REPURPOSING THE OVERARCHING RISK ASSESSMENT

CANADIAN BIOSAFETY SYMPOSIUM 2019

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IT ALL STARTED WITH AN INNOCENT QUESTION:

Can the Overarching Risk Assessment (OAR) be used to:

- to determine the underlying strength and weakness of the program,
- identify gaps and risks,
- prioritize and develop action plans, and
- aid in knowledge transfer and business continuity?

Choosing a standardize process and reporting format can:

1. facilitates on going reporting,

2. demonstrating to senior management the complexity and value added by the Biosafety Program, and

3. illustrate the need for additional resources (personnel, time, financial) and partnerships/3rd party accountabilities.

HOW DO YOU SEE YOUR BIOSAFETY PROGRAM ?

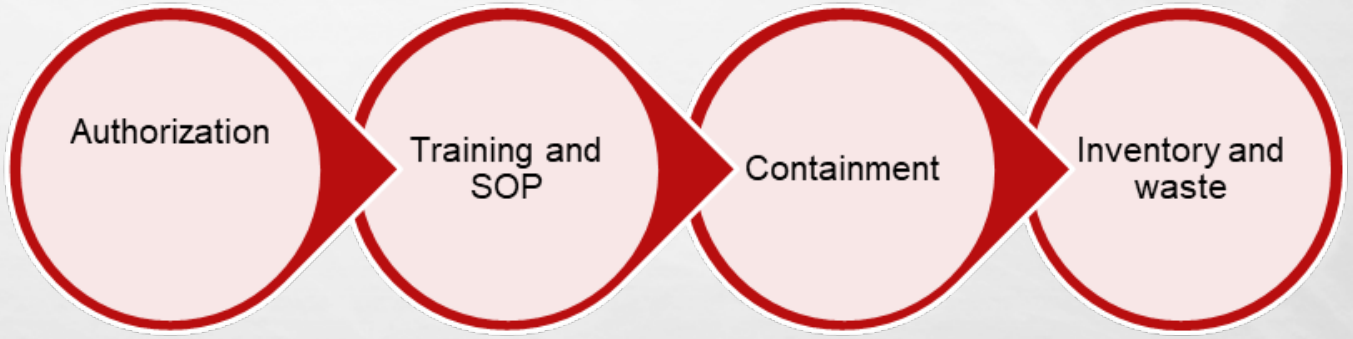
IT MAY DEPEND ON:

- How Long Your Program Has Been Established,
- The Size Of Your Program,
- The Level Of Experience
- Infra Structure Support

A Collection Of Activities

- In House Approval (Certificate Authorizing Use)
- User Forms
- Training
- Inventory
- Waste
- Biological Safety Cabinets

A SERIES OF ACTIVITIES



AN INTEGRATED PROGRAM

IF THIS …..THAN THAT !

WHILE THE PROGRAM ELEMENTS DO NOT CHANGE, THERE IS A BETTER UNDERSTANDING OF THE RELATIONSHIPS TO BE CONSIDERED.

“How can I issue a certificate if:

- *I don’t verify their BSC is certified,*
- *they have the correct waste procedure,*
- *training and sops?”*

OVERARCHING RISK ASSESSMENT

“A broad risk assessment that supports the biosafety program as a whole and may encompass multiple containment zones within an institution or organization. Mitigation and management strategies reflect the type of biosafety program needed to protect personnel from exposure and to prevent the release of pathogens and toxins.”

PUBLIC HEALTH AGENCY OF CANADA - CANADIAN BIOSAFETY STANDARDS, VERSION 2

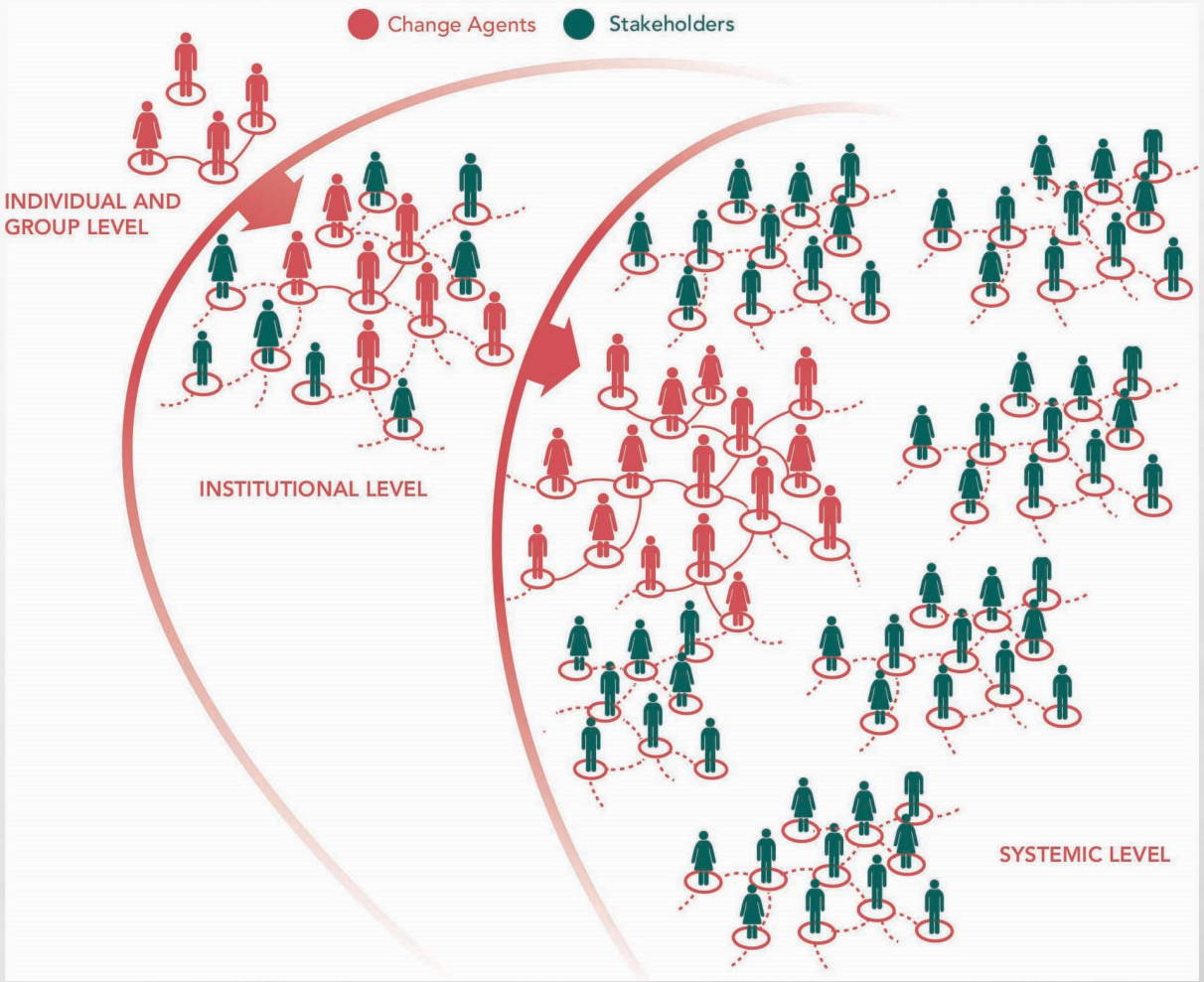
AUDIT APPROACH

SHOW ME THE PROOF

KNOWLEDGE TRANSFER

BUSINESS CONTINUITY

Build on the success of others



HOW TO REPORT THE FINDINGS

It depends on:

- your goal,
- use of data
- who receives the information, and
- what actions are to be taken

Report Approach	Pros	Cons
Yes – No	Clear and concise	Does not allow for influencing factors, existing bias to say Yes
Pass – Fail	Clear and concise Academically Sensitive	Does not allow for influencing factors, Existing bias to say Pass
Exceeds, Meets, Below, Significantly Below	Accommodates factors, aids in prioritizing risk	Will need to prescribe what criteria must be met to assign a grade
A, B,C,D, E	Appropriate to an academic setting, heighten sensitivity	Need to prescribe criteria, open to debate between the grade assigned

OVERARCHING RISK ASSESSMENT (OAR)

GOAL

1. Identify gaps and risk
2. Prioritize these and develop action plans
3. Develop a template and standard for future OAR.

SCOPE

1. BIOSAFETY PROGRAM
2. IDENTIFICATION AND RISK ASSESSMENT
3. CONTAINMENT ZONES
4. MITIGATION STRATEGIES
5. COMMUNICATIONS

HOW TO REPORT THE FINDINGS

What is good for the goose is good for the gander….

Using the same performance evaluation reporting matrix applied to the research community.

ADVANTAGES ARE:

1. In an academic environment an A-E grading system, has **inherent traction**
2. Demonstration equality and consistency in evaluating compliance when applied to the PI and the program
3. Avoids yes and no answers and the inherent pressure to say yes

A tool to help identify best practices, and areas require additional resources (time, personnel, funding).

You can not fix what you don't identify, communicate, or are not allocated the right resources.

- A – EXCEEDS REQUIREMENTS
- B – MEETS REQUIREMENTS
- C – BELOW REQUIREMENTS
- D – SIGNIFICANTLY BELOW REQUIREMENTS
- E – UNACCEPTABLE LEVEL OF NON-COMPLIANCE

A consistent set of criteria must be applied in order to for trend analysis to be relevant .

- ✓ Open and Transparent
- ✓ Applying regulatory standards to an in-house assessment process.
- ✓ To assess the BIOSAFETY PROGRAM, you need to now what differentiates an A from a B.

A - Exceeds Requirements

- programs meet and consistently exceed
- any problems or issues that arise are promptly addressed
- do not pose an unreasonable risk

B – Meets Requirements

- meet the intent or objectives of regulatory requirements and performance expectations.
- only minor deviation from requirements
- deviations do not represent an unreasonable risk
- some slippage
- those issues are considered to pose a low risk

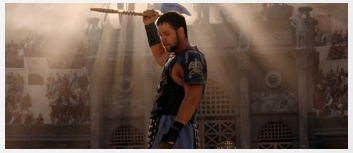
C – Below Requirements

- Performance deteriorates and falls below expectations,
- assessment topics or programs deviate from the intent or objectives of UO BSP requirements,
- moderate risk
- risk of failing to meet regulatory requirements in the short term remains low,
- licensee or applicant has taken, or is taking appropriate action.

D – Significantly Below Requirements

- significantly below requirements
- evidence of continued poor performance
- whole programs are undermined
- high probability that the deficiencies will lead to an unreasonable risk
- Issues are not being addressed effectively by the licensee or applicant

E – Unacceptable Level Of Non-compliance



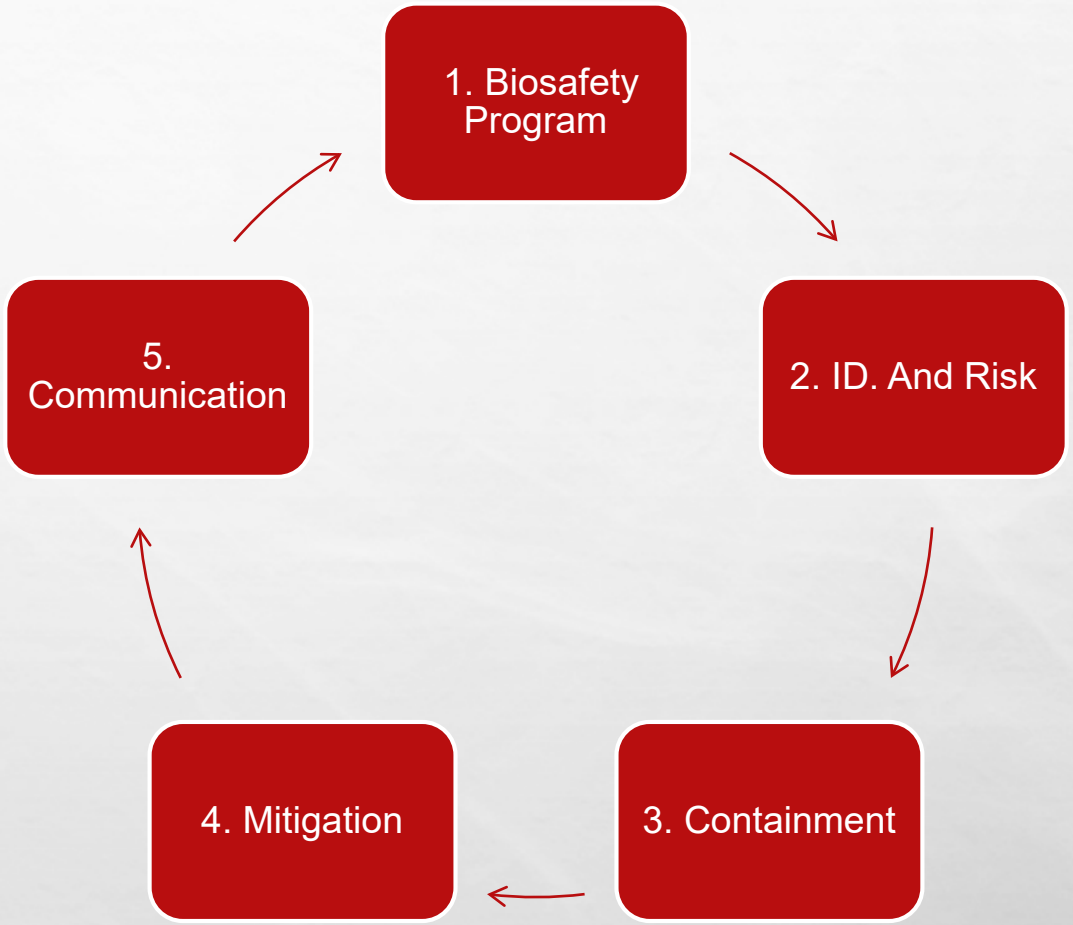
- an absence, total inadequacy, breakdown, or loss of control
- a very high probability of an unreasonable risk
- An appropriate regulatory response, such as an order or restrictive licencing action has been or is being implemented to rectify the situation.

OVERARCHING RISK ASSESSMENT & ANNUAL REPORTING

Each program comprises of five critical activities that can be reviewed.

Each of these are comprised of a number of activities which are undertaken to ensure:

- Health and Safety
- Compliance
- Due diligence



1. BIOSAFETY PROGRAM

- Plan Of Administrative Oversight
- Biosafety Program Structure and Evaluation
- Institutional Approval
- Regulatory Compliance and Monitoring
- Biorisk and Biosecurity
- Business Continuity

2. IDENTIFICATION and RISK ASSESSMENT

- Institutional Biosafety Approvals
- Inventory (Risk Groups)
- Risk Assessment
- Trends Analysis (Profile Of Risk Groups)
- Waste Management Practices
- Inspection Findings and Follow-up

3. CONTAINMENT ZONES

- Canadian Biosafety Standards
- Assessment of Facilities
- Identification of Lab Use
- HEPA Certification
- Mapping and Disclosure Of Risk Assessment

4. MITIGATION STRATEGIES

1. Biorisk Assessment
2. Medical Surveillance
3. Exposure Control Plan
4. Emergency Control Plan
5. Security
6. Sop, Cheat Sheets, Guidelines

5. COMMUNICATION

1. Strategy
2. Reports Provided (Committee, Deans…)
3. Inspections and Follow-up
4. Annual Reports (A Year In Review, PHAC)
5. Biosafety Committee Reporting

Now for the reporting:

- Based on the grading of each component of the 5 areas reviewed and overall grade is assigned.
- Multiple grades can be applied for the same area as evidence may have been found that it was partially developed, deployed, meets regulatory expectations, or complied with.
- Action plans were developed and assigned a priority.

SUMMARY OF FINDINGS OF THE BIOSAFETY OVER ARCHING RISK ASSESSMENT	Grade
BIOSAFETY PROGRAM	B
summary of results *action plan*	
INDENTIFICATION AND RISK ASSESSMENT	B/C
summary of results *action plan*	
CONTAINMENT ZONES	B/C
summary of results *action plan*	
MITIGATION STRATEGIES	B
summary of results *action plan*	
COMMUNICATION	**A**
summary of results *action plan*	

After each component is assessed, results are summarized and an over all grade awarded

example: Mitigation Strategies Overall Grade: B

Mitigation strategies that are associated with the development and management of the BSP were reviewed and with the exception of additional review required, were deemed to be adequate.

1	*Biorisk Assessment*	*b*
2	*Medical Surveillance*	*b*
3	*Personal Exposure Control Plans*	*b*
4	*Emergency Response*	*b*
5	*Security*	*b/c*
6	*SOP, Cheat Sheets, Guidelines*	*b*

Actions Required:

5	*Security*	*b/c*

Based on the recently published PHAC – "Developing a Comprehensive Biosecurity Plan ", an assessment of current practices at the University will be reassessed, and revised if necessary.

ACTION PLAN

A BIOSAFETY PROGRAM (MEDIUM PRIORITY)

4. Regulatory Compliance and Monitoring b/c

CBS v2 outstanding issues will be addressed, current remedial action is currently underway to address issues, in most cases obtaining evidence or lack of documentation.

5. Biorisk and Biosecurity b/c

Biorisk assessment currently begin rolled out over the year.

C CONTAINMENT ZONE (MEDIUM PRIORITY)

1. Canadian Biosafety Standards a/b/c/

Confirm missing or uncertain information, rectify all low grades or prioritize and schedule resolution, meet with Facilities to verify training practices

D MITIGATION STRATEGIES (HIGH PRIORITY)

5 Security b/c

Based on the recently published PHAC – "Developing a Comprehensive Biosecurity Plan ", an assessment and formalization of current practices at the University will be assessed, and the appropriate plan developed.

PRIORITIZING

LOW (B)

- meets regulatory requirements
- minor deviations
- low risk *

MEDIUM (C)

- below expectation
- low risk* of failing to meet regulatory requirements
- Necessary actions have or are being taken

HIGH (D & E)

- Significantly below or absence/totally inadequate control
- High or very high of unreasonable risk
- Necessary action not taken or inadequate and/or no adequate action plan in place.

** Risk pertains to health, safety, security, environmental protection or compliance*

DISTRIBUTION OF THE OAR

- Short And Sweet
- Relevant To The Target Audience
- Transparent
- Identifies The Risk Holder
- Appendices Add The Details

By clearly identifying who is responsible/accountable in terms of resolving the issue,

you empower those Directors, Deans, V.P.s to assess their own risk tolerance

(given competing interest in resources (time, people, $$$)

DUE DILIGENCE

- All parties want to do what is correct.
- What varies is the priority assigned to actions or competing interest.
- The grading that is applied can help reprioritize the risks and identify accountable parties.
- Diligence requires that you assess, inform, and empower when applicable.

WHAT IS A REASONABLE EXPECTATION ?

- ONE PERSON CAN NOT DO IT ALL
- IT WON'T BE SOLVED OVERNIGHT
- CONTINUOUS IMPROVEMENT
- DILIGENCE AND COMMUNICATION

OAR BENEFITS:

- ✓ Identifies gaps and risks, and
- ✓ Prioritizes these and develops actions plans, and
- ✓ Strengthens the over all program.

- ✓ Acts as a standardized template facilitating trend analysis.
- ✓ Demonstrates regulatory oversight, scope, and complexity of the program.
- ✓ Increases credibility of the program and yourself.