BIOSAFETY PROGRAM
EVALUATION OF PERFORMANCE RISK AND COMPLIANCE GRADE

GOAL

The university's biosafety research activity tends to be categorized as low risk. While the risk is low, it still is important to monitor compliance. To do so a graduated grading format was adopted and allows for more effective monitoring, reporting and trending.

The goal is to be able to identify best practices, areas in need of improvement, and those areas that would benefit from additional support in terms of training, procedures, and monitoring.

PERFORMANCE RISK

Performance risk is used to describe the overall evaluation of how well a laboratory is performing and if there is a risk of exposure, release or failure to achieve compliance. It is based on both objective and subjective findings. The primary goal is to ensure that all impacted parties are aware of any concerns being identified by the Biosafety Professionals within the Office of Risk Management. As there is a subjective component; it requires a discussion between the parties of any difference of assessment.

Higher the risk rating require reporting to accountable parties (i.e., appropriate Deans, Directors, and Committees) to ensure the appropriate action is taken and to support of the University of Ottawa's Accountability (Governance) Framework.

This reporting format is applied to both an individual inspections and overall performance factoring in past assessments.

- High Risk
    - Level of compliance is unacceptable.
    - Conditions place the University's Regulatory Human Pathogen and Toxin Licences at risk, or
    - Immediate health, safety or security at risk exists.
    - In addition to the responsible party, the Dean/Director and Biosafety Committee are informed (their direct involvement may be required to resolve the issues).
- Medium
    - Level of compliance is a concern if not resolved or potential for a health, safety or security risk exists.
    - In addition to the responsible party, the Dean/Director and Biosafety Committee are informed (their direct involvement is not required to resolve the issue).
- Low
    - Level of compliance either meets requirements or deficiencies are minor, or potential for a health, safety or security risk is negligible or minimal.
    - Only individual party is informed.

When assessing overall performance, a number of mitigating factors should be considered:

- the degree and the duration of on-going non-compliance,
- if the performance is traceable to systemic vs random events
- in-lab management process anticipate personnel changes to ensure compliance

COMPLIANCE GRADE

In response to consistently low risk ratings, it was necessary to develop a more meaningful way to track, trend and evaluate performance. To ensure alignment with federal expectations the CNSC model system was adapted to be used for biosafety assessments. The general description and grading was applied. To help in the assessment and trend key evaluation areas were set with general descriptions of the type of indicators to be applied.

Grade Summary

A – Exceeds Requirements

B – Meets Requirements

C – Below Requirements

D – Significantly Below Requirements

E – Unacceptable Level Of Non-compliance

Evaluation Topics

1. Responsibility and Accountability
2. Physical Containment
3. Operational Practices
4. Decontamination and Waste Management
5. Comprehension and Risk Assessment
6. Inventory and Security

Grade	A – Exceeds Requirements
Grade Description	Assessment topics or programs meet and consistently exceed applicable regulatory requirements and performance expectations. Performance is stable or improving. Any problems or issues that arise are promptly addressed, such that they do no pose an unreasonable risk to the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed.
Responsibility and Accountability	Seeks out information with regards to proposed work in a fashion to allow all issues to be addressed in a timely fashion. Has implemented a clear accountability and responsibility procedures, to avoid gaps in information transfer and mitigating the risk of the "someone else's responsibility" syndrome. Has a biosafety program for which all requirements are established as to be able to continue in the absence or turnover of staff.
Physical Containment	The laboratory/ies meet the appropriate containment standards, and maintenance schedule has been implemented. Should deficiencies be noted they are immediately reported to the appropriate faculty/service group. A system is put in place to ensure that the service request is followed up and repairs are met in a timely fashion. Life cycle management of equipment and anticipated replacement timelines are in place. In ability to obtain the necessary services are reported to both the faculty/service and ORM.
Operational Practices	The difference and application of Universal Precaution and Good Microbiological Practices are well understood and implemented. A documented risk assessment and risk mitigation strategies are well understood and implemented. Standard operating procedures have been developed and are in use. These are reviewed, and updated yearly and each individual has signed they have read and understood these.
Decontamination and Waste Management	The rationale behind the decontamination selection is based on the characteristics of the pathogen and the biological waste. Changes in the waste are monitored and the waste management process is modified accordingly. These are communicated to staff and students who can explain them when questioned.
Comprehension and Risk Assessment	Each individual has undertaken a risk assessment for their work or has assessed if the existing lab specific risk assessment is applicable. The knowledge of biosafety principles and good microbiological practices is understood and application of these can be demonstrated. Knowledge of the Canadian Biosafety Standards and other pertinent regulations as they apply to the laboratory is good.

Inventory and Security	Records are maintained and inventory is secure, in a fashion that demonstrates chain of custody, and life cycle management. The labelling of all samples is such that samples are traceable to experiments, all unnecessary samples are disposed. Records are kept and available to be inspected. Proactively informs ORM of any anticipated material transfer. Cradle to grave tracking is demonstrated.

Grade	B – Meets Requirements
Grade Description	Assessment topics or programs meet the intent or objectives of regulatory requirements and performance expectations. There is only minor deviation from requirements or the expectations for the design and/or execution of the programs, but these deviations do not represent an unreasonable risk to the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed. That is, there is some slippage with respect to the requirements and expectations for program design and execution. However, those issues are considered to pose a low risk to the achievement of regulatory performance requirements and expectations.
Responsibility and Accountability	Provides the necessary oversight of the facilities. Ensures best practices, adherence to uO and regulatory requirements. When informed of any concern acts promptly to address these within the timelines, and informs key stakeholders (lab staff, dept. and Faculty support personnel). Ensures practices incorporate the necessary action into the SOP.
Physical Containment	Meet containment requirements set out by regulatory bodies (CFIA, PHAC) for human, animal, aquatic, avian, plant pathogens and pest. Equipment is maintained and verified. Deficiencies are reported for repair, and should the remedy not be for with coming informs ORM of the deficiency (for additional action).
Operational Practices	Standard practices in the facilities adhere to GMP. UO guidelines, procedures and "CHEAT Sheet" are available and followed (i.e., waste, autoclave, spill, lentivirus ...). Operational requirements are implemented according to Risk Group and Containment Level.
Decontamination and Waste Management	Waste managed in such a fashion to prevent inadvertent release, further contamination, and exposure. Decontamination process is appropriate and the Waste Management SOP are known and complied with. ORM is consulted when requirements are not clear to the users.

Comprehension and Risk Assessment	Is aware of the University and regulatory requirements as they pertain to lab practices. Is knowledgeable of the characteristics of the martial used (PSDS, supplier data); and can demonstrate how their work practices are linked to GMP and risk.
Inventory and Security	Records are maintained and are inventory is secure. The labelling of all samples is such that samples are traceable to experiments, all unnecessary samples are disposed. Material Transfer agreements or conditions are t centrally available for all parties to reference. Storage areas are regularly reviewed to assess the potential for unauthorized use, transfer of disposal of material.

Grade	**C – Below Requirements**
Grade Description	Performance deteriorates and falls below expectations, or assessment topics or programs deviate from the intent or objectives of UO BSP requirements, to the extent that there is a moderate risk that the programs will ultimately fail to achieve expectations for the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed. Although the risk of failing to meet regulatory requirements in the short term remains low, improvements in performance or programs are required to address identified weaknesses. The licensee or applicant has taken, or is taking appropriate action.
Responsibility and Accountability	While the Supervisor has been informed of issues of risk and non-compliance, there is a reluctance and a delay in taking the necessary steps. Multiple reminders are required. No evidence of changes to lab practices to ensure that the issue does not reoccur when staff turnover occurs. Certificate requires minor amendments.
Physical Containment	Although no major issues of non-compliance to standards exist, medium and low risk issues are not addressed or followed up. Aging infrastructure is not being addressed I.e. no action taken to fix damaged countertops, reseal floor (wash/wax, re-glue tiles). Shared equipment is not managed in a comprehensive fashion.
Operational Practices	Most operational practices meet portions of the BSP, the culture or practice in the facilities is not to adhered to corporate standards (BSP) when personal belief contradict the standard . No risk assessment exist.
Decontamination and Waste Management	Waste management processes may at time not meet the standards; decontamination process selection is based on the common practice in the department, rather than knowledge of if being appropriate and validated. UO SOP on Waste management no used.

Comprehension and Risk Assessment	General knowledge levels are good, but the specific operational rational can not be provided. A reliance on one key knowledgeable person in the lab represents a risk - should that person leave. In addition, this person may not have the authority over other members in the lab to ensure compliance.
Inventory and Security	Inventory records are maintained in multiple laboratory books. There is no consistency in labelling potentially hindering the inventory identification. Samples no longer required are not disposed of. Material Transfer agreements or conditions are not centrally available for all parties to reference. Breaches in inventory would be identified but only after a significant lapse of time.

Grade	**D – Significantly Below Requirements**
Grade Description	Assessment topics or programs are significantly below requirements, or there is evidence of continued poor performance, to the extent that whole programs are undermined. This area is compromised. Without corrective action, there is a high probability that the deficiencies will lead to an unreasonable risk to the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed. Issues are not being addressed effectively by the licensee or applicant. The licensee or applicant has neither taken appropriate compensating measures nor provided an alternative plan of action.
Responsibility and Accountability	There is a refusal to implement the necessary actions to be compliant to the UO Program or Regulations. Redirects all follow-up to the laboratory delegate. No evidence of internal communication of compliance related issues exist.
Physical Containment	Aging or damaged infrastructure exist and has not been addressed. Equipment maintenance practices inadequate and those which fail to meet validation are continued to be used.
Operational Practices	GMP and lab practices are not in evidence, material handled in such a fashion the risk of exposure or contamination exists. No evidence of internal accountability related to operation practices exist.
Decontamination and Waste Management	Selection criteria for decontamination process is incorrect, non-validated or expired products continue to be used. Waste inappropriate managed during generation and prior to disposal or decontamination: representing a significant risk of exposure and/or contamination.

Comprehension and Risk Assessment	Individuals are not registered as authorized users and do not have uO Biosafety Training and are not operating under interim training requirements. Lab users are unaware of the UO BSP and can not demonstrate significant knowledge of the risk factors associated with their material and experimental procedures.
Inventory and Security	No central inventory record system exists, or is adequate to demonstrate control and management of the inventory. No cross referencing capacity of inventory to records is possible. Security breaches would not be able to be identified.

Grade	**E – Unacceptable Level Of Non-compliance**
Grade Description	Evidence of an absence, total inadequacy, breakdown, or loss of control of an assessment topic or program. There is a very high probability of an unreasonable risk to maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agree. An appropriate regulatory response, such as an order or restrictive licencing action has been or is being implemented to rectify the situation.
Responsibility and Accountability	There is no adherence to the UO BSP. Certification and training is not in place. The potential to jeopardize UO compliance, HPTA Licence, good standing with Regulators exists.
Physical Containment	Laboratory no longer meets the regulated standards. No reporting or follow-up of reported deficiencies and service request exists. Containment is not appropriate for the material in use and operational practices.
Operational Practices	Operational practices do not reflect the standards set by the UO, the regulators or internationals standards. Exposure risk high, contamination and inadvertent release likely.
Decontamination and Waste Management	Containment of waste is not evident; the decontamination process is inadequate to the characteristics of the waste and pathogen.

Comprehension and Risk Assessment	Lack of understanding of the characteristic of the material. Users did not attend training and in-lab training was inadequate. Unable to identify the risk or characteristics of the material being used. No knowledge of the UO standard operation practices and biosafety program.
Inventory and Security	Inventory records not available. Possession and/or transfer of unauthorized regulated materials.