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BIORISK MANAGEMENT IN (DIAGNOSTIC) LABORATORIES: THE FUTURE CHALLENGES

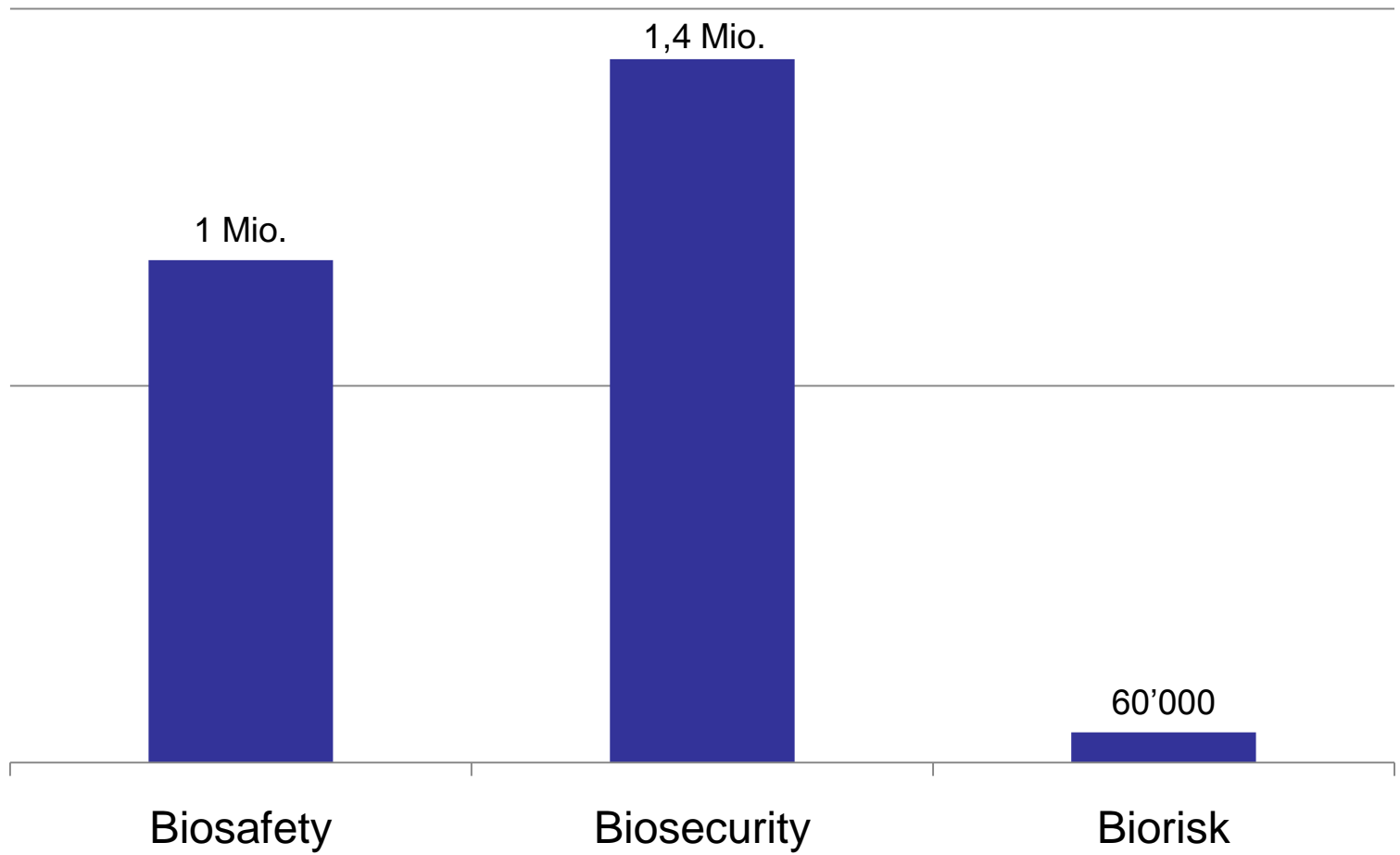
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BRM is more than....







Biorisk

= Risk associated with biological materials

Biorisk has two components:



Safety

Security





Definitions

Biosafety: containment principles, technologies and practices implemented to prevent unintentional exposure to pathogens and toxins or their unintentional release

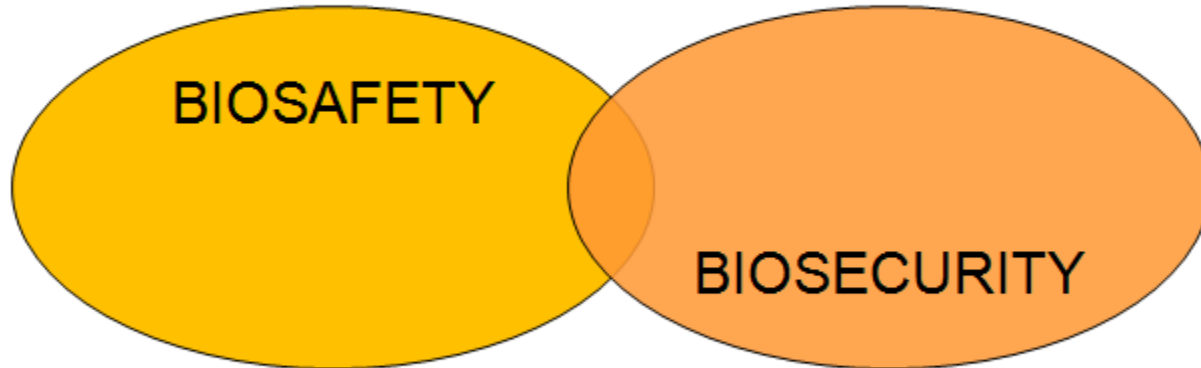
Biosecurity: institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins

Biosafety is to keep bad **bugs** from people
Biosecurity is to keep bad people from **bugs**

E Kampert, RIVM, NL



Biosafety and Biosecurity





Synergy Biosafety and Biosecurity

- Raising awareness of risk
 - Implementation of graded levels of protection based on risk management
 - Access management and control
 - Registration of biological agents
 - Redundancy of building installations to ensure continuation
 - Waste management
 - Training
 - etc
-



Biorisk management model

3 key components:

Biorisk **A**ssessment

Biorisk **M**itigation

Biorisk **P**erformance



AMP Model





Biorisk Management

Biorisk Assessment

Biorisk Mitigation

Biorisk Performance





A = Assessment

What is a hazard?



Hazard is a source that has the **potential** for **causing harm**



A = Assessment

What is a risk? Is hazard = risk?



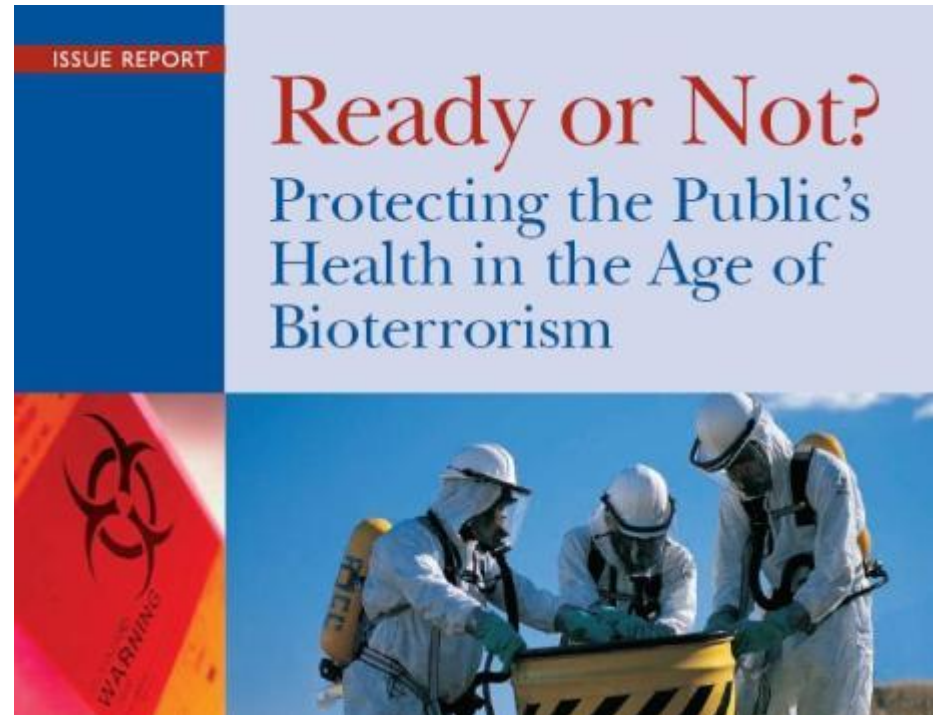
Hazard is **only a risk** in a specific environment or situation



A = Assessment

What is a threat?

Threat is a human who can cause harm - intentionally or unintentionally - to other people, animals, or the institution





Risk

Risk can be based on either a hazard and/or a threat

Street Calculus





A = Assessment

Risk is the **combination** of the **likelihood*** and the **consequences**** of an undesirable event related to a specific hazard or threat



- * probability of occurrence
- ** severity of event



A = Assessment

Where is the higher risk for an infection of the personnel?

1. Spill of 0.5 ml cell culture with high concentration of Influenza A H1N1 on the floor of a BSL-2 laboratory

OR

2. Spill of 5 ml Ebola Zaire virus culture over the positive pressure suit in a BSL-4 laboratory



A = Assessment

e.g. infection of chicken with H5N1



No PPE, no isolator

		Likelihood		
		Low	Medium	High
Consequences	High	Yellow	Orange	Red Star
	Medium	Green	Yellow	Orange
	Low	Green	Green	Yellow



Biorisk Management

Biorisk Assessment

Biorisk **Mitigation**

Biorisk Performance





M = Mitigation

Engineering controls: equipment, materials or any other aspect of work environment that reduce or prevent exposure to hazards

Administrative Controls: policies, standards, guidelines to control risk

Practices and Procedures: processes, activities that have been shown in practice to be effective

Personal Protective Equipment: devices worn by workers to protect against hazards



Engineering controls



Waste water treatment
at the IVI



Administrative Controls



Training courses,
SOP...



Practices, procedures and methods





PPE



H5N1 Infection studies



M = Mitigation



Full PPE or isolator and proper training (operation and emergencies) and vaccination

Consequences

Likelihood

	Low	Medium	High
High	Yellow	Orange	Orange
Medium	Green	Yellow	Orange
Low	Green with red star	Green	Yellow

e.g. infection of chicken with H5N1



M = Mitigation

	Advantages	Disadvantages
Engin. Controls	Efficient, eliminates hazard	Costs, complexity
Admin. Controls	Authority approach	Indirect approach, addresses human factor
Pract. & Proced.	SOP based (standardized)	Training and supervision requirement
PPE	Ease of use, relative cost	No elimination of hazard, uncomfortable



Biorisk Management

Biorisk Assessment

Biorisk Mitigation

Biorisk **P**erformance





P = Performance

- is the way in which someone or something functions
 - is the result of all the efforts of an organisation or a facility
 - assures that a system works, that it is sustainable and that the risk is acceptable
 - e.g. No laboratory associated infections.....
-



P = Performance

- is managed by control of procedures, processes, structures and responsibilities
 - is assured by checking the system through audits and inspections
 - is improved by setting and achieving (new) goals based on internal and external feedback
-

CWA 15793:2008

Identification of biorisks

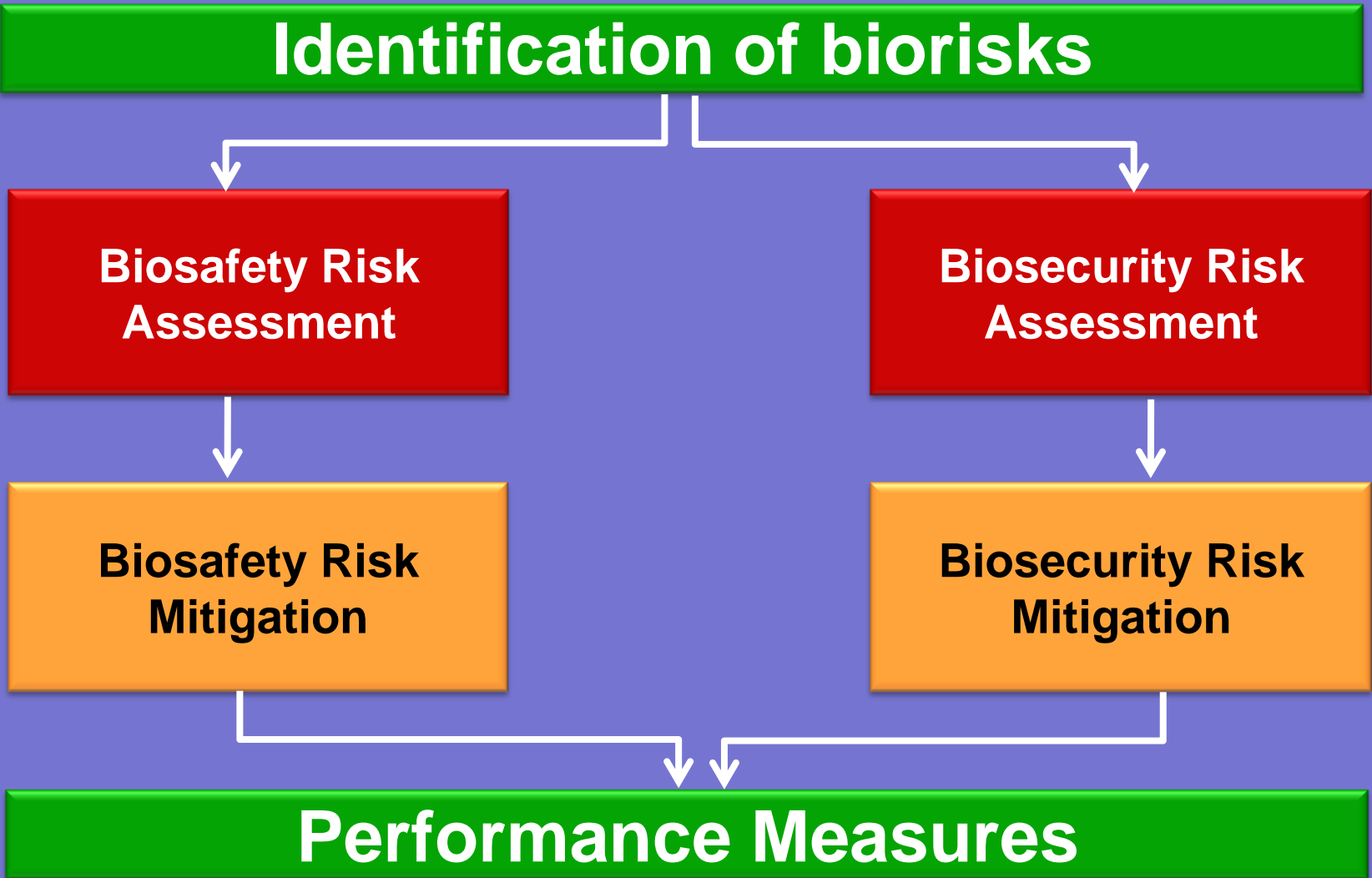
Biosafety Risk
Assessment

Biosecurity Risk
Assessment

Biosafety Risk
Mitigation

Biosecurity Risk
Mitigation

Performance Measures





CWA 15793:2008

Is a management System

Is consistent with ISO 9001/14001

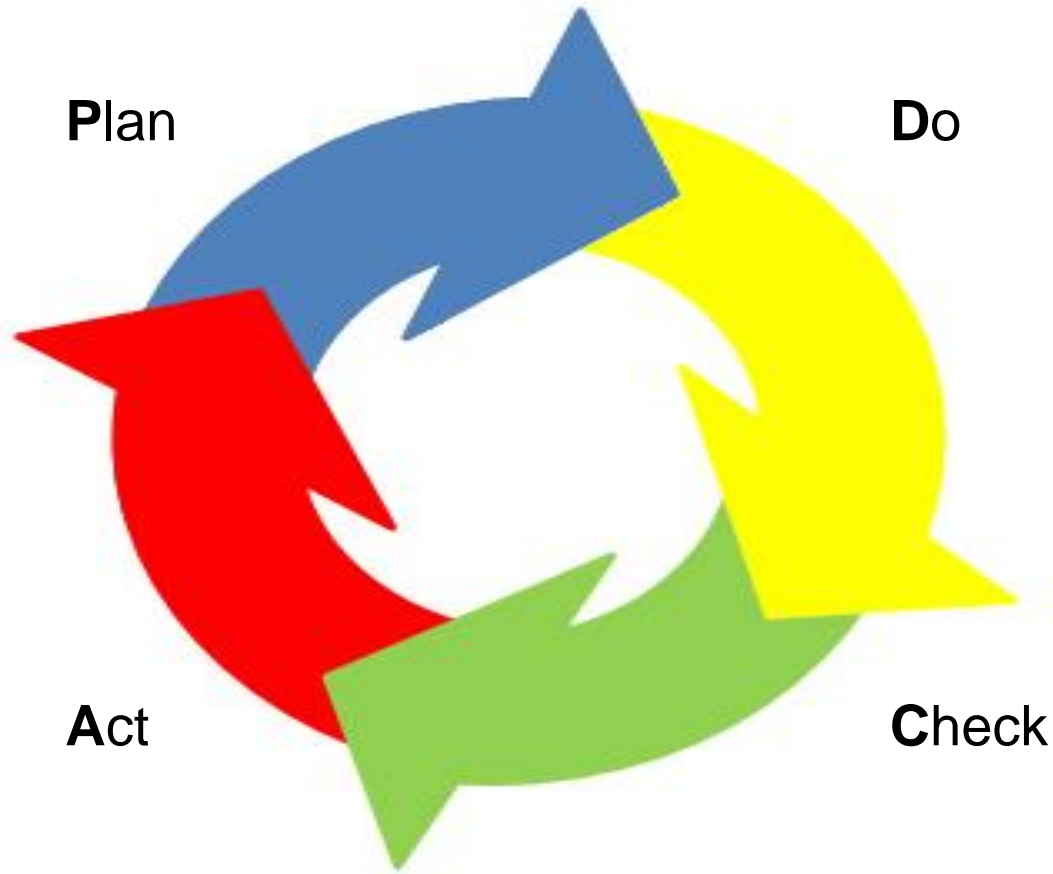
Is performance based

Is voluntary

Is plan-do-check-act-based (PDCA)



PDCA (= tool of quality control)





AMP vs PDCA

Plan

- Identification of potential for improvement
- Analysis of current situation
- Development of new concepts

Do

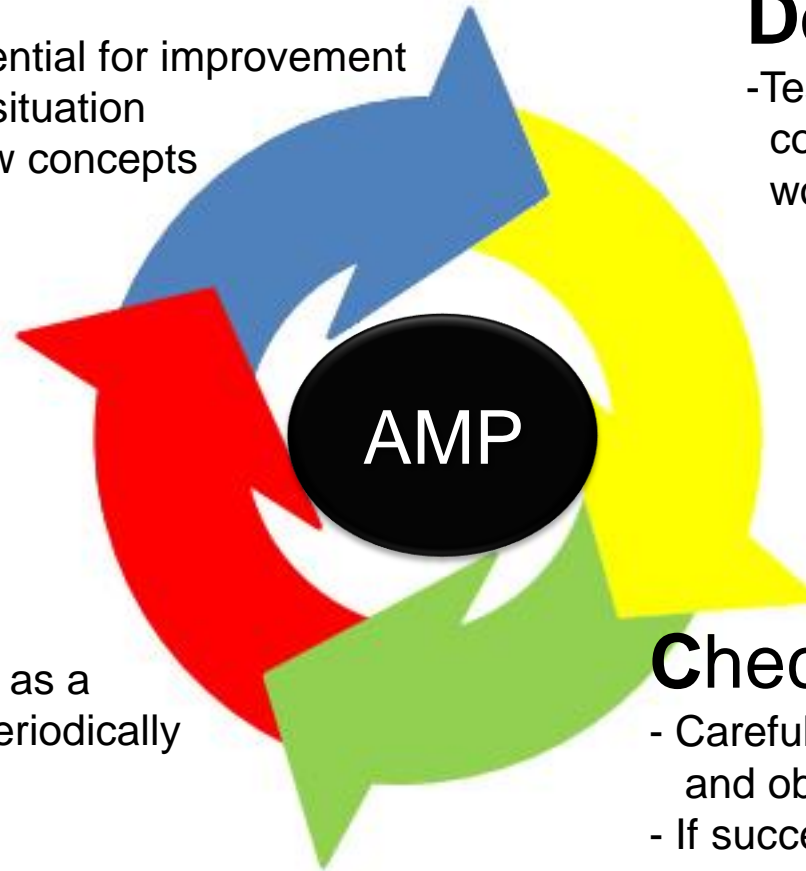
- Testing and optimization of new concepts by basic means at one working place

Act

- Full implementation as a standard which is periodically checked by audits

Check

- Careful checking of process and obtained results
- If successful → full approval as a standard process





Implementation of CWA

Appointment of a biorisk manager, who

- ensures that all requirements of the standard are identified and addressed (e.g. gap analysis)
- interacts with different sections involved
- manages tasks and timelines





Implementation of CWA

Gap analysis:

- Existing documentation
 - Responsibilities
 - Document owner
 - Status of requirement
 - Location
 - Review and approval
-



From theory to praxis



LARS Grid ^{11.1.2010}



Audits: who should conduct them?

- 1. Regular inspections for legal compliance (biosafety, occupational safety, radiation safety, etc)
 - National authorities
 - Important: not any of your funding agencies
 - QA audits (ISO 17025)
 - 2. Internal audits: BRM
 - 3. Biorisk management audits by independent review team
-

External Management Audit

Institute of Virology and
Immunoprophylaxis IVI

Review of Biorisk Management System

Paul J Huntly, Denise Elson, Evelyn Vancauwenberghe & Anna Hayman
03 September 2007



Needs to be planed well in advance
Consider the costs!
www.dnv.com



Accidents

Nanaimo Daily News. 8°C Light rain showers Detailed Forecast

Home Search for in the Daily News find Friday, March 20, 2009

Bird flu, Ebola virus accidents in Europe labs raise biosecurity concerns
Laura MacInnis and Debra Sherman, Reuters
Published: Thursday, March 19, 2009

GENEVA/CHICAGO - Lab accidents involving bird flu and Ebola viruses have increased biosecurity fears in Europe, where public health experts say research on dangerous pathogens needs to be more strictly monitored.

A scientist in Germany last week pricked herself with a needle that was believed to be contaminated with a strain of the Ebola haemorrhagic virus with a mortality rate of around 90 per cent. She is still under observation in hospital.

That accident added to public health concerns following the recent disclosure that deadly H5N1 bird flu virus samples were mixed with seasonal flu samples at a Baxter International contracted laboratory in Austria.

Health authorities and industry groups reviewing European lab safety standards concluded in a new report that scientists and managers needed to be better trained in ways to prevent, handle and report such incidents.

While stressing that research on viruses and pathogens is important for vaccine, drug and

Related Links

*„An unfortunate event in which the presence of mind is good,
but absence of body is better“*

Gordon Weier, General safety officer, University of Alberta, Canada



Laboratory incidents/accidents

- **Incident:**
 - Small spill inside a laboratory
 - Large spill inside a laboratory without any consequences for the environment
- **Accident:**
 - Laboratory acquired infections
 - Spills/leakages resulting in release of infectious agents to the environment
 - Failure of technical safety measures, with or without consequences for the environment
 - Inadvertent release without anybody being aware of

Do you have a reporting system in place?



Accident reporting

- Not a „blame“ culture
 - Reporting needs to be encouraged
 - Same type of accident?
 - Same person involved?
→ why?
-



Conclusions

- Biorisk management system to manage biosafety and biosecurity risks
- Integration into existing management systems
- Responsibility for the biorisk management lies upon top management

How is it in your organisation?



Acknowledgement:

2nd International Biorisk Management Workshop, May 11-14, 2010 Winnipeg

- IVI and others for providing the pictures

