contamination is found in c or d, notify the RSO.

9. Instructions for personnel working in restricted areas.

a,b,&d. Students, laboratory technicians, and animal caretakers. These individuals learn to work with radioactive materials in course N261 - Radioisotope Methodology (page 16 of submitted application) or F261 - Radiological Health (page 18).

Re: 6c.(4)

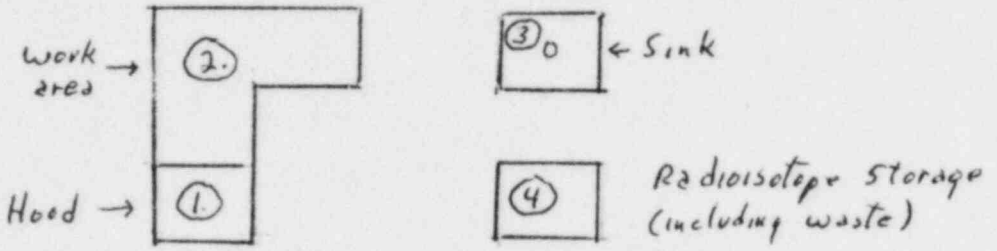
(Sample Form)

Radiation Safety Office Drexel University

AREA SURVEY REPORT

1. Survey equipment used:

2. Area surveyed Building_____Room_____



(Sketch of laboratory)

3. Exposure levels (mRem/hr)

		Corrective action (Check)	Post action levels
Area	1._____	( )	_____
	2._____	( )	_____
	3._____	( )	_____
	4._____	( )	_____

4. Contamination levels (dpm/100cm^2)

		Corrective action (Check)	Post action levels
Area	1._____	( )	_____
	2._____	( )	_____
	3._____	( )	_____
	4._____	( )	_____

5. Comment:

Surveyed by _____

Date _____

Equivalent training and/or experience is required in lieu of the courses.

c & d. Receiving, housekeeping and security personnel. Formal course work is not required for these individuals, but they are instructed in basic safety procedures for the area in which they work and in the terms and conditions of the license covering the operation.

10. Additions to "Laboratory Handling Procedures" (p.42 of application).

a. Except when using small sealed sources, lab coats or aprons and protective gloves will be worn when handling (pipetting, transferring, etc.) radioactive materials.

b. Personnel monitoring equipment will be worn as required in 10 CFR Part 20 Section 20.202.

11. Emergency procedures.

The principal objectives in handling an emergency are to prevent or reduce radiation exposure to individuals, prevent spread of contamination and minimize potential damage to facilities and equipment.

These objectives are best achieved by prior planning, clear thinking, and by observing emergency procedures as follows:

a. The most common kind of accident is the spill. When a minor spill (microcurie quantities) occurs:

(1) Notify all persons in the area that a spill has occurred.
(2) Prevent spread of contamination by covering with absorbent paper.
(3) Clean up the spill while wearing disposable gloves and using remote handling equipment. Use a plastic bag to contain absorbent paper and other discard material. Dispose of in radioactive waste container.
(4) Survey the area with a GM survey meter to check on the adequacy of the clean up. Be sure to include hands and clothing as well as areas adjacent to the spill.
(5) Report the incident to the Radiation Safety Officer.

b. When a major spill (millicurie quantities) occurs:

(1) Clear the area of all persons not involved in the spill.
(2) Prevent spread of contamination by covering with absorbent paper. Shield the source if possible. Turn off air conditioners, ventilator, or hot air heat equipment. Close windows if open.
(3) Close the room. Lock the door to prevent entry.
(4) Call for help. Notify the Radiation Safety Officer immediately.

(5) Personnel decontamination. Remove decontaminated clothi ng and store for possible further evaluation. Flush contaminated skin areas thoroughly with water and wash with mild soap and lukewarm water. Induce vomiting in an individual who may have ingested radioactive material.

12. Animal Use

No radioactive material are currently being used or contemplated to be used employing live animals. However, an Animal Care Committee exists and would be involved in such use if a future need developed. Attached are: (1) Memo to faculty covering review of research proposals using laboratory animals and (2) job descriptions of personnel charged with the resporsibility for animal care.

13. Waste Disposal.

Radioactive waste will be disposed of in accordance with 10 CFR Part 20 Section 20.301 - 20.305.

a. Individual laboratories will handle wastes as follows:
   (1) Solid waste materials to include used planchets, disposable gloves, contaminated absorbent paper, plastic petri dishes, etc. will be placed in heavy plastic bags, segregated according to type of radionuclide.
   (2) Liquid wastes will be held in leak proof containers segregated according to type of radionuclide.
   (3) With respect to security, shielding and labeling the waste will be treated with the same care as that accorded the material before it was used. The label will specify the type and quantity of radioactive material contained and the reference date.
   (4) Short half-life wastes will be held for natural decay, at least ten half-lives or until background levels are reached.

b. Centralized disposal will be accomplished as follows:

   (1) Personnel from the Radiation Safety Office will periodically collect waste material and move it to a centralized isolated storage site where conditions can be provided for appropriate safety. (The supply stock room of the Department of Chemistry or the radioisotope laboratory of the Department of Biological Sciences.)

   (2) Low temperature storage will be provided for biological material prone to bacteriological decay.

   (3) A commercial disposal company(e.g. Isodyne Corp.) will be used for final disposal.

Drexel University • Philadelphia, Pennsylvania 19104

The Graduate School
(215) 895-2496

Re: 12

January 13, 1977

TO: ALL FACULTY

FROM: DREXEL ANIMAL CARE COMMITTEE
Dr. Bruce A. Eisenstein, Chairman
Dr. S. Dubin, V.M.D., University Veterinarian
Dr. R. Klafter
Dr. S. Segall
Dr. E. Fromm
Dr. B. Weiss

SUBJECT: REVIEW OF RESEARCH PROPOSALS INVOLVING LABORATORY ANIMALS

The Animal Care Committee is responsible for the supervision of all uses of warm-blooded laboratory animals in research and instruction. In order to implement this responsibility as well as to render all possible assistance in the preparation of research proposals, a review procedure has been established as follows:

(1) During the preparation of the proposal the principal investigator is encouraged to consult with the University Veterinarian (S. Dubin, V.M.D.--phone X2219) as to all matters relating to the use of warm-blooded laboratory animals.

(2) During the review procedure, the principal investigator will be referred to the University Veterinarian for preparation of the "Review of Research Proposal for Animal Care Committee". Approval of this form should be achieved before the proposal is approved by the Dean of the Graduate School.

(3) The principal investigator shall have a copy of the proposal available for review by the University Veterinarian and the Animal Care Committee.

(4) In any case where approval by the University Veterinarian cannot be achieved, the matter will be referred to the Animal Care Committee, except that all proposals in which immobilizing or paralyzing agents such as curare, etc. are used will be reviewed a priori by the Animal Care Committee.

In order to assist in the preparation and review of research proposals, the following are available.

1. A brief outline of U.S.D.A. regulations regarding laboratory animals, available from the University Veterinarian.

2. A brief outline of "Guide for the Care and Use of Laboratory Animals" of the U.S. Department of H.E.W., available from University Veterinarian.

3. A sample form "Review of Research Proposal for Animal Care Committee", appended hereto.

4. A sample of the form "Report on the Use of Pain Relieving Drugs", appended hereto.

(To be filled out by Principal Investigator whenever applicable)

REVIEW OF RESEARCH PROPOSAL FOR ANIMAL CARE COMMITTEE

Date _____

1. Title of Proposal:

2. Name of Principal Investigator:

3. Name of "Qualified medical or biological scientist" who will supervise work involving animals:

4. Is the above (Line 3) familiar with the laws, regulations, and agency guidelines regarding animal care and intends to follow them?

5. Is any pain or discomfort to the animals anticipated? (If so, append DU Animal Care Committee Report on Use of Pain-Relieving Drugs)

6. Are adequate facilities available or planned for housing and experimentation?

7. Are adequately trained and supervised personnel available or planned?

8. Will sufficient financial support be available to ensure adequate care of animals?

9. Brief description of specific experimental procedures.

APPROVED: _____
University Veterinarian

_____
Associate Dean of the Graduate School

RECEIVED:

2862

DREXEL UNIVERSITY ANIMAL CARE COMMITTEE

Date_____

REPORT ON USE OF PAIN-RELIEVING DRUGS

Year 19____

1. Title of Research Project or Course _____

_____

2. GENERAL QUESTIONS ON DRUG USE AND PROCEDURES:

yes no

( ) ( ) A.) Does the procedure use immobilizing agents such as curare, succinylcholine or gallamine? If "yes" indicate below what means will be used to allay pain or anxiety on the part of the experimental subject.

_____

_____

yes no

( ) ( ) B.) Is any part of the induction, maintenance, or aftercare to be performed by students other than licensed practitioners? If "yes" describe below the training and supervision provided for the students in this regard.

_____

_____

yes no

( ) ( ) C.) In the opinion of the investigator, will the procedure in question, including recovery, cause more pain or anxiety than an ordinary therapeutic operation such as ovariohysterectomy as performed in a modern veterinary hospital?

yes no

( ) ( ) D.) Will the subject emerge from anesthesia? _____

_____

3. DESCRIPTION OF THE PROCEDURE

In some cases (splenectomy, cannulation of blood vessels etc.) where a standard procedure is used, the name of the procedure and animal species is a adequate. Otherwise the description should indicate the surgical approach, e.g. which body cavities are entered, will there be traction on the mesentary etc.?

_____

_____

_____

_____

_____

Re: 12

ANIMAL CARE TECHNICIAN

Qualifications:

The Animal Care Technician shall have educational qualifications equivalent to high school graduation. Other training or experience such as previous occupational training or millitary experience in laboratory animal care may substitute for this requirement. He/she shall be of robust good health and shall have no disabilities which preclude the ordinary work of laboratory animal care; such as, lifting and restraining animals, assisting in surgery, use of the microscope, etc.

Duties:

The Animal Care Technician shall be directly responsible to the Senior Animal Technologist and the Campus Veterinarian. He/she shall carry out the daily feeding, sanitizing, and record keeping work under the supervision of the Senior Animal Technologist. He/she shall also perform the other duties of the Senior Animal Technologist, to the best of his/her ability, in the absence of the Senior Animal Technologist.

SENIOR ANIMAL TECHNOLOGIST

Qualifications:

The Senior Animal Technologist shall have educational qualifications equivalent to either the bachelors degree in animal husbandry, biological science, laboratory animal science, etc. or graduation from an accredited program in laboratory animal science or veterinary assistantship leading to the Associate degree or shall have training and experience equivalent to the above. He/she shall be of robust good health and shall have no

disabilities which preclude the ordinary work of laboratory animal care such as lifting and restraining animals, assisting in surgery, use of the microscope, etc. He/she shall have aptitude and ability to perform routine clerical tasks such as record keeping, maintenance procurement of supplies, etc.

Duties:

The Senior Animal Technologist shall be directly responsible to the Campus Veterinarian with respect to the laboratory animal medicine science and technology aspects of use of laboratory animals. He/she shall be responsible to the Campus Veterinarian and to (administrative offices) with respect to the animal care aspects. He/she shall supervise the animal care technician(s) in the feeding, housing, and sanitation of the animals. He/she shall perform these duties in the absence of the animal care technician(s).

He/she shall see to the acquisition and maintenance of the supplies needed for use of laboratory animals including food and sanitary supplies. He/she shall prepare surgical supplies under the supervision of the Campus Veterinarian. He/she shall assist in surgery and shall assist in the production and development of animal radiographs. He/she shall prepare and maintain all records including clinical records associated with the use of laboratory animals.

CAMPUS (UNIVERSITY) VETERINARIAN
(Job Description)

Qualifications:

The Campus Veterinarian shall be a graduate of an accredited college of veterinary medicine, shall be licensed to practise veterinary medicine

in the state of Pennsylvania and shall meet any legal requirements pertaining to veterinarians under federal, state and local laws. He/she shall be of good ethical and professional standing within his profession. He/she shall have professional qualifications and interest in the specialized field of laboratory animal medicine as evidenced by postdoctoral training, experience, public presentations and publications, membership in specialized professional groups, etc. He/she shall be well informed as to the various rules, procedures and regulations promulgated by government and other public agencies with regard to the use of laboratory animals and the relationship between animal and human health.

Responsibilities:

The Campus Veterinarian shall be directly responsible to an administrative office of the University and should be guided by the University Committee on Animal Care.

The Campus Veterinarian shall be directly responsible for the laboratory animal science, medicine and technology aspects of the use of laboratory animals in the University, including compliance with federal, state and local regulations, preventive medicine (quarantine, immunization, parasite control). He/she shall participate in the preparation and execution of research protocols in matters such as experimental surgery, anesthesia, animal radiology, anatomic and clinical pathology. He/she shall supervise the laboratory animal technician(s) with respect to the above matters and he/she shall participate in the supervision of the laboratory animal technician(s) and other personnel with respect to the Animal Care aspect of the use of laboratory animals, such as feeding, housing, sanitation, procurement of animals, assignment of space, procurement and preparation of supplies and fiscal matters.

The Campus Veterinarian shall provide instruction to the technical staff and to the students of the University in areas related to laboratory animal medicine, science and technology.

He/she shall act as the executive arm of the Committee on Animal Care in ensuring compliance with the laws, regulations and guidelines of government and other public agencies.

He/she shall conduct research in the areas of laboratory animal medicine,science and technology, and/or the interface of animal and human health.

c. No waste will be disposed of in the public sewer without first checking with the Radiation Safety Officer for compliance with 10 CFR Part 20 Section 20.303

d. No waste will be disposed of as normal trash without first decaying to background.

e. No waste will be incinerated.

14. Personnel monitoring devices.

a. Personnel dosimeters include film badges and pocket dosimeters, both self-reading and charger-reader type electroscopes.

b. Pocket dosimeters are designed for whole body monitoring. Film badges are designed for whole body or wrist monitoring.

c. Routine processing of film badge dosimeters will be made on a monthly basis, more frequently if condition warrant. Pocket dosimeters will be read and recorded after each wearing period.

d. Additional hand monitors in the form of ring TLD's will be used when appropriate. These will be processed on the same basis as film badges.

15. Survey instrument calibration.
Attached is a copy of procedures utilized by Radiation Management Corporation in their calibration program.

Re: 15

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

X 1. Survey instruments will be calibrated at least annually and following repair.

X 2. Calibration will be performed at two points on each scale.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ±10% of the calculated or known values for each point checked. Readings within ±20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

3. Survey instruments will be calibrated

____ a. By the manufacturer

____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
Accuracy _____
Traceability to primary standard _____

____ (2) The calibration procedures in Section I of Appendix D will be used

or

____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

X c. By a consultant or outside firm

(1) Name Radiation Management Corp.

(2) Location 3508 Market St., Phila, Pa

(3) Procedures and sources

____ have been approved by NRC and are on file in License No. _____

X are attached