ISO/CWA Analysis Mapping Question Sets

1. What are the policies that govern biorisk management at the institute? (5.2)
   * Gather any documents or links or connections to biosafety/biosecurity specific policies. If no specific or separate biosafety/biosecurity policy, then perhaps the policy is embedded in or describe in general EHS policies.
   * Policies
   * Evidence (supporting documents, links, connections, etc.)
2. What are the boundaries, scope, applicability of the BRM system (may be part of the policy, part of the IBC charter, etc.)? (4.1, 4.2, 4.3)

* Gather or note where this is documented.
* Context/Boundaries/Scope
* Interested Parties (external and internal)
* Evidence (supporting documents, links, connections, etc.)

1. How is the BRM system are established, documented, implemented, communicated, maintained, and continually improved? (4.4)

* Established
* Documented
* Implemented
* Communicated
* Maintained
* Continually Improved

1. What are all the ways that the institute does risk assessments (both biosafety and biosecurity)?

* Gather any policies, documents, SOPs, written descriptions, etc.
* Include a summary of the timing and scope of the various risk assessment processes: when are they done, how often, who, and the scope. (6.1, 6.2)
* Risk Assessment Policies/Processes
* Timing and Scope (When, How, Who)

1. How are hazards identified, documented, mitigated/addressed, and effectiveness of controls? (6.1.1.)

* Hazard Identifications and Documentation (6.1.2)
* Hazard mitigation (6.1.3)
* Evaluations of effectiveness of controls (6.1.4)

1. Define, outline, provide references and documentation, etc. the roles and responsibilities related to Biorisk Management at The institute for the following tiers:

* Top Management
* Senior Management
* Institutional Biosafety Committee members and Chair
* Biosafety Officers (Biorisk Management Advisors) including EHS coordinators and other safety advisors.
* Principal Investigators (Scientific Management)

1. What are the biorisk management objectives at SNL? (Think similar to the ESHIP, EMS objectives)

* How is it:
  + Related to biorisk management policy;
  + measured;
  + take into account applicable requirements;
  + monitored;
  + communicated;
  + updated as appropriate.
* How are biorisk management objectives documented and carried out (planning)?

1. Define, outline, provide references and documentation, etc. that related to the The institute Medical program in regard to biosafety/biorisk and the vaccination program. (Who, what, how, when)
2. Define, outline, provide references and documentation, etc. how MOWs are deemed competent before they start performing ALW.
   * Items to consider:
     + How do we determine what type of training MOWs should receive?
     + Is there OJT?
     + How is it determined that they are competent to perform a certain task?
     + How do we prevent non-competent workers from performing tasks that they shouldn’t be?
     + How do we review/reevaluate tasks performed by MOWs?
     + How is it determined that MOWs duty and adequately qualified and trustworthy to execute their job responsibilities?
3. How are MOWs aware of the:
   * the biorisk management policy;
   * updates to the biorisk management plan;
   * the outcomes of investigations of relevant incidents and accidents;
   * the effectiveness of the biorisk management system,
   * the implications of not conforming with the biorisk management system requirements;
   * the legal requirements that govern biorisk management.
4. How does The institute identified, established, and maintained training?
   * Consider:
     + How do we identify of biorisk training needs?
     + What the requirements for biorisk training in relation to the biorisk management plans?
     + How is effectiveness of biorisk training determined?
     + What is the frequency of refresher biorisk training?
     + How do we assess to ensure that workers are competent to perform assigned tasks?
     + How are biorisk training records maintained?
5. Define, outline, provide references and documentation, etc. that related to the The institute Medical program in regard to biosafety/biorisk and the vaccination program. (Who, what, how, when)
6. How are documents
   * Created and updated?
   * Controlled?
     + Distribution
     + Storage
     + Control of changes
     + Retention and disposition
   * Secured?
     + Are there review processes?
7. How are visitors, suppliers, and other non-employee personnel made aware/communicated biorisk policies and procedures
8. How are employees made aware of priority threats and vulnerabilities from biorisk assessment?
9. Are acquisition of products and services from suppliers are evaluated to ensure conformance to specified requirements depending on their potential impact on the biorisk management system?
10. How do we track incidents, nonconformity and corrective actions?

* What’s the process?
  + Is there another processes besides the standard fact finding and RCAs?
* How is it documented? (Occurrence Reporting…anything else unique?)
* How do we track corrective actions? (SAGE…anything else unique?)

1. How do we strive for continual improvement? Are there any processes or initiatives? How do we promote continual improvement?
2. What policies, processes. and procedures ensure that facilities, equipment, and processes are designed, operated, and maintained in a safe and secure way with respect to biorisk management?

* Think about:
  + New or modifications to lab spaces
  + How are requirements of the lab designed communicated to facilities/construction team?
  + How do we approve overall plans?
  + How do we validate that everything went according to plan?
* What is the documentation on commissioning and decommissioning of lab spaces?

1. What procedures are in place to ensure maintenance, control, calibration, certification, and validation of equipment?

* How are the following performed on equipment?
  + maintenance,
  + control,
  + calibration,
  + certification, and
  + validation?
* How and where are the records kept?

1. What are the ways that we control the physical security of biological materials?

* What are the procedures for maintenance of these systems?

1. What are the methods of an maintaining accurate, verifiable, and up-to-date inventory, or itemized record, of biological materials with biological agents and toxins?

* What systems is being used?
* What is the frequency of reviewing inventory?

1. How are workers trained on good microbiological technique?

* What methods are used to be trained? Consider:
  + centrifugation;
  + control of needles and sharps;
  + correct use of vacuum pumps;
  + culture, purification and storage techniques;
  + minimization / containment of aerosols;
  + pipetting;
  + sonication and other mechanical forms of cell / tissue disruption;
  + use of biological safety cabinets;
  + use of disinfectants, including spill control, routine decontamination, hand washing and showering; and
  + properly manage biowaste generated

1. What are the methods to determine the proper PPE to wear?

* How are PPE maintained?
* What are the frequencies of cleaning and decontamination of applicable PPE?
* Are there any training for PPE trainings for MOWs?

1. What are the methods of disposing and decontaminating waste?

* What are those waste streams?
* What are the methods of decontamination? How do we validate if items have been decontaminated? What are those procedures?

1. What are emergency response and contingency plans?

* How does it incorporate:
  + Emergency scenarios
  + Emergency plan training
  + Emergency exercises and drills
  + Contingency plans

1. What are the procedures for transporting biological materials?

* Consider:
  + Between labs
  + Receiving biological materials at The institute
  + Sending biological materials to external parties outside of The institute

1. What metrics used to analyze the performance of the BRM? How often does this analysis occur?
   * Examples can be:
     + identification of matrices appropriate for biorisk management, e.g. data from performance measurements from staff, equipment and training;
     + results of the risk assessment analysis and controls;
     + results of walk-through inspections and audits, both internal and external;
     + reported accidents, injuries and near misses and the actions taken to prevent reoccurrence;
     + quality control, performance results and calibration of the equipment (e.g. safety and security equipment and systems testing);
     + environmental sampling;
     + results of security and emergency response exercises;
     + analysis of documentation and records (e.g. review of biological material inventories);
     + employee surveys;
     + unanticipated events which were not considered during the risk assessment, e.g. failure of equipment previously unknown or events in similar facilities; and
     + response to non-conformances resulting from an inspection or a biorisk management system audit or job hazard assessments.
2. What internal audits that are conducted regarding BRM? Does internal audit group audit biosafety/biosecurity/biorisk? What are the repositories for audit documentation?
3. Is management review of BRM conducted with Top Management?
   * How often does management review take place?
   * What information is presented during management review?
   * How is the management review documented/recorded?