

Texas Department of State Health Services Radiation Safety Licensing Branch

Regulatory Guide 3.03

GUIDANCE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR THE USE OF RADIOACTIVE MATERIAL AT ACADEMIC INSTITUTIONS

I. Introduction

This guide describes the information the Department of State Health Services' (DSHS) Radiation Safety Licensing Branch (Branch) staff needs to evaluate license applications for use of radioactive material at academic institutions. It is intended only as general guidance and should not be considered as containing all the information that may be required for a particular application.

II. Types of Licenses

It is generally desirable, and preferable to the Branch, that a single license be issued to an institution to cover the institution's entire radioisotope program. However, if the institution's usage of radioactive material is rather limited and not easily amenable to central control, separate licenses may be issued to the institution to cover individual departments. In either case, the institution is the licensee.

III. Completing The Application

All items of the application should be completed in sufficient detail to allow the Branch to make a realistic review of the institution's program for safe use of radioactive materials in education and research. The application must be submitted in duplicate (including all attachments), and an additional complete copy must be retained by the applicant because the license issued will require adherence to the procedures and limitations set forth in the application.

Because the space on the application (BRC Form 252-2) is limited, additional sheets should be used when necessary. Specific items of the application are listed below:

<u>Item 1</u> - The applicant is the institution. For a department, the department's name is listed below the institution's name.

Regulatory Guides are issued to assist applicants and licensees/registrants in developing operational procedures acceptable to the Department of State Health Services, Radiation Safety Licensing Branch (agency), that are compliant with specific sections of Title 25 Texas Administrative Code Chapter 289. Regulatory Guides are NOT substitutes for regulations and compliance with them is not required. Methods for compliance with regulations different from those set out in guides will be acceptable if they are considered by agency staff to provide for public health and safety and demonstrate compliance with

Comments and suggestions for improvements in Regulatory Guides are encouraged. Letters containing comments and suggestions should be sent to the, Department of State Health Services, Attn: Manager, Radioactive Material Licensing MC-2835, P.O. Box 149347. Austin, Texas 78714-9347. Regulatory guides may be reproduced or may be obtained by contacting the agency at (512) 834-6688 or accessing the agency web page at www.dshs.state.tx.us/radiation <u>Item 2</u> - List all locations where radioactive material will be used. Give street addresses, building names, floor, and room numbers. A portion of the laboratory should be set aside only for radioactive procedures. Locate these work areas away from heavy traffic and doorways. Provide full-page drawings of each lab, labeling all related equipment, use, storage, exhaust hoods, refrigerators, waste holding, and dedicated waste disposal sinks.

Item 3 and 4 - Self-explanatory.

<u>Item 5</u> - List all faculty or staff personnel who will use or directly supervise the use of radioactive material, and provide training and experience for those individuals focusing on formal coursework in radiation safety and radioactive material handling techniques. Describe isotopes used, the form(s) of these isotopes and duration of experience.

<u>Item 6</u> - The Radiation Safety Officer (RSO) is responsible for the radiation safety program and maintenance of the license and associated records. The RSO serves as the primary contact with the Branch in administering the license. Evidence must be provided in a statement from Executive Management that this individual has the authority to set radiation safety policy, suspend activities deemed unsafe, and require and direct remedial action when necessary.

<u>ltem 7</u> -

- a. List by radionuclide, such as "H-3, C-14, P-32" etc.
- b. For radioactive material contained in a sealed source, give manufacturer's name and model number of source. If material is not sealed, give chemical form (such as "sodium iodide") or physical form (such as "liquid," "solid," "accelerator targets," "plated foils," etc.). Be aware that sealed sources must be approved in accordance with Title 25 Texas Administrative Code (TAC) Section (§) 289.252(v) and you should maintain evidence of that from the manufacturer.
- c. Show total maximum number of millicuries to be possessed at any one time for each form listed. Include total activity for all material in storage, in use, on order or as waste, to prevent the possibility of exceeding that possession limit.
- d. Describe the use of the particular form. If used in a device, give the make and model number of device. If used in animals, field applications, classroom experiments, or demonstrations, please specify. Typically, authorizations will be for "Research and educational purposes."

Item 8 - Self-explanatory.

<u>Item 9</u> - See section IV below for the basic content of the operating, safety and emergency procedure manual. This manual shall also incorporate all procedures that demonstrate how the applicant will satisfy these minimum regulatory requirements. In

addition to this procedures manual, the applicant must also possess a written Radiation Protection Program that assures compliance with all associated aspects identified in 25 TAC §289.202.

<u>Item 10</u> - List the portable survey instruments (including probe model), and confirm they will be calibrated each year by an individual licensed for calibration services and that instruments will not be used for surveys if the calibration is older than one year. If instruments are to be calibrated at the institution, a detailed description of how they will be calibrated for all meter scales must be provided (Regulatory Guide 5.2, "Guide for the Preparation of Survey Instrument Calibration Applications," may be obtained from the Branch). Also identify any other instruments that may be used to analyze removable contamination and describe the testing of those instruments each day-ofuse and determination of instrument efficiency at intervals not to exceed 12 months.

<u>Item 11</u> - Confirm that sealed sources will be leak-tested every six months (or at other periods as reflected in the manufacturer's sealed source and device evaluation) by a person licensed to perform that service. If the sources are to be leak-tested by the licensee, a detailed description must be provided for the leak-test procedure (Regulatory Guide 5.1, "Guide for the Preparation of Leak Test Applications," may be obtained from the Branch).

<u>Item 12</u> - Self-explanatory. If the individual's resume fails to reflect the scope and specifics of prior radiation experience, you may provide evidence of previous licensed authorizations by providing a copy of a radioactive material license where the individual is named as an authorized user or the statement of a broad-licensee's RSO that summarizes the individual's past authorizations, dates, and compliance standing upon leaving.

Item 13 - Self-explanatory. (Also, see section IV.I. below.)

<u>Item 14</u> – See 25 TAC §289.252(gg) to determine if financial assurance must be provided. Unless license authorizations include large amounts of long-lived radioactive material (i.e., half-lives of greater than 120 days), financial assurance is not required and financial qualification can be established via self-attestation on BRC Form 252-1, Business Information. Only Federal, state or local government licensees, may use a Statement-of-Intent as a method of providing financial assurance. The state government provision encompasses state institutions of higher learning (e.g., state universities, state medical schools), and a sample of the Statement-of-Intent will be provided upon request.

<u>Item 15</u> - The application must be signed by a person duly authorized to commit the institution to the performance of the activities as specified in the application. This will be the University President unless an alternative representative is to be designated by the President. Renewals of existing licenses can be also be signed by the currently approved RSO.

IV. Radiation Safety Procedures

The applicant must submit operating, safety and emergency procedures, which must include a single list of general laboratory safety practices that reflect basic radiation safety standards that will be followed by all persons who will handle radioactive material. An example has been provided in the Appendix B. The procedures should have serially numbered pages with a table of contents for ease of reference. A copy of the approved operating, safety and emergency procedures must be provided to all named users and made available to all under their supervision who are to use radioactive material, including students.

The radiation operating, safety and emergency procedures should cover these items:

- A. Procedures for the control and management of the radiation safety program including a description of the duties and responsibilities of the RSO and the responsibilities of the users at all levels. The procedures should discuss supervision and safety audits during normal work schedules, vacation schedules, and summer sessions.
- B. Procedures for ordering radioactive material, for receipt of materials during off-duty hours, and for the RSO maintaining inventory. These procedures should be adequate to ensure that possession limits are not exceeded, that radioactive material is secured against unauthorized removal at all times, and that radioactive material is dealt with within the appropriate time constraint. If ordering is performed by other than the RSO, explain how the RSO approves individual orders for new inventory.
- C. Procedures for examining incoming packages for leakage, contamination, or damage, and for safely opening packages. The monitoring should be performed as soon as practicable after receipt of the package of radioactive material (see 25 TAC §289.202(ee) for minimum requirements). The procedures may vary depending upon the quantity of radioactive material received, but should, at a minimum, include instructions for surveying packages, wearing gloves and lab coat, and checking packing material for contamination after opening.
- D. A description of training required for laboratory personnel and/or students who are involved in handling radioactive material as directed by a principal investigator. The description should include the form of training (formal course work, lectures, videos, etc.), the duration of training, the subject matter included, and frequency of training for all users and handlers of radioactive material. The training program should be of sufficient scope to ensure that all personnel receive adequate instruction for safe use of radioactive material prior to working with radioactive material; refresher training should be provided at least annually.
- E. General instructions to be followed by laboratory personnel and/or students while working with radioactive material. These instructions should:

- 1. Outline control procedures for obtaining permission to use radioactive material at the institution; give limitations on quantity to be handled per student, or allowed per experiment, etc. Each authorized user and the RSO should maintain a current list of individuals who will be handling radioactive material.
- 2. Explain what laboratory apparel to wear and what personal protective equipment to use.
- 3. Prescribe limitations and conditions relative to handling liquid or loose radioactive material and what laboratory equipment to use in working with them. For example, explain what materials and what operations should be confined to fume hoods. Indicate what shielding equipment will be employed when hard beta and/or gamma emitting materials are used.
- 4. Describe routine survey and monitoring procedures to be followed for contamination control. Specify a frequency for frisking personnel (every time leaving restricted areas) wipe tests and portable instruments surveys of radioactive material storage areas. Include the instruments and methods.
- 5. Give instructions concerning movement of materials between rooms or in halls, buildings or across campus, if applicable.
- 6. Explain requirements for storage of materials, labeling of containers, and identification of areas where radioactive material is used with a particular emphasis on security precautions. Explain where and how contaminated articles and glassware are to be handled and stored and how access is limited to authorized personnel.
- Specify personnel monitoring devices to be used, how to obtain them, and who should wear them. If some persons will not be monitored, then provide justification criteria as per 25 TAC §289.202(q).
- Indicate waste disposal procedures, either by decay-in-storage (DIS), discharge to the sanitary sewer (25 TAC §289.202(gg)), transfer or as exempt (25 TAC §289.202(fff)) after Branch approval. If the program involves experiments in animals, outline instructions on cleaning animal quarters and handling excreta and carcasses for disposal.
- 9. Explain what records are to be kept on materials use and disposal to maintain an accurate inventory.
- 10. Explain the precautions against mouth pipetting, the need to use absorbent paper on lab surfaces, and prohibitions against smoking, eating or applying cosmetics in restricted areas.

- 11. If millicurie amounts of iodine-125 or 131, or hydrogen-3 are to be used in uncontained form outside of fume hoods, describe the bioassay procedures to be followed. (A bioassay guide may be obtained from the Branch.)
- F. A copy of the emergency procedures that are to be posted in all laboratory areas where radioactive material is used. These instructions should include a description of immediate action to be taken in order to prevent contamination of personnel and work areas, and the telephone numbers of the responsible persons to be notified in case of an emergency. This should include an alternative reporting procedure for after normal work hours, weekends or vacation periods. The manual shall include specific guidance for decontamination and notifications. See Appendix C.
- G. If radioisotopes will be used in animals, provide a sketch and a description of the animal housing facilities. This should include a copy of instructions provided to animal caretakers for the handling of animals and carcasses, and for cleaning and decontamination of animal cages. Also describe how animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material.
- H. A description of the routine survey program, including the areas to be surveyed, the levels of contamination considered to be acceptable, and provisions for maintaining records of surveys. Individual users are to be responsible for performing surveys at a greater frequency than the radiation safety staff. Laboratories using higher activities with regular use patterns should be surveyed for contamination at the end of each working day and a record must be kept of such surveys (also see Appendix A).
- I. A complete description of the specific methods for waste disposal of radioactive material. A licensee may dispose of waste by:
 - 1. Transfer to a person properly licensed to receive such waste.
 - 2. Release into a sanitary sewer in conformance with 25 TAC §289.202(gg).
 - 3. Disposal of limited concentrations of hydrogen-3, carbon-14 and lodine-125 in accordance with 25 TAC §289.202(fff)(1).
 - 4. Decay-in-storage following ten physical half-lives and to measured levels equivalent to background on container surfaces. Recorded surveys performed with a highly sensitive laboratory instrument, low background area, without interposing shielding, labeling made non-legible, and subsequently release into other waste streams once determined to be essentially no longer radioactive.

<u>NOTE</u>: No licensee may dispose of radioactive waste material by incineration, release to septic tanks, or burial unless specifically authorized by the Branch.

Appendix A

METHODS AND FREQUENCY FOR CONDUCTING RADIATION SURVEYS

I. Introduction

When radioactive material is handled in the form of solutions or powders, as may occur in a laboratory, both radiation surveys and contamination surveys should be performed to prevent unnecessary radiation exposure to personnel and to prevent the spread of contamination throughout the facility. Radiation surveys are performed using a radiation survey meter, and contamination surveys are performed by taking wipe samples from surfaces in the facility that would most likely be contaminated.

II. Frequency of Surveys

Survey frequency depends upon the amount and type of radioactive material used. Listed below are examples that may be useful in determining how often to perform surveys. The greater the workload, the more often the surveys should be performed.

- A. <u>Low Level Areas</u> Not less than once a month Areas such as where <u>in vitro</u> tests are performed, and liquid samples/specimens are normally in closed or sealed containers, and stock solutions are less than 1 millicurie each.
- B. <u>Medium Level Areas</u> Not less than once a week Areas where no more than a few millicurie amounts of very low energy beta/gamma emitting radioisotopes are routinely handled, and all work is performed exclusively in exhaust hoods.
- C. <u>High Level Areas</u> At least once a day Areas where volatile solutions, solids/liquids/ powder are processed over open counters, and liquid bulk quantities exceeding 10 mCi.

III. Methods of Surveys

Suggested methods for performing surveys are given below. Records of these surveys should be maintained for inspection by the Branch and for reference to determine whether the radiation levels or the contamination levels remain constant or increase over a period of time.

A. <u>Radiation Level Surveys</u> - A portable survey instrument with the greatest sensitivity capable of measuring levels as low as 0.1 mR/h should be used and the results recorded on a form showing location, date, person performing survey, instrument and probe used, exposure levels, and corrective action taken, if any. A sketch of the area should be used to make an easily prepared and easily understood survey record when annotated with this information.

B. <u>Contamination Level Surveys</u> - A series of wipes using filter papers or other suitable material should be taken from surfaces where contamination is expected. (e.g., where solutions are prepared or pipetting is performed). The wipes should be numbered and their location indicated on a sketch as described above. The wipes should be rubbed over an area of approximately 100 cm² to maintain a consistent means of determining the amount of removable contamination. The wipes may be counted using a gamma scintillation well counter, a liquid scintillation counter, or thin crystal scintillation probe with scaler, or any detector capable of detecting a small amount of contamination on the sample.

IV. Acceptable Limits

- A. <u>Radiation Level Limits</u> In unrestricted areas, radiation levels should not exist such that a person occupying the area could receive 100 mR in any one year or 2 mR in any one hour. If such areas are found, measures must be taken to lower radiation levels. Additional shielding or relocation of radioactive material may be required. For restricted areas, the applicant should establish radiation level limits that are as low as reasonably achievable (ALARA); ALARA is required to be an integral part of your radiation protection program.
- B. <u>Contamination Level Limits</u> If wipe sample results indicate more than your established limit, the area should be cleaned until the contamination has been removed. Because it is difficult to determine the precise extent of contamination when detected, it is recommended that, when such samples show an easily detectable amount of activity above background, the contaminated areas be cleaned. This action should help prevent the spread of contamination that could be ingested by personnel or interfere with laboratory results.

V. Surveys of Waste

- A. Below is a discussion of the various methods of disposing of radioactive material that may apply to your operations. Be advised that if not described in your procedures, an amendment may be required to dispose of radioactive waste if material is to be sent to the sanitary sewer or landfill. Records must be maintained for <u>all</u> methods of waste disposal. No guidance here or in 25 TAC §289 releases licensees from handling waste in accordance with other applicable rules (e.g., hazardous chemical or medical).
- B. <u>Decay-in-Storage</u>. To dispose of waste decayed in storage you must describe a labeled, secure and possibly shielded area that will hold the anticipated volume of waste. If more than one nuclide is used, segregation may be required to minimize storage time. Waste must be logged with information to include nuclide, date placed in storage and approximate activity (use 10% of original activity for empty containers). After the waste has decayed for ten half lives, it must be surveyed in a low background area with an instrument of sufficient sensitivity to show that the residual activity is indistinguishable from background. For this purpose a portable

survey instrument may suffice, preferably with a scintillation probe for gamma emitters, and a pancake GM for beta emitters. It is not required to remove or deface labels if they will be obscured in containers not designed to be reopened (e.g., sharps containers or medical waste boxes).

- C. <u>Exempt Wastes</u>. 25 TAC §289.202(fff)(1)-(3), permits some wastes to be disposed of without regard to radioactivity (e.g., ³H, ¹⁴C and ¹²⁵I as *in vitro* waste medium and animal tissue). The activity can be averaged over the entire waste volume or animal but must be less than 0.05 μCi per gram. Medium is interpreted to include vials, pipettes, paper and other material in contact with the radioactive material during the course of the test or experiment. Documentation must be retained to show that the waste being discarded meets these criteria and controls (administrative and physical) must be in place to ensure that the limits of activity are not exceeded. For ¹²⁵I, surveys should be performed and a assessment made, to determine the average amount of radioiodine in the container. A thin crystal scintillation probe has the sensitivity required to make these measurements. Title 25 TAC §289.202(fff)(4)-(9) describes how authorization can be obtained to dispose of nuclides with half-lives of less than 300 days. Prior authorization from the Branch is required before this method can be used.
- D. Disposal via Sanitary Sewer Systems. Title 25 TAC 289.202(gg) explains the conditions that must be met if liquid or readily dispersible biological material is to be discharged into sanitary sewer systems. Note that there is an annual limit of activity that may be disposed and monthly concentrations that must be met. These procedures and calculations should be sent for Branch review so as to be a part of your permanent license file. Average monthly volume of water released into the sewer by the licensee, if not directly metered, may require evaluating water volumes received and corrected for seasonal water use.

Appendix B

RADIOACTIVE MATERIAL LABORATORY SAFETY GUIDELINES

Keep the laboratory clean and orderly at all times.

Ensure non-essential personnel are not in laboratories when radioactive material is used.

Label radioactive material containers with the radiation trefoil and pertinent information.

Store all radioactive material in a locked room or cabinet.

Exercise deliberate care in handling radioactive material and store/transport it in shielded containers, when necessary, to protect against external radiation exposure.

Wear lab coats, rubber gloves, closed-toed shoes and eye protection were appropriate. No protective clothing will then be worn when leaving labs.

Cover work surfaces with absorbent paper when radioactive material is used.

Work with radioactive material should be done rapidly but carefully. Plan work and, if possible, perform practice runs to test procedures.

Never pipette by mouth.

Do not eat, drink, smoke, apply lip balm or cosmetics, or store food and personal effects.

Dispose of radioactive waste only in specially labeled and properly shielded receptacles.

Monitor hands, clothing, notebooks and writing instruments for contamination before leaving an area.

Survey areas where radioactive material in uncontained form is used after each procedure and/or at the end of the day. Decontaminate immediately if necessary.

Check survey meters routinely with a source of radiation to see if they are responding properly. A battery check should be performed before each use.

Wear radiation badges, if assigned, while in areas where radioactive material is stored or used. If assigned, finger badges must be worn when handling radioactive material.

Use unsealed radioisotopes only in approved laboratories that possess non-porous flooring and work sources, for purposes of easy decontamination.

Report radiation accidents involving radioactive material resulting in suspected or known overexposure or cross-contamination of a worker to the RSO as soon as practical.

APPENDIX C

SUGGESTED METHODS FOR COPING WITH SPILLS AND PERSONNEL CONTAMINATION

Facilities using non-contained radioisotopes should maintain a decontamination (DECON) kit to consolidate emergency DECON supplies that might be needed. Supplies for this kit should include necessary items for spill containment, cleaning, disposal packaging, labeling, personal protective clothing, and area posting needs. When the handler appears to be included in the solution spill, having this kit well labeled and accessible will be a great asset. The following are SAMPLE PROCEDURES (excluding volatile airborne and noble gases):

- 1. Minor Surface Contamination (less than 1 millicurie)
 - a. When contamination involves individuals or multiple locations, notify the RSO.
 - b. If unsure of contamination levels and extent, survey first and verify if removable.
 - c. If work surfaces become contaminated, remove the temporary protective covering by rolling or folding the contaminated surface to the middle and place the contaminated covering into labeled plastic bags. Replace protective covering.
 - d. If contamination covers multiple work surfaces, don protective garments (double rubber gloves, lab jacket, and shoe coverings) and obtain a DECON kit and survey instrument. Using the least amount of water possible, (e.g., damp wash-cloths), scrub surfaces. Cleaning efforts should work from points of lowest to highest contamination. Avoid spread of contamination by placing all contaminated waste into labeled plastic bags. Initiate detailed surveys (removable and fixed) of the involved surfaces and responders to determine if decontamination has been successful or if efforts must continue. Abandon efforts when levels can't be further reduced. Survey staff and their protective clothing, removing all waste to storage. Remedial steps may include taping an impermeable cover over remaining removable contamination or adding shielding to reduce fixed high exposure rates. If decontamination is required for multiple surfaces or an individual, documented surveys, remedial steps and results should be submitted to the RSO promptly.
- 2. Major Surface Contamination (greater than 1 millicurie)
 - a. Instruct staff not to enter the area and notify the RSO for assistance.
 - b. Have an uncontaminated person obtain a DECON kit and survey instrument.
 - c. With the RSO's supervision, remove and decontaminate involved persons while donning protective clothing, bagging contamination and changing outer gloves often. Utilize two persons when possible, one "clean" assistant documenting

survey findings and providing supplies, and another performing tasks outlined previously under minor surface contamination. Aggressive surface decontamination may be required and equipment may need to be isolated, secured, placed for disposal, or posted for decay-in-storage.

- 3. Hazardous Contamination (i.e., ruptured sealed sources of multi-millicurie activity)
 - a. Shield the source, if there is no risk of contamination/significant radiation exposure.
 - b. Remove all individuals at risk. If individuals might be contaminated, isolate them in a nearby safe location until surveys can be performed.
 - c. Secure all points of access and immediately contact the RSO (if inaccessible, contact his alternate) to manage all further DECON tasks, environmental, and/or facility ventilation considerations. The RSO must assume responsibility and initiate any required contacts with the Texas Department of State Health Service's Radiation Control staff via their emergency telephone number. (512-458-7460)
 - d. If fire, explosion, and/or a natural disaster create a potential hazard of this nature, remove all individuals from harm's way, deal with individual contamination, and warn responders of the associated radiological hazards involved.
- 4. Personnel Contamination
 - a. Contamination, other than on the hands, will usually be contained on the clothing.
 - b. After contaminated clothing is removed, survey the individual to determine if other portions of the body are contaminated.
 - c. Place contaminated clothing in a labeled plastic bag for storage until such time as radioactive decay assures background levels have been obtained.
 - d. To decontaminate skin, gently wash with damp cloths soaked in tepid tap water and a mild detergent, and/or irrigate open wounds or eyes that appear contaminated while avoiding spattering or rinsing contaminated wash water onto other bodily areas;
 - e. Particularly notice if contamination exists on the face or neck area when considering if internal contamination may have resulted and when suspected, nasal wipes and urine samples may yield valuable information.
 - f. Skin contamination is usually localized and would not indicate whole-body showers. Avoid using hot water and irritating brushes, which tend to increase absorption (internal deposition) through increased vascularity. Occasionally skin contamination cannot be removed. These sites may be wrapped with gauze and with plastic taped over to promote "sweating" the isotope out. Ingestion of

radioisotopes will necessitate bioassays and prompt evaluations may include nasal swabs, thyroid counting, urine and/or fecal collections for 24 hours. The RSO would direct and oversee such actions.

- g. If the contaminated individual also has a health condition (i.e., cardiac, seizure, fracture, etc.) that necessitates prompt medical treatment, do not delay this treatment. The nature of these laboratory spills may likely involve far more hazardous risks from associated chemicals in many laboratories, and appropriate action may necessitate prompt and/or modified actions for individuals who are additionally exposed to other hazardous chemicals. Provide guidance and assistance to the medical caregivers to contain the further spread of any contamination from the individual. Decontamination can proceed after the individual is treated or stabilized.
- h. For serious contamination events, advice may be sought from health physicists at Radiological Emergency Assistance Center/Training Site (REAC/TS) in Oak Ridge, Tennessee, (615) 576-3131, or the State's Radiological Emergency Assistance Number (512) 458-7460.

NOTE: FOR ALL CONTAMINATION EVENTS:

- 1. Document the entire process and associated survey results.
- 2. Consider risks and potential for internal contamination of all involved.
- 3. Determine appropriate notifications and reporting based on §289.202(xx), §289.202(yy), and §289.252(r).

Appendix D

Radiation Safety Procedures for the Use of Radioactive Material In Animals

All radioactive material use at the University must be approved by the Radiation Safety Officer, the Radiation Safety Committee, and authorized by DSHS. All forms can be found in the Radiation Safety Manual. A Principal Investigator (PI) planning to use radioactive materials in animals must fill out an Application for Use of Radioactive Material in Animals and send it to Radiation Safety, for review by the Radiation Safety Officer.

The use of radioactive material in animals requires additional safeguards in the handling of affected animals. Investigative procedures involving animal systems vary widely as do applicable safety techniques. The information provided on the application will enable Radiation Safety to formulate necessary safety measures and assist the PI in implementing these measures. It is important that all pertinent information is included and the application totally completed. Radiation Safety Personnel will perform a compliance inspection for postings, security and engineering controls prior to allowing new radioactive material use.

The Radiation Safety Officer will submit all applications to the Radiation Safety Committee and DSHS as necessary for approval.

Details concerning the actual use of animals must be worked out with the Institution's animal care operation (division) and the research protocol approved by the Animal Care Committee. No research activities can be started using animals without prior approval.

The PI is responsible for the overall radiation safety of the project, including radiation monitoring of the animals, cages, and procedures; analytical determination of radioactivity in urine, feces, and bedding; and labeling all cages containing radioactive animals. Tags for this purpose must indicate the radioisotope, the activity (in μ Ci or mCi) and the date. Animal Care Facility should be notified at least five working days prior to housing radioactive animals in Animal Care. Such notification is not necessary for use within the Principal Investigator's labs.

All animal remains, i.e., viscera, tissue, serum, or other fluids, and the carcass, containing radioactive material (except ³H, ¹⁴C and ¹²⁵I as described below) are to be disposed as follows. Place the remains in a yellow radioactive materials waste bag. Seal the bag closed with tape and attach a Tag for Waste Municipal Landfill disposal as authorized by the University's waste disposal program, showing the radioisotope, the activity (in μ Ci or mCi) and the date. The bag is to be placed in the radioactive material labeled freezer in the Animal Care Facility as prearranged with Animal Care personnel.

Animal remains containing ³H, ¹⁴C and/or ¹²⁵I, in quantities less than 0.05 microcuries per gram weight, are exempt and may be disposed of as non-radioactive waste. Place these remains in a clear waste bag without a radioactive material label. The bag is to

be placed in the non-labeled freezer in the Animal Care Facility as prearranged with Animal Care personnel. The Principal Investigator must continue to keep an inventory showing stored waste intended for disposal with activities, dates, and radioisotope ³H, ¹⁴C, or ¹²⁵I used in the animal. The following table will help in determining activity levels in animal remains that may be disposed of as non-radioactive waste. [The three radionuclides above this exempt concentration and other radionuclides may only be disposed of at a municipal landfill if the University has been granted special permission by DSHS and TCEQ.]

AMOUNT OF H-3, C-14 OR 1-125 IN ANIMAL REMAINS THAT MAY BE DISPOSED OF AS NON-RADIOACTIVE WASTE

Maximum Animal Weight		Activity	Maximum Animal Weight		Activity
gm	lb.	μCi	kg	lb.	μCi
100	0.22	5	2.5	5.5	125
200	0.44	10	3.0	6.6	150
300	0.66	15	3.5	7.7	175
400	0.88	20	4.0	8.8	200
500	1.1	25	4.5	9.9	225
600	1.32	30	5.0	11	250
700	1.54	35	7.5	16.5	375
800	1.76	40	10	22	500
900	1.98	45	20	44	1.0 mCi
l kg	2.2	50	30	66	1.5 mCi
1.5 kg	3.3	75	40	88	2.0 mCi
2.0 kg	4.4	100	50	110	2.5 mCi