

Biorisk Management

Audits



Group Activity – Discuss the following 2 questions:

Question	Your Answer
What is an Audit	
What is the difference between an Audit and an Inspection?	



Audit

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

(ISO 19011:2002, 3.1)

Audit

Audit evidence:

Records, statement of fact other information which are relevant to the audit criteria.

Personnel performance?

Audit criteria:

Set of policies, procedures, or requirements.

Audit

- Systematic, independent and documented process for obtaining *records, statement of fact, other information* and evaluating it objectively to determine the extent to which the *policies, procedures, or requirements* are fulfilled.

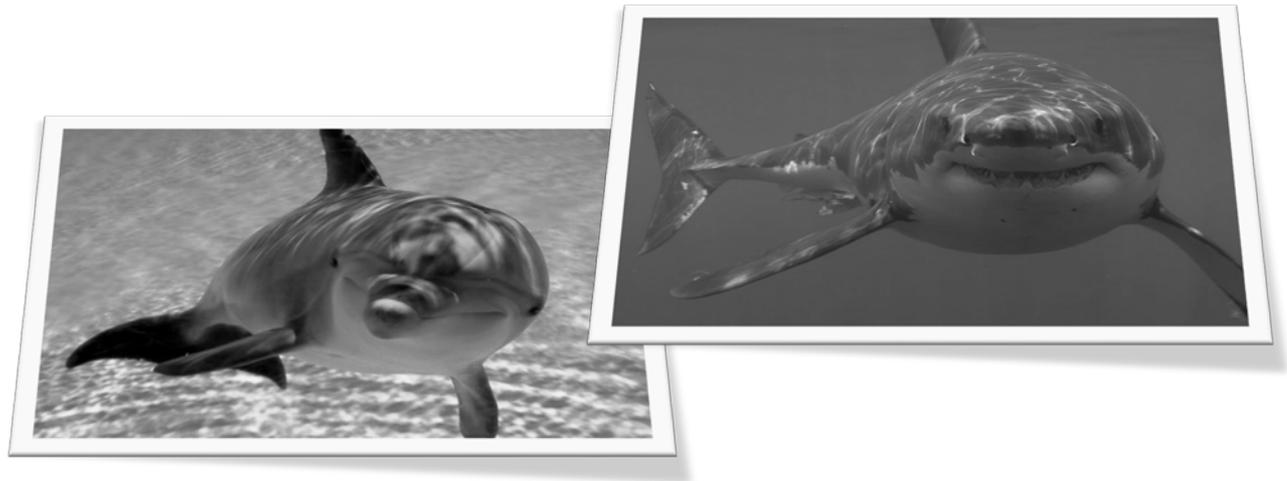
Inspection

Conformity / Compliance evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging.

(ISO 9000:2005 modified)

Inspection

- The act of examining something, often closely.
- Upon closer inspection, the animal turned out to be a dolphin, not a shark.



Conformity vs. Compliance

Conformity:

- Fulfillment of a requirement
- *Voluntary*

Compliance:

- Fulfillment of legal/statutory requirements
- *Mandatory*

Group Exercise



Question	Your Answer
What is required for an audit?	
What are the characteristics of a good audit?	
Who should perform audits?	
List the different types of audits?	

Key Audit Requirements

- Objectives
- Scope
- Criteria
- Plan
- Expertise
- Resources

Principles of “Good” Auditing

- Principles relating to auditors
 - Ethical conduct
 - Fair presentation (report truthfully)
 - Due professional care (e.g. competence)
- Principles relating to the audit
 - Independence
 - Evidence-based approach

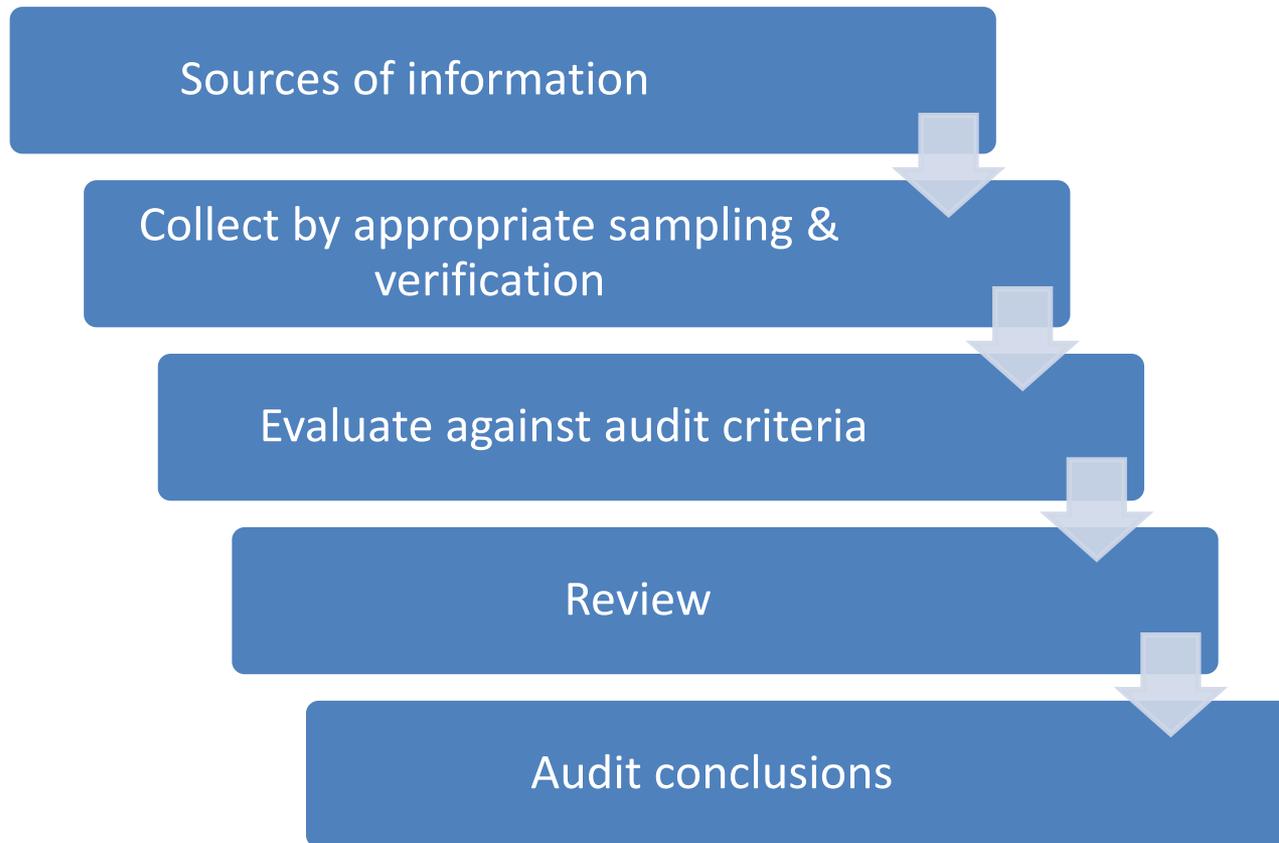
Group Exercise

In your group, take 30 min and prepare for an audit of a process of your choice by addressing the following questions:

Question	Your Answer
What do you need (be specific)?	
How are you going to do it (be specific)?	
How will you determine if the process to be audited is meeting requirements (what will you be looking for)?	



Auditing Process



Group Exercise

In your groups, read the assigned scenario and using the CWA 15793:2008 accomplish the following:

Question

Determine the primary subject matter of the scenario and cite what you believe to be the subject of the scenario and the most relevant clause(s).

Determine whether or not nonconformity exists in the scenario.

If there is nonconformity, state what the **requirement** is and what the **evidence** is.

If there is **no** nonconformity state what you can or should **do next** (audit trail, questions, interviews, review documents etc.).

Do not try to outguess the scenarios or read too deep within them!

Summary

- Audits are integral part of assessing laboratory performance
- Audits require a systematic approach

