

**INSTITUTION-BASED FACILITY SAFETY PLAN for  
SAFETY IN THE RESEARCH ENVIRONMENT**

**UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER  
DALLAS, TEXAS**

Prepared In Accordance With  
Appendix L Safety Program Guidance by  
The United States Army Medical Research  
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Attachments:		
•	Radioactive Material License No.L00384, Amendment 92, Acknowledged March 29, 2005, Signed May 5, 2006	
•	Facility Safety Director/Manager Assurance	

## ACRONYMS

BCSAC	Biological/Chemical Safety Advisory Committee
BSL	Biosafety Level
BSO	Biological/Chemical Safety Officer
CDC	Centers for Disease Control & Prevention
CSO	Controlled Substances Officer
DEA	United States Drug Enforcement Administration
EH&S	Environmental Health and Safety
EPA	United States Environmental Protection Agency
HAZCOM	Hazard Communication
HAZWOPER	Hazardous Waste Operations and Emergency Response
IAQ	Indoor Air Quality
IRB	Institutional Review Board
MSDS	Material Safety Data Sheet
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
PPE	Personal Protective Equipment
RAM	Radioactive Materials
RCRA	Resource Conservation and Recovery Act
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
TCEQ	Texas Commission on Environmental Quality
TxDSSH	Texas Department of State Health Services
U.S.	United States
USAMRMC	United States Army Medical Research and Materiel Command
UT Southwestern	University of Texas Southwestern Medical Center at Dallas
UV	Ultraviolet

## 1.0 Introduction

### 1.1 Scope and Application

As indicated in the United States Army Medical Research and Materiel Command (USAMRMC) Appendix L Safety Program, this Facility Safety Plan is a description of the University of Texas Southwestern Medical Center's safety program relevant to safe operations in research laboratories.

The programs described in this document<sup>1</sup> are applicable to all University of Texas Southwestern Medical Center at Dallas (UT Southwestern) employees who work in research laboratories in any capacity: researchers, technicians, emergency responders, environmental health and safety inspectors, housekeeping staff, and laboratory maintenance and repair staff from the Physical Plant Department.

### 1.2 Commitment

UT Southwestern is committed to providing a safe work environment for all of its employees. Best Management Practices, safety staff experience and training, and compliance with various guidelines and regulations ensure that UT Southwestern safety programs: 1) minimize risk of illness and injury to research laboratory and research-support workers; and 2) provide for fast and effective corrective action and emergency response if needed.

### 1.3 Regulatory Agencies

Some of the agencies that provide resources and/or guidance for UT Southwestern's laboratory safety programs are listed below.

United States (U.S.) Department of Health and Human Services

- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control & Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH)
- CDC Emergency Preparedness & Response Branch
- National Institutes of Health (NIH)

The National Fire Protection Association (NFPA)

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<sup>1</sup> Although this document focuses on safety in the research laboratory, it should be noted that UT Southwestern also operates under numerous other compliance and best management programs that do not directly impact research laboratory safety. Examples of programs that are not covered by this facility safety plan:

- Packaging and Shipping of Hazardous Materials; covers proper shipping from campus in accordance with United States (U.S.) Department of Transportation regulations
- Safety Program for Physical Plant shops (Auto Shop, Paint Shop, etc.)
- Environmental compliance programs such as 90-Day Resource Conservation and Recovery Act (RCRA) Hazardous Chemical Waste Management, Spill Prevention Control and Countermeasure, Storm Water Protection, and Emissions Compliance

## The U.S. Nuclear Regulatory Commission

### The Texas Department of State Health Services (TxDSHS)

- TxDSHS provides guidance and enforces compliance with many state and federal regulations that protect workers from biological, chemical, and radiological hazards.

### The U.S. Environmental Protection Agency (EPA) and the Texas Commission on Environmental Quality (TCEQ)

- UT Southwestern's Compliance and Best Management Programs for protection of the environment contribute to the safe work environment at UT Southwestern. Indoor Air Quality, Hazardous Chemical Waste Management, Mixed Waste Management, and Radioactive Waste Management are all environmental programs that protect employees as well as the environment and the community. Additionally, EPA and TCEQ inspectors of UT Southwestern facilities include compliance with chemical safety protocols and chemical hazard communication to employees in their compliance inspections.

About OSHA: State facilities in Texas are not subject to inspection by or reporting to the United States Department of Labor's Occupational Safety & Health Administration (OSHA). Despite its OSHA-exempt status, UT Southwestern strives to not only meet, but exceed OSHA safety standards. TxDSHS inspections of OSHA-exempt state facilities ensure compliance with OSHA-equivalent regulations specified in the Texas Administrative Code (TAC) and in the Texas Health and Safety Code. Also, various regulatory and funding agencies with specific interests at UT Southwestern (e.g. the College of American Pathologists and the Association for Assessment and Accreditation of Laboratory Animal Care International) audit UT Southwestern for compliance with the TAC, OSHA and/or OSHA-equivalent regulations, and other safety regulations.

## 1.4 Responsibilities

The UT Southwestern Environmental Health and Safety (EH&S) Department is responsible for keeping abreast of regulatory requirements and recommending means for compliance to UT Southwestern administrators, faculty, and staff. EH&S provides safety training, develops safety programs, functions in an advisory capacity, and provides a wide range of biological, chemical, radiological, fire, and occupational safety services.

The Occupational Health Department joins EH&S in assuring a safe work place for employees. Occupational Health staff operate a Worker Protection Program, provide immunizations where applicable, assess employee fitness to work in respirators, and respond to emergencies involving work-related injury or illness.

Principal Investigators are responsible for ensuring safe operations in their laboratories. Laboratory operations must be conducted in a safe manner, employees must be well trained and understand the hazards in their work places, and safety plans for new projects must be approved by safety committees before commencement of work. Work performance in any given laboratory must comply with safety rules and procedures of UT Southwestern EH&S and Occupational Health as

well as with safety rules and procedures required by funding and/or regulatory agencies that oversee the type of work performed by that laboratory.

All UT Southwestern employees are responsible for knowing how to work safely in their work places, understanding the hazards of the materials they work with, attending orientation training, and seeking additional guidance and training from their supervisors, EH&S, and Occupational Health if needed.

## 2.0 USAMRMC Facility Safety Plan Appendix L: Part 2a(a) - Skills, Training, Committees, and Procedures That Ensure Safe Research Operations; and Part 2a(b) Medical Surveillance and Support

Well trained and educated EH&S staff, well trained and educated Occupational Health staff, various safety committees comprised of faculty and non-faculty members, mandatory and optional safety training programs for laboratory workers, numerous hard-copy and electronic training materials, and numerous written policies and procedures are key elements of the master program that ensures safe research operations at UT Southwestern.

### 2.1 Skills and Training of EH&S and Occupational Health Staff

EH&S professional staff hold Bachelor's and advanced degrees from accredited universities in fields of Chemistry, Biological Sciences, Radiation Safety, Environmental Science, Environmental Health Sciences, Public Health and Epidemiology, Chemical Engineering, Civil Engineering, and Occupational Health and Safety. Post-graduate certifications among EH&S staff include Licensed Medical Physicist, Certified Nuclear Medicine Technologist, Certified Hazardous Materials Manager, Certified Fire Protection Specialist, Certified Fire Inspector, Certified Fire Plans Examiner, Radiological Technology in Radiology and Mammography.

EH&S employees maintain and improve their training by self-study using various hard-copy and electronic materials; attending on-campus and off-campus classes, workshops, conferences, and seminars; preparing for and teaching classes; preparing for and giving presentations; and participating in emergency response drills. Classes, workshops, conferences, and seminars attended by EH&S staff cover topics such as biological safety, chemical safety, radiation safety, fire safety, occupational safety, pandemic flu, Hazardous Waste Operations and Emergency Response (HAZWOPER), bio-terrorism, hazardous waste management, hazardous waste operations and emergency response, disaster response, transportation of hazardous materials, and environmental compliance.

Occupational Health Department staff includes a registered nurse who holds a Bachelor of Science Degree in Nursing and a licensed physician who holds a Master of Science in Public Health in addition to his undergraduate and medical degrees and Board Certifications in Internal Medicine, Pulmonary Medicine, Critical Care Medicine, and Occupational Medicine.

## 2.2 Functions of Safety and Health Groups and Safety Committees

The EH&S Department's responsibilities are divided among five groups:

- Biological/Chemical/Environmental Safety Group
- Radiation Safety Division
  - Radioactive Materials Group
  - Radiation Producing Equipment Group
- Occupational Safety and Fire Protection Group
- Laser Safety Group

These five groups plus the Occupational Health Department are the managers/operators of UT Southwestern safety and health programs for research laboratories. EH&S groups implement, operate and maintain safety programs; Occupational Health is concerned with medical aspects of injury and disease.

Safety committees support the EH&S Department's authority to enforce safety policies, review and approve EH&S policies and procedures, review and approve research projects, and review and approve research project-specific safety plans. Safety committees ensure that risks to employees are minimized and that the community and the environment are protected from negative impact by UT Southwestern operations.

### 2.2.1 EH&S Biological Safety/Chemical Safety/Environmental Compliance Group and UT Southwestern Biological Safety/Chemical Safety Committees

The EH&S Biological Safety/Chemical Safety/Environmental Compliance group (Bio/Chem/Enviro group) is comprised of the Biological/Chemical Safety Officer (BSO) and staff. Bio/Chem/Enviro group operations relevant to research laboratories are guided by the UT System Institutional BioSafety Committee (IBC) at UT Southwestern, designed in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), and the Biological/Chemical Safety Advisory Committee (BCSAC).

- The Bio/Chem/Enviro group provides information and services applicable to hazardous chemical and hazardous biological operations, and has the primary responsibility for the biological, chemical, and environmental safety of employees, the community, and the environment. Bio/Chem/Enviro group programs are consistent with prudent and best management practices as well as with legal and funding agency requirements.
- The IBC oversees all recombinant DNA activities; ensures that recombinant DNA research complies with NIH Guidelines; and reviews and approves project-specific recombinant DNA safety plans submitted by faculty.
- The BCSAC provides guidance and authoritative support for Bio/Chem/Enviro group operations not involving Recombinant DNA; and reviews and approves project-specific hazardous chemical and hazardous biological (other than recombinant DNA) safety plans submitted by faculty.

The Bio/Chem/Enviro group programs most relevant to safe operations in research laboratories are listed below<sup>2</sup>:

- Training Program for Laboratory Staff
- Safety Plan Program
  - Labs are required to prepare and submit project-specific safety plans for review and approval by the BCSAC and/or the IBC.
- Mandatory procedures for laboratory management of hazardous chemical products, hazardous chemical wastes, and hazardous biological materials
- Chemical Waste and Medical Waste Pick Up Programs
  - Wastes are picked up from laboratories and subsequently managed in waste storage areas controlled by EH&S under the RCRA Waste Management Program.
- Laboratory Inspection Program
- Indoor Air Quality (IAQ) Program
  - UT Southwestern engineering and operational controls are designed to provide and maintain healthy indoor air to employees.
  - The Bio/Chem/Enviro group staff respond to chemical and biological odor calls, reports of indoor mold contamination, and reports of adverse respiratory reactions.
  - Two examples of procedures under the IAQ program are testing for formaldehyde exposure and a Histoplasmosis policy for construction sites that prevents contamination of indoor air by *Histoplasma capsulatum*, the causative agent of the lung disease Histoplasmosis.
- Respiratory Protection Program<sup>3</sup>
  - The Respiratory Protection Program operates for incidents and operations that create unhealthy air despite engineering and operational controls. The program involves use of Air Purifying Respirators (APRs). The APRs used include N95 Masks, Half-Face APRs, and Full Face APRs. Incidents that require use of supplied air are turned over to the City of Dallas Fire Department.
- Chemical Fume Hood Policy
- Eye Wash and Safety Shower Policy
- Biological Safety Cabinet Policy
- Twenty-four Hour Emergency Response Program for Indoor Spills and Other Emergencies
- Programs for acquisition, tracking, record keeping, auditing, and reporting relevant to Select Agents, Controlled Substances, and other highly hazardous biological and chemical materials
  - The EH&S Bio/Chem/Enviro Group controls acquisition and use of specific highly hazardous biological and chemical substances where required by regulatory and funding agencies and/or when necessary as a best management practice due to the hazardous nature of the substances. Record-keeping, auditing, and/or reporting

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<sup>2</sup>This is only a partial list of programs operated by the Bio/Chem/Enviro group as all programs, such as many of the environmental compliance programs, are not directly applicable to research laboratories.

<sup>3</sup>The Respiratory Protection Program is jointly operated by the Occupational Health Department and the EH&S Bio/Chem/Enviro group. Occupational Health manages an OSHA-based medical questionnaire and medical review for use of a respirator and the Bio/Chem/Enviro group performs fit testing and training for laboratory staff.

requirements are included in Bio/Chem/Enviro programs as needed for compliance with regulations.

- UT Southwestern is registered with the CDC Select Agent Program and operates under a Select Agent Policy.
- The UT Southwestern EH&S Department's Controlled Substances Officer (CSO) manages receipt and distribution of Controlled Substances in accordance with U.S. Drug Enforcement Administration (DEA) regulations. Faculty are responsible for compliance with all aspects of security, accountability, disposal, and record-keeping procedures. The CSO audits faculty for compliance and has authority to confiscate controlled substances if necessary.
- UT Southwestern requires that a material transfer agreement (MTA) is processed through the Contracts Management Office when a faculty member transfers or receives research material to or from another investigator or facility. The Bio/Chem/Enviro group receives copies of MTAs so that they are alerted to the arrival of hazardous materials from other institutions.

#### 2.2.2 EH&S Radiation Safety Division and UT Southwestern Radiation Safety Committees and Sub-committees

The Radiation Safety Division is divided into two groups: 1) the Radiation Safety Officer (RSO) for Radioactive Materials (RAM) and staff; and 2) the RSO for Radiation Producing Equipment and staff. Radiation Safety Division operations relevant to research laboratories are guided by the Radiation Safety Committee (RSC), the Human Use Sub-committee, the Non-Human Use Sub-committee, and the Enforcement Sub-committee.

- The Radiation Safety staff promulgate the safe use of radiation, seek to minimize radiation exposure to staff and the general public, ensure compliance with regulations governing use of ionizing and non-ionizing radiation, ensure compliance with Broad Scope Radioactive Materials License No. L00384 issued by the TxDSHS, respond to annual state and federal inspections, participate in radioactive materials emergency response drills for the North Texas region, and manage radioactive and mixed waste in storage areas controlled by EH&S.
- The RSC serves as the official regulatory body for UT Southwestern faculty and staff in all matters relating to the use of radiation in research, medical diagnosis, and medical therapy.
- The Human Use Sub-committee reviews and approves applications for the use of radiation in humans, assists the Institutional Review Board (IRB) in review of research protocols that involve the use of radiation in humans, and issues human use RAM Sub-licenses to approved faculty.
- The Non-Human Use Sub-committee reviews and approves applications for the use of RAM in research not involving human subjects, and issues non-human use RAM Sub-licenses to approved faculty.
- The Enforcement Sub-committee reviews non-compliance records of delinquent users and stipulates further restrictions on the use of RAM. The Enforcement Sub-committee will terminate a RAM sub-license if necessary.

Radiation Safety programs directly applicable to research laboratories include:

- Radiation Safety Training
- Gamma Irradiator Safety Training
- Personal Dosimetry Program
- Laboratory Inspection Program
- Procurement and Distribution of RAM to Laboratories
- Mandatory procedures for management of radioactive and mixed wastes in laboratories
- Radioactive Waste and Mixed Waste Pick Up Program (wastes are picked up from laboratories and subsequently managed in waste storage areas controlled by EH&S)
- Registration and Audit of Radiation-Producing Equipment
- Twenty-four Hour Emergency Response Program

### 2.2.3 EH&S Occupational Safety and Fire Protection Group and the UT Southwestern Occupational Safety and Fire Protection Advisory Committee

The UT Southwestern EH&S Department's Occupational Safety and Fire Protection Group is operated by the UT Southwestern Fire Marshall and staff. The Occupational Safety mission is to promote a safe work environment and to prevent work place injuries. The Fire Safety mission is to ensure compliance with the National Fire Protection Association (NFPA) codes and to prevent fires by minimizing or eliminating fire hazards on campus.

Functions and programs of this group include:

- Fire Prevention, Life Safety, and Emergency Preparedness Training Program
- Hands-on Fire Extinguisher Training Program
- Training of employees in various areas of occupational safety such as prevention of back injury
- Burning and Gas Odor Response Program
- Fire Protection System Inspection and Maintenance Program (fire extinguishers, fire alarm systems, automatic sprinkler systems, fire pumps)
- Laboratory and Facility Fire Safety and Code Compliance Inspection Program
- Development and enforcement of fire prevention, injury prevention, and life safety policies
- Fire Drill Program
- Ergonomics Program
- Hot Work Permit Program
- Twenty-four Hour Emergency Response Program
- Fire protection review of construction and renovation projects
- Investigation of Workman's Compensation Insurance injury claims

The Occupational Safety and Fire Protection Advisory Committee meets regularly to discuss various fire and life safety code issues, review fire prevention and life safety code policies, and rule on corridor clearance appeals.

## 2.2.4 Laser Safety Group and the Laser Safety Committee

The Laser Safety group actively supports all staff, faculty, and residents with the use of lasers across campus including employees working in research laboratories. Laser safety is responsible for overseeing operations of all lasers to ensure compliance with federal, state, and institutional regulations and policies and provides advice to employees for the purchase, maintenance, repair, documentation, registration, utilization, disposal, and administration of all medical lasers. The laser safety team also plays a significant role in the training and education of the staff, faculty, and residents on the basic physics of lasers and light-tissue interactions. The Laser Safety staff has the unique ability to bring clear and understandable terms to the most complicated of light procedures and methods in support of UT Southwestern's employees.

The Laser Safety Committee plays a significant role in ensuring that federal and state regulatory issues relevant to Laser Safety are addressed.

## 2.2.5 Occupational Health Department (USAMRMC Facility Safety Plan Appendix L: Part 2a(b) Medical Surveillance and Support)

The Occupational Health Department has the primary responsibility for Medical Surveillance and Support. Occupational Health programs and services include:

- Annual TB Testing Program
- Vaccinations for influenza, measles, mumps, rubella, hepatitis A, and hepatitis B
- Specialized vaccinations for animal handlers as needed
- Pneumonia vaccinations for qualifying employees
- Prophylactic treatment for human or primate blood and body-fluid/body-tissue exposures
- Assessment and referral for non-life-threatening on-the-job injuries
- Respiratory Protection Program<sup>4</sup> - OSHA-based medical questionnaire for use of an APR<sup>5</sup>
- Assessment of employees suffering from potentially contagious illnesses who need a medical opinion exempting them from work
- Assessment of exposure to air-borne illness
- Immediate action following injury or exposure
- Management of the Worker Protection Program for Animal Workers

The Worker Protection Program is designed to promote a safe work environment by minimizing the risk of illness from diseases, injury, and allergy associated with working with or around research animals. The program includes initial registration and general education of all animal-exposed staff,

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<sup>4</sup>The Respiratory Protection Program is jointly operated by the Occupational Health Department and the EH&S Bio/Chem/Enviro group. Occupational Health manages an OSHA-based medical questionnaire and medical review for use of a respirator and the Bio/Chem/Enviro group performs fit testing and training for laboratory staff.

<sup>5</sup>APR users include primarily Physical Plant staff, EH&S staff, and Animal Resources staff that support laboratory research. Most laboratory researchers have no need to work in APRs as engineering and operational controls are sufficient for respiratory protection.

health history screening, routine and special immunizations, medical care, workforce health surveillance, and wellness promotion.

## 2.3 Safety Training of Laboratory and Laboratory Support Staff, and Written Policies and Procedures

The UT Southwestern Safety Training Program for all UT Southwestern laboratory employees includes mandatory and optional training provided by EH&S, mandatory and optional training provided by Occupational Health, plus electronic and hard-copy materials that are readily available for all staff. Laboratory employees receive additional one-on-one training by EH&S as needed; for example, if an EH&S inspector is alerted during an inspection that an employee does not fully understand a hazard in his/her work place, that inspector will take the opportunity to provide one-on-one training for that employee.

### 2.3.1 Safety Training and Procedures Under the EH&S Bio/Chem/Enviro Group and the Occupational Health Department<sup>6</sup>

UT Southwestern faculty and staff who may be or may have been exposed to hazardous chemicals and/or human blood in the workplace are required to attend the EH&S Department's Hazard Communication (HAZCOM) / Chemical Safety / Waste Handling / Bloodborne Pathogen Training Class. This class includes HAZCOM, safe use and storage of hazardous chemicals, chemical waste management at the laboratory level, medical waste management at the laboratory level, and bloodborne pathogen training. Employees attending this class receive personal copies of EH&S manual entitled *Hazardous Chemicals in the Laboratory - A Guide for Their Safe Use and Disposal* and an EH&S procedure entitled *UT Southwestern Medical Center Medical Waste Handling and Disposal*. Employees are also offered free Hepatitis B vaccinations.

- HAZCOM and Safe Chemical Use and Storage Training includes rights of employees under the Texas HAZCOM Act, interpreting chemical labels, labeling secondary containers, interpreting information provided by Material Safety Data Sheets (MSDSs), instruction on how to obtain MSDSs from EH&S, health hazards associated with classes of chemicals, physical hazards associated with classes of chemicals, proper use and care of personal protective equipment (PPE), proper use of fume hoods, safe laboratory practices, proper storage of chemicals, dangerous chemical storage practices, and emergency procedures. In addition to this training and its written procedures, the UT Southwestern HAZCOM Program includes participation in the Texas Tier Two Chemical Inventory Program and Community Right-to-Know and posting of the Emergency Response and Waste Disposal Guide Flip Chart in every laboratory.
- Bloodborne Pathogen Training includes sharps handling, sharps disposal, and use of Universal Precautions. The trainer presents information using lecture, questions and answers, videos, slide presentations, hand-outs, and demonstrations using equipment.

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<sup>6</sup>The EH&S Bio/Chem/Enviro Group and the Occupational Health Department are linked in this topic because the strongest work link between EH&S and Occupational Health involves interactions between the EH&S Bio/Chem/Environ Group and Occupational Health.

In addition to the materials referenced above, the EH&S Bio/Chem/Enviro Group provides numerous other guidance documents, videos, DVDs, and Power Point presentations for self-training and small group training purposes. Some of the available training materials are hydrofluoric acid safety, gas cylinder safety, prevention of animal allergies, templates for preparation of biological and chemical safety plans, Material Safety Data Sheets (MSDS), and hazardous chemical technical bulletins.

Training for specific hazardous biological and chemical materials in laboratories is facilitated by biological and chemical safety plans that laboratories must prepare and submit to the BSO and to the BCSAC for approval. A given laboratory's safety plan must cover hazards in the laboratory submitting the plan. The plans include, but are not limited to, hazard information, standard practices for safe use, emergency response procedures, and requirements for safety training. The UT Southwestern EH&S website provides guidance documents to assist laboratories with plan preparation. The plans must be approved before a laboratory is allowed to use hazardous materials such as carcinogens, teratogens, mutagens, highly toxic materials, reactive chemicals, Biosafety Level (BSL) 2 or BSL3 materials<sup>7</sup>, and Recombinant DNA.

Employees that work in BSL3 laboratories go through extensive training provided by the Principal Investigators operating those laboratories. Principal Investigators ensure that BSL3 employees know how to work safely in BSL3 environments and how to respond appropriately in emergencies. Additionally, Select Agent Laboratories participate in periodic emergency response drills. The BSO and the BCSAC provide additional assurance that employees potentially exposed to BSL3 level materials are trained to work in a manner that minimizes risk.

UT Southwestern's Animal Research Training Program requires animal workers to enroll in UT Southwestern's Worker Protection Program managed by the Occupational Health Department. The Worker Protection Program is designed to promote a safe work environment by minimizing the risk of illness or injury associated with working with or around research animals. The program's training responsibilities include general education of all animal-exposed staff.

Some UT Southwestern activities require employees to work in N95, half mask, or full face APRs because engineering and/or operational controls do not sufficiently prevent inhalation of hazardous biological or chemical substances. Respiratory Protection-APR Training starts with the OSHA-based medical questionnaire for medical evaluation of employees intending to work in APRs. The questionnaire, which is assessed by Occupational Health staff, raises awareness that there can be hazards associated with working in a respirator and offers the employee the option of talking to a medical professional. Direct training information included with the questionnaire is found in OSHA's Appendix D which provides hazard information and instructions to the respirator user. Once the Occupational Health staff designates an employee as fit to work in a respirator (based on the questionnaire and any needed stress testing), EH&S provides additional respiratory protection training during APR fit testing activities. This training (and fit testing) is repeated annually.

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<sup>7</sup>There are no BSL4 materials at UT Southwestern.

The Occupational Health Department provides employees with hard copy and electronic web page information including:

- a procedure for Blood and/or Body Fluid Exposure Control and Response;
- a brochure describing the Worker Protection Program plus a full electronic description of the program;
- web page links to informative materials available on the Internet; for example, a NIOSH alert for prevention of latex allergies
- a web page link to a UT Southwestern handbook for the care and use of animals that includes animal waste disposal procedures, strong discouragement to use ether and reference to the ether policy if ether must be used, and emergency response to animal bites or other animal-related injuries; and
- a web page link to the UT Southwestern written ether policy which indicates that due to its highly flammable and explosive characteristics, ether is not approved for use in animal research with the exception that an individual case can be approved by the Institutional Animal Care and Use Committee (IACUC)

### 2.3.2 Safety Training and Procedures Under the EH&S Radiation Safety Group

UT Southwestern faculty and staff who use RAM are required to attend the EH&S Department's Radiation Safety Seminar. Classes cover the basics of radiation, radiation safety principles, badge monitoring, use of survey equipment, performance of radiation surveys, ordering RAM, receiving radioactive packages, risk assessment, handling radioactive waste at the laboratory level, and decontaminating spills. Trainers present information using lectures, questions and answers, videos, slide presentations, demonstrations using equipment, and hands-on practical exams for selected class members who must demonstrate proper use of equipment, package receiving, and spill decontamination. Employees attending this class receive training on and personal copies of the UT Southwestern EH&S Department's manual entitled *Radiation Safety Seminar Manual*.

UT Southwestern faculty and staff who use gamma irradiators are required to receive one-on-one training for Safe Use and Care of Gamma Irradiators. The trainer presents information, answers questions, and demonstrates proper use and care of a gamma irradiator.

UT Southwestern employees with a potential to enter any room containing a Magnetic Resonance Imaging (MRI) system is required to take magnet safety training annually. This training program is mandatory for a wide group of employees that includes EH&S staff, Physical Plant staff, and housekeeping staff in addition to medical and research staff.

Other written procedures offered by the Radiation Safety Division include, but are not limited to, the *Radiation Safety Procedures Manual* (Obtaining a Non-Human Use Sublicense; Obtaining a Human Use Sublicense; Badge Monitoring; Ordering Radioactive Material; Radioactive Material Accountability; Radiation Surveys; Radioactive Waste; Use of Gamma Irradiators; Leak Testing of Sealed Sources; Dose Calibrator Tests; Use of <sup>99m</sup>Tc Generators; Use of High Dose Rate Remote Afterloader; Use of Bone Mineral Analyzers; Use of Radiopharmaceuticals for Therapy; Use of Brachytherapy Sources; Radioactive Waste Compactor; Medical Diagnosis Procedures Using <sup>133</sup>Xe Gas) and the *Radiation Safety Handbook* and *Radiation Safety Records Notebook* (Authority; Broad

Scope License; Definitions; Radiation Safety Committee; RSO Responsibilities; Administrative Protocols; Radiation Protection Program; Medical Research and Academic Radiation Safety Program; Medical Radiation Safety Program; Radiation Safety Records Notebook; Standard Operating Procedures with Forms and Examples)

### 2.3.3 Safety Training and Procedures Under the EH&S Fire, Life, and Occupational Safety Group

The EH&S Department's Fire and Life Safety Class is mandatory for all UT Southwestern employees. Topics include fire prevention, fire protection and suppression, life safety, and emergency preparedness and response. The trainer presents information using lecture, questions and answers, hand-outs, videos, and slide presentations. All class members are offered an opportunity to demonstrate proper use of a multi-purpose ABC dry chemical fire extinguisher by putting out a live fire.

The UT Southwestern Fire, Life, and Occupational Safety Group offers additional safety training classes as needed. These classes cover Back Injury Prevention, Office Safety, Electrical Safety, and various other topics.

Some of the important written procedures are the policy on purchasing and use of portable space heaters, the policy on use of circulating water baths, hand-outs on proper use of fire extinguishers.

### 3.0 USAMRMC Facility Safety Plan Appendix L Part 2b(a): Description of the Facility

The UT Southwestern campus, located near the center of Dallas, Texas is comprised of more than 200 acres divided into South, North, West, and East Campuses plus additional facilities located off-campus. The South, North, and West campuses are connected by an interconnecting private shuttle bridge.

Buildings include research laboratories, teaching laboratories, classrooms, clinical service facilities, an extensive medical library, auditoriums, a fitness center, an advanced imaging building, two hospitals, office space, Physical Plant facilities, hazardous waste management facilities (for biological, chemical, and radioactive wastes), food service facilities, and other facilities needed to support the medical research, patient care, and teaching operations at UT Southwestern.

4.0 USAMRMC Facility Safety Plan Appendix L Part 2b(b): Description of Personal Protective Equipment and a List of Specialized Safety Equipment

Safety Equipment Installed Campus-wide

<ul style="list-style-type: none"> <li>• safety showers</li> <li>• eye wash fountains</li> <li>• chemical fume hoods</li> <li>• portable fire extinguishers</li> </ul>	<ul style="list-style-type: none"> <li>• fire alarms</li> <li>• autoclaves</li> <li>• biological safety cabinets</li> </ul>
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PPE, Monitoring, and Safety Equipment Used by EH&S Staff

<ul style="list-style-type: none"> <li>• safety glasses</li> <li>• chemical splash goggles</li> <li>• face shields</li> <li>• full face APRs with combination<sup>8</sup> P100/organic chemical/acid gas cartridges</li> <li>• ear plugs, ear muffs</li> <li>• various gloves for protection from chemicals, biological materials, and mechanical injury</li> <li>• steel-toed shoes</li> <li>• disposable shoe covers</li> <li>• hard hats</li> <li>• Tyvek coveralls and equivalent</li> </ul>	<ul style="list-style-type: none"> <li>• lab coats</li> <li>• scrubs</li> <li>• radiation badges</li> <li>• radiation survey equipment</li> <li>• spill clean-up materials</li> <li>• flammable gas detector</li> <li>• oxygen meter</li> <li>• equipment for mold testing</li> <li>• equipment for detecting volatile chemicals in air</li> <li>• pH test strips</li> <li>• flashlights</li> <li>• two-way radios</li> </ul>
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PPE and Safety Equipment Used by Physical Plant Staff

<ul style="list-style-type: none"> <li>• safety glasses</li> <li>• N95 Masks</li> <li>• half-face APRs with P100 cartridges</li> <li>• ear plugs</li> <li>• various gloves for protection from mechanical injury</li> </ul>	<ul style="list-style-type: none"> <li>• steel-toed shoes</li> <li>• hard hats</li> <li>• protective coveralls</li> <li>• fall protection equipment</li> <li>• flashlights</li> <li>• and two-way radios</li> </ul>
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PPE and Other Safety Equipment Used by Research Laboratory Staff and Laboratory Support Staff Other Than EH&S and Physical Plant Staff

<ul style="list-style-type: none"> <li>• safety glasses</li> <li>• chemical splash goggles</li> <li>• face shields</li> <li>• N95 Masks</li> <li>• ear plugs</li> <li>• various gloves for protection from chemicals, biological materials, temperature extremes, and mechanical injury</li> <li>• disposable shoe covers</li> <li>• disposable head covers</li> <li>• disposable gowns</li> <li>• Tyvek or similar coveralls</li> <li>• lab coats</li> </ul>	<ul style="list-style-type: none"> <li>• scrubs</li> <li>• chemical aprons</li> <li>• radiation badges</li> <li>• radiation survey equipment</li> <li>• safety shields for protection from explosions</li> <li>• radiation safety shields</li> <li>• sharps containers</li> <li>• flammable chemical storage cabinets</li> <li>• acid storage cabinets</li> <li>• flammable liquid and other hazardous chemical waste containers</li> <li>• germicidal ultraviolet (UV) lamps</li> <li>• UV eye protection</li> </ul>
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<sup>8</sup>If a spill response requires Level A or Level B personal protection, EH&S staff will cordon off and secure the hot zone from a safe distance and contact the City of Dallas Fire Department Hazardous Materials Response Team for clean-up.

## 5.0 USAMRMC Facility Safety Plan Appendix L Part 2c: Radioactive Materials Licence

A copy of UT Southwestern's RAM License is attached. Identifiers are listed below:

- Radioactive Material License No.L00384
- Amendment No. 92
- Issued by the TxDSHS
- Acknowledged March 29, 2005
- Signed May 5, 2006

## 6.0 USAMRMC Facility Safety Plan Appendix L Part 2d: Hazard Analysis Related to the Research Environment

Use of hazardous chemicals and hazardous biological agents require filing of safety plans with and approval by the UT Southwestern EH&S Department's BSO working in conjunction with the BCSAC. Hazard analysis is included as part of this overall procedure.

Hundreds of hazard analyses on toxic chemicals, hazardous biological agents, and other hazards have been performed at UT Southwestern. Although these analyses have not specifically followed the formal plan outlined by the USAMRMC Facility Safety Plan guidelines, (1) numerous hazards have been identified; (2) information on effects of inhalation, skin and eye contact, ingestion, and injection has been collected and reviewed; (3) information on physical hazards has been collected and reviewed; and (4) safety protocols to minimize hazards and emergency response protocols have been developed. These hazard analyses have not formally identified maximum credible events. Some UT Southwestern hazard assessments that have been performed are listed below as examples:

- Use of hydrofluoric acid in laboratories
- Use of perchloric acid in laboratories
- Use and storage of large quantities (two 50-gallon drums) of sulfuric acid
- Working in the Prosthetics Shop
- Working in Prosthetics/Orthotics laboratories
- Working with mammals
- Use of carcinogens in laboratories
- Use of monofluoroacetate in laboratories
- Use of phorbol esters in laboratories
- Use of diisopropyl phosphorofluoridate in laboratories
- Use of mercury-containing equipment
- Use of ether as an anesthetic (approved only as a last resort) or euthanasia agent (not approved due to risk assessment) in animal research
- Alternatives to formaldehyde
- Potential emissions of volatile organic compounds due to hazardous waste management practices

The EH&S Bio/Chem/Safety group's Senior Chemist has prepared Technical Bulletins that are used to convey chemical safety information to all relevant UT Southwestern staff. The Technical Bulletins include chemical descriptions, physical hazards, physical and chemical properties, potential

health hazards, signs and symptoms of acute and chronic exposure, exposure limits and toxicology, control measures for prevention of exposure, and emergency spill response procedures.

In addition to the types of hazard analyses described above, various inspections serve as tools for performing hazard analyses. Inspections designed to identify and correct fire, life safety, electrical, chemical, radiation, and biological hazards are performed by EH&S. Items/systems/procedures inspected include sprinkler systems; fire alarms; flammable liquid storage; proper storage of other chemicals including separate storage of incompatible chemicals; proper storage, use, and disposal of RAM; radiation surveys; safety shower function; eye wash function; status of exit signs; means of egress; equipment grounding; temperature controls on electric heating equipment in laboratories; gas cylinder storage; proper storage of supplies and equipment in laboratories; proper disposal of sharps; proper disposal of broken glassware; safety training; container labeling; fume hood testing; evidence of annual biological safety cabinet testing by a contractor; solid hazardous waste management; medical waste management; emissions monitoring and controls; and petroleum storage tank and drum inspections. Based on inspection results, corrective action is recommended or taken. Corrective action includes correction of existing problems as well as changes in design intended to prevent particular problems from re-occurring.

- 7.0 USAMRMC Facility Safety Plan Appendix L Part 2c: Biological Defense Research Program Requirements: For those institutions where Principal Investigators are supported by the USAMRMC and are conducting research with Bio-safety Levels 3 and 4 material, a Facility Safety Plan must be prepared in accordance with 32 Code of Federal Regulations (CFR) 626.18.

UT Southwestern BSL3 work is not funded by the U.S. Department of Defense. Safety Plans for BSL3 laboratories at UT Southwestern and BSL3 Laboratory Procedures are compliant with the CDC guidelines. The BSL3 program provides procedures for controlling laboratory mishaps, emergency procedures to follow in the event of an incidental release, training material, a staff approval list, training documentation, and medical surveillance. The laboratories contain the necessary equipment for controlling mishaps and employ highly trained staff.

- 8.0 USAMRMC Facility Safety Plan Appendix L Part 2f: The Facility Safety Director/Manager Assurance

The signed and dated Facility Safety Director/Manager Assurance is attached.

## **Attachments:**

- **Radioactive Material License No.L00384, Amendment 92, Acknowledged March 29, 2005, Signed May 5, 2006**
- **Facility Safety Director/Manager Assurance**



## TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.  
COMMISSIONER

1100 W. 49<sup>th</sup> Street • Austin, Texas 78756  
1-888-963-7111 • <http://www.dshs.state.tx.us>

March 29, 2005

THE UNIVERSITY OF TEXAS  
SOUTHWESTERN MEDICAL CENTER  
AT DALLAS  
ATTN JOHN C WHITE  
5323 HARRY HINES BOULEVARD  
DALLAS TX 75390-9053

Re: License No. L00384  
Log No. 2005-03-1352

Dear Mr. White:

This is to acknowledge receipt of your application dated March 22, 2005 for renewal of your Radioactive Material License No. L00384. Because your application for renewal was submitted in a timely fashion, you are hereby authorized, under the provisions of Title 25 Texas Administrative Code (TAC) Section 289.252(z), to continue to operate under the authorizations of your present license until the Agency has completed action on your request.

This letter should be retained in your files as verification that your license remains valid until a renewal amendment is issued, or the request is denied.

Please note that due to the current backlog of renewals, it may be 12-18 months before we are able to review and approve your application. If your application contains requests which you wish to have authorized quickly, you should submit those requests as amendment requests separate from the renewal (e.g., adding new users; adding or moving a location of use; deleting uses of radioactive material which would result in a reduction in your annual licensing fee).

Provide two copies of the above information within 30 days from the date of this letter in order that we may expedite the processing of your amendment request. In your response, please reference Radioactive Material License No. L00384 and Log No. 2005-03-1352.

If you have any questions concerning this transmittal, please contact Mr. Paul Sanford at (512) 834-6688 extension 2204; or by electronic mail at [paul.sanford@tdh.state.tx.us](mailto:paul.sanford@tdh.state.tx.us).

Sincerely,

A handwritten signature in cursive script that reads "J. Scott Kee".

J. Scott Kee, Chief  
Medical and Academic Licensing Program  
Radiation Safety Licensing Branch



Department of State Health Services

**RADIOACTIVE MATERIAL LICENSE**

Pursuant to the Texas Radiation Control Act and Texas Department of State Health Services (Agency) regulations on radiation, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Agency now or hereafter in effect and to any conditions specified below.

**LICENSEE**

1. Name **THE UNIVERSITY OF TEXAS  
SOUTHWESTERN MEDICAL CENTER AT  
DALLAS  
ATTN JOHN C WHITE**

2. Address **5323 HARRY HINES BOULEVARD  
DALLAS TX 75390-9053**

This license is issued to correct an error

3. License Number <b>L00384</b>	Amendment Number <b>92</b>
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**PREVIOUS AMENDMENTS ARE VOID**

4a. License Expiration Date <sup>†</sup>  
**March 31, 2007**

4b. Technical Renewal Application Due Date <sup>†</sup>  
**March 31, 2005**

**RADIOACTIVE MATERIAL AUTHORIZED**

5. Radioisotope	6. Form of Material	7. Maximum Activity*	8. Authorized Use
A. Any radioactive material with Atomic Number less than 84	A. Any (except sealed sources or gases)	A. 5 Ci of any single isotope Total: 40 Ci	A. Medical research, diagnosis, therapy, education and calibration.
B. Any radioactive material with Atomic Number less than 84	B. Sealed source	B. Any single source not to exceed 5 Ci Total: 20 Ci	B. Medical research, diagnosis, therapy, education and calibration.
C. Any radioactive material listed in UT Southwestern's Itr <sup>†</sup> dated 2/2/98	C. Sealed source	C. Any single source not to exceed 500 mCi Total not to exceed 530 mCi	C. Medical research, diagnosis, therapy, education and calibration.
D. Any radioactive material with Atomic Number of 84 or greater except special nuclear material	D. Any (except sealed sources or gases)	D. 2 Ci of any single isotope Total: 10 Ci	D. Medical research, diagnosis, therapy, education and calibration.

\* Ci-Curies mCi-Millicuries μCi-Microcuries ° Texas Administrative Code (TAC) <sup>†</sup> see next-to-last condition



Department of State Health Services

# RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER	AMENDMENT NUMBER
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5. Radioisotope (continued)	6. Form of Material (continued)	7. Maximum Activity* (continued)	8. Authorized Use (continued)
E. Any radioactive material listed in UT Southwestern's letters dated 2/16/01	E. Any as listed	E. Any single source not to exceed 500 mCi Total not to exceed 10 Ci	E. Storage, preparation and transfer to authorize recipients; use of eye applicators in accordance with Texas Administrative Code (TAC) §289.256(bb); limited to Site 004.
F. Any radioactive material with Atomic Number of 84 or greater, except special nuclear material	F. Sealed source	F. 500 mCi of any single isotope Total: 600 mCi	F. Medical research, diagnosis, therapy, education and calibration.
G. H-3	G. Any (except sealed source or gas)	G. 100 Ci	G. Medical research.
H. Xe-133	H. Any (except sealed source)	H. 5 Ci	H. Medical research and diagnosis.
I. Cs-137	I. Sealed source (J L Shepherd 6810)	I. 2000 Ci	I. Irradiation of samples in a J L Shepherd Mark I Series, Submodel 25-1 Irradiator.
J. Cs-137	J. Sealed source (ORNL ISO-1000)	J. 720 Ci	J. Irradiation of samples in an AECL RCC Gammacell-1000 Irradiator, Model A.
K. Cs-137	K. Sealed source (J L Shepherd 6810; A/S CDC.PEn series)	K. 1100 Ci	K. Irradiation of samples in a J L Shepherd Mark I Series Submodel 30-1 Irradiator.
L. Cs-137	L. Sealed Source (Nordion C-3001)	L. Two sources not to exceed 1524 Ci each Total: 3048 Ci	L. Up to two sources for use in a Nordion Gammacell 3000 Elan - Type II self-contained (self-shielded) irradiator for irradiation of blood and blood components.
M. Ir-192	M. Sealed source (Omnitron SL-777V; Varian SL777V, VS2000)	M. One source not to exceed 13 Ci on receipt and 11Ci at installation, one source not to exceed 7 Ci Total: 20 Ci	M. One source for treatment of humans with a Varian VariSource HDR afterloader and the other source for storage in an authorized shipping container during periods of source exchange.



Department of State Health Services

# RADIOACTIVE MATERIAL LICENSE

LICENSE NUMBER	AMENDMENT NUMBER
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5. Radioisotope (continued)	6. Form of Material (continued)	7. Maximum Activity* (continued)	8. Authorized Use (continued)
N. Cs-137	N. Sealed source (J L Shepard 6810; AEA CDC.PE1 Through CDC.PE8)	N. One source not to exceed 1780 Ci	N. Irradiation of samples for research in a J L Shepard model Mark I Series Submodel 68-A-1 Irradiator.
O. Y-90	O. Sealed source (microspheres in solution)	O. No single source to exceed 300 mCi Total: 300 mCi	O. Interstitial treatment of cancer as indicated in 25 TAC §289.256(aa).
P. Cs-137	P. Sealed source (J L Shepard 6810; AEA CDC.PE1 through CDC.PE8)	P. One source not to exceed 4000 Ci	P. Irradiation of samples for research in a J. L. Shepard model Mark I Series Submodel 68-1 Irradiator.
Q. Cs-137	Q. Sealed Source (Nordion C-3001)	Q. Two sources not to exceed 1524 Ci each Total: 3048 Ci	Q. Use in a Nordion Gammacell 1000 Elite Model I self-contained (self shielded) irradiator for irradiation of blood and blood components. One additional source for storage, present in an identical model during device exchange

9. Radioactive material shall only be stored and used at:
- | <u>Site Number</u> | <u>Location</u>   |
|--------------------|---|
| 000                | Dallas - 5323 Harry Hines Boulevard, The University of Texas<br>Southwestern Medical Center at Dallas (UTSWMC), Parkland<br>Memorial Hospital (PMH), Children's Medical Center (CMC),<br>Zale-Lipsky University Hospital (ZLUH), Southwestern Institute of<br>Forensic Sciences |
| 002                | Dallas - 1311 Record Crossing   |
| 005                | Dallas - 5909 Harry Hines Boulevard, St Paul University Hospital  |
10. Each site shall maintain documents and records pertinent to the operations at that site. Copies of all documents and records required by this license shall be maintained for Agency review at Site 000, except those required by 25 TAC §289.201(d) that are directly related to radioactive materials for human use and unsealed reference sources for instrument calibration, 25 TAC §289.202(m) and 25 TAC §289.202(tt).
11. The licensee shall comply with the provisions (as amended) of Title 25 Texas Administrative Code (TAC) §289.201, §289.202, §289.203, §289.204, §289.205, §289.251, §289.252, §289.256 and §289.257.



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12. Radioactive material shall be used only by, or under the supervision of, individuals designated by the Radiation Safety Committee (RSC), George C. Curry, M.D., Chair. Individuals authorized to serve on this committee are:

- |                               |                                     |
|-------------------------------|-------------------------------------|
| ·Jon Anderson, Ph.D.          | Radiology                           |
| ·Victor Aquino, M.D.          | Pediatric Oncology                  |
| ·Frederick Bonte, M.D.        | Nuclear Medicine                    |
| ·William H. Craig, M.P.A.     | Executive Director, UTSMCC          |
| ·George C. Curry, M.D., Chair | Radiology                           |
| ·Kenneth M. Forster, Ph.D.    | Medical Physics                     |
| ·Jimmy N. Hayman, R.Ph., M.S. | PMH, Management                     |
| ·Yui K. Ho, Ph.D.             | Molecular Genetics Research         |
| ·Padmakar V. Kulkarni, Ph.D.  | Radiochemistry                      |
| ·Thomas J. Lane, Ph.D.        | Medical Physicist, Diagnostics      |
| ·Jose A. Lopez, Ph.D.         | Director EHS                        |
| ·Carlos Lugo, M.D.            | Nuclear Medicine                    |
| ·Kevin McIver, Ph.D.          | Microbiology                        |
| ·Nicolai van Oers, Ph.D.      | Center for Immunology               |
| ·Orhan Öz, M.D.               | Nuclear Medicine                    |
| ·Mark Petersen                | Assistant Director, Radiology, ZLUH |
| ·John C. White                | Radiation Safety Officer            |
| ·Suzan Younger                | Senior Management                   |
| ·Osvaldo Zamudio, RT          | Children's Medical Center           |

The RSC may authorize the following:

- A. physician users, principal investigators, and other handlers of radioactive material.
  - B. clinical use of radioactive material;
  - C. use areas in sites authorized by license condition 9;
  - D. close-out of use areas in accordance with 25 TAC §289.202;
  - E. non-substantive changes to reference documents (e.g., phone numbers, reformatting)
13. The individual designated to perform the functions of Radiation Safety Officer (RSO) for activities covered by this license is John C. White.
  14. The licensee shall not open sealed sources containing radioactive material.
  15. The leak tests for sealed sources may also be performed by Jose A. Lopez, Ph.D., P.E., or any individual under his supervision.
  16. In accordance with 25 TAC §289.201(g), each sealed source that is not designed to emit alpha particles may be tested at intervals specified by the Registry of Radioactive Sealed Sources and Devices (SSD) safety evaluation.
  17. Radioactive material shall not be used in humans until its pharmaceutical quality and assay have been established.



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18. The investigational use of radioactive material in or on human beings shall either be directly authorized by the United States Food and Drug Administration (FDA) or approved by a properly constituted Radioactive Drug Research Committee and Institutional Review Board.
19. A current copy of the licensee's radiation safety manual shall be readily available to each person who uses radioactive material authorized by this license.
20. Proposed substantive changes in or additions to the licensee's radiation safety manual shall be submitted to the Agency and approved before being incorporated into this document.
21. Qualifications of new members of the licensee's RSC shall be submitted to the Agency, and their membership approved prior to their participation as full-voting members in the committee's deliberations. Interim appointments for replacements of departing members may be made by executive management, pending Agency approval, when the interim appointee has equivalent credentials of the departing member and represents the same department as did the departing member.
22. The licensee shall conduct a physical inventory every six months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for inspection by the Agency for three years from the date of the inventory and shall include the quantities and the kinds of radioactive material, location of sealed sources, the name of the individual taking the inventory, and the date of the inventory.
23. Detector cells containing tritium foils shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225° Celsius for titanium tritide foils and 325° Celsius for scandium tritide foils. Detector cells shall be installed so that their exhausts are vented to the outside atmosphere, to vented hood systems, or to process streams.
24. Animals administered radioactive materials or products from such animals shall not be used for human consumption.
25. The licensee may dispose of certain radioactive materials whose half-lives do not exceed 300 days, in accordance with the provisions of 25 TAC §289.202(fff)(4).
26. The procedures contained in the manufacturer's instruction manuals Gamma Cell 1000 and the J. L. Shepherd Mark I shall be followed and a copy of this manual shall be made available to each person using the irradiators. Samples to be irradiated shall be adequately contained and appropriately sized to prevent interference with the irradiator mechanisms.
27. The irradiators shall be serviced only by authorized personnel at the manufacturer's recommended intervals.
28. An operable self-powered room radiation field monitor shall be present in the irradiator room for each J. L. Shepherd Mark I irradiator whenever the irradiator is in use.
29. Quarterly interlock checks shall be made and recorded for each Mark I irradiator to verify proper operation of the mechanisms.



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## RADIOACTIVE MATERIAL LICENSE

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30. All use of Mark I irradiator shall be under the supervision and in the presence of a trained operator of the equipment. A log of utilization shall be maintained for inspection.
31. The licensee is authorized to use a mechanical compaction device to assist in handling radioactive waste, in accordance with the manufacturer's operating instructions, maintenance procedures and schedule.
32. Radiation surveys for removable contamination shall be analyzed in well or liquid scintillation counters.
33. The licensee is authorized to store radioactive material with a physical half-life of less than 300 days for decay-in-storage before being discarded as being non-radioactive provided:
  - A. Radioactive waste to be discarded of in this manner is held for decay a minimum of 10 half-lives.
  - B. Prior to discarding as other waste, radioactive waste is monitored to determine that the radiation levels are not distinguishable from background with appropriate survey instruments. All radiation labels will be removed or otherwise obliterated or obscured.
34. The licensee shall not open or remove sealed sources containing radioactive material from an HDR device.
35. Prior to the initiation of a treatment program, each HDR unit shall be provided with electrical or mechanical restraints on its location, or the possible locations of its sources during therapy, so as to assure compliance with §289.202, as evidenced by a radiation survey. Necessary location and use restrictions shall be fully described in radiation survey reports prepared in accordance with Condition 37.
36. Written instructions shall be posted at the HDR control panel. These instructions shall inform the machine operator of the procedures to be followed if the source(s) fail to return on command to a shielded position. These instructions shall caution individuals to avoid exposure to the highest radiation fields when in the treatment room and shall include specific instructions for:
  - A. Locating and using the device for manually returning the remote control brachytherapy unit's sources to a shielded position (if applicable) while taking note of the time.
  - B. Removing the patient from the treatment room.
  - C. Securing the room against unauthorized entry.
  - D. Notifying the responsible physician or RSO.



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37. Prior to initiation of a treatment program, and subsequent to each exchange of therapy source(s), radiation surveys and tests shall be performed in accordance with the following requirements.

A. A radiation survey shall be made of:

1. The HDR device source housing, with the therapy source(s) in the "off" or shielded position. The maximum radiation levels at 20 centimeters from the surface of the source housing shall not exceed 6.25 milliroentgens per hour.
2. All areas adjacent to the treatment room, with the maximum source activity to be used in any treatment in the "on" or therapy position. The survey shall clearly establish:
  - a. that radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 25 TAC §289.202(f).
  - b. that radiation levels in unrestricted areas do not exceed the limits specified in 25 TAC §289.202(n).

B. Tests shall be made to determine proper operation of:

1. Electrical interlocks on entrance doors to the therapy room.
2. The teletherapy source "on-off" indicators, both at the source housing (if present) and on the therapy machine control panel.
3. Electrical or mechanical restraints on machine or source locating during therapy.
4. The therapy machine timing device.

C. A report of the results of the above surveys and tests shall be maintained by the licensee for inspection by the Agency.

38. Any change made in treatment room shielding, location, or use of a HDR device which could result in an increase in radiation levels in unrestricted areas outside a therapy treatment room and made subsequent to the completion of the initial radiation survey performed in accordance with Condition 37 shall be evaluated by a radiation survey performed in accordance with Section A, Item 2. of Condition 37. A report describing the change(s), and giving the results of the survey(s), shall be sent to the Deputy Director, Radioactive Material Inspection and Enforcement, not later than 30 days following completion of such changes.

39. The licensee shall cease treatment of patients when any safety related system of an HDR device is found inoperative, including source drive mechanisms, treatment timing systems, safety interlocks and radiation field alarms. The licensee shall report to the Deputy Director, Emergency Response and Incident Investigation Branch any malfunction which requires the termination of patient treatments for more than 24 hours and shall submit a written report of the incident and corrective actions within seven calendar days.



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# RADIOACTIVE MATERIAL LICENSE

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- 40. The licensee shall maintain a current copy of the safety evaluation from "The Registry of Radioactive Sealed Sources and Devices" for each sealed source received under authority of this license, in excess of 100  $\mu$ Ci of  $\beta/\gamma$  emitting material of 10  $\mu$ Ci of  $\alpha$ -emitting material.
- 41. All maintenance on the HDR unit which involves the source, source shielding or beam control mechanism, safety circuits, control panel electrical circuits, or other mechanisms that could compromise safety of the unit shall only be performed by the unit's manufacturer or by other persons specifically licensed to perform such services by this Agency, an Agreement State, or by the NRC. Calibration and quality control procedures may be performed by the licensee provided the unit is under the direct control of an authorized user identified by the RSC.
- 42. The next two-year fee payment is due by March 31, 2007. If fee payment is not received by this date the license expires and the licensee must comply with Title 25 Texas Administrative Code Section (TAC) §289.252(y) by (1) terminating the use of radioactive material; (2) properly disposing of radioactive material; (3) submitting a record of disposal of radioactive material and radiation survey(s) of the locations of use and/or storage to show that the locations are releasable for unrestricted use; (4) paying any outstanding fees in accordance with 25 TAC §289.204; and (5) resolving any outstanding notices of violation. The next technical renewal application for this license, in accordance with 25 TAC 289.252(z), is due by March 31, 2005.
- 43. A. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material authorized by this license in accordance with statements, representations, and procedures contained in the following:
  - application dated May 30, 1996,
  - letters dated November 3, 1997, February 2, 1998, May 15, 1998, April 26, 1999,
  - September 8, 2000, February 16, 2001, February 14, 2003, April 24, 2003,
  - June 18, 2003, July 23, 2003, August 22, 2003, February 6, 2004,
  - February 13, 2004, April 13, 2004, May 18, 2004, May 24, 2004, June 24, 2004,
  - and February 22, 2005.

Title 25 TAC §289 shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.



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# RADIOACTIVE MATERIAL LICENSE

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43. (Continued)

- B. The licensee shall comply with the requirements described in the DSHS letter dated September 22, 2005 and attached document entitled "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern." The licensee shall complete implementation of said requirements within 6 months from the issuance of License Amendment 89 or the first day that radionuclides in quantities of concern are possessed at or above the limits specified in Table 1 of the attachment, whichever is later. Within 30 days after the implementation of the requirements of this condition, the licensee shall notify the Radiation Safety Licensing Branch in writing that it has completed the requirements of this condition.

HTW:hw

FOR THE DEPARTMENT OF STATE HEALTH SERVICES

Date

May 5, 2006

*J. Scott Kee*  
J. Scott Kee, Chief

Medical and Academic Licensing Program

## Facility Safety Director/Manager Assurance

I assure that this institution has an existing institutional safety and occupational health program that meets appropriate Federal, State, and local regulations as required by law, as well as the National Institute of Health Guidelines for Research Involving DNA Molecules, dated Jan 2001.

I assure that all hazards associated with the research laboratories have been identified, eliminated, and/or controlled in such a manner as to provide for a safe research laboratory environment.

I accept full responsibility for submitting the annual Facility Safety Plan Status Report including significant changes in facility, safety equipment, and safety procedures:

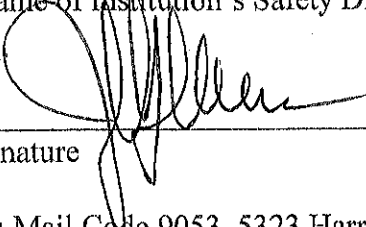
- by fax to 301-619-6627
- by e-mail to [mrmc-zc-sse.usarmc@amedd.army.mil](mailto:mrmc-zc-sse.usarmc@amedd.army.mil)
- by mail to Commanding General, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-ZC-SSE, 504 Scott Street, Fort Detrick, MD 21702-5012.

I assure that I have consulted with all current PI's holding USAMRMC awards concerning this institution's safety policies and procedures and will consult with all future PI's holding USAMRMC awards concerning this institution's safety policies and procedures.

Use of etiologic agents as defined in 32 CFR 626 (agents which cause human disease and are either listed in 42 CFR 72.3 or pose a hazard similar to agents listed in 42 CFR 72.3)? Yes. Note that UT Southwestern BSL3 work is not funded by the U.S. Department of Defense. Safety Plans for BSL3 laboratories at UT Southwestern and BSL3 Laboratory Procedures are compliant with the CDC guidelines.

Jose A. Lopez, Ph.D. Director of Environmental Health and Safety Department

Name of Institution's Safety Director/Manager

  
Signature

12/12/06  
Date

Mailing Address: Mail Code 9053, 5323 Harry Hines Blvd., Dallas, TX 75390-9053

Phone: 214-648-2250; Contact: Terry Capone, 214-648-9736

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website: <http://www.utsouthwestern.edu/utsw/home/admin/ehs/index.html>