I. PURPOSE:

The purpose of this standard operating procedure is to outline the emergency response and reporting procedures for certain incidents involving recombinant or synthetic nucleic acid molecules at the University of Texas Health Science Center at San Antonio.

The University of Texas Health Science Center at San Antonio is required to report incidents involving recombinant or synthetic nucleic acid molecules (rDNA) to the National Institutes of Health (NIH) Office of Science Policy (OSP) and other regulatory agencies. This policy outlines the information necessary to determine the nature and extent of the incident, appropriate spill management and reporting requirements according to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).


II. SCOPE

This standard operating procedure (SOP) applies to all individuals (employees, students, visiting scientists, and volunteers) at the University of Texas Health Science Center at San Antonio who work with recombinant or synthetic nucleic acid molecules (rDNA).

III. DEFINITIONS

In the context of the NIH Guidelines, recombinant and synthetic nucleic acids are defined as:

(i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;

(ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or

(iii) molecules that result from the replication of those described in (i) or (ii) above.

IV. RESPONSIBILITIES

Deans, Directors and Department Heads are responsible for:
• the overall implementation of this policy.
• ensuring that all Principal Investigators, researchers, instructors, laboratory/clinical managers, students and other personnel are aware of, understand and follow the procedures outlined in this policy.

Principal Investigator is responsible for:
• ensuring that all personnel are knowledgeable of the incident and spill response procedures in this policy and that spills are addressed in a prompt manner.
• ensuring that these Standard Operating Procedures are used to tailor spill response plans specific to their laboratory or clinic (See the Biological Spill Response and Laboratory Specific Emergency Plan template) at: http://research.uthscsa.edu/safety/Biological%20Spill%20and%20Lab%20Specific%20Emergency%20Plan
doc
• adhering to Institutional Biosafety Committee approved lab specific emergency plans for handling accidental spills and personnel contamination. NIH Guidelines Section IV-B-2-b-(6), Appendix G-I (Emergency Plan). This plan is to be posted in the laboratory.
• immediately reporting spills to the Institutional Biological Safety Officer in the Department of Environmental Health and Safety (210-57-2955) if they involve rDNA/biohazardous materials and; are large, or occur outside of containment or if personnel are exposed.

Users (Employees, Students, Visiting Scientists and Volunteers) are responsible for:
• adhering to Institutional Biosafety Committee approved lab specific emergency plans for handling accidental spills and personnel contamination per- NIH Guidelines Section IV-B-2-b-(6), Appendix G-I (Emergency Plan).
• attending all appropriate safety training.
• notifying their immediate supervisor of any incidents, spills any injuries or possible exposures.

V. SPILL PROCEDURES
The written spill procedure including emergency contact name(s) and phone numbers shall be posted in the lab. Disinfectants suitable to the biological agents/rDNA being used shall be available. The Department of Environmental Health and Safety (210-567-2955) will provide consultation on spill response and will assist with decontamination and cleanup of large spills.

A. Large Spill
In the event of a large spill (greater than 100mls) or a spill involving a highly infectious agent outside the containment of the biological safety cabinet,

• Evacuate room, close doors, prevent others from entering, and wait 30 minutes for aerosols to settle.
• Follow procedures for small and moderate spills or contact Environmental Health and Safety at 567-2955 for assistance.

B. Small to Moderate Spills
These procedures address small to moderate spills of less than 100mls involving small quantities of recombinant or synthetic nucleic acid molecules (rDNA)/biohazardous materials.

**Small or Moderate Spill in a Biological Safety Cabinet**

A spill that is small and confined within a biological safety cabinet generally presents little or no hazard to personnel in the area. Wear protective gloves, a lab coat or gown, and eye protection during the procedure. Chemical disinfection procedures are to be initiated immediately while the cabinet continues to operate. The disinfectant shall be one that is active against the biohazardous material. Minimize the generation of aerosols as the walls, work surfaces, and equipment are sprayed or wiped with the chosen disinfectant. Allow the disinfectant to remain on the surface for the appropriate contact time.

The following procedures should be followed.

- Notify others in the area. Notify the Principal Investigator.
- Leave the cabinet running.
- Wipe down all interior surfaces with appropriate disinfectant and observe the appropriate contact time.
- Determine if spill has gone beyond the work surface such as in the grilles or side seams. Disassemble and decontaminate if necessary.
- If the cabinet has a catch basin below the work surface that may be involved in the spill, flood the basin with disinfectant. Do not use a large quantity of alcohol, as it presents a flammable hazard. Clean basin after 20 minutes.
- Autoclave or wipe down all items in cabinet with disinfectant.
- Let cabinet run for at least 10 minutes after cleanup.
- Dispose of spill clean-up materials as biohazardous waste.

**Small or Moderate Spill in the Open Laboratory**

For a spill in the open laboratory outside a biological safety cabinet, the spill response depends on the size of the spill and hazard of the material. A minimally hazardous material spilled without generating appreciable aerosols can be cleaned with a paper towel soaked in a chemical disinfectant. For other small or moderate spills of low risk agents outside the biological safety cabinet, the following procedures should be followed:

- Notify other workers in the area of the spill and control traffic through area.
- Remove any contaminated clothing and put in autoclavable bag. Be aware that autoclaving may damage fabric.
- Wear shoe covers if spill is on floor, may be splashed beyond immediate area of spill.
- Put on gloves, lab coat and safety goggles
- Cover spill area with paper towels.
- Pour disinfectant over towels from edges of spill to center, be careful not to splatter.
- Decontaminate all objects in spill area.
- Allow 20-30 minutes of contact time.
- Use squeegee and dust pan to recover spill materials and put in biohazard bag.
• Pick up any sharps, including broken glass, with forceps and place in sharps container.
• Wipe area with disinfectant and clean towels, mop if spill on floor.
• Remove gloves and foot covers before leaving area of the spill, put in biohazard bag, and wash hands.

VI. PROCEDURE FOR PERSONNEL EXPOSED TO RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (rDNA)/BIOLOGICAL AGENTS

If Spill Results in a Hazard Exposure (i.e. face and/or eye splash, cut or puncture with sharps, contact with non-intact skin):

• Administer first aid (Wash wound with soap and water or flush eyes with water for 10 minutes) or call 911 or 567-8911 for serious accidents (use of a university phone will contact UTPD and speed the dispatch process)
• Report the incident to your Principal Investigator/supervisor as soon as possible.
• Seek medical attention as soon as possible.
  - During business hours, employees may go to the UT Health Employee Health and Wellness Clinic (EHWC) located in the Nursing School, room 1.445 (567-2788). Students may go to the Student Health Clinic (567-9355). These clinics are familiar with occupational exposures (i.e. contaminated needlestick injury).
  - After business hours, EH&S suggests that you go to the Emergency Room at University Hospital (358-2488). The Express Med clinic, 4150 Medical Drive (358-5510) is open until 10:00PM.
Note: Workers’ Compensation Insurance allows you to seek medical attention from alternate healthcare providers.
Complete the required forms including the Employer’s First Report of Injury form available on the UT Health Science Center’s Environmental Health and Safety website under Worker’s Comp..
• Report all rDNA/biohazard incidents requiring medical treatment to Environmental Health and Safety at 567-2955 (FAX: 567-2965). Note: It is important to fill out all of the appropriate paperwork in order to be eligible to collect workers compensation should any illnesses arise from the hazardous exposure in the future

VII. PROCEDURE FOR REPORTING INCIDENTS INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES TO NIH/OSP

Lab incidents or illness involving recombinant or synthetic nucleic acid molecules or noncompliance with the NIH Guidelines may be brought forward by any person, and should be promptly reported to EHS (210-567-2955) for investigation and reporting of the incident to the National Institutes of Health Office of Science Policy (NIH/OSP) and the Institutional Biosafety Committee if required.

University of Texas Health Science Center San Antonio must report any significant problems or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/OSP within 30 days. Examples include needlesticks containing recombinant or synthetic nucleic acid molecules, the escape or improper disposition
of a transgenic animal, or spills of high-risk recombinant or synthetic materials occurring outside of a biosafety cabinet.

Spills and accidents which result in overt exposures to risk group 2 (RG2) organisms or overt or potential exposures to risk group 3 (RG3) organisms containing recombinant or synthetic nucleic acid molecules must be immediately reported to EHS (210-567-2955) for investigation and reporting of the incident to the National Institutes of Health Office of Science Policy (NIH/OSP) and the Institutional Biosafety Committee as required. Medical evaluation, surveillance, and treatment will be provided as appropriate and written records will be maintained.

The Biological Safety Officer will immediately report the incident to NIH OSP (301-496-9839) for any incidents that involve:

- overt personnel exposure at Biosafety Level 2 (BSL-2, BL2) and/or Animal Biosafety Level 2 (ABSL-2, BL2-N),
- overt or potential exposure in the Biosafety Level 3 (BSL-3, BL3) and/or Animal Biosafety Level 3 (ABSL-3, BL3-N) laboratories

Other incidents that are reported to NIH OSP within 30 days include:

- a violation of the NIH Guidelines containment or biosafety practices, or significant problems leading to a breach of containment (including escape or improper disposal of a transgenic animal)
- failure to obtain Institutional Biosafety Committee approval
- a significant-research-related accident or illness.
- incomplete inactivation
- spills

The Biological Safety Officer will notify the Chair of the Institutional Biosafety Committee, the Vice President for Research and other institutional officials of the incident as required.

The Biological Safety Officer will work with the Principal Investigator to complete the NIH OSP Template for Reporting Incidents Subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

The incident report must be sent to NIH OSP within 30 days.

The Biological Safety Officer will submit the final incident report on behalf of the university to NIH OSP via email to NIHGuidelines@od.nih.gov within 30 days.

The final incident report will be reviewed by the IBC and corrective actions recommended and instituted as necessary. Copies of the incident report will be provided to the Assistant Vice President for Risk Management and Safety, the Vice President of Research, and other institutional officials as necessary.

Template for Reporting Incidents Subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules to the National Institutes of Health, Office of Science Policy (OSP)