Risk Assessment Recipe

From: Yale EHS Biosafety Office

Ingredients (THE 6 P’s of Risk Assessment & Risk Management):

(Risk Assessment)

- PATHOGEN review
- Review of all proposed PROCEDURES with the biohazard
- PERSONNEL evaluation

(Risk Management)

- Formulation of work PRACTICES to mitigate identified risks
- Selection of PROTECTIVE EQUIPMENT to place barriers between staff and the biohazard
- Utilization of a PLACE or lab that is suitable for the proposed research

Directions:

Step 1:

Pathogen (Gather ALL information on the biohazard or agent)

- Download the Pathogen Safety Data Sheet (Google “Pathogen Safety Data Sheet.”)
- Obtain the Agent Summary Statement from the CDC/NIH BMBL if available.
- Understand the signs and symptoms of infection.
- Learn preventive therapies (immunizations and post-exposure treatment.)
• Know all clinical syndromes that can be caused by the agent.
• Identify what medical conditions may make a person more susceptible or at higher risk of infection or serious disease.
• Let staff know to seek counsel from Employee Health prior to starting work with biohazards for a private consult regarding their health status.
• Identify the incubation period, the infectious dose, the starting Risk Group.
• Google laboratory-acquired infections with the proposed biohazard and identify how it was transmitted if known.
• Learn how the biohazard is transmitted in nature and in a lab setting.
• Understand how it may be transmitted in the lab.
• Review unnatural exposure routes with staff, including aerosol deposition to lower lung, aerosol contamination of mucous membranes, aerosol contamination of surfaces, hand to face (eyes, nose & mouth) transfer of pathogens, eye to nasal cavity to back of throat to gut transmission.
• Find out how long the biohazard can survive on surfaces or the environment.
• List the disinfectants that are effective at inactivating the biohazard and identify the concentration of the disinfectant and contact time required for kill.
• Highlight pertinent Risk Assessment information and share with your staff (list at start of site-specific standard operating procedures).
• Post unique risk information on the lab door biohazard sign to ensure all visitors are informed of potential risks.

Step 2:
Procedures (review all proposed procedures with the biohazard or agent)
• Identify and list all the procedures, equipment and supplies that will be used in your research or lab protocol.
• Ensure that every step is included, from removal of the biohazard from the freezer, transport to work areas, all protocol steps, through decontamination and disinfection and/or return to frozen storage.

• Identify any steps performed outside your lab, such as in core facilities (i.e. specialized microscopy, flow cytometry) and any shared equipment locations.

• Once all of the steps, supplies and equipment have been documented and written down, identify all of the risks and potential exposures that could possibly occur during the course of the work (splashes, splatter, spills, aerosols, cuts, lacerations, punctures, bites, scratches, etc.).
  o Pay particular attention to punctures from contaminated sharps (if not working with animals – eliminate sharps and use plastic alternatives!)
  o Any step with a liquid can generate splash or splatter that could contact facial mucous membranes, skin, or personal clothing and contact surrounding work areas.
  o Procedures that impart energy to a culture (basically all of them) from pipetting to vortexing to centrifugation and highlight these steps that may produce aerosols.

• For animal experiments consider the use of sharps for inoculation, bites and scratches from the animal, exposure to contaminated bedding from excretion of the biohazard.

• Identify the potential for spills (dropped flasks, broken flasks in shakers, leaks in centrifuges, etc.).

• Write down all the steps and risks identified and detail the potential for exposure (this is your required written site-specific risk assessment!).

**PAUSE:** ask your Biosafety Officer or assigned safety representative to review your risk assessment at this point. Also ask your IACUC, IBC or IRB rep where applicable to review. Your Biosafety Officer will confirm your Risk Assessment and help identify any procedures with potential risk that may have been missed. Update your written risk assessment after this review.
Step 3:
Personnel Evaluation (review who will be handling biohazards)

- Do all staff have prior experience working with this biohazard or very similar biohazards? If not, an internship to gain hands-on experience with the agent can be arranged with another lab or within your lab.
- Have all staff completed all required Biosafety and other applicable laboratory safety trainings prior to initiating work?
- Do staff have a positive safety attitude and a healthy amount of respect for the risks involved with the proposed biohazard?
- Have the proposed staff exhibited a strong safety record in the lab?
- Are all staff informed of the risks presented by this work and the proposed procedures?
  - Are any staff at greater risk due to their health status?
    - Have they met with and been cleared by Employee Health?
      - This discussion of likely elevated risks and review of proposed participation is critical.
  - Do any staff have contraindications with any of the pre- or post-exposure treatment options?
    - Has a suitable treatment been identified for them if they are?
- Have you documented the proficiency of the staff with the lab protocols and the associated biocontainment practices required to mitigate risks?

NOTE: This is a basic recipe for Risk Assessment, the main course, but is not inclusive of every potential ingredient. You can spice this recipe up by addition other elements to your site-specific risk assessment recipe as appropriate.
Every good main course requires a perfect marriage of sides and a finishing dessert course. For Risk Assessment, the corresponding dish is Risk Management or the selection of biocontainment procedures to safely handle the biohazard. Invariably, your biosafety training will cover a lot of Risk Management. Risk Management includes the Biosafety Work **PRACTICES** that will help to reduce or minimize the opportunity for exposure in the lab. This includes the elimination of sharps for lab procedures by the substitution with plastic alternatives.

The identification of **PROTECTIVE EQUIPMENT** which is a combination of:

the personal protective clothing (lab coats or gowns, gloves – double gloves for higher risk work, face protection – chin length face shield, safety glasses or goggles and a mask)

**AND**

All engineering controls such as a biological safety cabinet, bench shields, sharps containers, vacuum system filters, biomedical waste containers, etc. that will be used to place a barrier between the biohazard and the staff.

The final element of Risk Management is to review all of the **PLACES** (lab spaces) where this research will be conducted. Verify that all air flows into these laboratories and not the opposite, that all surfaces are easily cleanable, and benches are resistant to the disinfectants and other chemicals that will be used. Examine the impact of foot traffic in these locations and select times where this will be at a minimum when scheduling the times biohazards will be used there.

Once again, after you’ve detailed your written risk assessment and have crafted biocontainment standard operating procedures (SOP) for the proposed research or work, please contact your Biosafety Officer or
assigned safety representative to schedule a walk-through laboratory inspection to verify the suitability of the protective measures and the appropriateness of the proposed lab locations. The Biosafety Officer’s report will be required by the Institutional Biosafety Committee prior to their final review and approval of your protocol to use a biohazard or regulated biological material.

ALTHOUGH YOU MAY NEVER ACTUALLY EAT, DRINK, SMOKE OR APPLY COSMETICS, ETC. IN THE LABORATORY:

**BON APPETIT**

*(BON SOP)*