VETBIONET

Veterinary Biocontained facility Network for excellence in animal infectiology research and experimentation

Deliverable D3.3

Biorisk management programme for facilities handling large farmed animals to achieve CWA 15793 standard

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Table of contents:

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1. Summary

Objectives: WP3 focuses on the elements and principles of the CEN (European Committee for Standardization) workshop CWA 15793: 2011[1] agreement/standard applicable to farmed animal BSL3/BSL3+ facilities. The CEN agreement is about laboratory biorisk management and the emphasis for VetBioNet is on what is different and challenging about the management of terrestrial farmed animal facilities, and the objective of D3.3 is to define **the Biorisk management programme for facilities handling large animals to achieve CW15793 standard** and any subsequent ISO standard derived from it.

A workshop was organised to discuss and analyse the various clauses of the agreement with project partners and concerned members of the GOHLD (Group Of High containment Laboratory Directors). The objective was to identify steps needed to achieve conformity with any resultant ISO standard, where the requirements of terrestrial farmed animal BSL3/BSL3+ facilities differ from laboratories. This was achieved and additional technical information will be put on the VetBioNet site to help partners achieve this.

2. Introduction

The CEN Workshop Agreement (CWA 15793:2011[1]) provides a management system approach for addressing laboratory biosafety and biosecurity and is compatible with the ISO management systems standards. The bulk of the document is generic, such as commitment by top management and general lab safety, and is applicable to all biocontainment facilities. The purpose of this workshop was to examine where terrestrial farmed animal infection facilities might differ from standard facilities in terms of their requirements and to identify the steps needed to enable these facilities to conform to any emerging ISO standard for biocontainment.

At a basic level terrestrial farmed animal facilities differ from laboratories in terms of the room being the primary containment of the infection unlike a laboratory where microbiological safety cabinets and other mechanical equipment would be. This means there are substantial differences in design to allow the safe working, not only physical protection from the animals but the staff working with them have to rely on personal protective equipment to prevent infection in the case of zoonotic organisms and spread out of the unit. There are also larger amounts of potentially infectious material produced (liquid effluent, used bedding and air volumes). As these animals are experimental animals it is also necessary to consider animal welfare under European Directive 2010/63/EU, which has been translated into national legislation in the member states.

[1] http://www.uab.cat/doc/CWA15793_2011 accessed 18/02/2018

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Consequently, farmed terrestrial infection facilities have particular but individual requirements and generic criteria or guidelines cannot be universally applied. This workshop was to build for a consensus on the types of approach (1) to achieve the standard, (2) to validate performance and (3) developing best practices in biocontainment in this sector**.** Through discussions at the workshop (attendees given in Appendix 1), it has also been possible to identify areas where further information is required in order to help partners achieve this goal.

3. Results

The meeting identified the following key differences or additions to the agreement to the use of biological agents and toxins in the farmed animal BSL3/BSL3+ facilities.

If followed in conjunction with the agreement, it will enable organisations to:

a) Establish and maintain a management system to control or minimize biorisk to acceptable levels in relation to employees, the community and others as well as the environment (VetBioNet =including animals external to the facility) which could be directly or indirectly exposed to biological agents or toxins
b) Provide assurance that the requirements are in place and implemented effectively
c) Seek and achieve certification or verification of the biorisk management system by an independent third party (e.g. licencing authorities)
d) Provide a framework that can be used as the basis for training and raising awareness of laboratory (VetBioNet = animal facility) biosafety and biosecurity guidelines and best practices within the scientific community

The meeting then went through the various clauses of the standard (heading number relate to clause numbers in the agreements.

3.1 Informative references

In addition to guidance documents in the CWA agreement, the following are part

GOHLD Final Admin Update 042516.pdf

O.I.E Chapter 1.1.4 Biosafety and Biosecurity: Standard for Managing Biological Risk in the Veterinary Laboratory and Animal Facilities.

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Other additional standards, relating to specific aspects of containment (e.g. sealability) were also identified during the workshop and these will be added to VetBioNet website when collated.

3.2 Terms and definitions

No additional terms or definitions were identified. It was considered adding a definition of farmed animal but the definitions found were loose i.e. an animal raised on farm, so it was considered not worth adding.

4. Biorisk management system requirements

4.1 General Requirements

There was considered no difference in biorisk management systems (4.1.1) and the need for continual improvement (4.1.2) between a laboratory and BSL3/3+ farmed animal facility

4.2 Policy

There was considered to be detailed differences between a laboratory and BSL3/3+ farmed animal facility, these are given below:

4.2 Biorisk management policy

Change 4.2 e) to: ensuring that the need for effective biorisk management is combined with ensuring the welfare of the farmed animals and that these two elements take precedence over all non “health and safety and animal welfare” operational requirements.

4.3 Planning

There was considered no difference in this section between a laboratory and BSL3/3+ farmed animal facility.

4.4 Implementation and operation

There were considered detailed differences between a laboratory and BSL3/3+ farmed animal facility, these are given below.

For farmed animal BSL3/BSL3+ work there needs to be clear definition of roles and responsibilities between the Facility Management (4.4.1.7) and the Animal Care manager (4.4.1.9) due to the animal room being the primary containment, so needing to maintain uninterrupted containment function for the duration that live infectious material is present. The NADIR project had the concept of building officer having overall responsibility for the operation

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of the facility, assesses competence of staff (both in biosafety and animal welfare aspects) as well as acting as a contact point for staff, engineers or others working in the facility. This is important to meet the agreement on operational control (4.4)

The workshop also agreed that in cases of conflict on decision making e.g. in cases of biosafety issues whilst an animal experiment is ongoing, that organisations should have clear procedures in place to balance the risks to biosafety, animal welfare and successfully completing the experiment (thus having eventually to repeat it using additional animals).

One of the partners had also established the position of Risk and Biorisk Manager to deal with this potential issue and their guidance/procedural document would be forwarded to the group.

4.4.2.4 Personnel training, awareness and competence

Working with in primary containment with infected farmed animals requires additional training to that outlined in the agreement. The teaching of animal handling techniques should be done in a lower containment safer environment, similar with the training for procedures controlled under European Directive 2010/63/EU, which often sharp objects such as needles that can penetrate PPE. More detail will be produced by VetBioNet in task 3.5.

4.4.4 Change management

This was considered as particularly important as the room is the primary containment, and therefore any changes to the engineering or operation of the building are likely to have an effect on the biorisk and therefore need to be suitably managed and documented. A concept of building “history file” was discussed.

4.4.4.5 Working practices, decontamination and personnel protection

Good microbiological technique (4.4.4.5.1). Although the list presented is recognised as not comprehensive what is not specifically mentioned is the prevention of cross contamination between animal rooms under different experimental challenge and the management of animals to prevent development of intercurrent disease, a particular problem when animals are mixed from different sources. A farmed animal BSL3/3+ facility will need procedures in place to manage this.

Inactivation of biological agents and toxins (4.4.4.5.2). There are also substantial differences in the detail in the flows of material requiring inactivation for biological agents and toxins from a farmed animal BSL3/3+ facility. Not only the room being the primary containment, but also the amount of waste produced, particularly by those facilities that use bedding. The need to validate these processes is critical as is having contingency plans (Emergency Scenarios

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4.4.5.1) in case of equipment failure due to the volumes of material involved. This is being dealt with in task 3.3.

In addition, once the experiment has finished the room has to be cleansed and sterilised. A discussion was on the standards of fit and finish necessary (additional information will be put on the VetBioNet site) and methods. The use of the two main gaseous methods (formalin and vaporised hydrogen peroxide) of sterilisation were also discussed. The need for reliable validation and the techniques partners have used were also discussed.

Similarly, the Clothing and Personal Protective Equipment (4.4.4.5.4) is critical due to the room being the primary containment. Various discussions were had on types, methods of decontamination/use of disposable items.

The worker health programme (4.4.4.6) should also cover a wider spectrum of diseases e.g. those zoonotic diseases potentially carried by “healthy” farm animals as well as the physical aspects of working with them. In addition, consideration should be given to allergies to chemicals. A discussion was had about taking baseline samples from staff and then to regularly monitor their health status against this. The small number of partners that had started this have stopped it for legal/ethical reasons

Working with certain organisms may also require vaccination programmes (4.4.4.6.1). This is dealt with in more detail in Task 3.5.

To meet the standard, the meeting thought the processes for inactivation and decontamination should be defined by the specific disease or organism and validated. It was noted, however, that in some cases methods were historic and had limited validation data.

4.4.4.8.1 Planning design and verification

The animal room being the primary containment, the material flows in and out of the room and the need to house animals in compliance European Directive 2010/63/EU makes this a very specialised task.

In addition, consideration would need to be made to additional items such as surfaces being robust (and their seal not being easily broken by wear and tear of holding animals or the movement of associated equipment. They also need to be non-slip and but allow effective cleaning and decontamination.

The detail of this, including the design safety qualification (below) is being dealt with in task 3.4, which details with commissioning (4.4.4.8.2). Decommissioning will also be dealt with in this task.

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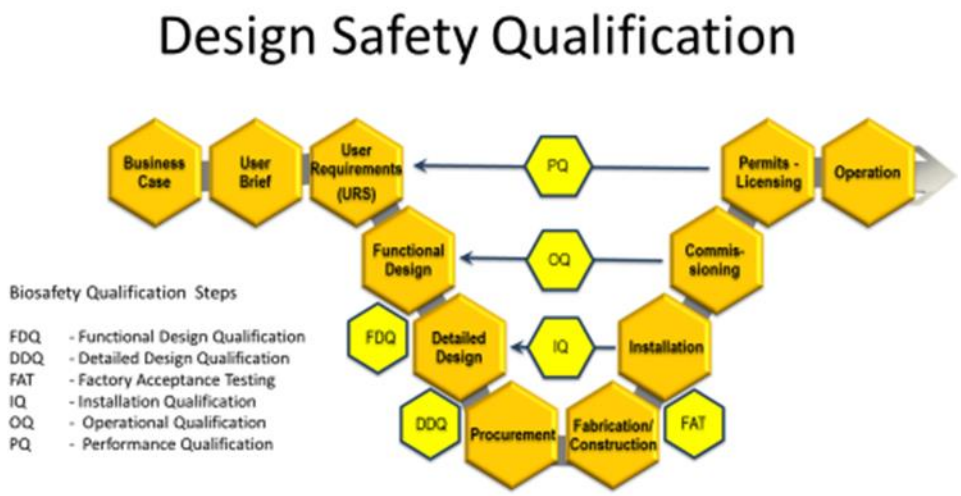

4.4.4.8.3 Maintenance, control, calibration, certification and validation

This section would need to include information relating to planned shutdowns for maintenance work and how these should be safely managed. Also that any work or calibration exercises etc. should be monitored for noise and vibration that may have adverse effects on any animals present in the unit and also to lighting as some species live in low light or reverse lighting conditions etc.

4.4.4.8.4 Physical security

Systems controlling physical aspects of the room/buildings, such as windows and doors need to be robust for animal use.

4.4.4.8.5 Information security

All electronic systems, whether for holding data, running building management systems or for animal monitoring have their limitations and would, in the course of time, require amendment/updates which may cause failures and disruption.

Building Management Systems using the internet for remote could also be comprised from hacking etc. The security of these links would need to be regularly validated and it was considered no sensitive information should be held on the cloud but internally and if possible on stand-alone systems.

4.4.4.9 Transport of biological agents and toxins

This section relates to the safe and secure transport of biological agents and toxins.

This needs to include the movement of diseased/infected animals – live and carcasses. Robust procedures are required detailing containment of live animals for transportation and also the packing, decontaminating and validation of such for infected carcasses.

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4.4.5.2 Emergency plans

Consideration must be made to units that may have difficult areas from which staff may need to be extracted in scenarios such as person down.

Specialist emergency response units may carry equipment to assist with such extractions, such as body boards, but it may be necessary for the establishment to provide certain items. The provision and use of such items must be included in emergency plan documentation.

Consideration must also be given to the health status/ physical ability of staff working in such units when plans are provided.

4.4.5.3 Emergency exercises and simulations

These should be undertaken on a regular basis and recorded. A discussion was held about the need to maintain biosafety during these exercises unless the facility is empty. There was a discussion over sprinkler systems (large amount of water needing to be decontaminated) and the risk analysis would be that these would not be needed in this type of facility as the amount of combustible material was low and biosafety risks when deployed high.

4.5 Checking and corrective action

There was considered no difference in this section between a laboratory and BSL3/3+ farmed animal facility. All partners monitored accidents, Incidents and Near misses were reported and trends reviewed and presented to Senior Management.

4.6 Review

There was considered no difference in this section between a laboratory and BSL3/3+ farmed animal facility.

As discussion was also had about organisationally who take the quality assurance function to ensure the standard is being met and the type of auditing necessary. Although some partners' organisation had quality management groups a requirement of the other quality assurance schemes they run (ISO 9001:2015, Good Laboratory/Manufacturing Practice) but it was considered this function would be undertaken by the biosafety/biorisk function.

Audits should cover systems, processes and product and be planned in to meet the standard.

5. Conclusions

5.1 Steps towards achieving CWA 15793 standard for terrestrial farmed animal high containment facilities

The workshop went through the CWA 15793 standard on laboratory biorisk management clause by clause and identified the differences between standard high containment laboratories and facilities used for terrestrial farmed animal high containment. The main

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differences were due to the animal room being he primary containment, the waste streams being larger and the need to integrate the requirements of European Directive 2010/63/EU which covers the welfare of animals used in research.

The workshop also found that due to the different design and nature of the various partner facilities, particularly with their variations in the types of waste streams needed to be sterilised or disposed of safely and how they cleansed and decontaminated the accommodation, to achieve the CWA 15793 standard on biorisk control objectives and targets, each individual institute will need to look at its current system in order to identify the hazards and pathways, and to document the actions in has in place to reduce or eliminate risks . This should include scientific evidence/justification and appropriate validation data. This process will dictate the monitoring controls the institutes require to maintain their systems, and these operational procedures will need to be documented as part of, for facilities management to achieve CWA 15793 as will staff training.

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6. Appendix 1. List of attendees

Hugh Simmons, APHA: meeting coordinator

Uwe Mueller-Doblies, Epibiosafe
Larry Barrett, DHS
Ryan Waters, Pirbright Institute
Xavier Abad, IRTA
Laurent Mostin, CODA- CERVA
Michal Reichert, Piwet
Mieke Jansen, Erasmus MC
Martje Fentener van Vlissingen, Erasmus MC
Ghislaine Legall-Recule, ANSES
Lucas Noldus, NOLDUS
Mickael Riou, INRA
Henk Wisselink, WUR
Wendy Shell, APHA
Helen Morton, APHA: minutes

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