



BWC 6th Review Conference, Geneva, 2006

Enhancing Biosafety and Biosecurity

International Standard for Microbiological Containment Laboratories

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European BioSafety Association

www.ebsaweb.eu

EBSA is committed to enhancing the knowledge and understanding understanding of biological safety issues throughout Europe.

It strives to establish and communicate best biosafety practices amongst its members and to encourage dialogue and discussions on developing biosafety and biosecurity issues.

EBSA will seek to influence and support emerging legislation and standards in the areas of biological safety, biosecurity, biotechnology, transport and associated activities and will act as a focal point for the consolidation of views on these issues.

EBSA will strive to represent the interests of its members in all areas relating to biosafety, with the objective of ensuring the prevention of harm to man or the environment from biological substances or materials.



European BioSafety Association

www.ebsaweb.eu

Annual conference

Heidelberg, March 28-30, 2007

Preconference workshops:

- Export, import and transport of GMOs and other biologicals from a practitioners point of view
- Biosafety audits and inspections
- Decontamination
- Training: how to set up an internal biosafety program
- Biosafety management: policy and procedures within the organisation





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Project participation

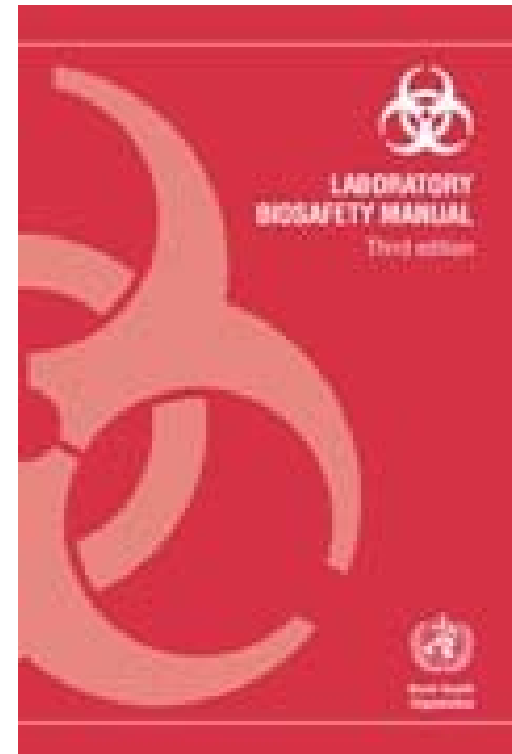
- **BIOSAFETY-EUROPE**
Coordination, harmonization and exchange of biosafety and biosecurity practices within a pan-European network. European Commission 6th Framework Programme.
- **Biosafety Officer Competence**
To identify competency requirements, tasks and skills of the Biosafety Officer (BSO) to understand training needs and develop suitable programs.
- **Laboratory Standard**
Development and adoption of internationally recognized standards for management of micro-organisms and their products within laboratory environments.



Laboratory Biosafety

.... the containment principles, technologies and practices that are implemented to *prevent the unintentional exposure to pathogens and toxins, or their accidental release.*

WHO Laboratory Biosafety Manual, 3rd ed., 2004



Laboratory Biosecurity

.... to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.

Biorisk management
Laboratory biosecurity guidance
WHO/CDS/EPR/2006.6



Biorisk management

Laboratory biosecurity
guidance

September 2006

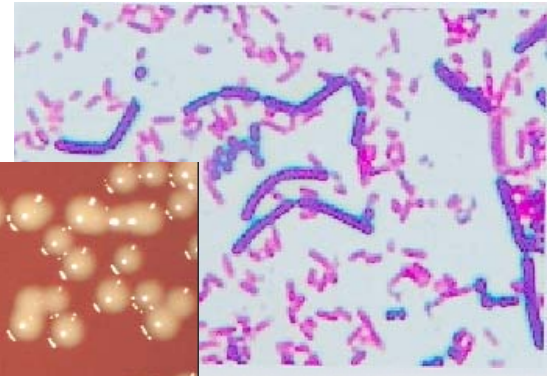
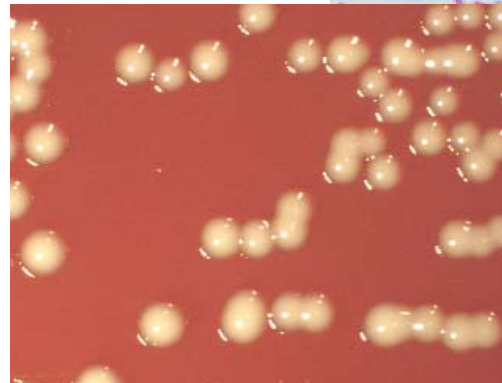


Laboratory infections, history

Sulkin and Pike (1951 -76)

active surveillance of 5000 laboratories: 3.921 cases
4,1% mortality

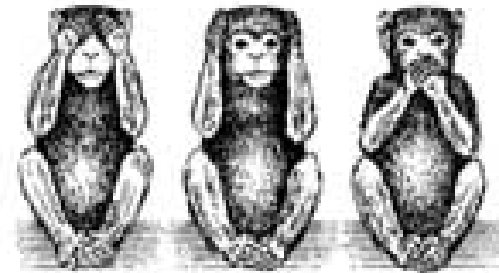
- brucellosis
- Q fever
- typhoid fever
- hepatitis
- tularaemia
- tuberculosis
- dermatomykoses
- VEE



Laboratory acquired infections, causes

Known accident or incident in **only 18 %**
of laboratory infections, of which

- 25 % needle stick injuries
- 27 % “spills”



Natural transmission routes

- Airborne
 - Aerosol (liquid particles) or dust: *varicellae, measles,*
 - *legionella, tuberculosis, antrax*

- Contact
 - Direct contact: *herpes virus (sore lip), syphilis, gonorrhoea*
 - Indirect contact: *hospital-acquired infections, influenza*

- Water- foodborne
 - *Hepatitis A, salmonellosis, cholera*

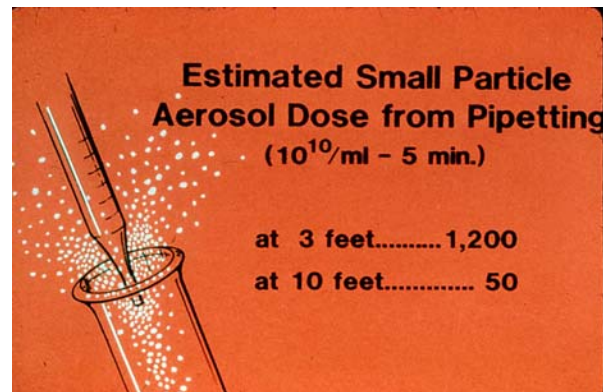
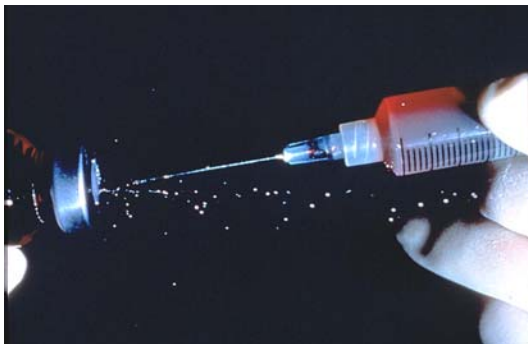
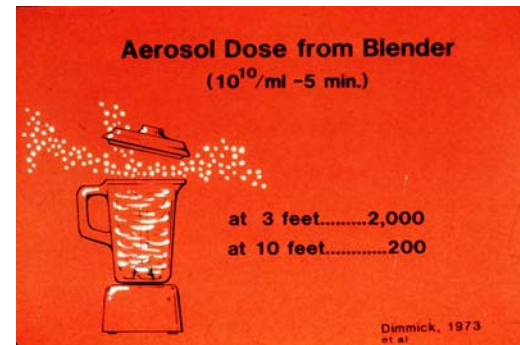
- Inoculation (blood)
 - *Hepatitis B and C, HIV*

- Vector borne
 - *(TBE), tularaemia, borreliosis*



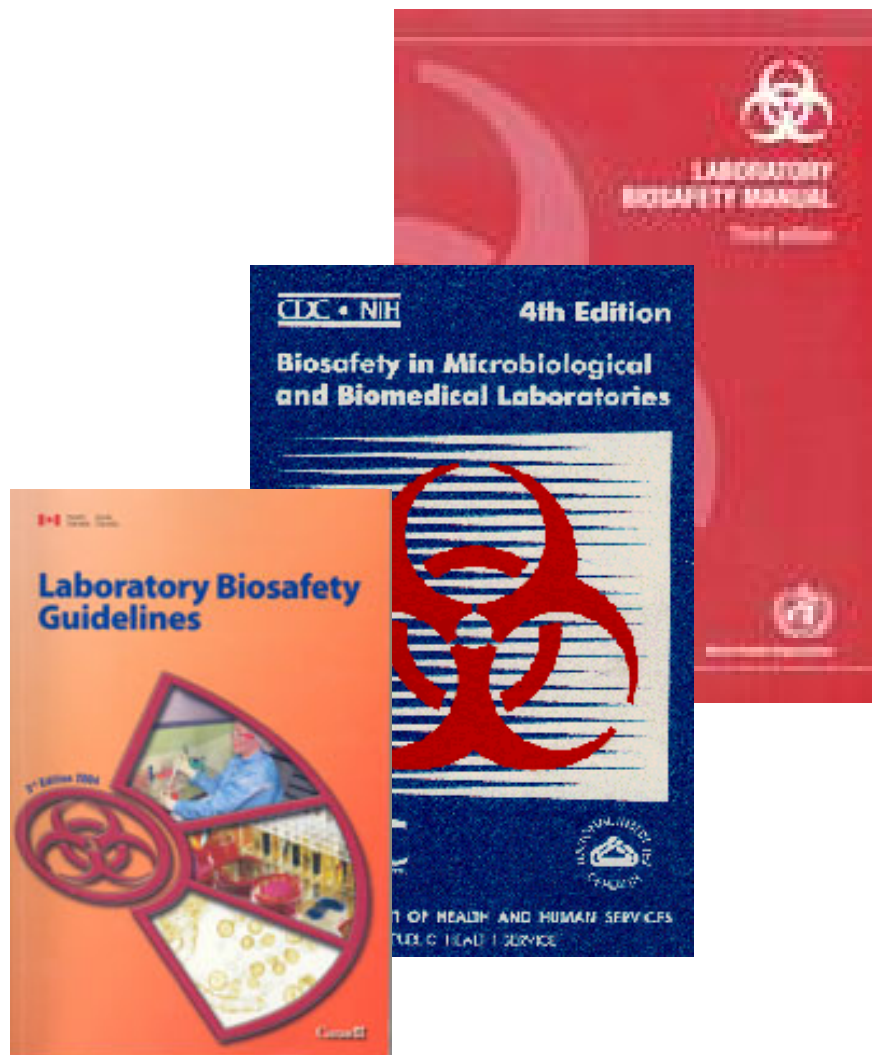
Transmission routes in the laboratory

Airborne, aerosol



Guidelines

- WHO Laboratory Biosafety Manual, 3rd ed. 2004
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) CDC/NIH, 4th ed. 1999
- Laboratory Biosafety Guidelines, Health Canada, 3rd ed. 2004





The EC regulatory framework related to biosafety/biosecurity

Worker protection

- Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work
- Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work

Genetically Modified (Micro) organisms

- Directive 98/81/EC on the contained use of micro-organisms
- Directive 2001/18/EC on the deliberate release into the environment
- Regulation (EC) 1829/2003 on genetically modified food and feed

Dual use

- Regulation (EC) No. 1334/2000 setting up a Community regime for the control of exports of dual-use items and technology

Plant pathogens and protection of the environment

- Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community
- Directive 95/44/EC ... harmful organisms, plants, plant products and other objects ... may be introduced into or moved within the Community

Environmental liability

- Directive 2004/35/EC

Transboundary movement of GMOs

- Regulation (EC) No. 1946/2003 on transboundary movements of genetically modified organisms

Environment

- Directive on hazardous waste 94/31/EC(2)



International conventions, recommendations, standards

Cartagena Protocol on Biosafety (Montreal, 2000)
www.biodiv.org/biosafety/ UN

Recommendations on the Transport of Dangerous Goods. Model
Regulations. 14th rev.ed (2005).
www.unece.org/trans/danger/publi/unrec/rev14/

ISO/CE ... Standards on quality, technical installations and equipment

ISO EN 15189 Medical laboratories - Particular requirements for quality
and competence (2003)

OECD Principles of Good Laboratory Practices and Compliance
Monitoring ENV/MC/CHEM(98)17 (1-11)

CEN/CR 12739 Biotechnology - Laboratories for research, development
development and analysis - Report on the selection of equipment
needed for biotechnology laboratories according to the degree of
hazard (1998)



Classification of biological agents

WHO/LBM 2004; AFS 2005:1

- Risk Group 1** *(no or low individual and community risk)*
A microorganism that is unlikely to cause human or animal disease
- Risk Group 2** *(moderate individual risk, low community risk)*
A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment...
- Risk Group 3** *(high individual risk, low community risk)*
A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
- Risk Group 4** *(high individual and community risk)*
A pathogen that usually causes serious human or animal disease and that can be readily transmitted... Effective treatment and preventive measures are usually not available.

Risk classification of biological agents

EG-Directive 2000/54/EG; AFS 2005:1

Examples of microorganisms in risk group 3 or 4

Virus		Bacteria	
Hantaa virus	3	<i>B. anthracis</i>	3
Flaviviridae (TBE)	3	Brucella spp	3
SARS CoV	3	<i>E. coli</i> , VETEC	3 (**)
Avian flu H ₅ N ₁	3	<i>Francisella tularensis</i> A	3
HBV, D	3 (**)	<i>M. tuberculosis</i>	3
HCV, E, G	3 (**)	<i>Salmonella typhi</i>	3 (**)
HIV	3 (**)	<i>Shigella dysenteriae</i> 1	3 (**)
Rabies	3 (**)	<i>Rickettsia prowazekii</i>	3
Prions	3 (**)	<i>Yersinia pestis</i>	3
Variola (major/minor)	4		
Ebola och Marburg	4		
Lassa fever virus	4		
CCHF	4		

(**) = not airborne under normal conditions, see AFS 2005:1

Laboratory Biosafety

.... the containment principles, technologies and practices that are implemented to *prevent the unintentional exposure to pathogens and toxins, or their accidental release.*

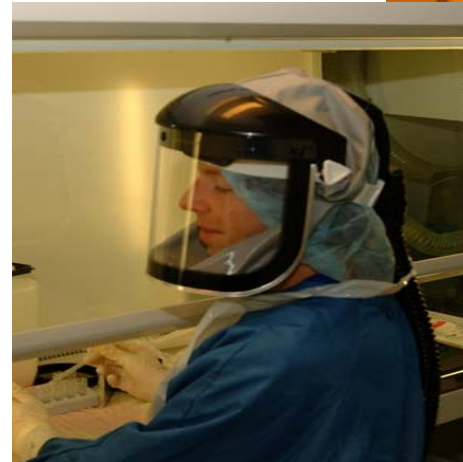
Containment

- Primary barrier
- Secondary barrier

Containment...

Primary barrier

- Safety equipment
 - ❖ Biosafety cabinet (BSC) class I, II, III
 - ❖ Automatic pipettes
 - ❖ Safety cups for centrifuges
- Personal Protective Equipment (PPE)
 - ❖ Gown/coverall
 - ❖ Gloves
 - ❖ Respiratory protection
 - ❖ Goggles/visir



Containment

Secondary barrier

Facilities

- ❖ outer boundary; wall, floor, window, tightness
- ❖ ventilation; airducts separate, filter, directional airflow, tightness
- ❖ waste water decontamination; hyperchlorination, heat disinfection, tightness
- ❖ waste disposal; decontamination/autoclaving, final deposit



Biosafety levels of laboratories

Level 1-4

Biological Safety Level (BSL 1-4), US et al.

Physical Containment Level

(PCL 1-4, P 1-4, CL 1-4), Europe

High containment (security) laboratories: P 3 o 4



Requirements on facilities for microbiological laboratories, EN 12128

Requirement for biosafety levels	2	3	4
Separate location	Avgränsbar	Y	Y, sep.building
"Biological hazard" sign	Y	Y	Y
Air lock entrance	No	Y	Y
Observation window	No	Y	Y
Separate ventilation system	No	Y	Y
HEPA on exhaust	No	Optional	Y
Negative air pressure, directional airflow	No	Y	Y
Personal shower out	Optional	Optional	Y
Biosafety cabinets	Optional	Y	Y
Sealable for decontamination (fumigation)	Optional	Y	Y
Decontamination of waste (autoclave)	Y	Y, in lab.	Y, double door
- of waste water	Optional	Y (risk ass)	Y
Back-up power supply	No	Optional	Y
Alarm for safety installations	No	Y	Y

Laboratory Biosafety

.... the containment principles, technologies and practices that are implemented to *prevent the unintentional exposure to pathogens and toxins, or their accidental release.*

Containment

- Primary barrier
- Secondary barrier

Good laboratory praxis (GmLP)

Recent laboratory acquired infections

- SARS 2003-04: 4 lab staff, 7 secondary cases, Singapore, Taiwan, Beijing
- Ebola, 1 death, Russia
- Tb 2004: 3 cases from leaky aerosol chamber, USA
- Legionella 2003: lab. Technician, pneumonia, Sweden
- Cutaneous anthrax 2002: lab technician, Texas
- Vaccinia 2002: lab technician, Brazil
- West Nile virus 2002: 2 cases, USA
- Melioidosis 2000: microbiologist, USA
- Herpes B encephalitis 1997: 23-y woman, dead
- HIV, HBV, HCV, plague, meningococcaemia (clinical lab., polio (prior-76)



BIOSAFETY – EUROPE

A project mandated by the European Commission within the 6th Framework Programme on Research and Technological Development

Coordination, Harmonisation and Exchange of BIOSAFETY and BIOSECURITY PRACTICES within a Pan-European Network

OBJECTIVES

Development of recommendations for future policy making in biosafety and biosecurity

Reference list of containment level 3 and 4 laboratories with respect to human, animal and zoonotic pathogens

Inventory of existing criteria, definitions and legal frameworks applicable to containment level 3 and 4 laboratories

Identification of current practices in containment level 3 and 4 biosafety and biosecurity training in Europe

Assessment of current biosafety/biosecurity measures and methods and their cost effectiveness

Relative contribution of physical design, personnel selection and management and best practices for the reliability of biosafety and biosecurity precautions



Biorisk management system...

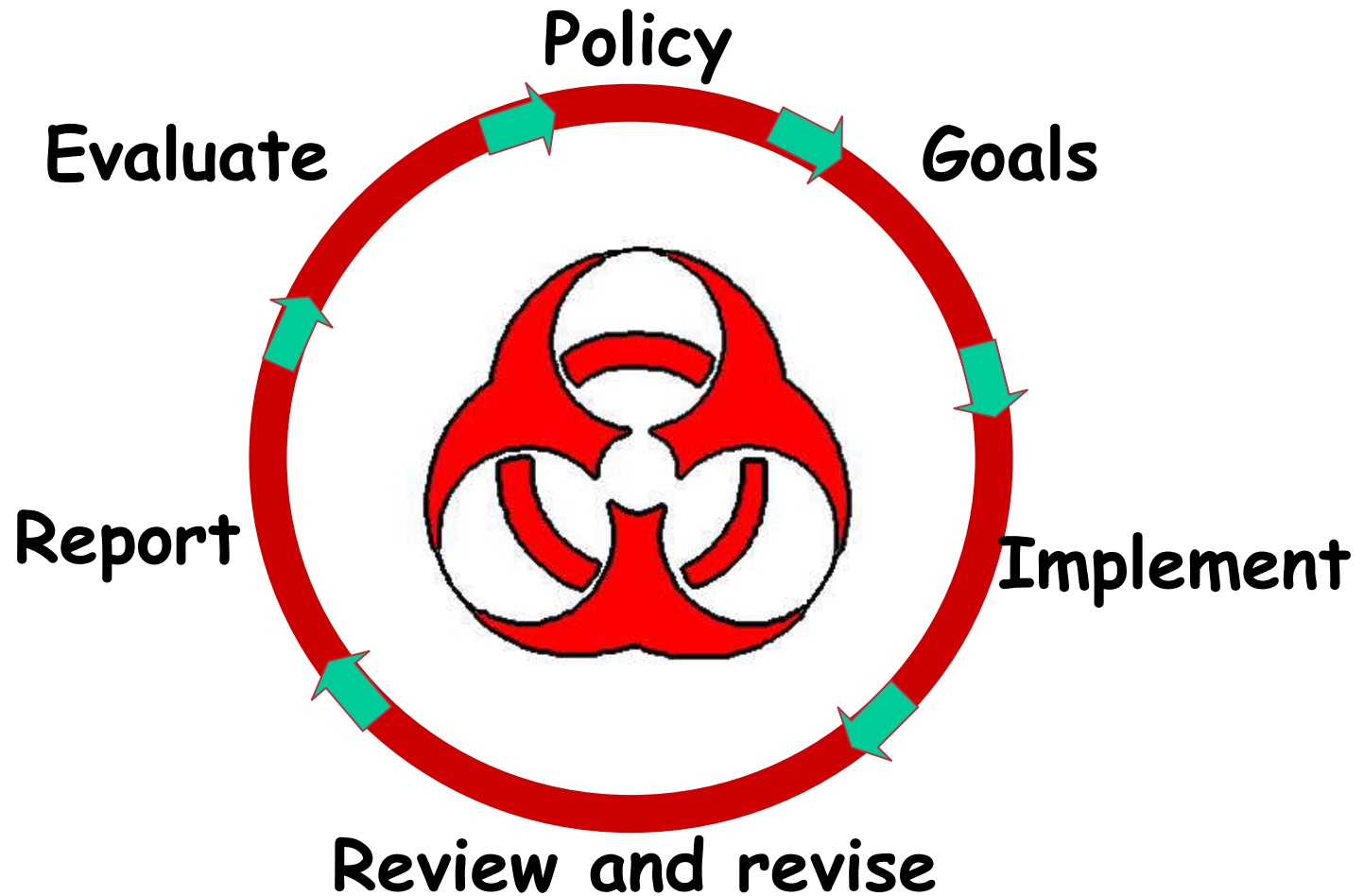
- Policy
- Management organization, commitment
- **Biosafety Management Program**
 - Risk management
 - Biosafety Officer
 - Biosafety Committee
 - Recruitment, education and training
 - Safety equipment and personal protective equipment
 - Disinfection and decontamination
 - Microbial inventory



Biorisk management system

- Worker's health/Medical surveillance
- Engineering and maintenance
- Accident/incident reporting
- Audits, reviews and revisions
- Emerging issues, new technologies
- Transport
- **Biosecurity**

Biosafety management system





New challenges for laboratory biosafety

- Avian influenza H5N1 Prions
- SARS
- Polio post-eradication
- Genetically modified microorganisms
- Multidrug resistant tuberculosis, M(X)DR TB
- Antimicrobial resistance
- Vector borne diseases
- Biosecurity
- B weapon - terrorism



Biorisk management standard

Aim

Safeguard life, property and the environment from biological risks from handling biological materials, micro-organisms and their products, primarily within the laboratory environment

- *through the development and adoption of recognized standards*



Biorisk management standard

Needs

- Adoption of international best practices
- International exchange and collaboration
- Management system approach
- Internal audit third and party certification
- Requirements for containment facilities



Biorisk management standard

Scope

- Based on the WHO Laboratory Biosafety Manual and Biosecurity guidance
 - any gaps identified or necessary updates may be addressed if required e.g. in the light of new knowledge,

- Focus on micro-organisms and biological materials in the laboratory setting
 - format and medium used will make the information relevant and of value to others working in related areas



Biorisk management standard

Scope

- Designed to address management structure
 - encompassing people, facilities and working procedures
- Not prescriptive in nature (no technical document)
 - The philosophy being that the operator must understand and manage risk



Biorisk management standard

Scope

- Adequate control measures
 - Evidence-based procedures, or recognized good practice, or be demonstrably effective on the basis of risk management

- Associated guidance



Biorisk management standard

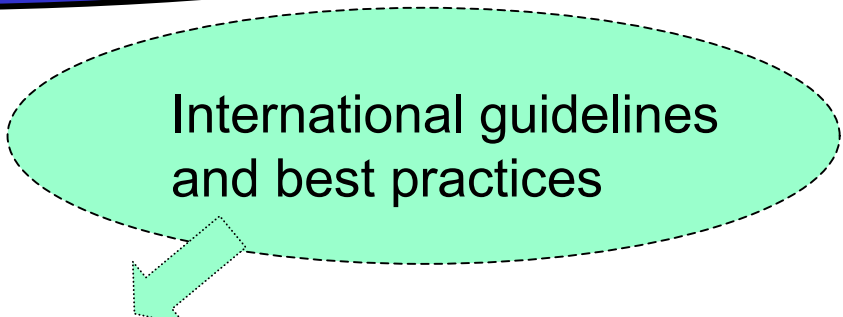
Scope

Compliance with national or sub-national legislation and regulatory requirements

National law,
regulations and policies



International guidelines
and best practices



Biosafety policy

***No (=0) laboratory
acquired infections***



Biorisk management standard

Objectives

Help laboratories/organizations establish a biosafety and biosecurity management system

Assist in the implementation of the existing WHO biosafety and biosecurity guidelines



Biorisk management standard

Objectives

Internationally recognized third party certification of biosafety and biosecurity management systems

- Controlled by Accreditation Board



Biorisk management standard

Partners



ABSA, EBSA, DNV are partners driving the project, where DNV is providing management support



A-PBA, WHO and others are facilitating the process



The Biosafety & Laboratory Community at large are invited to participate in the standard development





Biorisk management standard

CEN

www.cenorm.be

European Committee for Standardization

CEN workshop

- Fast agreements
- Less expensive than consortia
- Recognized standardization platform
- Technical specifications, good practice, guidance



Biorisk management standard

Phase I – 2005/2006

Development of a project proposal

- Concept
- Statement of Intent
- Business Plan
- Budget

September 2006:

European Commission decided to fund the initiative



Biorisk management standard

Phase II; 2006/2007

CEN Workshops

1st CEN Workshop 2007 at the CEN Premises in Brussels

- Open to any interested party
- Registration required
- Approval of the CEN Workshop Agenda & Plan

Standard draft as CEN Workshop Agreement



Biorisk management standard

Phase III...

- Establishment of an Accreditation Board
 - Certifier (inspector) criteria
- Approval of the CWA standard (2007)
- Distribution and implementation of the standard

Certification of facilities



Biorisk management standard

Continuous monitoring

Validity check after 3 years