Tennessee TECH

Environmental Health and Safety

Completing a Risk Assessment and Writing Standard Operating Procedures

I. Purpose

a. A risk assessment is required by the Occupational Safety and Health Administration (OSHA). A risk assessment is standard practice in public and private employment sectors, and protects workers and facilities. Principal Investigators, Faculty, and Supervisors are required to prepare written safety protocols to ensure compliance, avoid fines and penalties, and prevent accidents. The written safety protocol (Standard Operating Procedure) must be made available to everyone working on the procedure with specific training to ensure that everyone gets the information they need to conduct their research safely.

II. Scope

a. A risk assessment is a process that is used to determine if there are potential hazards and risks involved with a procedure.
b. A hazard is the way in which an object or a situation may cause harm. A hazard exists where an object, substance or situation has a built-in ability to cause an adverse effect. It is the intrinsic toxic properties of the chemical, radiological, or biological material.
c. Risk is the chance that an adverse effect will occur. Even if a chemical or biological material has hazardous properties, any risk to human health or environment is extremely low if the chemical is handled safely under controlled conditions. Risk assessment is a management tool to determine how and in what circumstances, harm might be caused. In order to assess risk, both hazard and exposure must be considered. Risk to self, co-workers, laboratory, building or the University must be considered.

III. Responsibilities

a. Faculty, Principle Investigators (PI), or supervisors are responsible for properly assessing the hazards in their individual areas.
b. The Environmental Health and Safety office is available to assist the supervisor with completing a risk assessment.

IV. Risk Assessment

a. The OSHA Laboratory Standard requires that a review of the hazards be conducted and written safety procedures be available when working with “particularly hazardous substances” as defined by OSHA and/or hazardous materials/processes.
b. A risk assessment is used to determine the appropriate protective measures needed to be implemented before the procedure is conducted to avoid accidents and injury. It is also used to write the SOP for the procedure and should become part of the research plan.
c. Risk assessments are conducted to prevent accidents and injuries and avoid legal liabilities that may result when all contributing factors are not fully considered, such as:

i. No documented safety procedures.
ii. No specific training is conducted or instructions given and documented.
iii. Out of date chemical inventory lists (required to be updated annually).
iv. Safety Data Sheets (SDS) not readily available.
v. Chemical storage not segregated by hazard class.
vi. Chemical containers not labeled.
vii. Improper sharps disposal.
viii. Machine guarding not in use.
ix. Blocked aisles and congested work spaces.
x. Safe laboratory practices not followed or not enforced.
xi. Improper use of personal protective equipment (PPE).
xii. Improper use of safety equipment.
xiii. Disabling or circumventing safety devices.

V. When to conduct a risk assessment

a. The Tennessee Tech University Chemical Hygiene Plan requires that any new procedure is subject to review to ensure that all safety considerations are in place prior to implementation. The PI, Faculty, or Supervisor should review and give approval to proceed with a laboratory or shop task whenever:
   i. There is a new procedure, process or test, even if it is similar to older practices.
   ii. There is a change, substitution, or deletion of any of the ingredient chemicals in a procedure.
   iii. There is a substantial change (25% or more) in the quantity of chemicals used.
   iv. There is a failure of any of the equipment used in the process, especially such safeguards as fume hoods or clamp apparatus.
   v. There are unexpected test results, in which case a review of how the new result impacts safety practices must be made.
   vi. When members of the laboratory staff become ill, suspect exposure, detect a chemical's odor, or otherwise suspect a failure of any safeguards.

VI. Steps to conducting a risk assessment

Start by taking the time to ask yourself these simple risk assessment questions:

- Why am I doing this?
- What could go wrong?
- How likely is it to happen?
- How could it affect me or others?
- What should I do about it?

If the risk is too great, stop. Control the risk and prevent the accident.

a. Step 1: Before you begin the risk assessment, you will need to know:

- Possible physical and health hazards of all chemicals and hazardous materials used in the procedure, including flammability, corrosivity, reactivity, toxicity, chronic and acute health hazards, and Permissible Exposure Limits (PELs).

- Hazards related to the equipment used in the procedure (vacuum, temperature, etc.)
- Hazards related to machine equipment (hand tools, saws, etc.) such as crushing, cutting, entanglement, severing, electrical contact, etc.
- Required engineering controls, administrative controls, and personal protective equipment.
- Waste disposal requirements.
- Emergency requirements such as reporting injuries, cleaning up spills, etc.

b. Step 2: You will also need to know what the exposure potential to these materials are, including:

   - Amount of material used
   - Dispersion Potential (Volatility, Aerosols, Dustiness)
   - Operating Temperature
   - Frequency of Use
   - Safety controls available

   This information will not always be available for all the hazardous materials and processes in the procedure. It is possible to group these during a risk assessment based on prior knowledge. This is similar to control banding used in industry.

   - Assign categories of risk to some or all chemicals (carcinogens, reproductive toxics, acutely toxics, explosives, unstable processes, pyrophoric materials), apparatus and equipment.
   - Apparatus under high vacuum, heated oil baths, ultra-centrifuges, NMR equipment and high temperature ovens are classified as presenting a greater risk compared with other apparatus and equipment.
   - Industrial tools and powerful portable small benchtop tools are higher risk than lower power and medium power hand tools.
   - Vacuum distillations, work with Class III and IV lasers, work with radioactive materials, work with unstable or explosive chemicals, handling highly toxic, reproductive hazards and carcinogens are high risk.

c. Step 3: Evaluate the risk: Hazard + Exposure = Risk

   A "What If" analysis can be used to perform the risk assessment. This is a brainstorming approach in which a group of experienced people familiar with the process ask questions about possible undesired events. It is a series of questions that begin "What if?"

   - Each question represents a potential failure in the procedure and is used to identify hazards, consequences, severity, likelihood, and recommendations.
   - The responses are evaluated to determine if a potential hazard can occur.
   - If so, the adequacy of available safeguards is weighed against the probability and severity of the scenario to determine whether modifications to the system should be recommended.

- What-If questions need to be asked about equipment failures, human error, and external events (utility interruptions).

Additional useful information on conducting a risk assessment can be found at Yale University's Office of Enterprise Risk Management.

If the assessment shows that the risk is too great, consider ways to lower the hazards, exposures or risks by:

- Substitute hazardous chemical for a less hazardous alternative.
- Reduce the quantity to lessen the intensity of any hazardous condition. Work with a few grams or a fraction of a gram.
- Purchase and use dilute solutions instead of concentrated solutions.
- Replace equipment requiring 120 volts AC with equipment that will run on 24 volts AC.
- Reduce buildup of static charge by grounding the containers or apparatus involved.
- Use lower temperatures instead of higher temperatures.
- Use machine guards, safe distance guarding, emergency stop devices, signage, etc.

VII. Writing a Standard Operating Procedure

a. A written safety protocol, also known as a "Standard Operating Procedure", is required by the OSHA Laboratory Standard. It is a document that includes the safety requirements developed in the risk assessment. It is used to ensure that everyone in the lab knows and understands the hazards, risks and protective measures needed to perform the procedure.

b. There is no required format for this written protocol. The information from your hazard and risk assessment is used to develop safe operating parameters. Developing safe operating parameters allows you to conduct research and change variables (i.e., substituting solvents, changing concentration or quantity, increasing temperature, etc.) without having to conduct a new hazard review and write a new safety protocol. These limits are critical when scaling up a procedure.

   i. Safe Operating Parameters: The process limits need to be defined and included in the written procedures. This information must be conveyed to everyone working on procedure.
   ii. Concentration: Be specific on the concentration of the stock solution concentrations to be used. Examples include Formaldehyde at 10% vs. 30% or Hydrogen Peroxide at 3% vs. 30% vs. 50%. The final concentration of the reaction mixture must also be within safe operating limits.
   iii. Flow Rate: Be specific on flow rates for gas and liquids being added to process.
   iv. Pressure: What pressure is the process running at? Vacuum and high pressure equipment have specific operating limits.
   v. Quantity: Is there a maximum quantity that can be handled safely? This limit must be in writing. Is the equipment only able to contain a certain quantity, allowing for off-gassing? This is important when scaling up a process.

vi. Temperature: What is the maximum temperature that the process can be heated before reaching the flashpoint or autoignition temperature of any flammable material? What is the lowest temperature the equipment can withstand if cooling with liquid nitrogen or dry ice?
vii. Volume: What is the equipment containment limits? This is important when scaling up a process. The equipment size must increase proportionally and allow for additional off-gassing.
viii. Additional Parameters: There are many other factors that must be considered when designing a safe experiment. Some of these include:

- Time - when scaling up, it is important to have more time to complete the process (loading, unloading, heating up, cooling down). Sometimes it goes into late night work without proper back up by second worker in the lab present.
- Environment - room temperature too high that require additional cooling or use of hood and humidity too high to make safe reactants/product transfer or even require special measures to reduce moisture in reaction vessel.
- Engineering/building supplies - uninterrupted power source, adequate cooling water flow, compressed air and/or vacuum line capacity.
- Redundancy - it is one thing if 10 ml vessel exploded because of failure of a single sensor on the setup, but a 10 L reactor should not have a single sensor.

ix. Information that needs to be included in the SOP includes:

- List all Personal Protective Equipment (PPE) needed for the procedure. Be specific on type of gloves or eyewear needed.
- List all chemicals (including concentration), biological materials and equipment needed for the procedure. Be specific on biological strain: E. coli could be risk group 2 (O157:H7) handled at biosafety level 2 containment or risk group 1 (K12) handled at biosafety level 1 containment. Include chemical concentrations, catalog numbers, equipment names, model numbers, etc.
- List hazards of chemicals and biological material used in the procedure. Remember- liquid nitrogen, dry ice and compressed gases are hazardous materials.
- List any special emergency equipment needed (i.e., eyewash, spill kit, dry sand/Class D fire extinguisher, HF antidote (calcium gluconate), effective disinfectant (EPA registered disinfectant for work with human derived materials)).
- List waste disposal requirements (chemical, biological waste, sharps containers, etc.).
- Describe any anticipated problems that may occur while performing this procedure, the course of action to be taken, including the job title to consult/report to if problem occurs.

x. The written SOP must be made available to everyone working on the procedure. It can be used to train new researchers on the different protocols used in the lab. It ensures that everyone gets the information they need to conduct science safely.

VIII. List of available hazard specific EHS SOPs

a. COMPRESSED GASES AND CRYOGENICS SOP
b. ETHIDIUM BROMIDE USE AND DISPOSAL
c. LECTURE BOTTLE SAFETY
d. PICRIC ACID SOP
e. PIRANHA SOLUTIONS
f. SAFE SHARPS HANDLING SOP
g. SAFETY AND HEALTH RESOURCES ASSOCIATED WITH ENGINEERED NANOMATERIALS
h. SOLDERING SAFETY GUIDELINES
i. CDC's BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (BMBL) 5TH EDITION

IX. References

OSHA Lab Standard 29 CFR 1910.1450
OSHA PPE Standard 29 CFR 1910.132
Stony Brook University EHS- Hazard Reviews and Safety Protocols
Yale University Office of Enterprise Risk Assessment