



Title:	<b>Incidents Involving Recombinant or Synthetic Nucleic Acid Molecules (rsNAM) and Materials</b>		
Program:	Environmental Health and Safety	Effective Date:	9/8/2015

1. **Purpose:** In order to comply with federal reporting requirements and to ensure timely and appropriate follow-up, Stony Brook University is required to report incidents involving recombinant and synthetic nucleic acid molecules (rsNAM) to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) and other regulatory agencies. This policy outlines the information necessary to determine the nature and extent of the release and appropriate spill management and reporting requirements according to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. (NIH Guidelines; [http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html)).
2. **Scope:** All Stony Brook University personnel working with, and responding to incidents involving, recombinant or synthetic nucleic acid molecules are responsible for adherence to this policy.
3. **Policy:** All Principal Investigators shall immediately report exposures and releases involving recombinant or synthetic nucleic acid molecules (rsNAM) as well as violations of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines, 2013) to the Stony Brook University Biological Safety Officer (BSO).
4. **Responsibilities:**
  - 4.1. Principal Investigators, Laboratory Supervisors and Laboratory Personnel
    - 4.1.1. Principal Investigators (PI), faculty and other Laboratory Supervisors have the ultimate responsibility for ensuring that all lab personnel are knowledgeable of spill response procedures and that spills are addressed in a prompt manner.
    - 4.1.2. The PI is responsible for immediately reporting incidents or violations of the *NIH Guidelines* to the Institutional Biological Safety Officer (BSO) in the Department of Environmental Health and Safety (EH&S) (631-632-6410 or [ehsafety@stonybrook.edu](mailto:ehsafety@stonybrook.edu)) if they involve rsNAM materials, are large, occur outside of containment and/or if personnel are exposed.
  - 4.2. Biological Safety Officer (BSO)
    - 4.2.1. Report to the Institutional Biosafety Committee (IBC), IBC Chair and Institutional Officials any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents illnesses of which he/she may become aware.
    - 4.2.2. Report any incident(s) that involves (nonexempt) rsNAM to the NIH OBA within 30 days.
    - 4.2.3. Report any incident(s) occurring in BSL-2 & BSL-3 laboratories resulting in a significant exposure immediately to NIH OBA.
    - 4.2.4. Provide technical advice to PI's and laboratory personnel regarding laboratory security, safety and emergency plans for spills and personnel contamination related to work performed with rsNAM.
  - 4.3. Institutional Biosafety Committee (IBC)
    - 4.3.1. Ensure that all Principal Investigators, Laboratory Supervisors and Laboratory Staff are aware of, understand and follow the procedures outlined in this policy.
5. **References:**
  - 5.1. *NIH Guidelines for Research Involving Recombinant Synthetic Nucleic Acid Molecules* Nov. 2013. <http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>

## 6. Definitions:

6.1 **Recombinant or Synthetic Nucleic Acid Molecules (rsNAM)**, according to the NIH Guidelines (Section I-B), are defined as:

- 6.1.1. molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
- 6.1.2. 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
- 6.1.3. molecules that result from the replication of those described in (6.1.1.) or (6.1.2.) above.

## 7. Procedures:

### 7.1. Personnel Exposure Procedures

#### 7.1.1. Exposures:

- Needle sticks or other percutaneous injuries from a contaminated sharp item
- Splashes to mucous membranes (eyes, nose, mouth)
- Bites/scratches from animals that have been exposed to any recombinant or synthetic nucleic acid material, whether or not the exposure leads to illness

#### 7.1.2. Immediate Response:

- SKIN exposure: Immediately remove contaminated personal protective equipment or clothing and wash the contaminated area with soap and copious water for 15 minutes.
- EYE exposure: Flush the eye with water for at least 15 minutes at an eyewash station.

7.1.3. Notify PI or supervisor. If PI/supervisor is not available, immediately proceed to next step.

#### 7.1.4. Medical Treatment

- If emergency, call X-333 (campus phone) or (631) 632-3333 (cell phone).
- For any significant or overt exposure to rsNAM materials, proceed to Stony Brook University Hospital Emergency Room.
- For minor exposures to rsNAM materials, follow up with a personal physician.

#### 7.1.5. Reporting

- Notify the Biological Safety Officer (BSO) immediately.
- The BSO will investigate the incident and notify the IBC Chair and EHS Assistant Vice President.
- The PI will complete an Incident Report Form (See section 8.1) and submit it to the BSO within 24hrs.
- If the IBC Chair and BSO determine that the incident involves (nonexempt) rsNAM the BSO will submit an NIH incident report to the NIH Office of Biotechnology Activities within 30 days. Incidents occurring in BSL-2 & BSL-3 laboratories resulting in an overt exposure will be immediately reported to NIH OBA.

### 7.2 Environmental Release Procedures

#### 7.2.1. Examples:

- A significant spill or release of any rsNAM outside of containment equipment.

- A theft, loss, or release of any rsNAM into the environment, including escape or improper disposal of a transgenic animal or plant materials.

## 7.2.2. Immediate Response:

7.2.2.1. Most spills involving rsNAM can be handled by researchers. Supplies to clean a spill appropriately must be available in any lab that works with or stores biohazardous materials.

### 7.2.2.2. Recommended Supplies

#### 7.2.2.2.1. Disinfectant

- Use appropriate disinfectant against the agents of concern, such as a fresh 1:10 bleach solution.

#### 7.2.2.2.2. Personal Protective Equipment (PPE) (minimally)

- Lab coat
- Gloves
- Face shield

#### 7.2.2.2.3. Other

- Sharps container for broken glass
- Absorbent pads
- Tongs
- Autoclave bags

7.2.2.3. Small spills- Wipe up spill with a disinfectant-soaked paper towel and clean the surface with a suitable disinfectant. Allow disinfectant 20 minutes of contact time before removal.

### 7.2.2.4. Large Spills

a. Spills outside of a containment device, i.e., the spill is not inside of a Biological Safety Cabinet (BSC), centrifuge, or other lab equipment

1. Close off spill area to traffic, and notify coworkers.
2. If the spill involved an aerosol, instruct all occupants to leave the room for 30 minutes to allow aerosols to settle.
3. Place a sign on the door warning staff not to enter the room due to a spill.
4. Remove contaminated lab coat or clothing and wash exposed skin.
5. Put on clean gloves and lab coat.
6. Prepare enough volume of a 1:10 dilution of chlorine bleach or other approved disinfectant to saturate the contaminated area.
7. Contain the spill with paper towels or other absorbent pads.
8. Flood the spill area with disinfectant. Leave on for 20 minutes.
9. Push the absorbent material at the edge of the spill into the spill's center. Add more paper towels as needed.
10. If glass is present, use tongs or forceps and a dustpan to remove pieces and place into a biohazard sharps container.
11. Discard the paper towels into a Regulated Medical Waste (RMW) container.
12. Using clean paper towels and a disinfectant, wipe all surfaces that may have come in contact with the spilled material.
13. Discard any disposable PPE into a RMW container.
14. Wash hands thoroughly.
15. Notify Principal Investigator or Supervisor and the BSO.

b. Spills inside of a Biological Safety Cabinet (BSC)

1. Leave BSC on.
2. Follow steps 4 through 15 above.

3. If the cabinet has a catch basin beneath the work surface and the spill resulted in liquids flowing into this area, more extensive decontamination is required.
4. Ensure the drain valve under the cabinet is closed.
5. Pour disinfectant onto the work surface and through the front and rear grilles into the drain pan. Allow 20-30 minutes contact time.
6. Absorb spilled fluid-disinfectant from work surface with paper towels and discard in an RMW container.
7. Prepare to empty drain pan. Place fresh disinfectant solution into a collection vessel. Attach flexible tubing to the drain valve. The tube should be of sufficient length to allow the open end to be submerged in the collection vessel to minimize aerosol generation.
8. Open the drain valve and empty the drain pan into the collection vessel containing disinfectant. Flush the drain pan with water and remove the flexible tubing. Manage contaminated materials as if they are infectious.
9. Remove protective clothing used during cleanup and place in a RMW container.
10. Wash hands thoroughly.
11. Notify Principal Investigator or Laboratory Supervisor and the BSO to determine if vapor/gas decontamination of the cabinet and filters is necessary.
12. Run BSC at least 10 minutes after cleanup, before resuming activity in the cabinet.

c. Spills Inside of a Centrifuge or breakage of containers inside of an operating centrifuge pose a serious potential for exposure due to the creation of aerosols. If a primary container has broken in a centrifuge without a closed rotor or bucket, immediately suspend use, notify lab staff and PI and request assistance from the Biosafety Officer. For suspected or confirmed spills/breakage in any centrifuge, wait at least 30 minutes after the centrifuge has stopped operating to initiate clean up.

1. Put on lab coat, gloves and a face shield prior to opening centrifuge. Open carefully to assess the damage.
2. If the spill is contained within a closed cup, bucket or rotor, spray the exterior with disinfectant and allow at least 20 minutes of contact time. Remove the carrier to the nearest biosafety cabinet (BSC). If a biosafety cabinet is not available, close the centrifuge; post a sign to indicate it cannot be used. Notify the PI and Biosafety Office for assistance.

### 7.2.3. Reporting

7.2.3.1. Notify the BSO immediately via email or phone if not already contacted for assistance with spill-clean up.

7.2.3.2. If the IBC Chair and BSO determine that the incident involves (non-exempt) rsNAM, the BSO will submit an NIH incident report to the NIH Office of Biotechnology Activities within 30 days. Incidents occurring in BSL-2 & BSL-3 laboratories resulting in an overt release will be immediately reported to NIH OBA.

**8. Related attachments, forms or documents:**

8.1. NIH OBA Incident Report Form;

<http://osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees/incident-reporting>

