

## **Business Plan for a CEN Workshop**

### **Laboratory Biorisk Management**

#### **1 Introduction**

This project has developed following initial discussions with key stakeholders including representatives of the European and American Biological Safety Associations (EBSA and ABSA respectively), the Asia Pacific Biological Safety Association, the World Health Organisation (WHO) and Det Norske Veritas (DNV). Three workshops have now taken place to discuss the background and related issues (Oslo, February 2005; Barcelona, April 2005; Brussels, June 2005). During these workshops a number of presentations have been made with associated discussion regarding the certification process, what might be regarded as best practice and where the biosafety/biosecurity community are at present in terms of standardisation, certification and their development needs.

Underlying this initiative are needs to:

- Improve performance through the adoption of recognised good practice;
- Facilitate international exchange and collaboration;
- Promote training and learning;
- Increase awareness and adoption of management system approaches within the sector;
- Provide organisations with a means for internal audit and third party certification of their facilities and management systems as a demonstration to stakeholders including regulators, funding organisations and the community that there are adequate measures in place to responsibly manage risk associated with biosafety and biosecurity;
- Provide stakeholders with a standard to be used as a benchmark in setting requirements for facilities in the areas of biosafety and biosecurity.

The key stakeholders have come to the agreement to establish this new standard in the form of a CEN Workshop Agreement (CWA).

#### **2 Status of this Business Plan**

Final adopted version.

### **3 Workshop proposers**

Three organizations propose this Workshop and will play a central role in steering the activity: ABSA, EBSA and DNV.

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European Biosafety Association  
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DNV Certification B.V.  
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The Netherlands

### **4 Workshop Objectives**

The objective of this CEN Workshop is to develop and promote the adoption of recognised standards for management of biological risks. It is appreciated that this is a wide ranging field, however commonly shared biorisk principles and practices do apply. Specifically, the objectives proposed will allow laboratories to:

- Establish a biosafety and biosecurity management system to minimise risk to employees, the community and the environment that may be exposed to biological materials as a consequence of its activities;
- Implement, maintain and continually improve biosafety and biosecurity management;
- Assure itself of conformance with its stated biosafety and biosecurity policy;
- Demonstrate such conformance to others;
- Make a self-determination and declaration of conformance;
- Seek internationally recognised third party certification of its biosafety and biosecurity management system.

Initially the following boundaries have been put forward, although these may need to be adjusted by agreement of the Workshop participants:

- The standard will be based around the latest edition of the WHO Laboratory Biosafety Manual and Biosecurity Guidance, although any gaps identified or necessary updates may be addressed if required (e.g. in the light of new knowledge);

- The main focus will be on all biological agents/materials in a laboratory setting, although it is intended that the format and wording used will make the information relevant and of value to others working in related areas;
- The format and content of the standard will be designed to address management system issues in order to allow for a holistic approach encompassing people, facilities and working procedures;
- The issues addressed will relate to biosafety and biosecurity management systems;
- The document will not be prescriptive in nature but will be based upon the philosophy that the operator must understand and manage risk and there may be a number of ways in which adequate control measures can be applied. However, these must be in line with evidence-based procedures, or recognised good practice or be demonstrably effective through the application of risk assessment;
- Associated guidance may be produced to support organisations in identifying how adequate measures can be identified and implemented.
- The proposed standard is not intended to replace any national or sub-national regulatory requirements that may apply to the laboratory/facility.

Although more specialised areas such as facilities designed to handle larger animals and or plants will not be specifically addressed by the proposed project, it is anticipated that many of the principles will be widely applicable to such areas. It is also envisaged that should further, more specialised work be required, this will be considered as part of the project process and additional specific annexes or other measures may be considered during subsequent development stages.

## **5 CEN Workshop Work Programme**

Following approval of the CEN Workshop Business Plan, interested parties must register at the CEN Workshop Secretariat.

A draft of the CWA will be made available for public comment for 60 days.

Participation in the CEN Workshop will remain open to additional interested parties until the end of the public consultation phase.

Timetable (may have to be amended in the light of progress):

Kick-off Meeting and first CEN Workshop Plenary, 12<sup>th</sup> and 13<sup>th</sup> April 2007

Second CEN Workshop Plenary Meeting, 27<sup>th</sup> and 28<sup>th</sup> June 2007  
(Boston, USA)

Draft Agreement published for comments, July 2007

Final Workshop Plenary, November 2007

CWA approved by Workshop participants electronically, and published,  
December 2007

The language of the CEN Workshop and its documentation will be English.

## **6 Workshop Organization**

EBSA and ABSA, with assistance from other national and international biological safety organizations, will provide biosafety and biosecurity expertise and will work to seek consensus on the precise scope and content of the document. These two organizations are the major representative organisations for biosafety/biosecurity in North America and Europe, and are at the heart of the international community in this field, with an ability to call on the greatest available pool of expertise.

DNV will provide a Project Manager for the overall project and draw on their extensive experience within management systems, standard development and certification to provide input into drafting the standard.

The Workshop officers are:

Chair: Dr. Stefan Wagener (ABSA)

Vice-Chair: Dr. Gary Burns (EBSA)

The responsibility of the Workshop Chair is the following:

- To preside at the Workshop plenary meetings.
- To manage the consensus building process
- Represents the CEN Workshop in outside meetings in cooperation with CMC
- To interface with the CEN/CMC regarding strategic directions, problems arising, external relationships, etc.

The responsibility of the Workshop Vice-Chair is the following:

- The co-chair will support and assist in all responsibilities outlined for the chair. In the absence of the Chair, the Vice-Chair will represent the CEN Workshop at outside meetings in cooperation with CMC and will interface with the CEN/CMC regarding strategic directions, problems arising, external relationships, etc.

The responsibility of the Project Manager is the following:

- To liaise with CEN

- To preside at the Steering Committee meetings;
- To ensure that the Workshop delivers in line with its Business Plan;
- To organize and administer the contractual framework between the project members (act as Contractor);
- To respond to queries of the project members and to deal with the financial aspects of it;
- To act as contact point to respond to any queries of interested parties;
- To administer Workshop web-pages open to non-members;
- To prepare agendas;
- To manage the project budget.

NEN, the CEN Dutch member, will provide the Secretariat of the Workshop.

The following activities will be carried out by the Workshop Secretariat:

- registration of WS participants;
- organizing WS plenary meetings (including electronic participation);
- producing WS meeting reports and action lists;
- administrative contact point for WS;
- managing WS membership lists;
- managing WS document registers;
- follow-up of action lists;
- consolidation of the comments received on the draft during the enquiry and sending them to the participants for discussion and resolution;
- sending the comments resolution report to participants and commenters;
- checking conformity of the draft to CEN rules.

## **7 Resources**

The main funding will be provided by the European Commission (Directorate-General Justice, Freedom and Security, European Programme on Critical Infrastructure Protection with additional sponsorship funding coming from ABSA, the Public Health Agency of Canada, AstraZeneca UK Ltd and DNV.

Other registered organizations including companies, Government Departments, etc. will be required to pay a one-time fee of Euro 800 as a contribution to the costs of the Workshop, which will allow for the participation of one representative in the Workshop consensus process.

The Chair, Vice-Chair and Workshop proposing organizations will seek to ensure sufficient involvement of as wide a range of interested parties and countries as possible.

## 8 Related activities

No standards activities are currently known that require liaisons from the Workshop.

## 9 Contact points

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