Risk Assessment: The Foundation of Every Good Biorisk Management System

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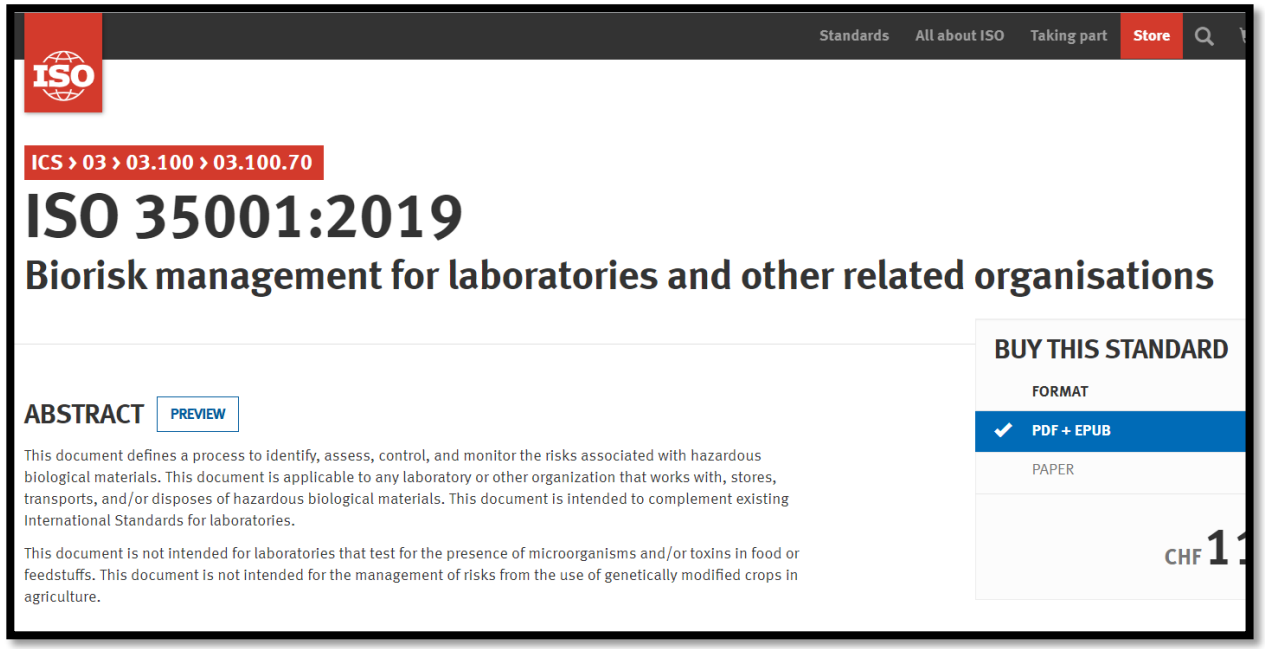
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Risk Management Well Accepted

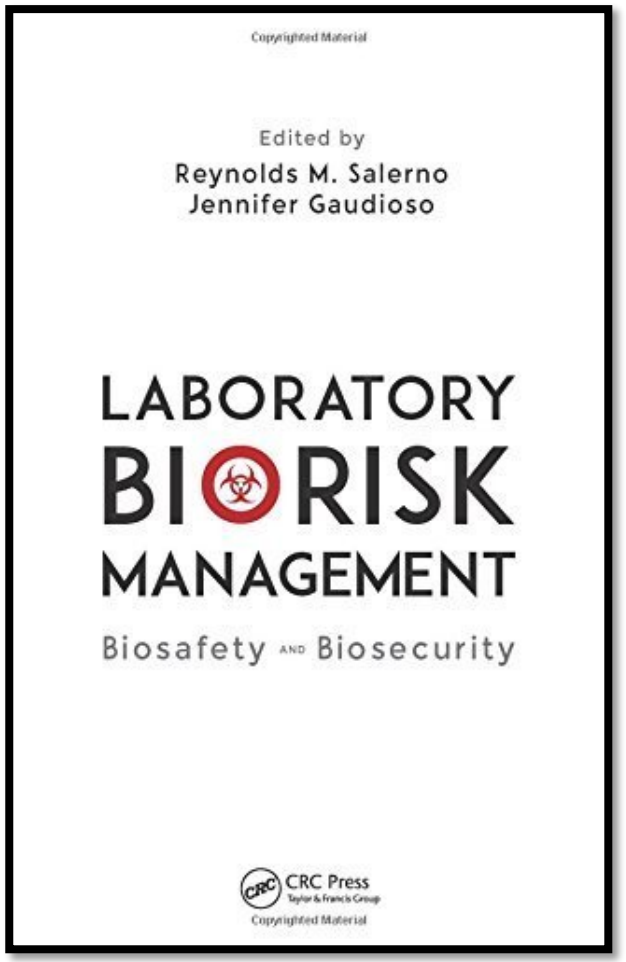
irm
Institute of Risk Management
Developing risk professionals

Biological Community Has Embraced Risk Management



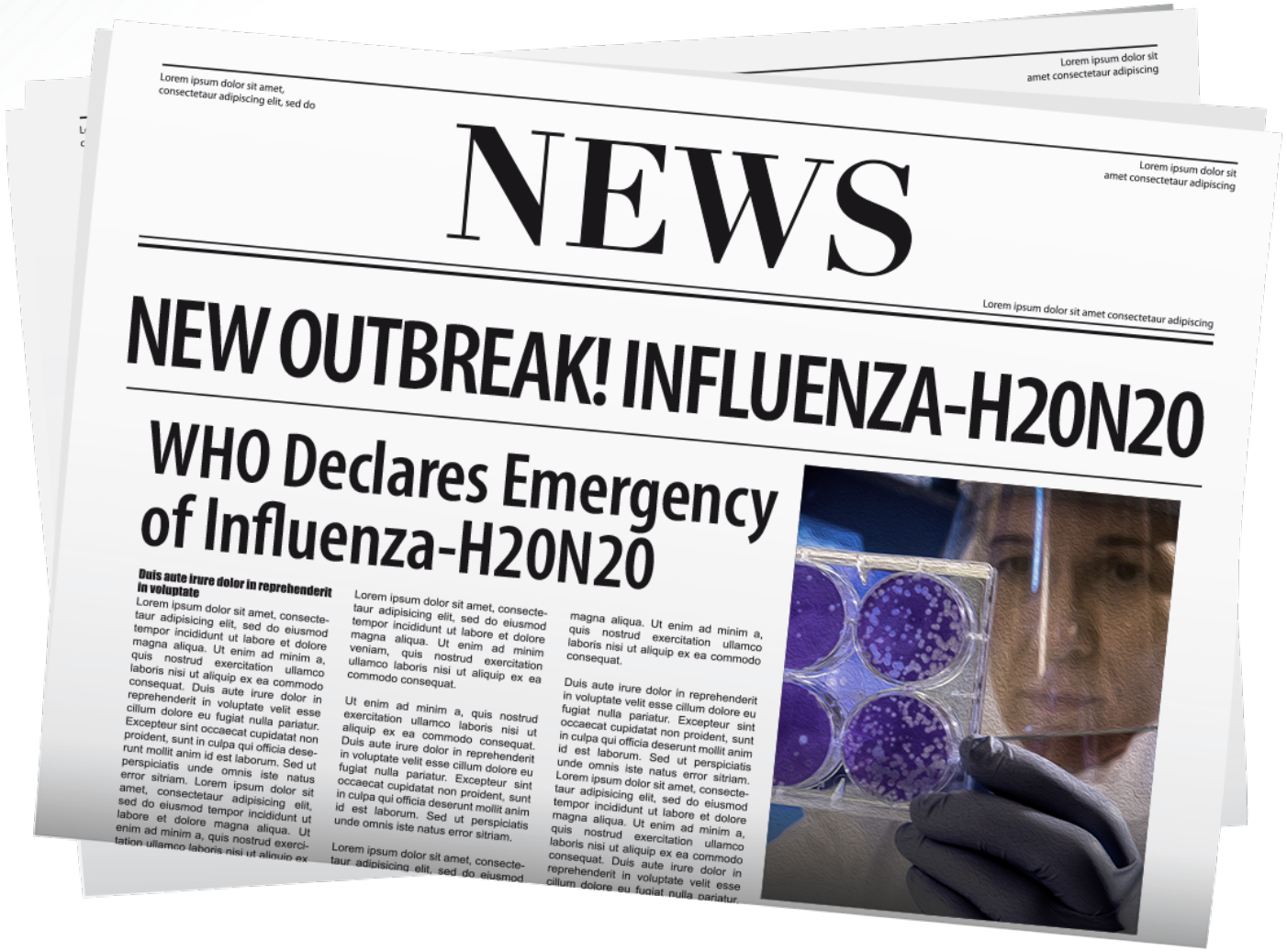
Laboratory Biorisk Management

- Risk Management
  - **A**ssessment
  - **M**itigation
  - **P**erformance/Evaluation
- Dynamic and iterative process
- Various models



LET'S PRACTICE

New (fictitious) Influenza Outbreak!



NEWS

NEW OUTBREAK! INFLUENZA-H20N20

WHO Declares Emergency of Influenza-H20N20

This and the subsequent slides are fictitious for this risk assessment presentation purpose only.

Risk Assessment Scenario

We are a **medical director** in charge of a **core microbiology laboratory** at a large academic teaching hospital.

Our laboratory is in the middle of a region of the country hard hit by **novel influenza virus H20N20**.

Our laboratory serves **as the referral laboratory** for **two** adjacent states, as well as its own.

Risk Assessment Scenario

Influenza-H20N20 has a high mortality rate (**2.5%**) and morbidity rate (**50%**); No treatment

US Food and Drug Administration has issued an **Emergency Use Authorization** (EUA) for a new diagnostic test

US Centers for Disease Control and Prevention has sent this **real-time RT PCR (rRT-PCR) kit** to our laboratory to verify and begin patient testing

Risk Assessment Scenario

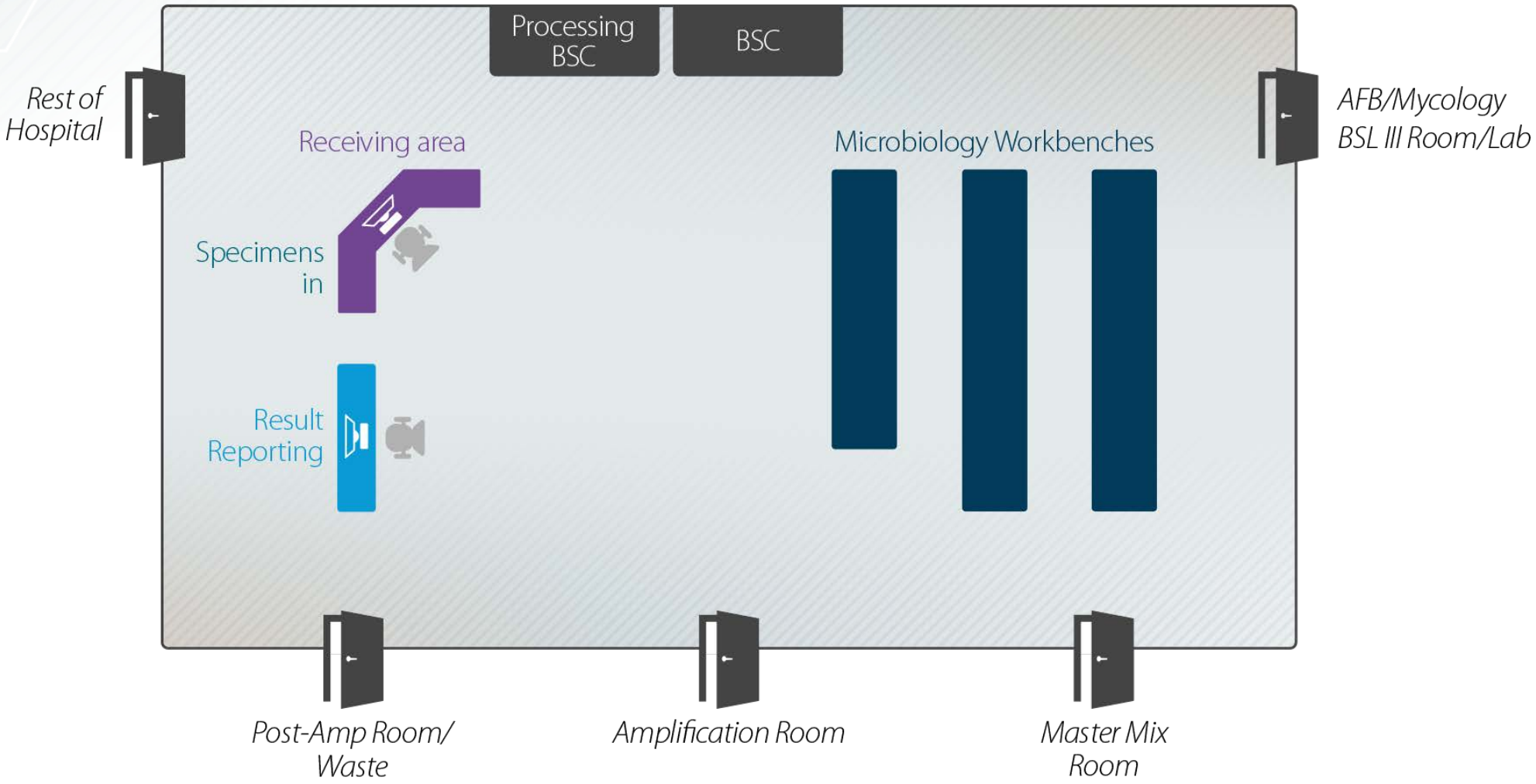
Few molecular technologists use the laboratory's biosafety cabinet frequently.

The majority of staff is moderately competent (good not great); staff competency is assessed annually.

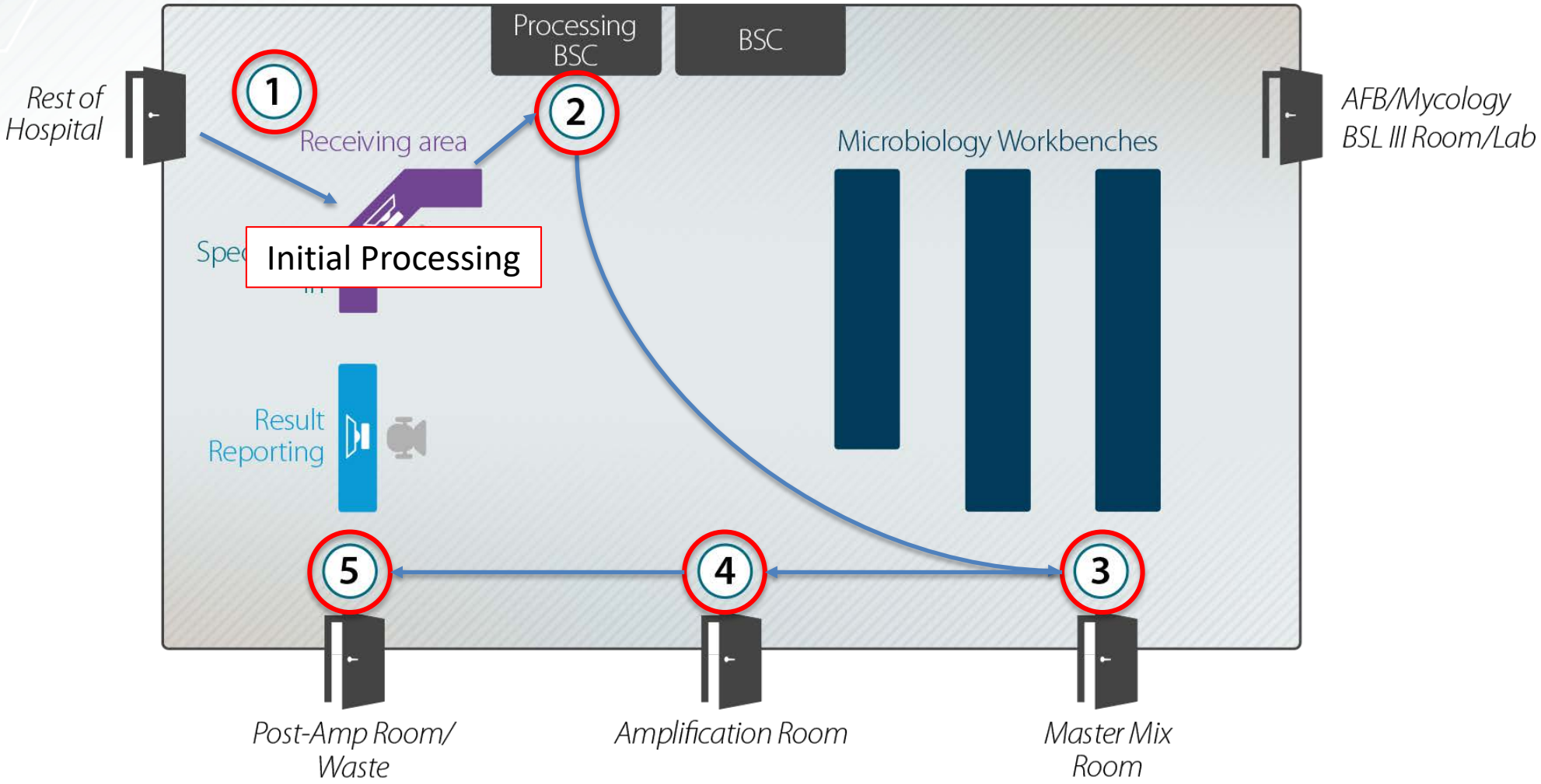
The facility usually double-bags its waste.

There are no additional laboratory staff to assist during high test volume periods.

Facility Design



Specimen Workflow



Examples of What Can Go Wrong During this Workflow

Sample Receipt (1)

- Suspected vs. confirmatory (sample mix up)
- Broken samples
- Improper packaging
- May not be decontaminated
- Misuse of personal protective equipment (PPE)
- Leaky package which leads to exposure

Extraction (2)

- Sample Contamination
- Master-mix reagent spill*
- Misuse of PPE
- Improper use of the biosafety cabinet (BSC)
- Improper inactivation during extraction

*Example of a chemical risk

Master Mix Room (3)

- Reagent contamination
- Master-mix reagent spill*
- Improper use of PPE

Amplification Room (4)

- Improper use of PPE
- Sample contamination
- Power failure

Post-Amplification/Waste (5)

- No/limited PPE
- Mishandling of waste
- Inappropriate waste disposal

Risks Selected for this Assessment

Sample mix-up during specimen unpackaging

Improper handling of waste from initial sample processing

Improper use of the biosafety cabinet during the extraction phase

Improper inactivation during the extraction phase

Misuse of personal protective equipment during the extraction phase

Misuse of personal protective equipment during the amplification stage

Improper handling of waste after the amplification stage

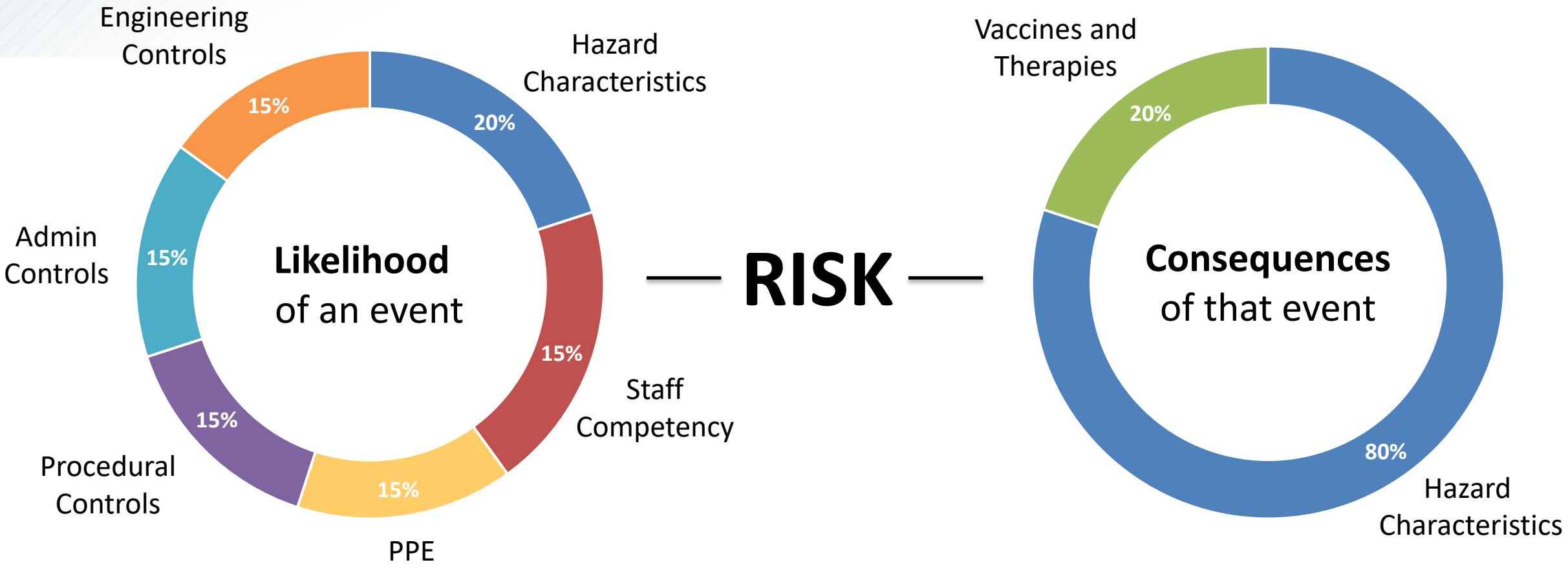
How to Assess these Risks?

Risk Matrix

	SEVERITY				
Probability	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	Low	Moderate	High	High	High
Probable	Low	Moderate	High	High	High
Occasional	Low	Moderate	Moderate	High	High
Remote	Low	Low	Moderate	Moderate	High
Improbable	Low	Low	Low	Moderate	Moderate

LET’S ASSESS OUR RISKS

Weighted Criteria to Assess the Risks



Likelihood Scoring Table: Sample Mix-up During Specimen Unpackaging

Likelihood Criteria and Weights	Raw Score	Weighted Score
Hazard characteristics (20%)		
1. The hazard is extremely fragile and has poor transmissibility		0
2.5. The hazard is moderately stable and/or moderate transmissibility		0
4. The hazard is very stable with strong transmissibility, or its stability/transmissibility is unknown	4	0.8
Staff training and competency (20%)		
1. All highly trained and competent staff for the specific activity		0
2. Most staff highly trained/competent staff but few moderately trained/competent	2	0.4
3. Few highly trained/competent staff and many moderately trained/competent		0
4. Most/all staff poorly trained and/or incompetent for the specific activity		0
Engineering controls (15%)		
1. All needed engineering controls in place and properly certified/maintained	1	0.15
2. Most but not all needed engineering controls in place and properly certified/maintained		0
3. Few/most of needed engineering controls in place and some of those not properly certified/maintained		0
4. Few/none of needed engineering controls in place and some/all of those not properly certified/maintained		0

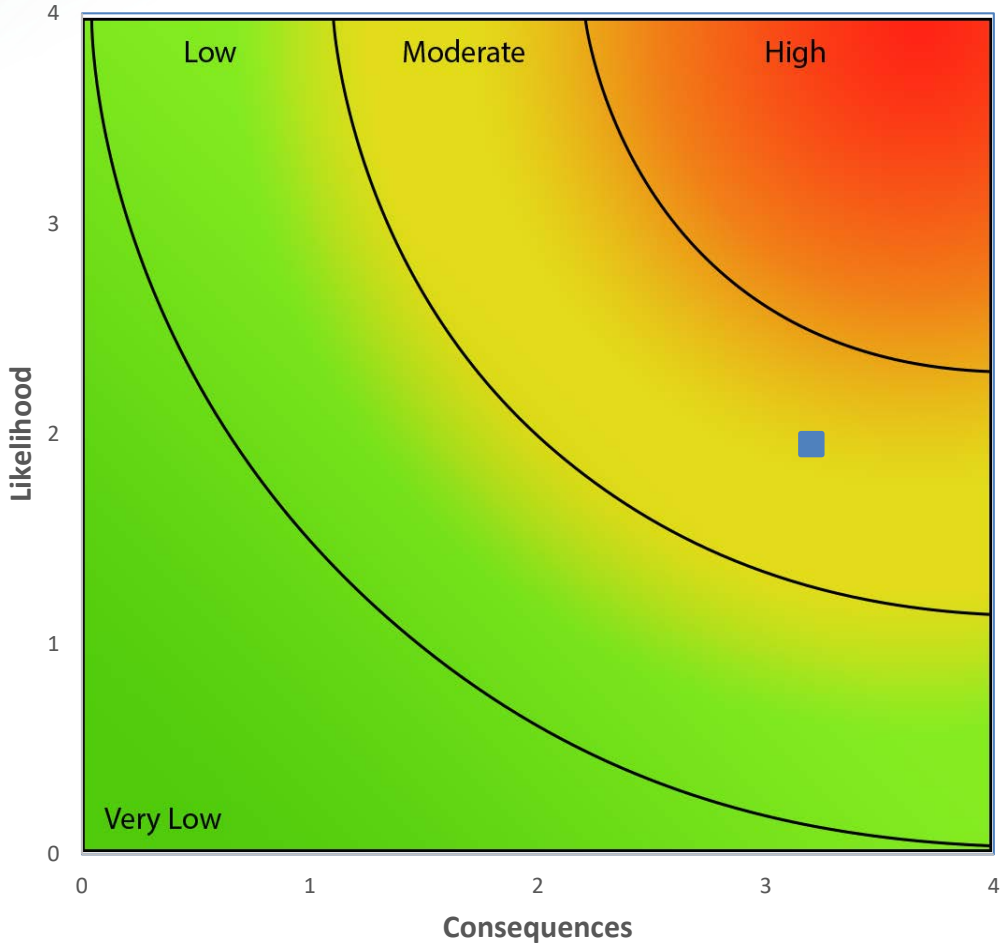
Likelihood Scoring Table: Sample Mix-up During Specimen Unpackaging

Likelihood Criteria and Weights	Raw Score	Weighted Score
Administrative controls (15%)		
1. All necessary administrative controls in place and appropriately maintained by management	1	0.15
2. Most but not all necessary administrative controls in place and appropriate maintained by management		0
3. Few/most of necessary administrative controls in place and some of those not properly maintained		0
4. Few/none of necessary administrative controls in pace and some/all of those not properly maintained		0
Procedural controls (SOPs, protocols) (15%)		
1. All necessary procedural controls in place and appropriately maintained		0
2. Most but not all necessary procedural controls in place and appropriate maintained	2	0.3
3. Few/most of necessary procedural controls in place and some of those not properly maintained		0
4. Few/none of necessary procedural controls in place and some/all of those not properly maintained		0
Personal protective equipment (15%)		
1. All necessary PPE in use and appropriately maintained	1	0.15
2. Most but not all necessary PPE in use and appropriate maintained		0
3. Few/most of necessary PPE in use and some of those not properly maintained		0
4. Few/none of necessary PPE in use and some/all of those not properly maintained		0
TOTAL LIKELIHOOD SCORE		**1.95**

Consequences Scoring Table: Sample Mix-up During Specimen Unpackaging

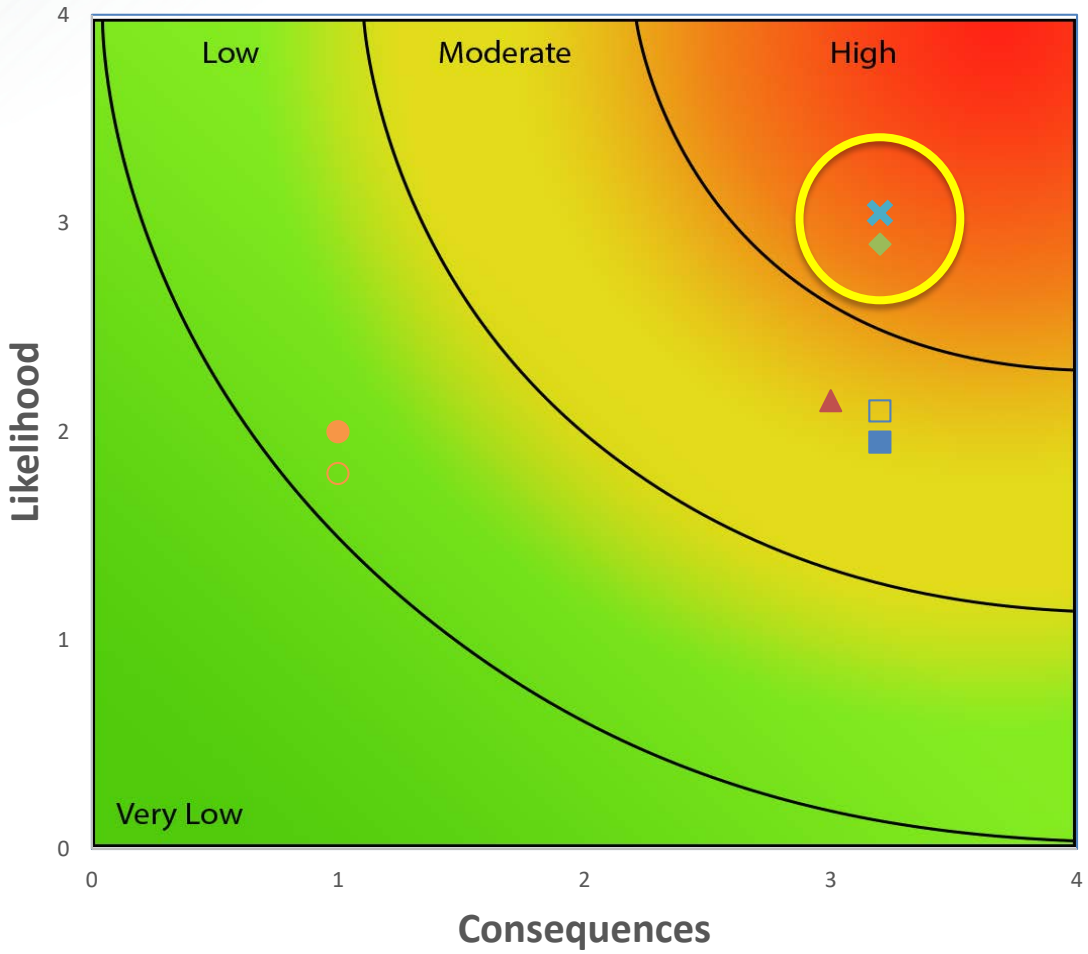
Consequences Criteria and Weights	Raw Score	Weighted Score
Hazard characteristics (80%)		
1. Exposure to the hazard would not cause any morbidity or mortality		0
2. Exposure to the hazard could only cause morbidity and only to immuno compromised or elderly		0
3. Exposure to the hazard could could cause serious morbidity but limited mortality	3	2.4
4. Exposure to the hazard would result in high rates of morbidity and mortality		0
Vaccines and therapies (20%)		
1. There are highly effective vaccines and therapies available and all staff are vaccinated against this particular disease or the disease causes no morbidity and mortality		0
2. There are highly effective vaccines and/or therapies available but only some staff are vaccinated	0	0
3. There are vaccines and/or therapies available but their efficacy is limited		0
4. There are no vaccines or therapies available for the disease that this hazard would cause	4	0.8
TOTAL CONSEQUENCES SCORE		**3.2**

Risk: Sample Mix-up During Specimen Unpackaging



A: Sample mix-up during specimen unpackaging

Assessment of the Selected Risks



- A: Sample mix-up during specimen unpackaging
- B: Improper handling of waste from initial sample processing
- C: Improper use of the BSC
- D: Improper inactivation during extraction phase
- E: Misuse of PPE during the extraction phase
- F: Misuse of PPE during the amplification stage
- G: Improper handling of waste after amplification stage

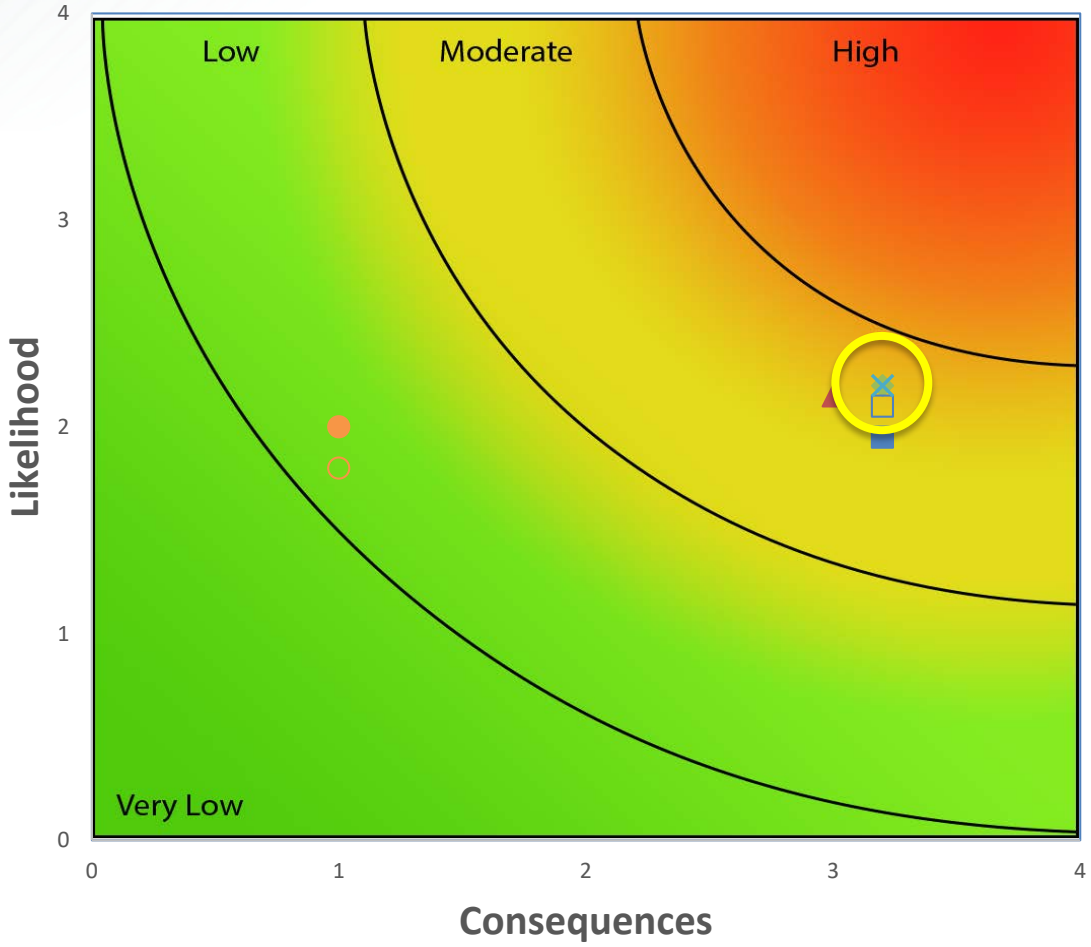
Risk Mitigation – Improper Use of the BSC

Likelihood Criteria	Before	After
Hazard characteristics	4	4
Staff training and competency	3	1
Engineering controls	3	2
Administrative controls	2	2
Procedural controls (SOPs, protocols)	3	1
Personal protective equipment	3	3
Total Weighted Likelihood Score	**2.9**	**2.2**

Risk Mitigation – Misuse of PPE during the Extraction Phase

Likelihood Criteria	Before	After
Hazard characteristics	4	4
Staff training and competency	3	1
Engineering controls	2	2
Administrative controls	3	3
Procedural controls (SOPs, protocols)	3	2
Personal protective equipment	3	1
Total Weighted Likelihood Score	**3.05**	**2.2**

Accepted Risks



- A: sample mixup during specimen unpackaging
- B: improper handling of waste from initial sample processing
- C: improper use of the BSC
- D: improper inactivation during extraction phase
- E: misuse of PPE during the extraction phase
- F: misuse of PPE during the amplification stage
- G: improper handling of waste after amplification stage

Performance/Evaluation

How will we monitor the effectiveness of our chosen mitigation measures?

Assess Training

Exercise Protocols

Document and disseminate the results of this evaluation!

Create a Culture of Risk Management

New Risk Assessment Course by CDC

Coming Soon!

Laboratory Risk Management

www.cdc.gov/labtraining

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Use of trade names is for identification only and does not imply endorsement by U.S. Centers for Disease Control and Prevention.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of Centers for Disease Control and Prevention.