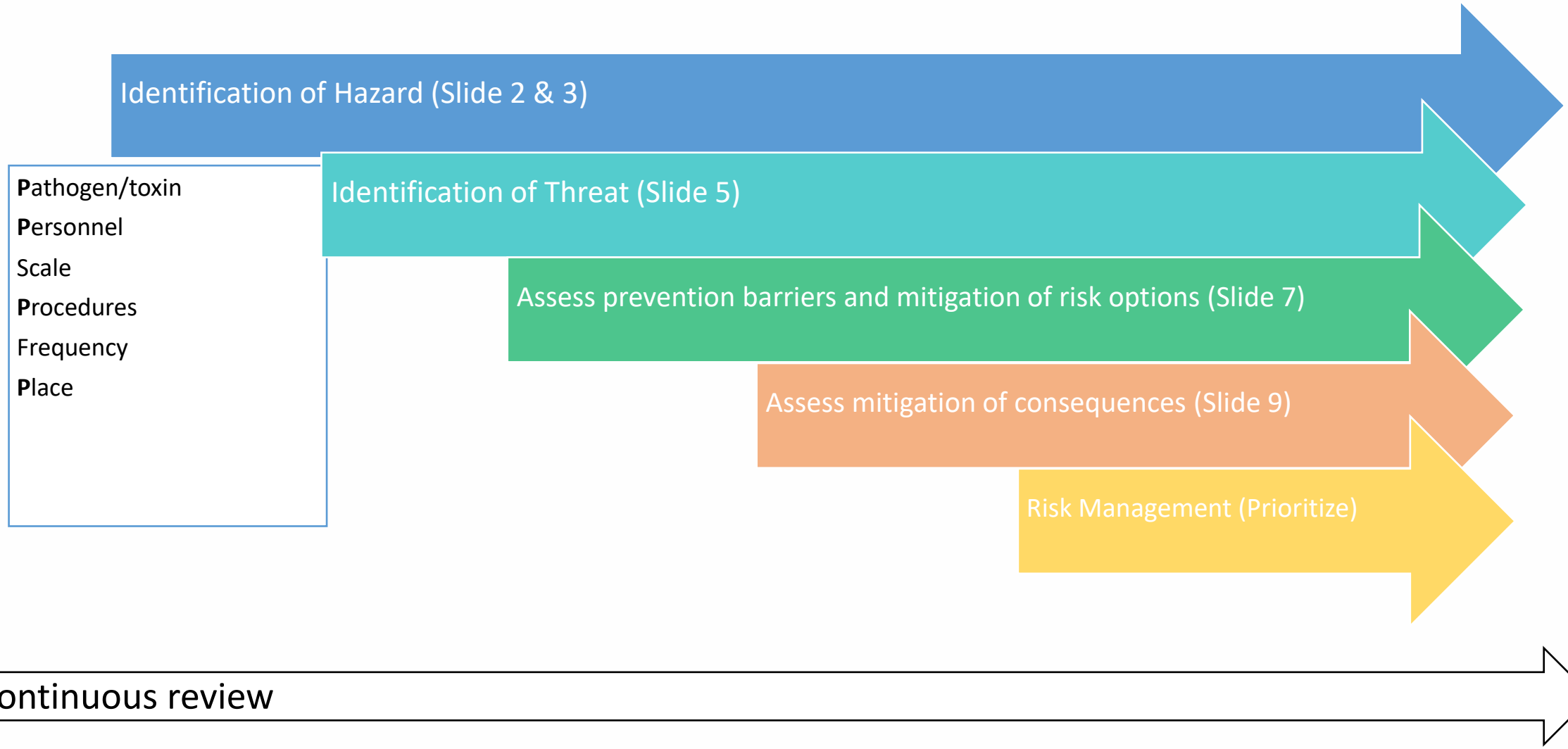
ABSA International BioRisk Evaluation Tool Fungi

Risk Management



Continuous review

Identification of Hazard/Pathogen

Pathogen	Fungi
Host range	Human Animal
Occupational Health considerations	Healthy Pre-Existing conditions Immunocompromised Additional risks
Type of samples & Proposed Activities	Sample type: environmental, blood, tissue, Other Potentially Infectious Material (OPIM) Activities: culturing, using sharps, centrifugation, tissue extraction, vortex
Fungi-specific recommendations included in the CDC/NIH BMBL 6th 2020 –Section VIII: Fungal Agents	Blastomyces dermatitidis and Blastomyces gilchristii Coccidioides immitis and Coccidioides posadasii Histoplasma capsulatum Sporothrix schenckii species complex Candida spp. Miscellaneous Yeast and mold organisms causing human infection

Identification of Hazard/Pathogen

Factors	What is known
Biological Agent	-Eukaryotic -Exists in multiple forms such as yeast and pseudohyphal -Encapsulated or acellular (parasite) -Diploid -Cell wall -Depending on the fungi, colonies appear within 48-72 h (*Candida albicans*)
Disease	-May colonize skin, nails (surface) -May colonize organs (systemic) -May be a commensal pathogen, that is, it is part of the normal flora. -There are genetic conditions such as chronic mucocutaneous candidiasis due to a defect in the immune response to Candida. -Risk factors: antibiotic therapy; administration of steroids, immunosuppressants, or chemotherapy; prior surgery; solid organ or hematopoietic stem cell transplants; diseases such as AIDS, leukemia, diabetes, and lymphoma; as well as trauma and burn patients
Treatment	-Specific drugs to treat fungi -May be resistant to one or more of the major classes of drugs that are typically used to treat fungal infections
Transmission	-Fungi may be found in soil, inanimate objects, fomite, food -Person to person -Animal to human (in the wild)
Host range	Humans, animals
Infectious dose	Unknown
Incubation time	Unknown

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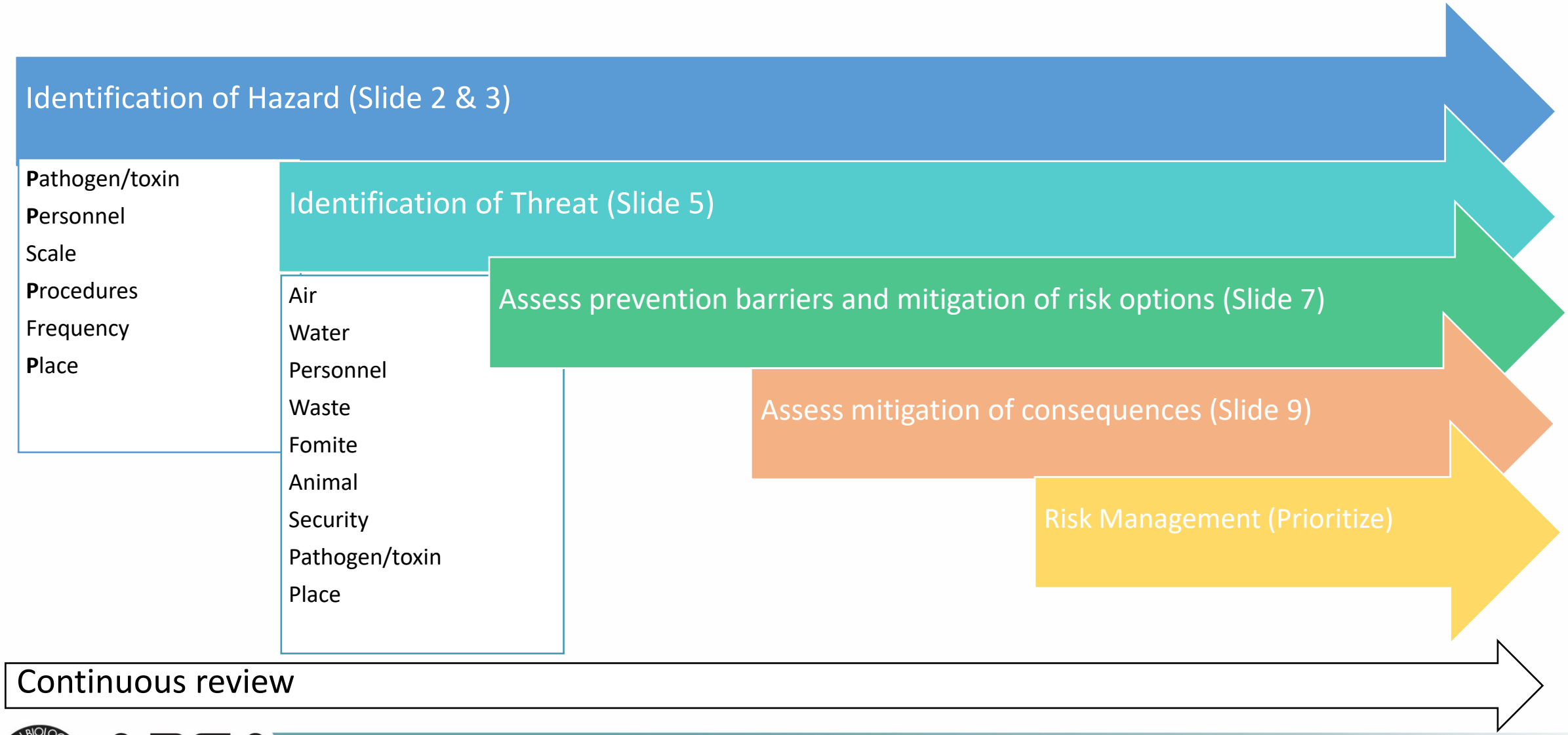

Identification of Threat

	What is known	Considerations
Air	Fungi may be transmitted as bioaerosols or individual particles (Tang JW. 2015)	- Where will the samples be handled? (Air supply, Air exhaust. Air flow) - Facility, engineering controls (e.g. BSC) - PPE
Water/soil	Fungal infection from freshwater is rare. (Baumgardner DJ 2017) Fungal infection from soil is common (Baumgardner DJ 2012) Coccidioidomycosis ("valley fever") may represent up to 29% of community acquired pneumonia cases (150,000 annually) in endemic areas.	- Will fresh water or soil be the source of the specimen?
Personnel	Laboratory-acquired infections have been reported for Coccidioides immitis, Histoplasma capsulatum, Blatomyces and others. Consult the ABSA LAI Database -https://my.absa.org/LAI	•Stress, pre-existing illnesses •Language barriers •Knowledge, Skills, Abilities
Waste	Fungi have been identified in untreated waste collected from households (Madsen AM, 2016)	-What type of waste will be generated? Solid, Liquid, Mixed, Sharps
Fomite	Surfaces – Candida albicans may survive on surfaces up to 4 months ; other Candida may survive shorter times (14 days) – (Kramer A. 2006)	- What surfaces may be potentially contaminated? Equipment used, counters, storage, door knobs
Work with animals	Some fungal diseases are zoonotic (transmission from animal to human) Additional information: One health and Fungal Diseases: https://www.cdc.gov/fungal/fungal-one-health.html and ASM Colloquium Report One Health: Fungal Pathogens of Humans, Animals and Plants S. Seyedmousavi (2015) – Table 1 shows Medically important fungi with the potential of zoonotic transmission to humans	-Size of the animal -Housing, Waste -Allergies, Shedding, Husbandry
Inactivation	UV light has been shown to reduce fungal load, but is ineffective in killing the yeast completely (Theraud M et al 2004). Most microorganisms are also inactivated by moist heat (121°C for 15 min- 30 min) (Pflug, IJ et al 2001)	- Will waste be disposed of through approved vendor? - Is autoclaving required based on local requirement?

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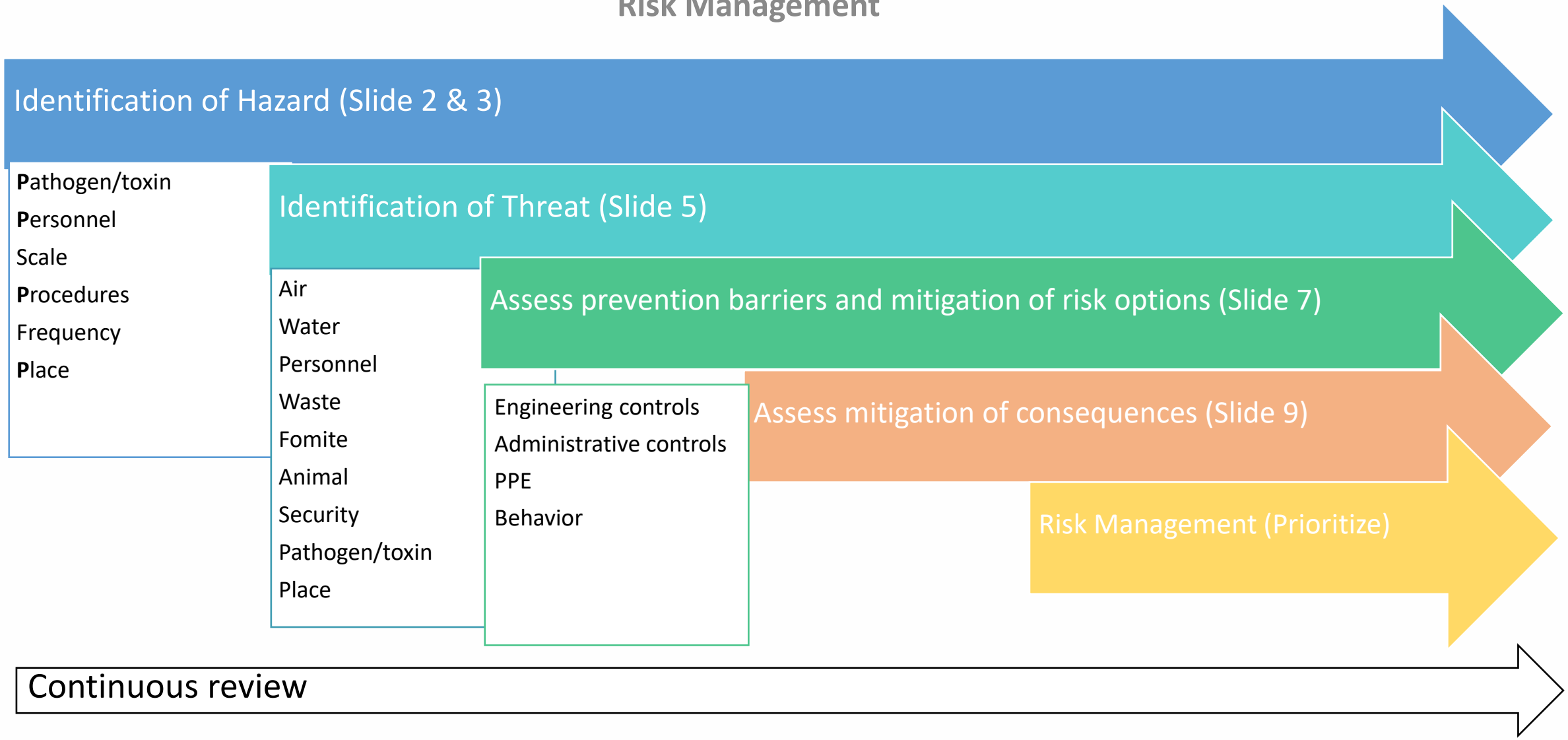


THREAT
Risk Path Category

AGENT

AIR

WATER

PERSONNEL

WASTE

FOMITE

ANIMAL

FACILITY

SECURITY

PREVENTION BARRIERS/MITIGATION OF RISK
Hierarchy of Controls

Engineering Controls
HEPA filter
BSC
Monitors
Alarms
Unidirectional or negative air flow
Facility design

Administrative Control SOPs Occ Health
Process validation
Procedures
Alarm response
Occ health Surveillance
Immunizations
Training
Competency check

PPE
Right size
Correct type
Competency check

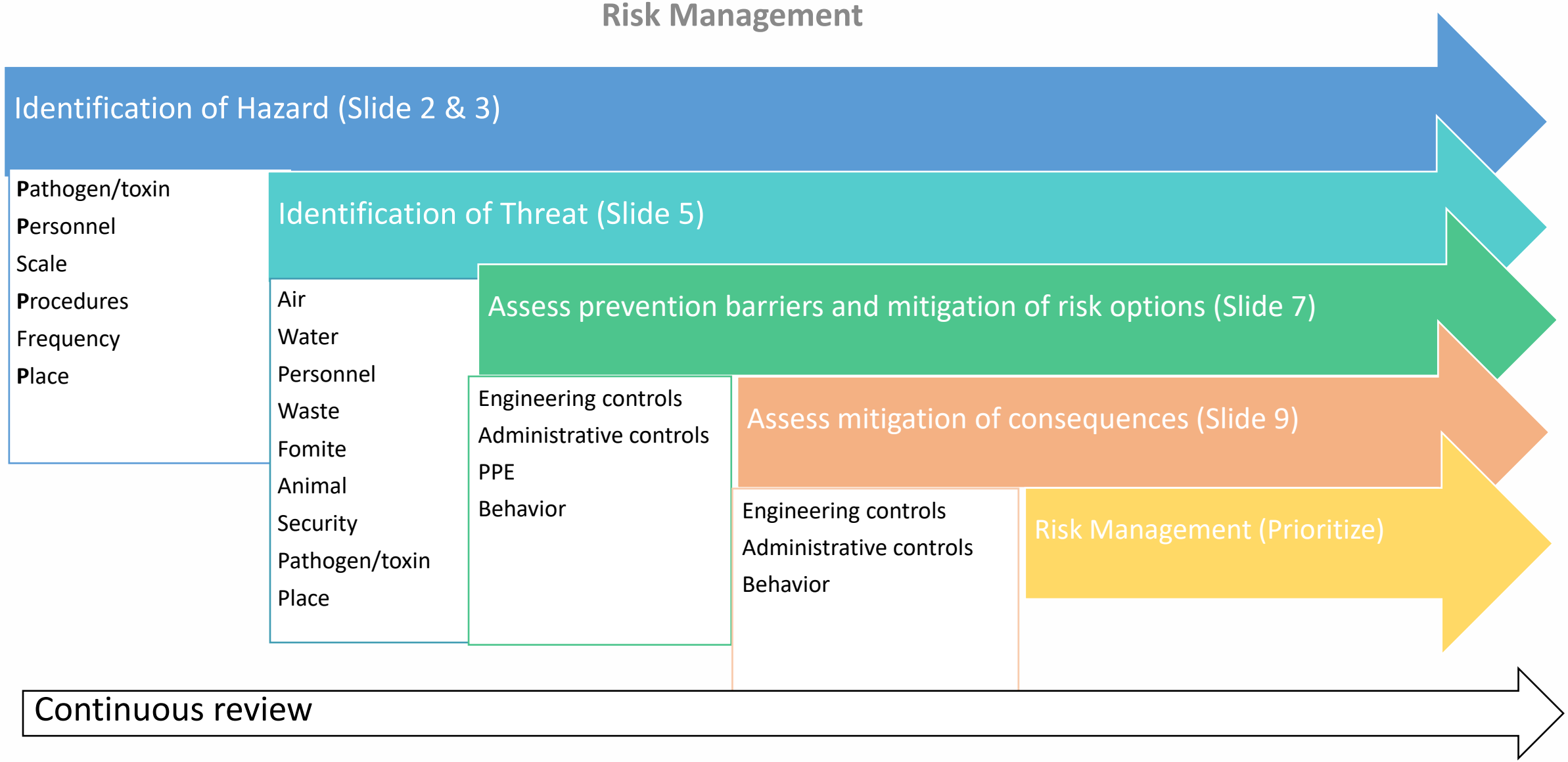
Behavior
Follow SOP
Report Incidents, Accidents and Near misses
Knowledge
Skills
Abilities

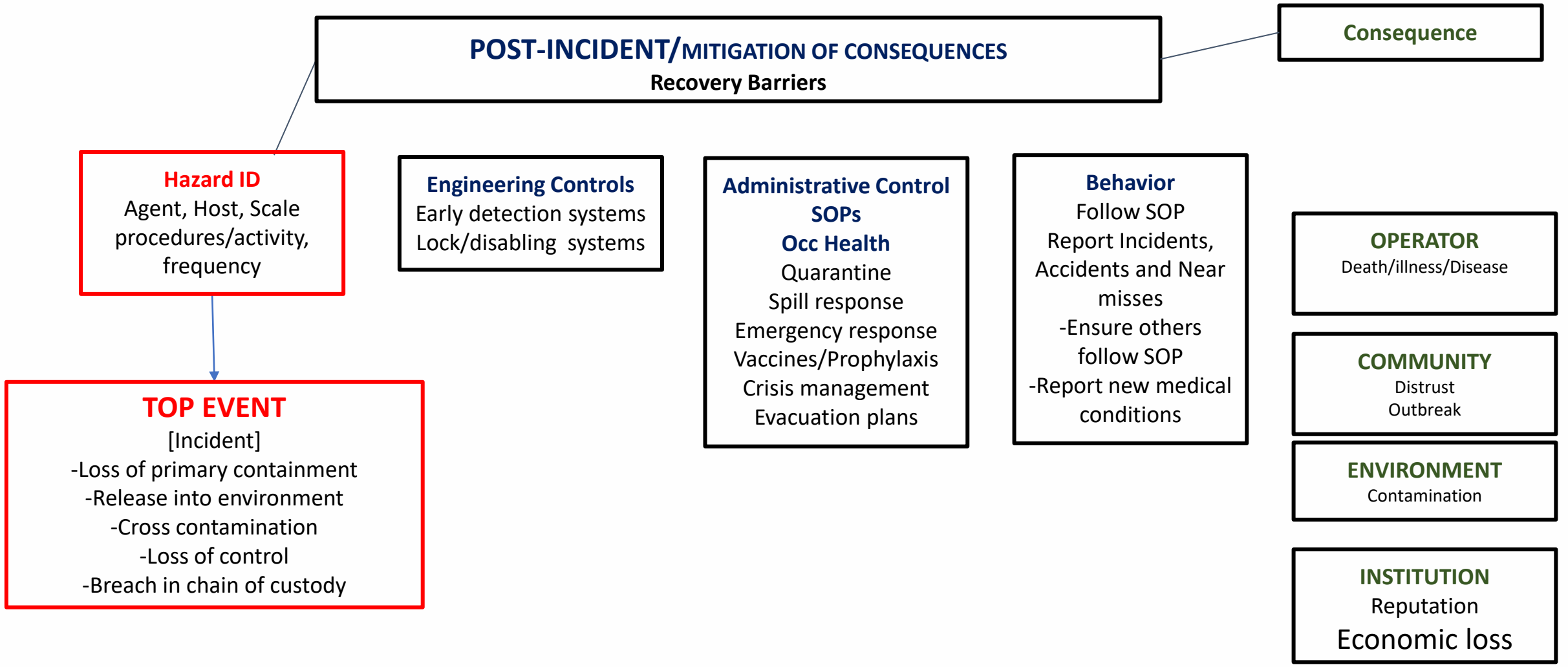
Hazard ID
Agent, Host, Scale procedures/activity, frequency

TOP EVENT
[Incident]
-Loss of primary containment
-Release into environment
-Cross contamination
-Loss of control
-Breach in chain of custody

Risk Analysis

Risk Management




POST-INCIDENT/MITIGATION OF CONSEQUENCES
Recovery Barriers
Consequence
Hazard ID
Agent, Host, Scale
procedures/activity,
frequency
Engineering Controls
Early detection systems
Lock/disabling systems
Administrative Control
SOPs
Occ Health
Quarantine
Spill response
Emergency response
Vaccines/Prophylaxis
Crisis management
Evacuation plans
Behavior
Follow SOP
Report Incidents,
Accidents and Near
misses
-Ensure others
follow SOP
-Report new medical
conditions
OPERATOR
Death/illness/Disease
COMMUNITY
Distrust
Outbreak
ENVIRONMENT
Contamination
INSTITUTION
Reputation
Economic loss
TOP EVENT
[Incident]
-Loss of primary containment
-Release into environment
-Cross contamination
-Loss of control
-Breach in chain of custody

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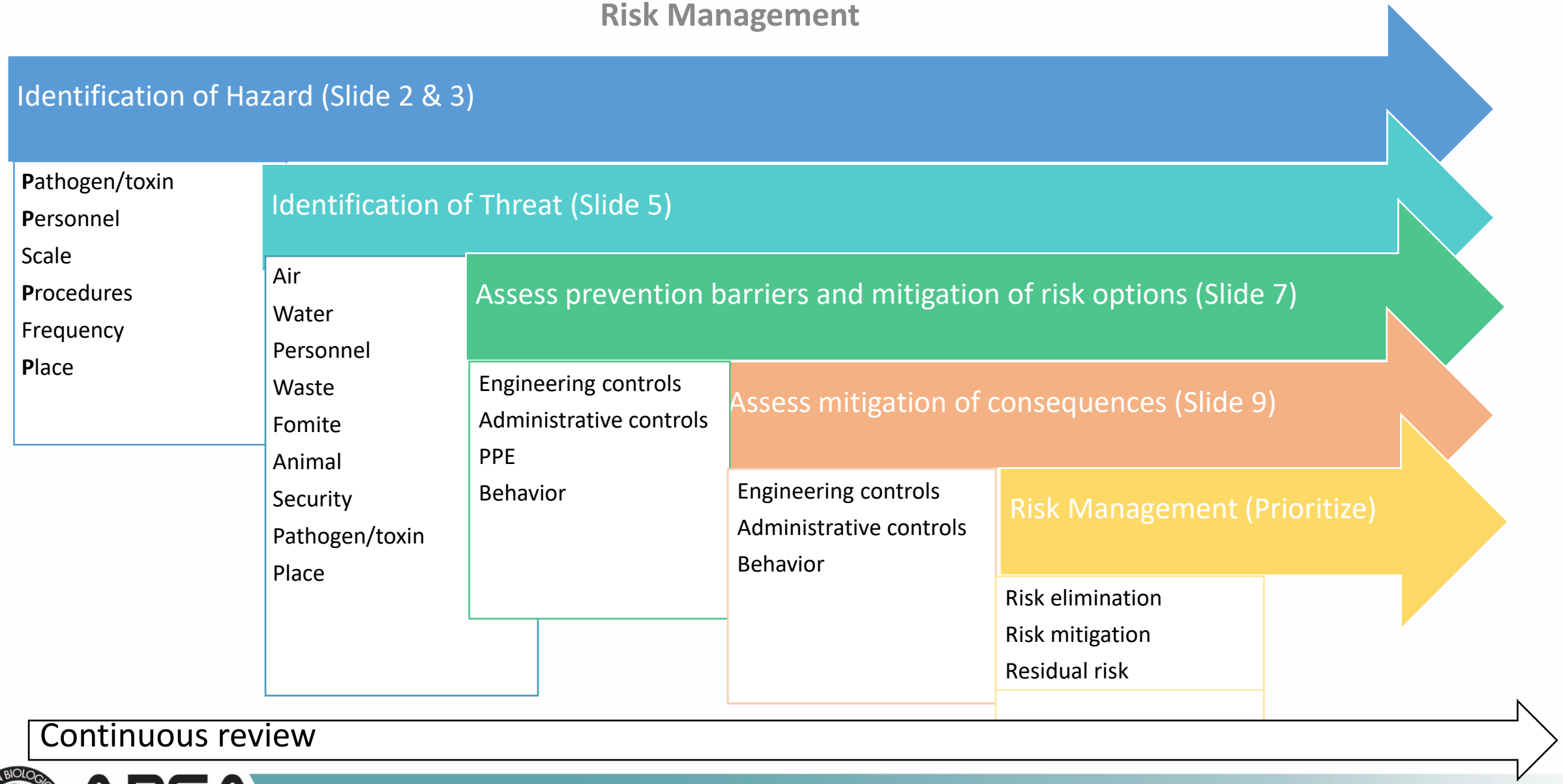

BioRisk Evaluation Tool (BET)

Instructions

The BET has been designed to aid the biosafety & biosecurity professional to conduct risk evaluations.

This tool may be used to assess biohazards in various scenarios (i.e. laboratories, hospitals).

Select a hazard and use the BET to perform a systematic risk evaluation. Each slide prompts you to evaluate your hazard and conduct a thorough analysis ending in a mitigation plan to address potential consequences (accidental or intentional).

Considerations when conducting a risk evaluation:

- The outcome of the risk evaluation is as robust as the hazard identification
- Evaluate how each hazard will become a risk or threat. Determine what barriers can be put in place to prevent or mitigate the
- consequences.
- Identify the stakeholders associated with the hazards and risks identified.

Acknowledgments

This tool was prepared by Aparupa Sengupta and Esmeralda Meyer as participants in the ABSA International BRM Connect led by Antony Schwartz (Duke University) and Eric Cook (SNL).
Special thanks to Kalpana Rengarajan, (Emory University) and Miguel Grimaldo (UTMB) for their time and great discussions around biorisk management.

Resources

Mueller-Doblies, Uwe. Managing Biological Risk Concerns in the Veterinary Laboratory and Animal Facilities. 2017. 18th WAVLD, 9th June 2017, Sorrento, Italy OIE Seminar: Implementing New Biorisk Standards

Caskey, S., et. Al. SANDIA REPORT SAND2010-6487 2010 Biosafety Risk Assessment Methodology https://www.osti.gov/servlets/purl/1325209

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Centers for Disease Control and Prevention. Biological Risk Assessment: General Considerations for Laboratories. https://www.cdc.gov/safelabs/resources-tools/bio-risk-assessment.html

World Health Organization Biorisk management: laboratory biosecurity guidance 2006. https://www.who.int/publications/i/item/biorisk-management-laboratory-biosecurity-guidance

Bullock JA, Haddow GD, Coppola DP. Mitigation, Prevention, and Preparedness. Introduction to Homeland Security. 2013:435–94. doi: 10.1016/B978-0-12-415802-3.00010-5. Epub 2012 Jul 27. PMCID: PMC7158272.

Definitions

Biorisk: The probability or chance that a particular adverse event (in the context of this document: accidental infection or unauthorized access, loss, theft, misuse, diversion, or intentional release), possibly leading to harm, will occur.

Hazard: A danger or source of danger; the potential to cause harm. An operation, activity on a material with the potential to cause harm to people, property, the environment or business; or simply a potential source of harm

Threat: The likelihood for an adverse event to occur, as an expression of intention to inflict evil, injury, disruption or damage. A possible initiating event that can result in a loss of control or loss of containment of the hazard (aka cause, initiating event)

Top event/Incident: a central event lying between a threat and a consequence corresponding to the moment when there is a loss of control or loss of containment of the hazard.

Prevention barrier: A barrier located on the left-side of the bow tie diagram and lies between a threat and the incident. It must have the capability on its own to completely terminate a threat sequence (aka proactive barrier)

Mitigation Barriers are employed after the top event has occurred and should help an organization prevent or reduce losses and regain control once it has been lost. The objective is possibly to stop undesired consequences
Consequences of loss of control of the hazard