

CALL FOR PARTICIPANTS

Biosafety and laboratory biosecurity are high on European and international agendas and public fora. The European regulatory framework is complex, covering all aspects of the utilization of biological material (both GMOs and non-GMOs), export controls and the cross-border movement. European Community Directives are transcribed by Member States into national legislation, with some detailed variation from country to country. Non-EU countries within the European continent have their own regulatory requirements although some have adopted regulations similar to those of the European Community.

For adequate laboratory biosafety and biosecurity the main pillars are a programme based on a biorisk management system and the availability of a person – a “biosafety professional (BSP)” with the appropriate skills to develop and manage such a programme. Through a CEN Workshop consensus process initiated by the American Biological Safety Association (ABSA), the European Biosafety Association (EBSA) and Det Norske Veritas (DNV), and financed primarily by the European Commission, the Laboratory Biorisk Management Standard was approved as a CEN Workshop Agreement, CWA 15793, by its international participants and published on February 2008.

The Laboratory Biorisk Management Standard recognizes a key role for the biosafety professional in a laboratory biosafety and biosecurity management programme. While the Laboratory Biorisk Management Standard defines the role of the BSP in general terms, the

present initiative complements the Laboratory Biorisk Management Standard by clearly defining the role profile, the tasks and competency requirements for the BSP, developing a curriculum to train the BSP and setting a framework for establishing training programmes. The document should be written and structured in such a way that it could provide means to facilitate any future initiatives for certification of biosafety professionals. For this purpose, the European Biosafety Association (EBSA) under the auspices of the European Committee for Standardization (CEN) proposes a CEN Workshop Agreement (CWA) process managed by the Nederlands Normalisatie-instituut (NEN) to define the BSP's role, tasks and training needs.

OBJECTIVES

Within an organization the responsibilities for a laboratory biosafety and biosecurity management programme are held by senior management. But the role and knowledge of the BSP is crucial to develop, implement, maintain and continually improve such a laboratory biosafety and biosecurity programme based on a management system approach

The objective of the proposed CEN Workshop is to reach consensus on:

1. the role profile of a BSP;
2. the tasks of a BSP;
3. the required skills of a BSP;
4. a curriculum to achieve the required skills:

- basic curriculum for containment levels 1 and 2 activities in microbiological, clinical, animal and plant handling facilities;
- additional curriculum for specialist areas such as:
 - containment level 3 activities in microbiological, animal and plant facilities;
 - work with laboratory animals;
 - gene therapy;
 - large scale production;
 - insect activities;
 - containment level 4 activities.

PARTICIPATION

The final document will be the result of the work of the participants built on consensus. You can participate in the entire process by registering as a participant of the Workshop or you can provide input during the public comment period. Plenary meetings will take place at the DECHEMA facilities in Frankfurt, Germany.

VENUE

DECHEMA e.V.
Theodor-Heuss-Allee 25
60486 Frankfurt am Main
Germany

<http://www.dechema.de>

TIMETABLE

- Kick off meeting – 17 December 2009
- First plenary meeting – 18 December 2009
- Second plenary meeting – 27-28 May 2010
- Public comment – 60 days – September 2010
- Final workshop meeting – May 2011

To initiate the discussion process, EBSA's Biosafety Professional Competence Task Group, in collaboration with the Swiss Biosafety Curriculum Development Group, has prepared a draft document.

REGISTRATION

The kick off meeting and public comment period are open to all those interested free of charge. You need to register to participate at the kick off meeting. Registration for the kick-off meeting is now possible on the CEN website:

<http://www.cen.eu/cenorm/sectors/sectors/iss/pm/ws+meeting+registration.asp>

At the kick-off meeting, CEN Workshop 53 will be officially launched. From that moment on, you can register as a member of the workshop at the Workshop secretariat.

Registered organizations including companies, Government Departments, etc. will be required to pay a one-time fee of Euro 200 as a contribution to the costs of the Workshop, which will allow for the participation of one representative in the Workshop consensus process. The number of individuals from

registered organisations admitted to the Workshop mailing list will not be limited. However, participation in meetings may be limited for logistical reasons.

Deadline: 4 December 2009

INFORMATION

More information can be found at the CEN website under the following link:

<http://www.cen.eu/cenorm/sectors/technicalcommitteesworkshops/workshops/ws53-bsp.asp>

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CONTACT

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CEN Workshop

on

Biosafety Professional Competence

WS 53-BSP