UMass Amherst | Environmental Health & Safety

SOP Development Fact Sheet

When Are SOPs Required?

As part of the Laboratory Standard (29 CFR 1910.1450), OSHA requires that standard operating procedures (SOPs) are developed to protect the health and safety of laboratory personnel for all operations involving the use of hazardous chemicals. For OSHA, a hazardous chemical is any material that presents a health hazard based on the GHS (Globally Harmonized System) classification as detailed in the Hazard Communication Standard (29 CFR 1910.1200). Examples of hazardous chemicals are included as an appendix to this document and include any items that have the following pictograms on the container label or safety data sheet (SDS):

In addition to the OSHA requirements, the University's Chemical Hygiene Plan (CHP) requires that SOPs are developed and submitted to the Institutional Chemical Safety Committee (ICSC) for review prior to work with any particularly hazardous materials. Particularly hazardous materials requiring SOPs and vetting with the ICSC include:

- Pyrophoric materials
- Materials of high acute toxicity
- Highly reactive materials
- Other high hazard operations

See the Institutional CHP for specific guidance.

Some items, such as pyrophoric materials, have specific SOPs that have already been developed by the ICSC. If PIs intend to work with pyrophoric materials, simply acknowledging to the ICSC that all work will be done according to the SOP is sufficient. Any work with pyrophoric materials deviating from the SOP should be submitted to the ICSC for review.

The ICSC has also developed more general SOPs for materials such as HF, and other lipophilic fluorinating reagents, and perchloric acid that may be referenced for emergency response procedures, appropriate engineering controls and PPE guidance, and exposure limits. Work with materials covered by general SOPs requires submission of specific procedures to the ICSC for review.

In addition to those items requiring institutional approval (and therefore, certainly PI approval), PIs can also set requirements for what SOPs they must review within their lab prior to the commencement of any experimental work by lab personnel. PIs are responsible for the health and safety of everyone working in their labs, and as such, should establish criteria for what operations require their approval and what the training should be for these processes. PIs are encouraged to document all training provided to laboratory personnel.

What Should Be In An SOP?

Appendix A of the laboratory standard provides guidance on what should be in SOPs. The first step in developing an SOP, and prior to beginning any laboratory work with hazardous chemicals, is to conduct a risk assessment. Risk assessments should be conducted and documented for every experiment that is performed in the lab. Risk assessments can be maintained in laboratory notebooks alongside experimental details, they can be maintained separately, or directly incorporated into formal SOPs. Experimental details, specialized emergency procedures, and specialized disposal and spill response requirements should also be part of an SOP. Usually these latter items can simply be a reference to the University's CHP, which already incorporates general emergency procedures, disposal, and spill response that is presented as part of the EH&S provided laboratory safety training. The template for lab specific CHPs includes a template for SOP development that can be used to directly generate SOPs. Use of this template is not obligatory.

Risk Assessments

The following is an excerpt from the Institutional CHP covering risk assessments.

Risk is the combination of hazards and the probability that those hazards will lead to negative events. Thus, hazards give rise to risk, as do processes which enable the hazard to produce a negative outcome. As such, it is important to recognize all hazards and the processes in which these hazards are used, and mitigate all resulting risks in so far as possible.

Risk assessments are useful tools for uncovering hidden hazards and risks, and should be conducted for all new procedures before the procedure is initiated. Risk assessments seek to identify all hazards associated with a planned procedure, and remove or mitigate the risks created by those hazards, or otherwise change the procedure, to simultaneously accomplish the goals of the experiment, and ensure the health and safety of the researchers performing the experiment. Conducting a risk assessment can be daunting, even for individuals with years of laboratory experience, because there can be many types of hazards, not all of which are immediately obvious. Probabilities of negative outcomes can also be difficult to discern especially for inexperienced lab personnel. There are also many different ways to conduct a risk assessment, and certain approaches are better for some situations than others. Therefore, a prescriptive, "check list" type of approach is not necessarily desirable. The key feature of any good risk assessment is that it uncovers as many sources of potential hazards as possible, thereby effectively eliminating unrecognized hazards. Good risk assessments should also prioritize hazards and risks based on severity and probability of occurrence, and should most definitely eliminate all risks and hazards that are simultaneously high severity and high probability of occurrence. Contingency plans should be in place and communicated to all relevant parties in the event that something does go wrong.

Risk assessments should follow the principles of **RAMP**:

1. ***Recognize*** all hazards.

2. ***Assess*** the risks of those hazards.

3. ***Minimize*** the risks by mitigating hazards.

4. ***Prepare*** for emergencies.

Below is a very broad and general, but by no means all inclusive, series of questions that one might use to apply RAMP to a particular process.

1. **What is the goal of the experiment you wish to perform?** This is important to keep in mind as you go through the process of assigning hazards and assessing risk. Obviously, any modifications made to a procedure will still have to achieve the goals of the experiment.

2. **Identify all equipment, chemicals, biological organisms and other materials associated with the planned procedure.** A list might be helpful.

3. **Attempt to identify any hazards associated with the use of any of the items on the list, or the circumstances of the procedure.** This is the difficult part where things can be overlooked. It is a good idea to have multiple people review this area, particularly the PI and more experienced lab personnel. Their laboratory experience will enable them to recognize potential hazards that less experienced researchers might not be aware of. Here are some questions that might be helpful to guide you through this process.

a. **What apparatus is to be used, and what are the hazards?** For example, glassware containing a vacuum or higher than atmospheric pressure could implode or explode, respectively. Electronic instrumentation might present an electrical hazard if it is dismantled while plugged in or without discharging capacitors. Hoses can pop off of reflux condensers due to changes in water pressure or unsecure connections.

b. **What chemicals are to be used?** Look at the SDSs for these materials.

What are the health hazards of the material (*e.g.,* toxic, carcinogen, corrosive, etc.) and what are its routes of entry (*e.g.,* inhalation, skin absorption, etc.)?

What are the exposure limits to the materials?

What are the symptoms of exposure to the material (*e.g.,* noticeable odor, headaches or nausea)?

Are any of the chemicals highly reactive (*e.g.,* pyrophorics, shock sensitive materials, oxidizers, water-reactives, strongly incompatible with other materials, etc.)?

Do the materials degrade in storage to form something more hazardous (*e.g.,* peroxide forming materials, etc.)?

c. **What biological organisms are to be used?**

Are any of the organisms considered to be infectious or transgenic?

What are the potential routes of exposure?

d. **Are radioactive materials involved?**

e. **Are sharps used?**

f. **Is there a potential for exposure to harmful levels of electromagnetic radiation (*e.g.,* lasers, flash lamps, etc.)?**

g. **Are there temperature extremes involved (*e.g.,* cryogenics or heat)?**

h. **Are there synergistic hazards, *i.e.*, hazards resulting from the presence and interaction of two or more items?**

For example, is there a potential to form any highly reactive or otherwise hazardous byproducts during a reaction?

4. **What is the level of severity of each hazard, and the probability that it will create a problem within the given procedure?** Any items which create a risk that is high severity and high probability of occurrence must be removed or mitigated in the next step. Ideally, we would like all risk to be low severity and low probability of occurrence.

5. **Plan to remove or mitigate the hazards using substitutions of less hazardous items and procedures, engineering controls, administrative controls and personal protective equipment.** The list should always be applied in the order above with substitutions of less hazardous items or practices being tried first and personal protective equipment being the last line of defense against hazards. These items are discussed in more detail in the CHP. It will not always be possible to use all four options, but it is frequently possible to use more than one option to remove or reduce risk. Substitution might include changing the solvent of a reaction (e.g., using water instead of a toxic organic solvent.) Engineering controls eliminate or greatly reduce the hazard through use of mechanical equipment or other technologies. An example is the chemical fume hood or biological safety cabinet. Administrative controls reduce individual exposure to hazards by limiting individual contact with the hazard through work practices. Examples include many general and standard operating procedures, like keeping the lab tidy to minimize hazards, not recapping needles prior to disposal and not eating or drinking in the lab. Use of personal protective equipment (PPE), like goggles, gloves and lab coats, is the last line of defense, and is generally used in conjunction with other methods. In all cases where regulatory exposure thresholds (e.g., PELs, TLVs, STELs, RELs etc.) exist for given materials, these must be observed.

6. **Ensure that your modified procedure still meets the goals of your experiment and eliminates all high risk, high probability situations.** For example, if you have changed materials or equipment, ensure

that the new materials and equipment do not create new, unrecognized hazards. You should also have plans in place for emergencies, such as equipment failure, loss of power or a chemical spill.

The above are general principles to be used for risk assessments. More structured approaches are available. See for example the extensive materials available from the American Chemical Society: https://www.acs.org/content/acs/en/about/governance/committees/chemicalsafety/hazard-assessment/fundamentals/risk-assessment.html (and links therein).

Experimental Details

To perform an adequate risk assessment, the details of the experimental procedure must be known and considered as part of the process of doing the risk assessment. Details of experimental setups and procedures are also included in laboratory notebooks as part of the research process for documentation of work suitable for publication. As this documentation is so fundamental to the research process, it is expected that incorporation of this documentation into SOPs should be seamless. **Thus, for most daily experiments in the laboratory which do not require specialized emergency or spill response or specialized disposal of hazardous materials, the procedure that would typically be detailed in the laboratory notebook coupled with the risk assessment would serve as the SOP for that process.**

Many experiments involve repeated, standard processes that are employed in various sequences for particular experiments. For example, a reaction may require refluxing, followed by a work-up consisting of a liquid-liquid extraction, drying the organic layer over a drying agent, gravity filtering to remove the drying agent, and rotovapping. A different reaction may require refluxing, followed by a work-up consisting of rotovapping, recrystallization, and vacuum filtering. These two experiments involve different procedures, however, each procedure used in each of the two experiments is a standard synthetic technique that is described in detail in most undergraduate level organic chemistry laboratory text books. Therefore, it would be entirely appropriate to describe the experiment as above in the SOP, with quantities and identities of materials, coupled with a risk assessment indicating the hazards, exposure limits and exposure symptoms of the materials used, appropriate engineering controls, precautionary statements for any particular step that might warrant it, and PPE required. Additionally, the PI should ensure that descriptions of these standard techniques are available to all lab personnel, and that lab personnel are trained (or otherwise familiar from prior training) with how to perform these techniques. Documenting this training is recommended.

Procedures for Emergencies, Disposal, and Spill Control

Most experiments that do not involve the use of highly hazardous materials and processes will not require specialized emergency response, disposal, or spill control. In most cases, simply referencing the general procedures that already exist in the Institutional CHP is sufficient. There may be certain items, such as with the use of piranha or aqua regia, where disposal in a container with a pressure venting lid and separate from other materials is necessary, or for items such as elemental mercury where the presence in the lab of a spill containment kit is desirable. Materials requiring specialized exposure response (e.g., HF) typically have institutional level SOPs.

We hope that this document provides clear guidance on SOP preparation and content. Should you have any questions, please do not hesitate to contact EH&S, specifically the Chemical Hygiene Officer (Dr. Kristi Ohr, kohr@ehs.umass.edu), for additional clarification.

Appendix: Examples of Chemicals Classified As a Health Hazard Or Simple Asphyxiant By OSHA

- Acids and Bases (Hydrochloric, Acetic, Sulfuric, Nitric Acids; Sodium, Potassium, Ammonium Hydroxides)
- Acrylamide
- Ammonium persulfate
- Beta-mercaptoethanol
- CHAPS
- Compressed gases, including: nitrogen, helium, argon
- DTT
- EDTA
- Ethanol
- Ethidium bromide
- Imidazole
- Isopropanol
- Kanamycin sulfate
- Phenol
- SDS
- Sodium azide (including dilute solutions)
- Sodium carbonate
- Sodium fluoride
- Sodium phosphate (Na_3PO_4)
- Solvents, including:
  - acetone
  - acetonitrile
  - benzene
  - carbon tetrachloride
  - chloroform
  - cyclohexane
  - dichloromethane
  - DMF
  - ether
  - ethyl acetate
  - hexanes
  - methanol
  - p-dioxane
  - pentane
  - petroleum ether
  - THF
  - toluene
  - xylenes
- TEMED
- Triton-X