Texas Department of State Health Services
Radiation Safety Licensing Branch

REGULATORY GUIDE 3.13

GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR THE USE OF ACCELERATORS TO PRODUCE RADIOACTIVE MATERIAL

I. Introduction

This guide describes the information that the Department of State Health Services (DSHS or Agency) staff needs to evaluate license applications for the use of accelerators to produce radioactive material. It is intended only as general guidance and should not be considered as representing all the information that may be required for a particular application.

II. Types Of Licenses

It is necessary that a separate specific license be issued to an institution to cover the institution's accelerator and produced radioisotope program. When the institution already has a broad license for possession and use of radioactive material, some radiation safety functions can be shared, but a clear demarcation of activities will need to be made so that responsibilities are assigned under the appropriate license.

III. License Fees

The applicant should refer to Title 25 Texas Administrative Code (TAC) Chapter 289.204 to determine the amount of the fee that should accompany a new application. Review of the application will not begin until the proper fee is received by the Agency. This fee may be paid in cash, by money order, certified check, or personal check, made payable to the Department of State Health Services. In submitting an application for renewal of a radioactive material license, the fee should not be submitted until billed by this Agency. A fee is not required to amend a license, in most cases, unless the amendment changes the category and type of license. If there are any questions, the Agency accounting staff will clarify the fees.

IV. Completing The Application

Applications for a new license should be completed as instructed below. All items of the application, BRC Form 252-2, should be completed in sufficient detail to allow the Agency to make a realistic review of the institution's program for safe use of accelerators and produced radioactive materials. The application and all attachments should be submitted to the Agency in duplicate; an additional complete copy should be kept 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 as necessary.

All applications must be accompanied by a completed Business Information Form (BRC Form 252-1) providing information on the applicant's responsible officials and certifying the applicant's financial qualifications [25 TAC §289.252(d)(6)].

Item 1 - Indicate the name and mailing address of the applicant. The applicant is the institution. For the accelerator facility, the appropriate department's name should be listed below the institution's name.

Item 2 - List all locations where radioactive material is to be used under the license. Give appropriate street addresses, building names, floor and room numbers. This should include only the locations directly involved with the accelerator and its beam and the handling of radioactive material produced by the accelerator. It should not include areas such as clinical facilities, where products of the accelerator may be transferred for clinical use.

Item 3 - Self-explanatory.

Item 4 - Indicate where records are to be maintained. Records can be maintained at the accelerator facility or with other institutional records, if the institution has another radioactive material license.

Item 5 - List the names and titles of the individuals who will be using, or directly supervise the use of, the accelerator or produced radioactive material.

Item 6 - The Radiation Safety Officer (RSO) is the person designated to be responsible for the day-to-day radiation safety program. The RSO maintains all records required by the Agency rules, and is the primary contact with the Agency on matters pertaining to the license and the use of radioactive materials. The RSO's training and experience with types and quantities of radioactive materials for which a license is being requested should be submitted. Indicate the name of the RSO and telephone number(s) where the RSO may be contacted. The RSO must have the authority to set radiation safety policy, suspend activities deemed unsafe, and require and direct remedial action when necessary. This person may, in some circumstances, be the RSO for a related license also.

Item 7 -

a. List by isotope, such as "thallium-201," "gallium-67," "cobalt-60," etc. For accelerator-produced material, list significant collateral nuclides. See Appendix D for additional explanations.

b. If radioactive material is contained in a sealed source, give manufacturer's name and model number of source. If material is not sealed, give the chemical form (e.g., "sodium iodide") and physical form (e.g., "gas," "metal," "solid accelerator targets," "plated foils," etc.).

c. Indicate the maximum number of millicuries to be possessed at any one time for each form listed. Include total activity for material in storage, in use, or as waste. For accelerator-produced material, list significant collateral nuclide activities, based on nominal production parameters.

d. Describe the use of the particular form. If used in a device, give the make and model number of device. If used to produce radiopharmaceuticals, radiopharmaceutical generators, or radiochemicals for commercial distribution, please specify.

Item 8 -

a. Scaled drawings of the facility should include at a minimum, the following areas:

    1. Location of the accelerator within the building;

    2. Diagram of the accelerator and associated rooms;

    3. Diagrams of the rooms associated with radioactive material production or use;

    4. Locations of all area monitors, ventilation equipment (vents, filters) and other equipment and fixtures;

    5. Receipt, use, and storage areas for radioactive material;

    6. Location of hot labs within the facility;

    7. Diagrams of each hot lab identifying location of fixtures and equipment;

    8. Location of equipment cooling systems;

    9. Ventilation system room layout, including location of ducts, exhausts and intakes;

    10. Rooftop diagram of air intakes and exhausts;

11. Radioactive material waste storage and handling areas;

12. Radioactive material packaging and transport areas; and

13. Associated mechanical equipment rooms, including locations of their vents, stack penetrations, filters.

Illustrations for each room and major areas should be provided, as well as plan drawings for each floor and two orthogonal elevation drawings for the entire facility.

Area restrictions should be illustrated on each drawing, as appropriate. Locations where radiation field and contamination surveys will be performed routinely should be clearly marked.

b. Illustrations of systems within the facility, to include:

1. The accelerator and direct attachments, including beam piping, power supplies, magnets and related equipment, exclusive of target devices.

2. Target systems, including controls, monitors, piping, mounting and demounting mechanisms, containment, shielding and interfaces with transport systems. For commercial production, separate illustrations for each product system should be included.

3. Shielded work areas for target handling, processing, assaying and packaging, including manipulators, process equipment, containment, shielding, piping, other controls, monitors and local filters. For commercial production, separate illustrations for each product system should be included.

4. Ventilation (heating, ventilation, air-conditioning) equipment and systems, including fans, ducts, exhausts, intakes, controls, monitors and filters.

5. Accelerator and target cooling systems to include pumps, piping, supplies, isolation valves or devices, drains, controls, monitors and filters.

6. Vacuum systems, to include pumps, piping, intakes, exhausts, controls, isolation valves or devices, monitors and filters.

7. Dedicated gas exhaust or special liquid handling systems, including drains (e.g., glove boxes or fume hoods, etc.), showing areas evacuated or drained, piping, pumps, controls, filters and exhausts. (Generally, no connections to other systems should be made and this should be clearly illustrated where systems are in close proximity.)

8. Transport systems for radioactive material (automatic, remote control or pneumatic systems for targets, radiopharmaceuticals, etc). Drawing should show

each station and location, all routes, typical hardware for routes, stations and carriers, and controls and monitors.

9. Interlock systems, showing installed locations, controls, readouts and warning devices, and areas protected.

10. Area radiation monitoring systems, including installed locations and areas to be monitored, typical sensor and read-out hardware and controls and calibration devices. Portal monitor and portable survey instrument locations should also be included.

Illustrations can be in the form of engineering line drawings or blueprints, perspective drawings, detailed manufacturer's literature (service manuals), or multiple views by industrial photography, provided that enough detail is present for the Agency to perform a safety analysis for each system. Sales brochures or simple snapshots will not provide sufficient information and should not be submitted. Illustrations should be on 8.5" x 11" paper to facilitate recordkeeping.

c. Comprehensive descriptions of the use of each of the areas listed under a., above, including estimates of the amount of radioactive material, and the range of ambient radiation fields expected in each area during production. Access by authorized personnel should also be discussed. Areas designated as "clean areas" should be demarcated from those where contamination may be expected.

d. Descriptions, specifications and discussions of the operating principles and performance parameters of each of the systems under b., above. These should also include performance parameters as installed and how these were determined, logic of operation, trip points or set points for monitored parameters, and how the systems fail to a safe configuration with loss of power or loss of a major component (such as a fan, pump, cooling system or sensor). Discuss how requirements of 25 TAC §289.229, Therapeutic Radiation Machines and Simulators.

For the ventilation system, the final design and installation should be reviewed by a certified industrial hygienist with experience in radiation safety. His or her credentials and report should be submitted with the information described above.

Item 9 - See Appendix A for content of the radiation safety procedures and descriptions of the radiation safety program. Where topics in the following pages for this Item appear to repeat those from Item 8 (Facility Design), the intent in most cases is to obtain procedures for normal and emergency operations (of the facility systems which were described for Item 8). These procedures should be included in an operating and safety manual, to be made available to all facility personnel. To facilitate this, some information, such as illustrations and descriptions, may need to be repeated. For special operations, elaboration of basic facility descriptions may also be needed (e.g., Appendix A, Section VII). However, design bases and their evaluations for basic systems (Appendix A, Sections VIII and XIII) may be left out of the manual and included with the facility design information.

Item 10 - For the portable survey instruments, the applicant must provide the manufacturer and model number of each type of instrument to be possessed. The applicant should indicate who will be calibrating the instruments, and also describe the calibration procedures and frequency. If the portable survey instruments are to be calibrated at the institution, a detailed description of the instruments calibration procedures for all meter scales must be given, Regulatory Guide 5.2, "Guide for the Preparation of Survey Instrument Calibration Application," may be obtained from the Agency. If a survey instrument is to be calibrated by a service firm, the firm should be licensed or registered by the Agency. Instruments should be calibrated at intervals not to exceed one year [25 TAC §289.202(p). See also Appendix A, Section IV.

Item 11 - Sealed sources should be leak tested every six months [25 TAC §289.201(g)(1)(B) and (C)]; describe the method to be used for leak testing. If leak tests are to be performed by the licensed users, a detailed description should be provided. (Regulatory Guide 5.1, "Guide for the Preparation of Leak Test Applications," may be obtained from the Agency). Records indicating that leak tests have been performed and the results of the leak tests must be maintained for inspection by the Agency [25 TAC §289.201(g)(4)]. See also Appendix A, Section IV.

Item 12 - See the following pages (Appendix A, particularly Sections I and XI) for training and experience and descriptions needed for authorized and ancillary personnel.

Item 13 - See the following pages, particularly Appendix A, Sections XV and XVI.

Item 14 - See 25 TAC §289.252(gg) to determine if financial assurance for decommissioning 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 Form.

Item 15 - The application must be signed and dated by a person duly authorized to commit the institution to the performance of the activities as specified in the application. This should normally be the President or Chief Executive or Operating Officer.

IV. Completing The Application For Renewal

Because of the advances in radiation safety techniques, the changes in operation during the term of the license and possible Agency rule change, it is wise to complete a renewal application as if submitting the application for the first time.

For personnel added since the license was issued, a statement must confirm that the training and experience of new workers is in accordance with Item 12 of the application. If the application has made any changes in the training program, address those changes in Item 12 of the application.

The Agency should be contacted directly for assistance in answering questions concerning

the renewal and the procedure for addressing specific items.

V. Requesting An Amendment

A request for an amendment to a license should be in the form of a letter stating the license number, the portion of the application or license to be changed, the specific changes to be made, and the reason(s) for such a change. To prevent unnecessary delay in considering the amendment request, address the request to the Radiation Safety Licensing Branch. The only way to legally possess additional radioactive material, move to a new use and/or storage location, or change any service previously authorized on a license is to have that specific change considered and granted in an amendment by the Agency.

APPENDIX A

RADIATION SAFETY PROCEDURES AND DESCRIPTIONS OF THE RADIATION SAFETY PROGRAM

I. Administration of Program

A. Radiation Safety Program Management and Radiation Safety Officer (RSO) authority, duties and responsibilities.

Provide an institution organizational chart which includes the RSO and the positions superior to the RSO; and fully describe the lines of communication and authority. Discuss how authority and responsibilities are delegated through this structure from the Chief Executive Officer to the RSO.

Discuss the appointment of both the institution's RSO and an Assistant RSO for accelerator operations, including minimum qualifications, process for appointment and concurrences required.

Confirm that the RSO and Assistant RSO for accelerator operations has sufficient authority to halt operations, restrict areas, and detain employees or others at the facility (for decontamination) if, in his or her judgment, such actions are appropriate.

Describe duties and responsibilities for the Assistant RSO for accelerator operations. This individual should be assigned exclusively to the accelerator facility, but should not be directly involved in production or experimental work that would conflict with his or her duties to assure safety.

Describe how the responsibilities of the RSO and Assistant RSO for accelerator operations are implemented to assure that radiation safety is integrated into the program. Indicate procedures to accomplish each of the following and designate the individuals or staff positions at the accelerator facility who will be responsible for each task.

Responsibilities for radiation safety should include:

1. Inventory and control of radioactive sources, targets and other activated materials;

2. Observation and control of radiation hazards;

3. Radioactive waste storage and disposal;

4. General radiation monitoring procedures;

5. Instruction of personnel in observation of rules and monitoring procedures;

6. Maintenance of records related to exposures and accumulated doses received by the personnel;

7. Periodic routine surveys of the accelerator installation;

8. Surveys of new experimental setups;

9. Survey of unusual conditions including conditions during maintenance operations; and

10. Environmental monitoring and assessment of releases.

B. Radiation Safety Committee for accelerator operations

A local committee should be established to oversee accelerator operations. It should be composed of key staff at the accelerator facility and expert advisors on radiation safety. The Radiation Safety Committee of any institutionally related broad or specific license is not necessarily appropriate or useful in this regard (since few of its members may have any direct knowledge or concern with accelerator operations). Describe the applicable safety committee in terms of:

1. Membership and general qualifications;

2. Duties and responsibilities;

3. Frequency of meetings; and

4. Method of recording minutes.

The membership of this committee should be communicated to the Agency initially, but when individual changes are made later, which are within the guidelines established in B.1., above, these need not be communicated to the Agency.

C. Radiation Safety Officer (RSO) qualifications

1. Radiation Safety

Describe his or her comprehensive training and experience related to radiation safety for use and maintenance of accelerators capable of producing radioactive material in significant quantities. Additionally, describe training in mechanical and electrical safety related to:

a. Beam transport and high vacuum systems;

b. Target systems and target containment systems;

c. Auxiliary mechanical equipment;

d. Special fire protection; and

e. Control systems.

2. Training

Indicate areas of expertise that demonstrate his or her ability to train operators and technicians in specific problems for your accelerator and to provide information about radiation safety and special hazards relating to use of this accelerator. (See also below and Section XI for scope of training to be authorized.) If accelerator operator training is to be conducted by facility management instead, provide similar information.

3. Independent expertise

The RSO should be independent of production or operations management for the facility, but must be equally well trained in operations in order to perform effective audits. Indicate how this independence and equivalent training is to be accomplished and preserved.

D. Staffing patterns and authorized users of the accelerator and radioactive material

1. Describe the organization of the facility staff with a chart and a narrative explanation. Indicate which staff positions will perform irradiations, target and material transfers and radiochemical processing.

2. Describe how the staff positions directly involved with the handling of radioactive material and/or operating the accelerator will be supervised.

3. Describe the minimum shift complement in terms of staff positions, for each major type of operation, including:

a. Bombardment for commercial products;

b. Bombardment for experimental runs;

c. Operations involving target handling;

d. Processing radiochemicals and commercial product manufacturing, packaging and quality control; and

e. Manufacturing radiopharmaceuticals, including quality control, packaging and labeling.

4. Indicate who must be on call for emergencies, for each type of operation, in terms of staffing positions.

   Note: For training and experience requirements for other individuals or staff positions, see Section XI.

E. Scheduling and control

Discuss the mechanisms for scheduling users, production runs, experiments and maintenance. (See also Section V.D. on surveys to determine acceptable times for production activities and for maintenance activities.) Discuss what protocols will be followed and what notification of scheduling will be provided. Show how your system will provide at least 24 hours advance notice in writing to all affected accelerator personnel.

F. Area restriction

Discuss restriction of areas in the facility during the production of commercial products or radiopharmaceuticals. Also discuss security of areas within the facility and the facility as a whole, when unattended, or during off duty hours. (See also Section V on surveys.)

G. General authorization and evaluation of experiments

For the general authorization for radioactive material for research and development discuss the evaluation of experiments and how decisions are made regarding area restriction. Submit a formal review policy to address:

1. The details of a given experiment and possible interaction of the hazards of equipment and materials with other operations.

2. The layout and design of experiments, with regard to confining and containing any potential accident to the smallest area.

3. Describe the individuals involved with this review and the documentation that is to be retained for inspection by the Agency.

H. Internal Inspections, Audits and Reviews

Discuss in detail the formal program for on-going supervision and inspection of authorized users, facility and radiation safety program. At a minimum the following should be included.

1. Written guides and procedures for inspection;

2. Reports to users;

3. Schedules for inspections;

4. Assignment of personnel to perform inspections;

5. Schedules for review of reports; and

6. Follow-up and corrective action(s) for violations identified and escalated enforcement for repeat or flagrant violations.

II. Operating Procedures, Radiation Hazards and Safety Considerations - Descriptions to be included in a Radiation Safety Manual.

A. Provide a description of the type and uses of the accelerator. Indicate the following:

1. Type of accelerator;

2. The particles accelerated;

3. The energy of the accelerated particles;

4. The type of targets that will be utilized;

5. Geometry and shielding characteristics of the structural materials composing and surrounding the accelerator;

6. Long-lived activity in the machine after extended runs;

7. Time delay before the accelerator vault enclosure can be entered;

8. Activation process (nuclear reaction scheme) for each product produced (commercial targets and radiopharmaceuticals); and

9. The uses of the beam, including solid target irradiation, direct therapy, direct production of gases and liquids, etc.

B. Standard operating and safety procedures for accelerator startup, standby modes, shutdown and target exchange as well as down times. These should include:

1. Area restriction;

2. Steps for startup, standby and shutdown;

3. Acceleration parameter adjustment/checking;

4. Monitor checking (safety/production);

5. Visual/aural surveillance over access routes/accelerator areas; and

6. Minimum staffing patterns for various operational modes such as vault entry before irradiation, irradiation, standby, target handling, vault entry after irradiation, radioactive material (including target) processing.

C. Describe procedures for mitigating the radiation hazards associated with the accelerator sources in your facility (See also Appendix B). Include in your written operating and safety manual the appropriate safety procedures for the following:

1. Hazards of the primary beam of particles accelerated and any collateral radiation (example: synchrotron-type radiation) from the primary beam while under acceleration or in drift tubes, and hazards of the beam at the exit ports.

2. Scatter radiation produced when the primary beam strikes the target or other material. Describe auxiliary shielding materials used to absorb a beam that would otherwise strike metal components.

3. X-rays produced at the target end of the machine, and also at the high-voltage terminal by the back-streaming of electrons (for potential drop devices).

4. Neutrons produced by nuclear reactions in the target or other objects struck by the beam.

5. Targets which are radioactive before radiation, due to recycled feed-stocks or other causes.

6. Target activity and other induced radioactivity, after the beam is turned off, from machine components and targets. Discuss the radiation hazards from the activation process both due to radiation fields and due to contamination. Containment systems for handling radioactive material should be included here.

   In addressing the above areas, discuss targets in particular, but include vacuum chamber walls, electrode supports and other significant sources. Address safety, and submit procedures for personnel entering the room to perform maintenance, target changes, and routine or special adjustments. Specify radiation levels (as indicated by representative area monitors) for routine entry, levels requiring investigations and maximum levels for entry and/or occupancy, for each area.

7. Cooling water/other cooling media. Describe radiation safety for:

a. Re-circulating systems that may expose persons in other occupiable areas;

b. Residual activity present during scheduled maintenance work;

c. Shielding needs around circulating pumps, heat exchangers, and holding tanks;

d. Discharge into the sewer (Also see radioactive waste handling in Section XIII); and

e. Periodic analysis of cooling media to detect contamination and/or build-up of induced activity.

8. Airborne radioactive material. Discuss procedures for the following hazards:

a. Production of radioactive gases by the accelerator beam passing through air (depending on energy and intensity);

b. Radioactive gases produced internally in the targets that might escape into the target areas, or into the accelerator vault or other areas as a result of a target containment system failure;

c. Contamination by particulates or dust, rupture of a powder target or flaking of activated surface layers of solid target material and leakage of activity past the target containment system barriers into the accelerator vault or other area; and

d. For commercial production, each of the items above should be addressed for each product produced.

Note: Shielding criteria and evaluation should be discussed further in Part XII of this guide.

D. Maintenance and Inspection.

Provide schedules for maintenance and inspection of all radiological safety systems, discussing the following:

1. What will be done for each system and how often the operations are to be performed.

2. The individuals who will perform each task with respect to assignment of responsibilities and the minimum training and experience to be required to perform the task.

3. The records to be kept and who will review them for timeliness, completeness

and further work or investigation, as the need is indicated.

The above should address the more complicated routine tests and maintenance items, beyond surveys and observations of gauge readings. It should include such items as pressure tests of containment systems, mechanical or radiological re-evaluation of shielding, verifying potency of fluid handling systems (cooling, ventilation, exhaust) and comprehensive evaluation, maintenance and repair of mechanical systems needed for safety.

III. General Non-Radiological Safety Rules

A. Provide a copy of the general safety rules for users and maintenance personnel in addition to the requirement of Section II.C. These should include:

1. Use and maintenance of high voltage, high power electrical and radio frequency energy equipment;

2. Storage and safe use of chemicals;

3. Storage and safe use of gases;

4. Safety supplies;

5. Machine shop conditions;

6. Elimination of and control mechanisms for fire and mechanical hazards;

7. Emergency lighting and power;

8. Maintenance and use of special safety equipment, such as ventilation systems, respirators, safety glasses, self-contained breathing apparatus and air sampling equipment; and

9. Handling procedures involving toxic materials.

B. Also discuss specific procedures for non-radiological safety. These should include:

1. Fire and explosion of experimental equipment;

2. Containing potentially flammable materials and keeping sources of ignition to a minimum;

3. Examining tubing and connections in systems handling dangerous materials;

4. Providing dedicated exhaust systems for gases (other than for containment of radio-gases or particulates);

5. Testing and drills for emergency systems;

6. Defining hazardous areas;

7. Proper postings for all hazards;

8. Mechanical safety of set-up of experiment (railings, ladders, catwalks, platforms). This should also include initial and periodic load testing, in accordance with accepted engineering practice, of all lifting devices and systems used to handle loads in excess of 100 pounds; and

9. Vacuum Safety to include mechanical integrity against implosion and diffusion pump thermal safeguards.

Describe interactions (and prioritizing) of general safety rules and procedures with those for radiation safety, when they occur. For example, discuss how will general safety inspections or operations will be accomplished in radiation restricted areas, or how radioactive flammables will be safety stored.

Note: One safety manual may be developed to cover all safety topics. Sections should be labeled and a table of contents provided. Pages should be serially numbered.

IV. Radiation Monitoring Instrumentation and Leak Tests

A. Monitoring Instrumentation

List make and model number of survey instruments. Identify the type of radiation to be detected by each, the energy and dose rate dependence and the sensitive ranges of each instrument (see Appendix C also). Describe high and low range radiation instrumentation for monitoring beam exit ports and exhaust vents. Show where all instruments will be stored or made available.

B. Describe procedures for calibration of room area radiation monitors, portal monitors and survey instruments. (Regulatory Guide 5.2, "Guide for Preparation of Survey Instrument Calibration Applications," may be obtained from the Agency.)

C. Describe procedures for performing leak tests. (Regulatory Guide 5.1, "Guide for the Preparation of Leak Test Application," may be obtained from the Agency.)

D. Describe how stack monitors are calibrated or made quantitative.

E. If not described for Item 8.d., discuss visual/aural/monitoring systems used to maintain surveillance in the vault from each location where activities in the vault can be normally controlled (accelerator controls, remote target controls). Discuss recording systems for these monitors that would facilitate accident investigations, teaching op-

erations and performance review.

V. Survey Program

A. Drawings showing radiation hazards. Indicate on a scale layout, for typical uses, the projected or measured:

1. Exposure rates in all occupied areas when the beam is on, and for each type of production where there will be significant differences.

2. Determine sky-shine, where appropriate.

3. Measurement of residual radioactivity in the accelerator vault and any other equipment room when the beam is off.

4. Residual activity in targets and their locations.

This information should be much more comprehensive than that indicated in the facility design section, Item 8., b.10. or c., and should be process specifically.

B. Drawings showing administrative determinations. Indicate on floor plans the following areas based on projections or actual survey results:

1. Restricted areas;

2. Unrestricted areas;

3. Areas where limited occupancy may be permitted for operational reasons (personnel monitoring required);

4. Areas where supplementary shielding is needed in order to permit unrestricted occupancy; and

5. High radiation areas and access controls for these areas.

C. Define a formal survey and review program for determining:

1. Unintentional or uncontrolled creation of radiations (radiation due to misalignment);

2. Back-streaming (in potential drop accelerators) where the beam of charged particles accelerated from the ion source to the target causes a stream of particles of opposite charge to be released and accelerated in the opposite direction;

3. Ventilation ducts and shield wall penetrations for other ducts or conduits, and hatches or other shield openings. Also describe how these can be locked to

prevent their being opened inadvertently, during beam operation;

4. Beam stop surveys (appearance and/or mechanical indications should also be checked);

5. Sky-shine for neutrons in energy range from 1 to 10 MeV and scattered photon radiation. (Note: It should not be assumed that if radiation dose rates are within limits close to the shield of the accelerator, they are always lower further away);

6. Representative wipes of the floor where contaminated dusts or other contamination may be found;

7. Special situations which may exist or be created after each major beam current or energy change; and

8. Monitoring room air concentration when beam is on, and off, and prior to allowing entry to maintain or change a target or perform an adjustment. Give sample calculations for air activation by accelerator beams passing through air, if any exposed, or open beam, conditions will exist.

D. Survey results/records for planning purposes. This section is considered critical for accelerator facilities. Indicate how you will define:

1. Working times and authorizations required for urgent repairs (over time, long-lived activities may build up which are not appreciably affected by short delays).

2. Schedules, for maintenance or repairs, to minimize exposures.

3. Area restrictions based on studies of activation. You should address annual studies made to determine the levels of radiation intensity and to plot activation decay curves for several locations around the accelerator, and for each other location, where frequent routine maintenance or adjustment is required.

4. A prospective dose limitation system that prescribes maximum daily and quarterly doses that are allowable for routine operations. Show what will be done when these prospective limits are exceeded. Describe how operations will be accomplished when all trained accelerator facility individuals have exceeded their prospective dose limits. Indicate what pre-planning must occur for operations outside normal production and routine (repetitive) maintenance, where exposures are likely to be significant.

E. Contamination surveys (see also Appendix C)

Discuss details of methods for performing surveys, including:

1. Methods of counting wipe tests, including make/model of counting equipment, standard sources used, and the calculation of efficiencies.

2. Action levels for removable contamination.

3. Frequencies for routine wipe tests, areas to be wiped, records to be kept.

4. Wipe tests for special procedures or when airborne particles are possible or expected. For example, wipe tests should be made when grinding or surface abrasion operations are conducted, whenever targets or highly activated components (example: greater than 50 mR per hour at one foot) are removed or replaced, or whenever the vacuum is broken or opened near such a device or target.

5. Wipe tests for commercial product distribution, including wipes of preparation equipment, in-house transport equipment, and final containers, for each product and production system.

VI. Personnel Monitoring

Define the program for personnel monitoring for users, technical and maintenance personnel. Note that persons performing maintenance must wear pocket dosimeters along with appropriate (accredited) regular monitoring devices. Describe:

A. Radiations to be monitored and ranges for the dosimeters. Show that at least one dosimetry system is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) for the radiations and ranges described, and that this system's accreditation includes the NVLAP accident range.

B. How accumulated doses will be recorded.

C. A program for review of personnel monitoring records and use of the devices.

D. A program for maintenance and assignment of pocket dosimeters, including procedures for use and evaluation of the devices, and action levels and corresponding actions for pocket dosimeters.

Licensees are strongly encouraged to also provide an indirect reading pocket dosimeter program (pocket chambers), under total control of the Assistant RSO for accelerator operations. These chambers should be initialized, assigned, collected, read and recorded by the Assistant RSO or other safety staff representative for each individual who enters the accelerator restricted area. In this manner, safety staff can assure that daily doses are adequately monitored and controlled by a system not prone to reading errors/tampering, or dependent on voluntary compliance.

E. Individuals to be monitored and types of dosimeters to be used.

F. Routine bioassays to assess ingestion of radioactive materials. Detail methods used, action levels and corresponding corrective actions. Show how equipment is standardized and how activities of significance are detectable with these methods, (if the measurements and analyses are to be performed in-house).

Bioassays should be discussed where volatiles are handled in curie quantities inside containment systems or where non-volatile materials are handled in curie quantities, and for appreciable periods, outside containment systems. (Commercial production quantities need always to be handled inside containment systems, however.)

G. Analysis of data on a time basis to spot trends, estimate routine exposures and make prospective dose allowances. Recommended is maintenance of a 52-week running total for each individual and graphical analysis of trends.

VII. Safety for Special Handling Procedures

Describe the program for radiation safety for the following, as applicable to your operations:

A. Machining, grinding. Describe the controlled environment procedures and equipment to be used for removing radioactive metal by filing, drilling, grinding and sanding. Describe how the process will be closely monitored. Indicate how temporary or permanent tents, cabinets or hoods will be used to confine the particles. Describe ventilation to prevent inhalation, ingestion or spread of contamination throughout the building.

Include use of protective clothing, and special handling of specific tools. Describe containment of contaminated materials. Also see Section XIV on radioactive waste handling.

Note: All surface work or repairs on contaminated or activated components must be conducted in hoods, tents or other contamination control devices.

B. Vacuum system

1. Describe systems for vacuum pump exhaust streams to handle toxic or radioactive gases that result from leakage of targets or target failure. This is in addition to normal operations, described under Item 8.d.

2. Describe vacuum pump maintenance. Address vacuum system, pumps, pump oil, and contamination from over-heated, damaged, vaporized or burst targets.

C. Tritium - Describe special handling and safety procedures for this nuclide, including:

1. Any produced during bombardment by, or of, deuterium, with tritium gas being released, from the target or other device.

2. Out-gassing that contaminates beam tube assemblies, vacuum systems and exhausts.

3. Present as a material adsorbed or absorbed in a tritium target.

4. Leakage of tritium targets, inside and outside the vacuum system.

5. Build-up in electronic vacuum pumps. (Note: potentially lethal amounts of tritium may be present on the inner surfaces of the pumps.)

6. Tritium in various mechanical and diffusion vacuum pumps and trapped in oil.

7. On components of the accelerator system.

8. Material from pump exhausts which may be released to the environment.

9. Tritium in used oil and targets (particularly that contained in material through which it will not diffuse readily).

10. Storage of Tritium or Tritium targets, with controls for temperature, ventilation and releases (monitoring).

D. Targets for research and commercial products - Discuss utilization of (procedures for) targets, target systems (as opposed to general operating principles and illustrations requested in Item 8.).

1. Describe targets by radioisotope, activity and design.

2. Indicate gas supplies, transmission methods or chemical processing systems, as appropriate.

3. Describe cooling mechanisms, furnaces, and associated exhausts as applicable.

4. Describe utilization of target containment systems, including details of the contamination control steps to be followed for target installation, adjustment, verification and removal. Double bag (bag in/bag out) procedures should be described in detail, and illustration provided, if not submitted in Item 8., b.2. Describe handling procedures for targets having activity before irradiation and for targets after irradiation. Address target removal, storage in shielded areas, special handling tools and disposal.

5. Describe specific procedures for shielding, tool and area use for proper handling and storage of the radioactive parts, particularly the "dees," deflectors, and target supports. Discuss contamination control also.

   Note: These descriptions should include, or be contained in, a description of the

steps to be followed for radioisotopes production and their associated safe handling procedures. Separate descriptions should be provided for each commercial product. (See also F below)

E. Production and Distribution of Radiopharmaceuticals and Radio-chemicals. Discuss details of the commercial and in-house processes for:

1. Target preparation and fabrication

    a. Evaluation of fabricated targets and their impurities; and

    b. Handling and storage.

2. Analysis of Yield

    a. Determination of radioisotope and activity; and

    b. Chemical separation.

3. Packaging, labeling, prescriptions.

4. Transportation of products (methods and routes).

5. Access restrictions unique to any product because of high fields or risk of contamination.

6. Storage procedures for feed-stock, decay of intermediate products, or waste.

7. Waste disposition.

8. Radiopharmaceuticals. Provide process, feedstock and product quality control steps, specific to each radiopharmaceutical produced. Include the following:

    a. Quality control (radio-nuclide purity) testing;

    b. Radioactive impurities expected and their limits;

    c. Calibration time and storage/handling instructions and limitations;

    d. Chemical separation and radiochemical purity;

    e. U.S. Food and Drug Administration (FDA) Pharmaceutical Good Manufacturing Practices and New Drug Applications;

    f. Breakthrough testing for generator type devices and criteria to be met for each device;

g. Sterility and apyrogenicity; and

h. Product labeling, packaging and delivery methods.

9. Surveys specific to the manufacturing steps for each pharmaceutical.

10. Spill procedures for each pharmaceutical, specific to the manufacturing methods.

11. Order handling procedures for products, including verification of authority to order (particularly for radiopharmaceuticals), to possess the products, and documentation of orders and associated verifications.

F. Transportation of Radioactive Materials. For each transported product:

1. Describe the use of transport systems (lifting and moving equipment, packages, labeling, etc.) for in-house transport; and

2. Show compliance with appropriate Department of Transportation (DOT) rules for shipments outside the facility that use public thoroughfares.

G. Source Fabrication - Detail the following:

1. Receipt of material;

2. Chemical or physical preparations;

3. Source construction;

4. Final assembly of processing;

5. Quality assurance testing;

6. Leak testing;

7. American National Standards Institute (ANSI) testing procedures; Sealed Source and Device Registry or Radioactive Material Reference Manual evaluation;

8. Transportation containers; and

9. Shipping procedures.

VIII. Ventilation

Describe exhaust and ventilation safety procedures. Provide descriptions for how ventilation systems are to be used to assure safety in the facility, including:

A. Operable systems: Identify what systems must be operating and what systems must be operable and available as backup systems, for each of the areas of use and for each type of use specific to each area.

B. Controls: Identify how controls should be adjusted to produce adequate performance for each area in terms of flow rates and directions. Maintenance of acceptable pressure gradients from room to room should also be discussed.

C. Describe performance parameters (Item 8.d.) to be met for the ventilation system and how these are documented and made available to the operators of the equipment.

D. Discuss how personnel are to augment normal ventilation for special scheduled procedures or accidental spills.

E. Provide procedures for isolation of specific areas for routine production, if needed, or for control of spills or contamination that may become airborne.

F. Show design bases for releases from the facility by exhaust systems, including reasonable source term postulates, and discussion of trapping, holdup, and filtration methods.

G. Indicate how exposures and ingestion limits of 25 TAC §289.202, are met in unrestricted areas outside your facility for stack releases, showing all assumptions and calculations. National Council on Radiation Protection and Measurements (NCRP) Commentary No. 3 methods should be followed.

H. Indicate how ventilation system will design will adequately handle releases from vacuum systems within the facility, including vacuum lines of any central system, and individual vacuum pumps with the facility.

I. Describe a comprehensive maintenance program for the ventilation system including detailed performance checks of components (fans, ducts and filters) and routine non-radiological monitoring of flow rates, pressure differentials, and operating and control systems for primary and backup circuits. Also describe leak testing for those

IX. Radiological Air Monitoring

Show how the designs and results of safety and operating procedures (Item 8 and Section VIII) are verified by radiological monitoring.

A. Describe monitoring systems for:

1. Target rooms;

2. Accelerator rooms;

3. Occupiable areas;

4. Vacuum pump exhausts;

5. Exhausts to the environment;

6. Temporary or permanent enclosures (tents, cabinets, hoods) for maintenance operations that may generate airborne contamination; and

7. Breathing zone monitoring for unusual operations that pose significant risks to personal, or where breathing protection is to be used. (However, routine use of respirators for any operation, in lieu of containment systems, will not be normally considered).

B. Describe instrumentation, filters, standard sources, and efficiencies of the counting and analysis equipment to be used for these surveys, and show that these systems (particularly the stack monitor) have sufficient sensitivity, range and recording capability to:

1. Detect continuous releases that would result in exposures of ten percent of the annual limits in unrestricted areas;

2. Accurately measure bolus releases of maximum credible activity; and

3. Integrate bolus releases to determine the total activity released, in accident situations.

C. Show calculations to demonstrate compliance with 25 TAC §289, by design, for airborne concentrations of radioactive material in restricted and unrestricted areas of your facility. Postulate reasonable sources terms and explain your analysis and results here, if not addressed in Item 8.d. or Sections VIII.F. or VIII.G.

D. Discuss a schedule for radiological air monitoring, including the nuclides, methods, equipment, goals, (or action levels), and the frequency of sampling in each area.

E. Indicate methods of record keeping.

F. Filtration system and radiological monitoring - for systems with air filters provide the following:

1. Detailed drawings of the filter housings to illustrate radiological monitoring procedures;

2. Descriptions of the type of filters;

3. Procedures for the inspection of filters, including action levels and corrective ac-

tions;

4. Schedules for inspection of filters; and

5. Methods for replacement of filters with presumed or determined contamination.

X. Procedures for Storage of Radioactive Material

A. Discuss scheduling and/or schedules for available storage space and shielding for storage for decay of targets or other products which must be left to "cool" radiologically after bombardment, either to permit easier handling or to reduce impurities. Discuss the impact on these schedules on the storage of other material (accelerator components, etc.) that must occasionally be stored for decay.

B. Describe procedures for using shielded storage areas, and shielding containers, for bombarded targets and other radioactive items.

C. Indicate labeling, posting and access restriction rules.

D. Address radioactive waste storage comprehensively and discuss interactions and conflicts with the other storage discussed above.

Describe monitoring and surveillance procedures for each of the above, to assure adequacy of procedures and their effective implementation.

XI. Training and Experience of Users, Technicians and Maintenance Personnel

A. For individuals to be named on the license to work independently (without physical supervision) of others, describe their job duties and provide resumes, and describe minimum training and experience requirements for such staff positions. The resumes should detail their training and experience with accelerators and handling radioactive material that is commensurate with their job duties and with your established minimum requirements. At minimum, they should meet:

1. Training for radioactive materials users

Individuals to be authorized to handle uncontained radioactive material should have at least 200 hours of didactic training in basic radioisotope handling techniques and at least 500 hours of supervised laboratory experience with uncontained radioactive material in a situation germane to the licensee's situation (quantities of high energy beta-gamma emitters, in mixed fields).

2. Training for accelerator operators

a. General Training

Individuals to be authorized to operate or to supervise the operation of the accelerator should have resumes that indicate extensive familiarity with medium energy (10-100 MeV) accelerator operations in general, and a strong background in engineering and/or the physical sciences. It is usually not feasible for the licensee to undertake this type of general training. The staffing policy should establish substantial minimums for both general training and experience, and for advanced training and experience in accelerator operations. These criteria will need to be submitted with the procedures, for Agency concurrence.

b. Specific Training

Individuals who are to operate or supervise the operation of the accelerator will also need substantial training and experience with the particular make and model of unit before they can be named on the license. Discuss specific training experiences in terms of subjects covered, classroom hours of didactic training, and the duration of supervised training and experience, in a program of similar scope, with an equivalent accelerator. Indicate where and when the training occurred and was successfully completed as well as the qualifications of the supervising individuals involved. If this is to be provided at your facility, discuss details of the training program and staff time and personnel to be made available. (Such training will normally be allowed only when sufficient personnel resources and time are available at your facility, so as not to compromise day to day operations with the training workload.)

B. For individuals not to be named on the license, but rather to work in the presence of authorized users (usually certain operational and maintenance staff positions), describe their job duties and define acceptable safety education and training commensurate with those duties. This should include at a minimum:

1. All aspects of radiation safety related to their use of radioactive materials and accelerators, and, consideration of mechanical, electrical, toxic chemical fire and explosion hazards, as they pertain to your facility.

2. Radiological hazards specific to your accelerator and radioactive material production facility.

3. Title 25 TAC §289.

4. For any training to be given at your facility for these users, indicate the scope of training to be provided and submit a course syllabus with the hours of training for each subject or section indicated. Also discuss the training and qualifications of the instructors and explain how participation and successful completion of the training is documented. (Supply tests given and certificates, or equivalent.)

XII. Emergency Procedures

Provide a description of your radiological emergency procedures. These should include copies of specific methods for all types of emergencies and copies of summary procedures that will be posted in each room. Discuss:

A. Methods for calculating safe reentry times;

B. Protocol for conducting area surveys and contamination surveys to assure compliance with 25 TAC §289;

C. Frequencies of practice emergency drills and content of drills;

D. Handling of spills and contaminated items;

E. Notification of personnel in the area, of local responsible individuals, on and off normal hours, and a summary of the 25 TAC §289 requirements for Agency notification; and

F. Periodic in-service on past problems and incidents at other facilities with similar operations.

XIII. Shielding

A. Describe the initial analysis for design of shielding for the accelerator vault and auxiliary areas and structures needed for radiation safety.

   1. Submit vault shield drawings, shielding performance specifications and shielding measurements (mechanical/radiological, as available).

   2. Provide auxiliary laboratory shielding design descriptions and shield drawings, including shielded hot cells, glove boxes and fume hoods.

   3. Indicate shielding design provided for containers (storage, use, transport) including how the Department of Transportation (DOT) requirements are satisfied by such shielding.

B. In addition to initial design analysis for routine operations, describe precautions for special situations. These should include:

   1. Auxiliary shielding for special configurations of the accelerator, its beam, auxiliary devices and magnets, and targets;

   2. Low energy electrons scattering around corners;

   3. Radiation escaping through ventilation ducts and other (perhaps unused) conduits as designs or uses change (major changes require license amendment);

4. Leaks due to spacing around doors and weather-stripping;

5. Cracks or openings other than duct penetrations in existing shielding;

6. Modifications to the accelerator to produce higher beam energies, or intensities, or to accelerate different particles; and

7. Deterioration of shielding material or structures.

XIV. Interlocks and Posting

A. Interlocks - Describe how radiation warnings and interlocks are to be used. In particular, address how the system will be used to protect personnel (especially where an accelerator is used by several research groups). Discuss examples such as the potential interaction of commercial production groups with in-house radiopharmaceutical users, one of which may be using the machine while the other requires access to restricted areas to work with their equipment.

   Describe procedures for the use of fail-safe systems for:

   1. Key switch on-off system;

   2. Console automatic shut off when door opens;

   3. Prevention of starting accelerator from anywhere other than the console;

   4. Disabling (scram) switches in target areas and experiment rooms;

   5. Console circuits, warning lights and sound alarms;

   6. Procedures for mandated inspection of hazardous areas (to evict personnel) before startup;

   7. Room monitors; and

   8. Warning and status lights in the accelerator vault, irradiation rooms, corridors, and at the control console.

B. Signs - Indicate how the facility is marked to:

   1. Identify where hazardous radiation levels could exist or do exist;

   2. Designate established occupancy times; and

   3. Restrict areas by physical means (movable or permanent barriers).

C. Describe a program for review, and for inspection of the use and status, of the interlocks and of safety and warning signs and equipment, on a quarterly basis.
Note: This outline can also be used to supply the information needed for Facility Design, part D, on interlocks, but the information described by this section is to be provided in the radiation safety manual as instruction and procedures for use of these systems.

XV. Decontamination

A. Provide a separate procedures section, in addition to specific mention in other sections, for methods to be used for decontamination of equipment, materials and facilities.

B. Discuss contamination action levels (fixed and removable) for release of equipment, materials and facilities for unrestricted use.

C. Describe access restriction for those items or areas that cannot be decontaminated sufficiently for unrestricted use. Also discuss procedures for containment of such items or facilities and procedures for ultimate disposal or release.

XVI. Radioactive Waste

Provide comprehensive procedures that include at least the following items and their record keeping requirements.

A. Describe methods of compliance with 25 TAC §289 for the disposal of specific items, such as:

1. Protective clothing;

2. Contaminated tools and equipment;

3. Cooling media;

4. Targets and associated materials;

5. Grindings and filings or other contaminated maintenance waste; and

6. Radioactive gases.

B. Releases to environment - describe procedures to assure that limits of Section VIII.F. are met for airborne releases (unless provided earlier) and procedures and calculations to assure that releases to the sewer demonstrate compliance with 25 TAC §289.202(ggg)(2) limits.

C. Procedures for decay of waste in storage, including monitoring and record keeping.

D. Describe release limits for solid waste and procedures for assuring that these limits are met.

E. Recycled materials procedures and action levels to permit continued recycling.

   Note: Title 25 TAC §289 requires special waste licenses for receiving radioactive waste from others. A problem can occur when feedstock and irradiated materials are returned or transferred to licensees who also serve as suppliers of the feedstock. Explain carefully how such material that is transferred to other licensees is not transferred solely as waste to be disposed of by the recipient.

F. Discuss how "mixed wastes" are avoided or prevented. No near-term disposal options exist for "mixed waste" (material that is designated both hazardous under the Environmental Protection Agency's Resource Conservation and Recovery Act guidelines and radioactive, by 25 TAC §289. Describe methods for preventing such wastes to be generated and for keeping hazardous wastes separate from radioactive wastes.

APPENDIX B

Table 1. Radiation of Possible Concern in Occupiable Areas of Particle Accelerator Facilities

Accelerator	Particles Accelerated	Beam Energy MeV	Purpose of Operation	Radiation of Possible Concern in Occupiable Areas
Potential-drop	Protons	1-10	Research	Fast Neutrons
	Deuterons	1-10	Neutron Production	Thermal Neutrons
	Alpha Particles	2-20	Neutron Radiography	Gamma Rays
	Electrons	1-10	Processing Radiography Therapy	Electrons X-rays
Electron Linear	Electrons	1-10	Processing Radiography Therapy	Electrons X-rays
	Electrons	>10	Research Neutron Production Neutron Radiography Activation Analysis	Electrons X-rays Fast Neutrons Thermal Neutrons Gamma Rays
Cyclotron	Protons Deuterons Alpha Particles	15-50 7.5-24 15-50	Research Isotope Production Neutron Production Neutron Radiography Activation Analysis	Fast Neutrons Thermal Neutrons Gamma Rays
Betatron	Electrons	1-50	Radiography Therapy	Electrons X-rays

APPENDIX C

METHODS AND FREQUENCY FOR CONDUCTING RADIATION SURVEYS

I. Introduction

When radioactive material is produced by an accelerator, activation of air, cooling fluids, targets and machine components, and contamination by activated gases, liquids, and particulates can create radiation hazards. Both radiation surveys and contamination surveys should be performed to prevent unnecessary radiation exposure to personnel, to define restricted areas to determine safe reentry times for some of these areas, and to prevent the spread of contamination throughout the facility. Radiation field surveys are performed using a radiation survey instrument to assess the intensity of radiation fields from stored sources or fixed contamination, and removable contamination surveys are performed by taking wipe samples from surfaces and objects likely to be contaminated within the facility. Visual monitoring and surveillance should be employed to assure necessary restrictions are met. Monitoring of air/other media to determine concentrations of radioactive material present is not addressed here.

II. Methods Of Surveys

Suggested methods for performing the two types of surveys are given below. Records of these surveys should be maintained for inspection by the Agency and for the licensee's reference to document adequate safety procedure performance and to determine whether the radiation levels or the contamination levels remain constant or increase over a period of time.

A. Radiation Level Surveys - A survey instrument capable of measuring levels as low as 0.05 mR/hr and as high as 2 R/hr should be used and the results recorded on a standard form showing location, date, person performing survey, instrument 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. Where areas are encountered or expected that have fields exceeding 2 R per hour, a meter of higher range should be available and used.

B. Contamination Level Surveys - A series of wipes using filter papers or swatches of cloth should be taken from those surfaces where contamination could exist. (Areas where solutions are prepared, uncontained solids are handled, incoming packages are received, pipetting is performed, etc., are areas that may be contaminated.) The wipes should be numbered or labeled and their location indicated on the sketch record as previously described. Each wipe should be rubbed over a surface area of about 100 square centimeters to maintain a consistent means of determining the amount of removable contamination. The wipes may be counted using a scintillation well counter, a proportional counter, or any other detector capable of detecting the small amount of contamination on the sample which would exceed the predetermined acceptable limits (see IV below).

III. Frequency Of Surveys

The frequency of surveys depends upon the amount and type of radioactive material used and the circumstances of use. 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. Where accelerator schedule constraints do not allow adequate time for decay of induced activity to occur, surveys must be performed frequently and before entry into production areas or removal of objects from the accelerator vault.

A. Low Level Areas - Not less than once a month - Areas where in vitro tests on small samples are performed, samples are analyzed, (samples usually less than 100 microcuries each), areas where radioactive materials or low level radioactive wastes are stored, unrestricted access is allowed, etc.

B. Medium Level Areas - Not less than once a week - Areas adjacent to the accelerator room, areas where millicurie amounts of contained radioactive material are handled or areas where contained activated components or radioactive waste in the millicurie range are stored.

C. High Level Areas - Not less than once a day - Areas used for storage of active solutions, preparation, production and packaging of radioactive materials; fume hoods, glove boxes; emergency situations to determine safe reentry times, special procedures; any area where uncontained material in excess of 100 millicuries is handled or radioactive waste or activated components, in several hundred millicuries, are stored.

IV. Acceptable Limits

A. Radiation Levels - In no unrestricted (uncontrolled) area may radiation levels exist such that a person could receive 100 mR in any one year or 2.0 mR in any one hour. If such areas are found, measures need to be taken to eliminate the excessive radiation levels. Additional shielding or relocation of radioactive material may be required. For restricted areas, the applicant should establish and submit descriptions of acceptable radiation levels that are as low as reasonably achievable.

B. Contamination Limits - If the wipe samples counted indicate more than 1,000 disintegrations per minute (dpm) beta/gamma or 100 dpm alpha, the area should be cleaned until the contamination has been removed. If the contamination is not removable, the area should be restricted, the contamination contained and shielded, and allowed to decay to acceptable levels. Title 25 TAC §289.202(ggg)(6) limits need to be met for unrestricted areas. This will help prevent spreading of contamination/ingestion of activity by personnel.

V. Performance of Surveys

Accelerator facility operators and technicians should be assigned to perform surveys, and facility management staff should be assigned to supervise the performance of these surveys, to review the results, to determine and enforce restrictions based on those survey results, and to perform surveys themselves on an emergency basis. The personnel designated to routinely perform these surveying duties should have proper training and experience in the surveys required for accelerator facilities including mixed-field surveys, knowledge of 25 TAC §289 limits, reporting, and notification requirements, and be aware of who should be informed at the facility when problems are discovered. The accelerator facility Radiation Safety Officer and the institution's Radiation Safety Officer should provide consultation, oversight and review of the accelerator facility management's and staff's performance and should conduct independent surveys for audits of the program.

APPENDIX D

GENERAL LABORATORY RULES

The following is an example of typical rules that could be specified for a laboratory in an accelerator facility using, producing or preparing radioactive material. The applicant is encouraged to develop their own set of rules specific to individual needs and reflective of the actual laboratory situation. Use of material that may become airborne (aerosols, gases, or volatiles) or activated (objects, structures) will necessitate additional rules, as will alpha emitters and the use of large activity sealed sources. Rules should be written in the form of directions to be followed by employees.

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

2. Wear disposable gloves at all times while handling uncontained radioactive material (material not in the form of manufactured sealed sources). Wear shoe covers at all times when in restricted areas.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area, and when leaving an area equipped with a portal monitor.

4. Always use remote handling devices and shielded containers with millicurie amounts of activity.

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

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

7. Wear personnel monitoring devices (film badge or TLD, and pocket dosimeters, as appropriate) at all times while in areas where radioactive material is used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices, when not being worn to monitor occupational exposures, should be stored in a designated low background area, as should the control badge.

8. Wear TLD finger badges when handling millicurie amounts of radioactivity.

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

10. Never pipette by mouth.

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

12. Confine radioactive solutions in covered containers that are plainly identified and labeled with name of the compound, radionuclide, date, activity, and radiation level, if applicable. Shield the containers as necessary.

13. Transport radioactive material in shielded containers when necessary, to protect against external radiation exposure.

14. Work over surfaces that are easily cleaned or covered with disposable, absorbent coverings when handling small quantities of open solutions of radioactive material. Work only in designated restricted-use areas and with the prescribed shielding and contamination control equipment. Process volatile radioactive materials in fume hoods. Use glove boxes, or equivalent containment, when processing radioactive material, such as alpha-emitting materials or accelerator targets, whose activity or type of emission presents a significant hazard.

15. Survey and wipe test all objects and materials before removal from the accelerator vault.

16. Perform area surveys before entering the accelerator vault, after the end of target bombardment.

17. Perform maintenance and repairs only after receiving clearance from the Radiation Safety Officer.

18. Perform contamination surveys upon entry into accelerator vault, when uncontained radioactive material may be present.

19. Consult remote read-out area monitors, portable survey instruments, and air monitors before entering, and during entry of the accelerator vault, or other high radiation areas

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APPENDIX E

Requests for authorizations for production of radioactive material with accelerators should be patterned after those listed below. Provision for materials in storage, for pharmaceutical precursors, and for commercially distributed materials and their co-produced and daughter products should be made as indicated. The quantities given in the third column should be nominal production values based upon proper machine operation at design specifications. Operation outside normal parameters that would affect yields to the extent that requested possession limits would be exceeded (for co-produced or daughter nuclides) should be undertaken only subsequent to a specific license amendment authorizing such operation and which includes any changes needed in possession limits.

The last sample authorization is for miscellaneous trace materials expected to be produced by typical systems, but for which specific safety measures are not likely to be needed.

A. Activation products	A. Solid articles associated with the cyclotron, beam-line or rooms of the facility	A. As activated by operation of the cyclotron	A. For use and storage in place, or storage on site, as incidental products of cyclotron operations. Not for production of radioactive material.
B. C-11	B. Carbon monoxide and carbon dioxide, as gases	B. 2 Ci	B. For preparation, from bombarded targets, of radio-chemicals and radiopharmaceuticals.
C. Pb-201 and co-produced or daughter nuclides Tl-201, Pb-202m, Pb-204m, Tl-202	C. Solid (plated accelerator targets)	C. 30 Ci/15 Ci/3.2 Ci/1.7 Ci/0.48 Ci, respectively	C. Production of Tl-201; testing and distribution to authorized recipients.
D. Ga-67 and co-produced nuclides Ga-68, Ga-66	D. Solid (plated accelerator targets)	D. 50 Ci/5 Ci/0.3 Ci, respectively	D. Production of Ga-67; testing and distribution to authorized recipients.
E. In-111 and co-produced nuclides In-112m, In-112	E. Solid (plated accelerator targets)	E. 10 Ci/3 Ci/3 Ci, respectively	E. Production of In-111; testing and distribution to authorized recipients.
F. Co-57 and co-produced nuclide Ni-57	F. Solid (plated accelerator targets)	F. 5 Ci/0.5 Ci, respectively	F. Production of Co-57; testing and distribution to authorized recipients.

G. W-178/Ta-178 and co-produced nuclides W-179, Ta-179	G. Solid (plated accelerator targets)	G. 5 Ci each/1 Ci/1 Ci, respectively	G. Production of W-178/Ta-178; testing and distribution to authorized recipients.
H. Any radionuclide with Atomic Number less than 84 as a co-produced or daughter nuclide from the production of Tl-201, Ga-67, In-111, Co-57 and W-178/Ta-178	H. Solid (plated accelerator targets)	H. 0.2 Ci	H. Production of radioactive material as otherwise authorized by this license.

ADDITIONAL SAFETY PROCEDURES

Additional procedures in use at a hot-cell equipped medical facility with a mission of radiopharmaceutical and commercial radiochemical production are mentioned below. While these procedures may be appropriate at an accelerator facility as experience, prudence and workload increases dictate, they are not being required with initial submissions.

1. For the facility as a whole, real-time air monitoring and chart recording of radioactive gas releases is provided. Calibration of associated instrumentation is by release of known quantities of radioactive gases at two concentrations. This allows quantitative assessment of accidental releases after the fact, as well as calibrated monitoring of routine releases.

2. Personnel monitoring, for those involved in processing activities, includes indirect reading dosimeters, whole body, wrist and finger TLD's, and digital/audible monitors or direct reading dosimeters. Pocket dosimeter readings are posted weekly.

3. Bioassays of personnel include whole body counting (baseline and quarterly) with action levels at 1/10 of the International Commission on Radiological Protection (ICRP) 30 Annual Limits on Intake (ALI's). Calibration is with a Medical Internal Radiation Dose Committee (MIRD) chest phantom. H-3 and Iodine bioassays as applicable.

4. Supplemental air sampling is conducted in breathing zones, with action levels at 1/10 of ICRP 30 Derived Air Concentrations (DAC's).

5. Shoe covers are worn in all processing areas; hands washed and hands, clothing and feet monitored each time processing area is exited.

6. All fixed instrumentation for radiation detection is provided with local, as well as remote (control panel), readout.

7. Annuciator system is provided which integrates radiation, utilities and safety surveillance. Utilities surveillance includes water temperatures and pressures for the mains, chiller lines, cyclotron lines, target lines, and buffer lines. Waste sump level is also integrated. Safety systems surveillance includes all restricted area door positions and scram switches.

8. Operating mechanisms for doors to high radiation areas sound warnings before closure.

9. Safety glasses, gloves, head and shoe covers, all dosimeters and presence of two individuals is required for each entry into hot cells, irradiation rooms or the cyclotron vault, and is also required for maintenance on cyclotron peripheral equipment.

10. Automatic bypass air circulation is provided for rooms, which are individually isolated in case of accidents. This allows room-by-room shut-down of affected areas, without dis-

ruption (and loss of cooling and dilution/exhaust) to other areas, and a more graded response to emergency situations.

11. Written procedures for specific accident scenarios, including the following: target failure (rupture or vaporization), spills or releases outside a containment enclosure, personnel contamination, personnel inhalation or ingestion, personnel exposures greater than 100 mrad, leaks between buffer water and main chiller water, malfunction of air supply or exhaust systems, and high levels in exhaust monitors or systems.

Some of these procedures can be adopted for an ALARA program as the cyclotron health physicist establishes technical specifications for the production operations. Others may require extensive design or fitting, and alternatives may need to be sought if their importance is elevated, by experience or expansion of production, to the point where they need to be required.

The procedures mentioned above are in addition to full hot-cell containment and remote manipulation of all accelerator products, for the cited facility.