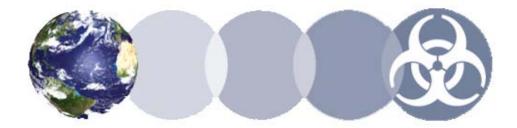


Ensuring Quality Biorisk Management through Certification of Professionals

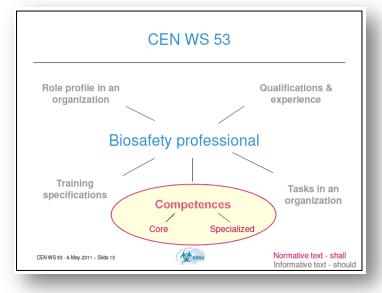
Reynolds M Salerno, PhD Sandia National Laboratories



Biosafety Associations Workshop Seoul, South Korea, 2010

- Many requests from IFBA membership for international certification scheme
- Creation of the IFBA Biosafety
 Professionals Working Group
 - Co-chaired by US & Pakistan with members from around the world
- Outreach questionnaire sent to all members, observers, interested parties
 - benefits, challenges of international certification scheme
- Coordination with CWA 53 on Biosafety Professionals Competency





IFBA Biosafety Professionals Working Group

- No international certification scheme exists
- Rely on individuals, consultants, professionals to manage biological risks – no system to assess their qualifications in many different technical specialties



- Widely divergent competencies (well qualified to severely under qualified)
- Clear international demand for graduated certification levels based on specific technical competencies
- Provide confidence that individuals are competent and knowledgeable

IFBA Five-Year Strategic Plan (2011)

Building, empowering and advocating for biosafety communities

- A new edition of the IFBA Compendium of Resources will be published
- Influential and internationally well-recognized individuals will be Champion Advocates for biosafety and biosecurity and the IFBA
- Biosafety and biosecurity is to be recognized as a priority for national public and animal health authorities in locations where, in 2011, there was little or no focus on this issue
- Partnerships/affiliations will be put in place with at least 10 organizations that interface with biosafety and biosecurity
- A new set of criteria for IFBA membership will be developed

Establishing a platform for linking and leveraging expertise and support

An international certification scheme will be established for at least five disciplines

- A biosafety/biosecurity curriculum will be established at three or more international academic institutions
- An electronic platform will be in place for establishing links with educational programs, aiding communication among members, and information/education/resource sharing

Delivering relevant resources and tools in response to emerging needs

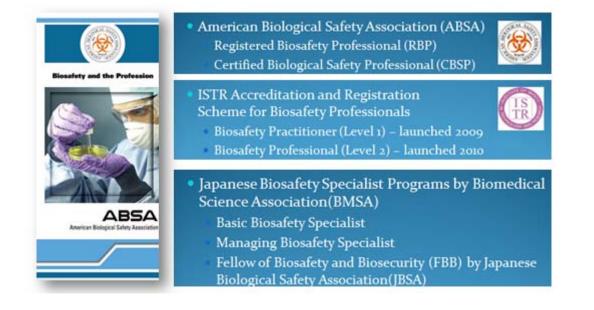
- A quarterly publication providing up-to-date information in the field will be disseminated
- A risk-based approach to biocontainment will be published by the IFBA and endorsed by OIE/FAO/WHO
- Targeted support will be provided to the Mekong Basin Biosafety and Biosecurity Training Centre

Implemented in partnership with biosafety associations & other key partners



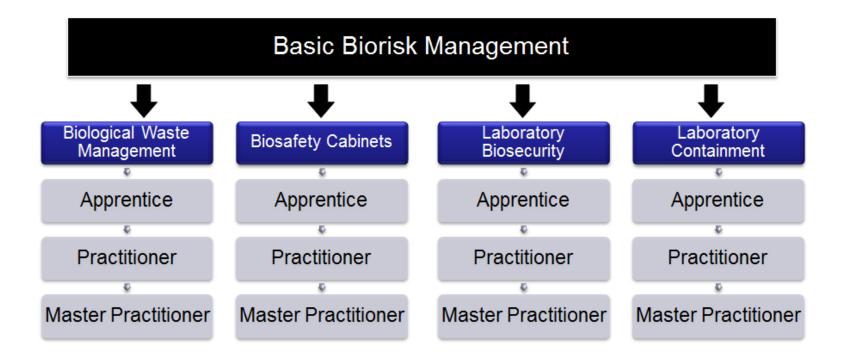
Complementing Existing Schemes

- Various national schemes offer an overarching "credential" & tend to focus on education and professional experience
- Not internationally representative of the various professionals in our field
- IFBA certification in specific disciplines would complement these national overarching schemes

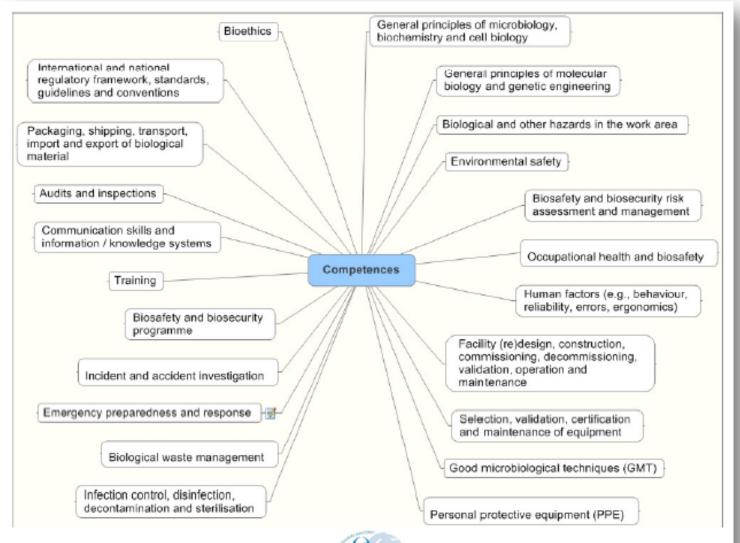


IFBA Certification Program

- Certification in specific technical disciplines rather than an overarching credential
- Graduated levels within each discipline
- Foster continual learning and professional development throughout an individual's career



Technical Disciplines Developed in Comparison with CEN WS 53 Competencies



Technical Disciplines

- Basic Biorisk Management
- Risk Assessment
- Laboratory Operations & Maintenance
- Waste Management
- Decontamination
- Containment Principles
- HVAC Systems
- Filtration Systems
- Personal Protective Equipment
- Biosafety Cabinets

- Laboratory Biosecurity
- Human Performance
- Incident Management
- Lab Planning and Design
- Operational Practices
- Program Management
- SOPs and Documentation
- Shipping & Transport etc.
- Bioethics
- Animal/Plant /Arthropod Biosafety (needs further clarification)
- Training

Certification Levels

• Apprentice

- Knowledge
- Based on an exam
- Lifetime

• Practitioner

- Application of knowledge
- Based on practical assessment
- Ongoing maintenance of certification

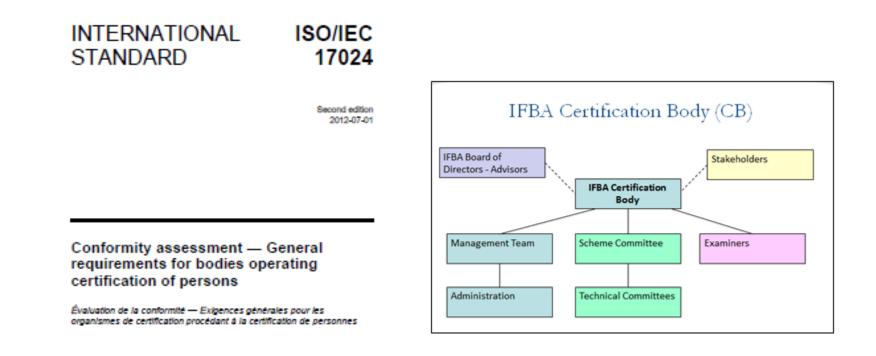
Master Practitioner

- Breadth and depth of experience
- Application to the certification body
- Based on ongoing maintenance of certification



IFBA Certification Program

- Created in accordance with international standards
- Establishment of an IFBA "Certification Body"
- IFBA assessment of competencies must be independent of delivery of training to teach those competencies



IFBA Certification Program

- Competencies and exams created in accordance with psychometrically sound principles for measuring knowledge and competence of individuals
- Valid, fair, reliable, defensible
- Exam blueprint based on job task analysis for each discipline
- Cut score studies to validate the exam

| Test Development Process |
|-----------------------------------|
| 1 Practice Analysis |
| 2 Development of a Test Blueprint |
| 3 Item Development and Validation |
| 4 Pretesting of Test Items |
| 5 Examination Assembly |
| 6 Review and Revision |
| 7 Passing Point |
| 8 Test Administration |
| 9 Psychometric Analysis |

"When establishing a passing score, how does the certification body know that this is the point that separates the candidates that pass from those who fail?"

Stakeholder Engagement







2nd Annual Conference Biosafety and Biosecurity: Building Sustainable Capacity

June 28-29, 2012 Johannesburg, South Africa Sandton Convention Centre

Working Group Three Ensuring Quality Biorisk Management through Certification of Professionals





June 28-29, 2012,

Johannesburg, South Africa

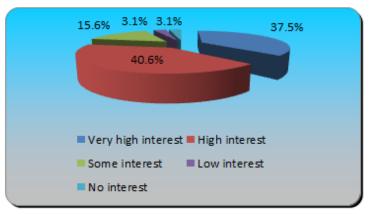
• 130 delegates from 47 countries



WG 3 – Certification of Professionals

• Provide feedback on certification framework & scheme

| 7.) To what extent would your local biosafety community | | | | | |
|---|-----------|--------|--|--|--|
| be interested in a certification program? (multiple choice) | Responses | | | | |
| | | | | | |
| Very high interest | 12 | 37.50% | | | |
| High interest | 13 | 40.62% | | | |
| Some interest | 5 | 15.62% | | | |
| Low interest | 1 | 3.12% | | | |
| No interest | 1 | 3.12% | | | |
| Totals | 32 | 100% | | | |
| | | | | | |



| 9.) To what extent do you think a certification program would enhance safety & security ? (multiple choice) | Res | Responses | |
|---|-----|-----------|--|
| Significantly increased safety & security | 20 | 60.61% | |
| Moderately improved safety and security | 13 | 39.39% | |
| Marginal improved safety and security | 0 | 0% | |
| Totals | 33 | 100% | |



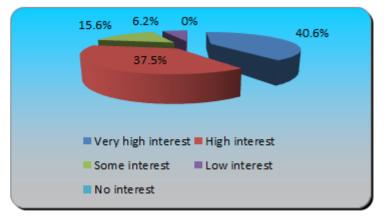
Complete data set available at <u>www.internationalbiosafety.org</u>

WG 3 – Certification of Professionals

• Role for national biosafety associations (e.g. training)

8.) Would your biosafety association or institution be interested in participating in this program? (multiple

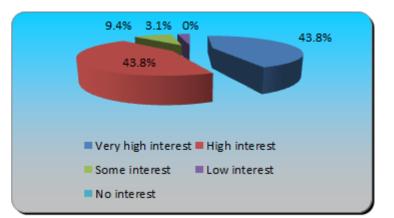
| choice) | Res | Responses | |
|--------------------|-----|-----------|--|
| 1 | | | |
| Very high interest | 13 | 40.62% | |
| High interest | 12 | 37.50% | |
| Some interest | 5 | 15.62% | |
| Low interest | 2 | 6.25% | |
| . No interest | 0 | 0% | |
| . Totals | 32 | 100% | |
| | | | |



11.) Would your association or institution be interested

in providing training programs in support of the

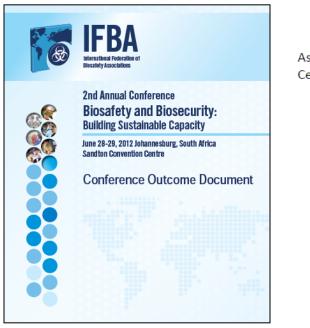
| 4 | certification program? (multiple choice) | Responses | |
|----|--|-----------|--------|
| .[| | | |
| ١ | Very high interest | 14 | 43.75% |
| ŀ | High interest | 14 | 43.75% |
| | Some interest | 3 | 9.38% |
| I | Low interest | 1 | 3.12% |
| I | No interest | 0 | 0% |
| 1 | Totals | 32 | 100% |



Complete data set available at <u>www.internationalbiosafety.org</u>

WG 3 – Certification of Professionals

- Group work to further refine the objectives and competency requirements for 3 technical disciplines (Risk Assessment, Biosafety Cabinets, Biological Waste Management)
- Identified 2 priority technical disciplines for pilot testing
 - Basic Biorisk Management & Biological Waste Management



As a result of the working session, the following priority actions are being taken by the IFBA's Certification Working Group:

- Developing a pilot project to include the basic biorisk management and waste management technical competencies;
- Identifying a country or countries for implementation of the pilot project (e.g. Tier 2 developing countries such Jordan/Thailand, and/or Tier 3 underdeveloped countries such as Sudan/Yemen) in collaboration with local biosafety association partners;
- Refining the certification framework to consider areas of overlap within like families of technical competencies (i.e., pyramid structure);
- Conducting broader market research to ensure adequate uptake of certifications and success of the program;
- Developing a business plan and cost estimate for implementation of the pilot project; and,
- Developing Standard Operating Procedures for the certification program in accordance with ANSI/ISO 17024 and other applicable international best practices & guidelines.

Basic Biorisk Management

Basic Biorisk Management

Specific objectives for this competency comprise the entry level certificant being able to:

- demonstrate a basic understanding of the key concepts, principles, and tools for risk assessment, risk mitigation, and performance at the level of the individual, group, and institution, and how they combine to create a biorisk management system;
- demonstrate awareness of current international guidelines, standards, and best practices for biorisk management, and
- <u>demonstrate</u> understanding of the risk-based approach necessary to begin pursuing, if desired, the practice and experience to qualify for apprentice-level certification in all other technical competencies.

Basic Biorisk Management

The competence requirements to meet this certification are:

- Domain A: Understand the fundamental concepts of a management system;
- Domain B: Define the elements of a biorisk management system;
- Domain C: Be able to explain the CWA 15793 requirements;
- Domain D: Possess knowledge of terms and definitions as defined by CWA 15793 including the importance and distinctions between key biorisk management terminology (i.e., biorisk, biosafety, biosecurity, biorisk management system);
- Domain E: Have an understanding of the World Health Organization's AMP model (Assessment, Mitigation, and Performance);
- Domain F: Identify the key factors in establishing and implementing a successful biorisk management system;
- Domain G: Demonstrate an understanding of the criticality of a comprehensive biorisk management system to reducing the safety and security risks associated with handling, storage, and disposal of biological agents; and,
- Domain H: Demonstrate an understanding of the importance of commitment by top management and a focus on continual improvement to the success of a biorisk management program.

Biological Waste Management - Apprentice

Biological Waste Management – Apprentice Level

Specific objectives for this competency comprise the Apprentice Level certificant being able to:

- demonstrate knowledge and understanding of the risks associated with biological waste;
- demonstrate knowledge and understanding of safe and secure methods for the management, segregation, transportation and disposal of biological waste based on waste type and risk; and,
- <u>demonstrate</u> the understanding of biological waste management necessary to begin pursuing, if desired, the practice and experience for practitioner level certification in waste management.

Biological Waste Management - Apprentice

The competence requirements to meet this certification are:

- Domain A: Understand the different types of biological waste (solid, including sharps; liquid; mixed waste (biological/chemical or biological/radioactive);
- Domain B: Possess knowledge of the fundamental risks associated with biological waste;
- Domain C: Demonstrate an understanding of the steps required to manage biological waste: segregation, labelling, collection, storage, transport, treatment, and final disposal;
- Domain D: Identify and understand the functioning of different types of safe and secure biological waste treatment and disposal options available and when they are appropriate to use (e.g. autoclaves and other steam-based equipment, incinerators, irradiators, liquid effluent treatment systems);
- Domain E: Identify categories of chemical inactivation methods and understand their limitations, advantages and disadvantages;
- Domain F: Understand validation efficacy monitoring procedures for each of the biological waste treatment options;
- Domain G: Possess knowledge of safety and security measures needed to manage biological waste (e.g. personal protective equipment, appropriate waste containers); and,
- *Domain H:* Be able to explain the local/national regulatory framework and industry best practices that govern the management of biological waste.

Biological Waste Management - Practitioner

Biological Waste Management – Practitioner Level

Specific objectives for this competency comprise the Practitioner Level certificant being able to:

- demonstrate knowledge, understanding and has practical experience in managing the risks associated with biological waste;
- demonstrates knowledge, understanding and has practical experience in applying the principles of safe and secure management and disposal of biological waste; and,
- demonstrate the understanding and have practical experience in managing biological waste necessary to begin pursuing, if desired, the master practitioner level certification in waste management.

Biological Waste Management - Practitioner

The competence requirements to meet this certification are:

Be able to constructively:

- Domain A: Design and manage a biological waste management plan/program, in accordance with best practices and local, national and international regulations;
- Domain B: Demonstrate skills and practical experience in administering a biological waste management program;
- Domain C: Implement and communicate the biological waste management program including through the development of Standard Operating Procedures;
- Domain E: Maintain biological waste management program documentation;
- Domain F: Continually review, assess and improve the biological waste management program; and
- Domain G: Communicate the risks associated with biological waste and to raise awareness on the importance of proper waste management in places where scarce regulations exist.

Possess knowledge of and have practical experience in:

- Domain H: understanding the different types of biological waste (solid, including sharps; liquid; mixed waste (biological/chemical or biological/radioactive);
- Domain I: understanding the functioning of different types biological waste treatment and disposal options available (e.g. autoclaves and other steam-based equipment, incinerators, irradiators, liquid effluent treatment systems);
- Domain J: Understanding the categories of chemical inactivation methods and their limitations, advantages and disadvantages;
- Domain K: Selecting the appropriate method of biological waste treatment and disposal option to manage biological waste safely and securely based on type and risk of waste;
- Domain L: Validating and efficacy monitoring of biological waste treatment options.



- Psychometrician working with Technical Committees on Job Task Analysis, exam development
- Further market research for business plan
- Development & implementation of pilot
 - Basic Biorisk Management
 - Biological Waste Management

Sponsored by:

- US Cooperative Biological Engagement Program
- Sandia National Laboratories



