



Conducting Audits & Inspections to Assess Biorisk Management Performance

Student Guide

2013




GLOBAL BIORISK MANAGEMENT CURRICULUM

Conducting Audits & Inspections to Assess Biorisk Management Performance


Welcome & Introductions





Introductions

- Instructors
- Students
 - Your name?
 - Where are you from?



Slide 2

Action Plan

By the end of this lesson, I would like to:

KNOW		FEEL		BE ABLE TO DO	
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Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.

What more do I need to know or do?	How will I acquire the knowledge or skills?	How will I know that I've succeeded?	How will I use this new learning in my job?

Use space on back, if needed



Key Messages

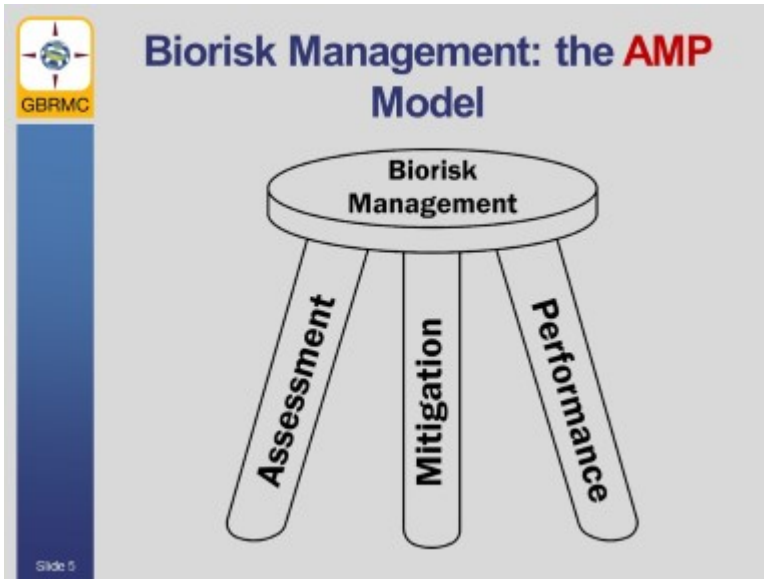
- Audits and inspections are often used as primary measures of biorisk management performance.
- Effective audits and inspections involved all impacted stakeholders and are not “gotcha” exercises.
- Audits and inspections must be standardized and used over time to be effective measurements.
- Evaluations of audits and inspections must only evaluate what the audit or inspection is designed to measure.


Slide 4

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Biorisk Management


What does the AMP model mean to you?






Key Components of Biorisk Management

- **Biorisk Assessment**
 - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable




Slide 6

Define **Biorisk Assessment**:



Key Components of Biorisk Management

- **Biorisk Mitigation**
 - Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins



Slide 7

Define **Biorisk Mitigation**:

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Key Components of Biorisk Management

- **Biorisk Performance**
 - Improving biorisk management by recording, measuring, and evaluating organizational actions and outcomes to reduce biorisk.



Define **Biorisk Performance**:



CWA 15793 and Performance

- CWA 15793 is a **performance-based standard**
 - Establishes biorisk management requirements, but **does not** specify how institutions must meet those requirements
 - **Organizations are responsible** for demonstrating "appropriate and validated risk reduction procedures have been established and implemented."

Slide 9



Swiss Cheese View on Measuring Performance


- Where are the holes in the BRM system "layers?"
- Are the holes where they were expected to be or have the holes shifted over time?
- How "big" are these holes? Grown larger over time?
- Are there new holes forming over time?
- Is the risk management system working as intended to obstruct potential paths leading to adverse consequences?



Slide 10


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Audit and Inspection Performance



Audits and Inspections

- Audits and inspections are one important method of performance measurement to evaluate how well the BRM system is working over time
- What is an audit?
- What is an inspection?
- **CWA 15793 4.5.5:**
 - *“The organization shall ensure that a programme of **inspection** and **audit** is conducted which is appropriate to the risk associated with the facility.”*



Slide 11

What is an audit?

What is an inspection?



Your Experience

Questions:

- Have you been involved in an audit or inspection (for any purpose)?
- What was the purpose?
- Who conducted the activity?
- What was the outcome?
- How did it make you feel?

Slide 12



Characteristics of Audits and Inspections


Audits

- Less frequent
- More formalized
- Larger scale/scope
- Often system or program based

Inspections


- Frequent, repeating or periodic
- Large number of inspections per year
- Focused/specific
- Often equipment or area based

Slide 13



Internal or External Audit?


- What are the benefits of internal audits?
 - What are the challenges & limitations?
- What are the benefits of external audits?
 - What are the challenges & limitations?



Slide 14

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Audit and Inspection Performance



Purpose of Audits or Inspections

Group Exercise:

In your small group, spend **10 minutes** to discuss and answer these questions?

- When should audits or inspections be conducted?
- When should audits or inspections **NOT** be conducted?

Put each answer on a **sticky note** and be prepared to discuss with the rest of the class.

Slide 15


When should audits or inspections be conducted?

When should audits or inspections **NOT** be conducted?


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Audit and Inspection Performance


 **Audits – Some Important Considerations**

- Management commitment and leadership is essential
- Audits should lead to actions
 - Correct deficiencies and nonconformities
 - Document opportunities for improvement and actions taken
 - Verification of follow-up activity




Slide 16

References: World Health Organization, Laboratory Quality Management System Handbook (2011); World Health Organization, Laboratory Safety Manual, 2nd Edition (2004)

 **Audits – Some Important Considerations**

- Audits should identify when components of a BRM system are working well
- Auditors (whether internal or external) should be technically competent and independent of the areas under audit




Slide 17

References: World Health Organization, Laboratory Quality Management System Handbook (2011); World Health Organization, Laboratory Safety Manual, 2nd Edition (2004)


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Audits – Plan Do Check Act




Keys to a Successful Audit

- Audits and inspections use the same approach – the PDCA cycle – that is used with other BRM processes



Slide 18



Audits and PDCA

Group Exercise:

Your small group will be assigned one phase of the PDCA cycle (**plan, do, check, or act**). For this phase, determine what aspects of an audit will occur.

For example, during the PLAN phase, allocation of resources for the audit should be considered.

Take **10 minutes** and capture your results on your **flipchart**.

Slide 19

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Audits – Plan Do Check Act




Keys to a Successful Audit

Plan

- Design of the audit
 - Objectives
 - Scope
 - Criteria
- Allocation of resources
- Internal or external
- Selection/identification of audit team and stakeholders
- Schedule and logistics




Slide 20




Keys to a Successful Audit

Do

- Provide/review requested documents
- Interviews and collection of information
- Take advantage of “teaching moments”
- Identify possible findings, concerns, noteworthy practices
- Communicate, communicate, communicate!




Slide 21


 **Keys to a Successful Audit**

Check

- Review data collection documents for completeness
- Obtain any follow up information required or get further clarification
- Write draft report and submit for review of accuracy
- Finalize report and communicate results




Slide 22


 **Keys to a Successful Audit**

Act

- Evaluate results of audit
- Communicate results to staff
- Determine corrective action(s) needed and owner(s)
- Implement any changes
- Verify effectiveness of changes




Slide 23



Plan the Audit – General Considerations


- Top-level leadership must buy into the process, recognize the advantages, and provide the resources (both material and personnel)
- Commitment by management that any inadequacies in the BRM system or issues identified will be prioritized and corrected
- A successful audit or inspection requires laying the ground work towards a commitment to BRM in advance of the actual audit

Slide 24


 **Plan the Audit**

The first **questions** that need to be answered are:

- What are the intended results?
- What are you trying to measure?
- How will you decide if what is being done is acceptable?
- Will it include one lab or many; one activity or many?



Slide 25


 **Plan the Audit**

The answers to these questions are used to develop the audit's **objectives, scope and criteria**

Audit objectives

- Define what the audit will achieve
 - May be influenced by management priorities or regulatory requirements
 - Use CWA 15793 provisions as touchstones for constructing the audit. Fill in with specifics as needed and identified.
- Determine the best method to do this

Slide 26

 **Plan the Audit**


Audit scope

- Define the extent and boundaries of the audit
Locations, organizational units, activities, processes, time period

Audit criteria

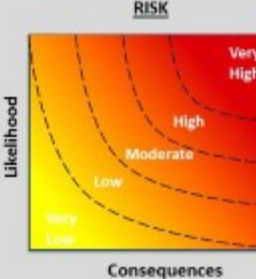
- Define what the auditor will compare the collected evident to in order to determine if acceptable
Regulatory requirements, standards, guidelines, internal policy

Slide 27

 **Plan the Audit**

The audit should be reflective of BRM performance indicators established with goals, objectives, roles & responsibilities.

Remember that the **audit** should be appropriate to the **risk** associated with the facility and the questions you are trying to answer




RISK

Likelihood

Very Low, Low, Moderate, High, Very High

Consequences

Slide 28




Plan the Audit

Next, determine **who will be responsible** for performing the audit

- Should it be one person or a team? If a team, who is the lead auditor?
- Is their job function independent of the activity or processes to be evaluated? (don't audit what you own)
- What tools will be used or needed to collect data? Do they need to be developed? (checklists, consistent questions for future audits for data comparison)
- **Others?**

Slide 29



Plan the Audit


Next, logistics - Establishing a **point of contact**

Responsible for:

- Finalizing the agenda with the auditor
- The collecting, forwarding, and maintaining a log of documents, records, maintenance records, ect. requested by the auditor

Don't lose sight of the reason we are doing this.....to improve our BRM system! The benefits are worth the effort!


Slide 30



Plan the Audit

Question:

What are the **advantages of using checklists** to gather data during an audit or inspection?



Slide 21

What are the **advantages** of using checklists to gather data during an audit or inspection?



Plan the Audit

Group Exercise:


In your small groups, read the scenario and additional information provided in the handout.

Take **20 minutes** to **identify team members** to **develop a tool** for performing an audit, using the template provided.

Slide 32

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Audits – Plan Do Check Act



Plan the Audit

Objective –
 Evaluate the baseline compliance with the waste handling SOP to ensure that the facility and personnel are not exposure to contaminated or potentially contaminated waste items and that no biorisks are present in materials removed from the facility that could be the source of an unintended release to the environment.

Criteria/requirement	Instruction/question examples	Results	Audit notes
1 State requirements	Who what when where questions to determine if requirement has been met		
2			
3			

Slide 33

Criteria/ Requirements	Instruction/ Question Examples	Results	Audit Notes
1.			
2.			
3.			



Perform (DO) the Audit


Formal audits typically have a very defined structure:

- Opening conference
- On-site activities
- Closing conference
- Report

Question:

What are some of the wildest thing you have heard people say to an auditor?


Slide 34

 **Check**

Next, check to make sure everything is working.

- Has all the information needed or requested been provided?
- Have all the audit objectives been evaluated?
- Was there sufficient data collected to obtain an accurate picture of the conditions? (especially important if tracking progress over time)
- Was the audit scoped, staffed, and executed properly?


Slide 35

 **Check**


Write it down!

Any record should include:

- Who** - performed it, participated in it?
- What** - was evaluated, what comparison criteria, what are the results, what are the recommended actions?
- When** - was it performed?
- Where** - was it performed (specific locations/component of organization)
- Why** - was it performed?



Slide 36




Gut Check

Question:

What if the audit shows that there is a massive disconnect between expectations and performance?

Slide 37

What is the audit shows that there is a massive disconnect between expectations and performance?




Act on the Audit

The results are in.....now what do you do with them?

- Share the results with relevant parties
- Compare the results to previous results (past audits or inspections) for the same objective (or metric) to see if there is improvement or a decline in performance
- Prioritize which findings are the most significant or impact the safety of the worker

Slide 38




Act on the Audit

Next, develop a plan (or a corrective action) using the results and any recommendations provided to outline what actions you want to take to close the gap

The 'easy' answer to a finding or a performance gap is to provide additional training or revise a policy, but that isn't necessarily always the right answer.

To do this, you need to understand why the gap exists.....

Slide 39



Act on the Audit

Getting to the why.....

What might be some of the reasons for the result?

What might be good actions to correct?

What is the difference between corrective action & preventive action?

Slide 40

What might be some of the reasons for the result?

What might be good actions to correct?

What is the difference between corrective action & preventative action?




Act on the Audit

An **action plan** needs to include:

- What are we supposed to do?
- Why do we need to do it?
- When (or how often) do we need to do it?
- Who is responsible for doing it?
- Where does it need to be done (if applicable)?
- When does it need to be completed?

Slide 41



Act on the Audit

Group Exercise:

Based on the scenario, determine what results are non-conformances or potential issues for each location or for the entire facility.

Then **develop an action plan** by listing corrective or preventative actions to address each finding

Your action plans should identify what is to be done, by whom, and when it needs to be completed

Take **20 minutes** and be prepared to report out to the class.

Slide 42



Act on the Audit

- Discuss corrective action plans with management to get their buy in on the approach and their commitment of resources in order to accomplish
- Implement the action plan
- Track progress toward completion to keep everyone on schedule
- Once completed, verify (re-audit or re-inspect) that the actions taken had the intended result
 - Metrics to continue to track over time to document things are moving in the right direction

Slide 43

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Review & Wrap-Up



Review

To wrap-up, let's discuss what we learned about **Conducting Audits & Inspections to Assess Biorisk Management Performance**

What did we learn?	What does it mean?	Where do we go from here?
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Slide 44

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Slide 45

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