

Template for comments on prCWA 53:2010 – Biosafety professional competence

Date: 2010-11-09

Document: prCWA 53:2010

1	2	(3)	4	5	(6)	(7)
EX ¹	Clause No./ Subclause No./ Annex (e.g. 3.1)	Paragraph/ Figure/Table/ Note (e.g. Table 1)	Type of comment ²	Comment (justification for change) by the EX	Proposed change by the EX	Proposal to address each comment submitted
	3/3.11	Competence Definition	Te	Competence may be demonstrated in number of different ways. The ability to apply knowledge may be accurately assessed through an observable metric. The current definition may not allow that consideration.	We propose the following edit to the “competency” definition: “a demonstrated ability to apply knowledge, skills and attitudes for achieving observable or measurable results”	
	3/3.23	Standard Operating Procedures Definition	Te	Some activities are non-routine. Some activities are non-repetitive. Activities may be done by individuals or organizations. The current standard operating procedure definition does not provide these recognitions or distinctions.	We propose the following edit to the “standard operating procedure definition: “set of written instructions that document a routine or periodic activity followed by an organization”	
	5	Role of the biosafety professional in an organization	Ed	In describing the role of the biosafety professional, some alternative work choice is suggested. The term, “advise” when used by itself, is more passive and reactionary. Use of the word, “guidance” would be more active and engaging of the role the biosafety professional plays in an organization. Use of the word, “monitoring” in the role description would be more indicative of the role the biosafety professional plays in the biosafety program improvement.	We propose the following edits to the description of the role of the biosafety professional: “The biosafety professional shall - Give advice and guidance to management and personnel on biosafety and biosecurity issues - Support the design, implementation, and monitoring of effective biosafety and biosecurity programmes or systems”	
	B15	Facility planning, (re)design, commissioning, decommissioning, validation, operations and maintenance	Ed	The biosafety professional should participate in the planning and (re)design of facilities. The biosafety professional should provide advice on the measures necessary to ensure biological safety and laboratory biosecurity in consultation with those responsible for the construction, transformation or relocation (architects, building site management, authorities, project leaders, etc.) of facilities. The biosafety professional should provide input to the commissioning process as well as operations and maintenance and decommissioning.	We would propose the following additional text to “Facility planning, (re)design, commissioning, decommissioning, validation, operations and maintenance”: “The biosafety professional should formally participate in the facility commissioning process, as well as any facility decommissioning process.	

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	6	6.1	Te	Relevant knowledge to be a competent biosafety professional may come from a formal education program at a university, but often it may need to be supplemented by post graduate training received in an academic or non-academic setting. Given the dynamic nature of microorganisms and applications done with microorganisms, possession of supplemental training and receiving pertinent supplemental training on an on-going basis is essential for continued competence of a biosafety professional.	We propose the following edit to clause 6.1 in paragraph on Biosafety professional qualifications and experience: “The biosafety professional shall have relevant education, current training and appropriate qualifications to ensure safe and secure handling of biological material .”	
	6	6.1, Note 2	Te	Examples of pertinent life sciences are given, some of them are rather specific. Absent in the examples is microbiology. Inclusion of microbiology should be done here to make possession of this body of knowledge explicit for a practicing biosafety professional.	I propose the following edit to Note 2: “NOTE 2: Some examples of life sciences or related field education include, but are not limited to: biology, biotechnology, medicine, veterinary medicine, pharmacy, agronomy, biochemistry, laboratory technician in biology, or microbiology; related fields include, but are not limited to :public health, environmental health, industrial hygiene, occupational health.	
	6	6.1, Note 3	Te	This clause speaks to the need of biosafety professionals to have pertinent qualifications, but it lack specific detail regarding how such qualifications are to be recognized. In CWA15793, section 4.4.1.2 notes that “the organization shall ensure that qualifications, experience, and aptitudes related to biorisk are considered as part of the recruitment process.” If CWA53 is to be supportive of CWA15793, then guidance should be provided as 4.4.1.2 applies to qualifications of biosafety professionals.	We propose the following edit to Note 3 to paragraph 6.2: “NOTE 3: Qualification [adapted from EN 4179:2005, definition 3.23] is the current, relevant skill, training, knowledge, experience, for persons to perform at a particular level. Qualification may additionally be demonstrated by registration, certification, or accreditation of the biosafety professional in accordance with a nationally recognized body.”	
	7	7.2.14	Ed	The need for validation is noted regarding biomedical waste management, but the need to validate the biomedical waste process should be made explicit.	We propose the following edits to Biological waste management: “The biosafety professional shall be able to develop and implement a biological waste management plan, including validation of the	

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					waste management process.”	
	7	7.2.16	Te	Without references to root cause determination and corrective actions, investigations maybe limited to gathering facts only to prepare required reporting by the institution or government. Providing the additional detail also supports the role the biosafety professional plays in continued improvement of the biosafety programme.	We propose the following edit to Incident and Accident Management: “The biosafety professional shall understand methods of accident and incident investigation to determine root causes and corrective action and shall be able to apply them.”	
	7	7.3	Te	Note 1 Provides examples of specialized competencies which may be required of some biosafety professionals. As written, “clinical/diagnostic” could reference activities in a patient care setting or a clinical diagnostic laboratory.	We propose the following edit to Note 1: “- clinical laboratory diagnostic testing”	
	7	7.4	Te	In order to better assure that a biosafety professional is engaged in proper activities needed to maintain competency, additional detail should be provided here. The edits suggesting these maintenance activities are consistent with biosafety professional’s qualifications and experience presented earlier in clause 6.	We propose the following edit to paragraph 7.4: “To maintain proficiency, the biosafety professional shall engage in professional continuing development as needed to maintain current requisite knowledge and qualifications needed to manage the biosafety programme.”	
	Annex A	A.6	Ed	The term, “biological substances” is used in the last sentence of this Annex. This term is not used elsewhere in the document. Use of a defined term, “biological materials” in its place is suggested to provide consistency and clarity.	We propose the following edit to Annex A.6: “The biosafety professional should know all activities involving biological materials of dual use potential and should be involved in the approval of acquisition, use, storage, and disposal of such materials.”	
	Annex B	B.7	Te	This section deals with emergency plans and exercises. It notes the need for the biosafety professional to participate in training programmes regarding accident prevention, but it does not note the need for the biosafety professional to participate in training programmes regarding emergency preparedness. Many biosafety professionals spend much time in this later training capacity to better assure that these emergency plans will be affective when activated.	We propose the following edit to Section B.7: “The biosafety professional should be involved in coordinating a comprehensive training programme for accident prevention and emergency preparedness “	

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	Annex B	Facility planning, (re) design, commissioning, decommissioning, validation, operations and maintenance	Te	Participation of the biosafety professional in the commissioning process provides the commissioning agents with needed technical detail during the process, and it provides the biosafety professional with additional insight in the facility's operation that would not come with their playing only an advisory role in this processes. Active engagement of the biosafety professional provides quality to this process.	We propose the following additional edit to the end of section B.15: "The biosafety professional should participate in the commissioning process."	
	Annex C	C.2.1.2.10	Ed	Some individuals may have personal medical conditions which would contraindicate their use of a respirator. Such conditions would be identifiable through a confidential medical consultation, and an individual without these considerations could then be medically cleared to wear a respirator. This consideration should be noted in the text of the document when discussing respiratory protection.	We propose the following edit to the Respiratory Protective text of "Personal Protective Equipment": "-Respiratory protection (types, medical clearance, fit testing, maintenance, training)"	
	Annex C	C.2.1.2.19	Ed	There are multiple classifications noted in the Dangerous Goods Regulations (DRG) that could be used to describe a shipment of clinical specimens or other biological material. Any shipper of these materials attempting to classify such shipments would need to be competent to do as per the DRG through applicable training and testing. Since transport of biological agents and toxins would be within the scope of the biological safety programme, a biological safety officer should have the competence to properly classify these shipments.	We propose the following edit to the text of "packaging, shipping, transport, import and export of biological materials" "Fundamentals of shipping classifications, packaging system and transportation."	
	Annex C	C.2.2.10	Ed	Gene therapy encompasses a wide variety of activities. Vector creation and vector administration are only some of the activities encompassed by gene therapy. Inclusion of some of the other significant areas would provide better confidence that the biosafety officer would be well-versed in the major areas encompassed by gene therapy, and, since it is an experimental procedure, the term "therapy" is replaced by "transfer".	We propose adding the following additional areas under "Gene Therapy Activities": "Generation of gene transfer vectors and administration to humans"	

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