VETBIONET

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

Deliverable D3.10

Report on Best Practice for facility management, including emergency response and planning

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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 best practice in laboratory biorisk management and the emphasis for VetBioNet is on what is different and challenging about the management of high containment farmed animal facilities (HCFAFs). The objective of D3.10 is to give examples of achieving best facility management of HCFAFs, including emergency response and planning.

A draft document produced and circulated then a workshop was organised to discuss and analyse the document with project partners and concerned members of the GOHLD (Group of High containment Laboratory Directors). The objective was to give the requirements under CWA 15793 :2011 and examples of best practice in achieving it in this area. This was achieved and additional technical information will be put on the VetBioNet area of the International Veterinary Biosafety Work group (IVBW) site to help partners achieve this.

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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 (ISO 35001).

Facility management differs at a basic level terrestrial between HCFAFs and routine laboratories in terms. In the HCFAF, the room is the primary containment of the infection where as in the laboratory the microbiological safety cabinets and other mechanical equipment are. This means there are substantial differences in the design, management and working practices to allow the safe working. Staff working in HCFAFs have to rely on personal protective equipment to prevent infection when working with zoonotic organisms, the maintenance of barrier procedures to stop spread of infection out of the unit and also to the personal have a need for physical protection from the animals. In addition, there is 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. All these factors not only substantially affect facility management but also significantly how facilities respond to some emergencies, and hence planning for those eventualities.

Through discussions at the workshop (attendees given in Appendix 1) and a document review process, best practice for facility management, including emergency response and planning in HCFAFs was written and published.

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

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3. Results

The workshop and report considered the management of HCFAFs could be divided into 3 elements:

1) Staff: the organisation of roles, responsibilities, authorities and ensuring they are performed correctly by competent staff so work can be delivered within biorisk management system. This includes any contractors who are used to provide specialist services such as engineering.

2) Maintenance: The upkeep of the physical elements of the building, as well as fit and finish this includes ensuring the complex mechanical, electrical, drainage (inc. effluent treatment) and building management and other electronic systems maintain their performance levels to ensure biosafety and biosecurity of operation of HCFAFs.

3) Planning: the processes which the organisation goes through to ensure that all the elements of the biorisk management programme are coordinated so it can deliver work in a biosafe manner. This includes coordinated planning of emergency response and contingency planning.

It then considered each of these in details.

Under staff it particularly looked at facilities management staff who are often in a different managerial chain to the scientists and animal care staff who work in the unit. Also facilities management can be contracted out and the amount of work contracted out can vary, from an in-house team just contracting out specialist tasks to all maintenance being done by a sub-contract facilities management company, who further sub-contracts specialist tasks. There is a lot of discussion about the merits and de-merits of each approach. For the purpose of best practice, no matter how much or little is contracted out, the institute licenced to operate the HCFAF is ultimately responsible for its biosafety thus must have the skills and knowledge to ensure that work contracted out is undertaken to meet the institutes biosafety management programme and legislative standards. Therefore, if the facilities management is contracted out, it is best practice that the institute retains an “intelligent customer”

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function that understands the engineering in HCFAFs, their particular biosafety challenges and the relevant legislation controlling biosafety. These staff should:

a) Have input into the performance criteria of the contractor in the contractual agreement.
b) Have the ability to audit the work done by the contractor and have the power of censure if work is not done to the appropriate standard.
c) Undertake inspections on the condition of the facility and the performance of its mechanical and electrical components to ensure the maintenance regime undertaken by the contractor is effective and is allowing the HCFAF meet the appropriate standards, as well as running performance tests as needed.
d) Ensure that records are kept on the original building design, specification and commissioning, operation manuals and ensure there is a recorded change control process for any modifications.
e) Provide a safe working environment for contractors, in particular taking into account what installations need to keep running.

Under Maintenance it reviewed various maintenance strategies and their appropriateness.

1. Reactive maintenance: This is often referred to as “run until breaks” strategy. The International Facility Management Association (IFMA) describes this strategy as “corrective action taken upon failure or obvious threat of failure”. This strategy can lead to unpredictable failures so fails to embrace an aspect of risk management, and thus should only be used as a strategy in HCFAFs for equipment that is not critical to the biosafety, biosecurity or animal welfare.

2. Preventive Maintenance: This strategy is designed to extend the life span of equipment and to increase reliability. IFMA describes it as “the periodic and planned actions taken to maintain and extend its life and performance before equipment failure or to prevent equipment failure”. This is very common form of maintenance which is performed according to pre-determined time intervals, number of utilisations or total hours used. For HCFAF the setting up of maintenance schedules allow for greater predictability in determining when the HCFAF or part of it will be unavailable, as well as giving more predictable costs

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and ability to minimise downtime by arranging parts and labour ahead of time (typical preventative maintenance plan for a HCFAF is given in Appendix 2). However, preventative maintenance plan does not consider the current condition of all the parts in the equipment, so the risk of failure of these other elements is not considered. However, the condition and wear rate can change if equipment is not used in ideal conditions established by the manufacturer or when the equipment gets older. Therefore, this is a weakness in this approach in maintaining HCFAFs, particularly older HCFAFs.

3. Predictive Maintenance: This is the use of measurements to quantify the level of degradation within a piece of equipment or system. IMFA definition is “maintenance consisting of activities involving continuous or periodic monitoring and diagnosis to forecast component degradation so as needed maintenance can be scheduled”. The primary difference between this and preventative maintenance is the method of determining when a piece of equipment needs to be replaced. The disadvantage for HCFAFs is that with the animal room being the primary containment and experiments having predetermined schedules, there will be clash if predictive maintenance is required during the experiment. This strategy would be appropriate to older systems where there is an increased risk of failure as it tries to predict timescale of deterioration and need to replace or where there is sufficient level of redundancy of plant and equipment therefore designed i to allow partial shutdown for maintenance but that operating parameters within the facility are maintained

4. Reliability Centred Maintenance: NASA the US Space Agency defines reliability centred maintenance as “the process that is used to determine the most effective approach to maintenance”. It seeks an optimal mix of Predictive, Preventative and Reactive approaches by taking a holistic system approach to determine relative risk, recognising that some equipment is more important than other and some failures will not compromise safety and security. Many organisations suggest flow charts and questions for determining this schedule. Below is an example from the Whole Building Design by the National Institute of Building Sciences:

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a) What does the system of equipment do? What are its functions?
b) What functional failures are likely to occur?
c) What are the likely consequences of these functional failures?
d) What can be done to reduce the probability of failure(s), identify the onset of failure(s) or reduce the consequences of the failure(s)

For routine planning, it was thought it should encompass the following:

a) The organisation of experiments so that they are biosafe and the facility is used efficiently
b) The integration of the experimental programme with the maintenance programme
c) The emergency response and contingency planning

4. Conclusions

4.1 A report on Best Practice for facility management, including emergency response and planning for HCFAFs has been produced.

4.2 The document produced fits with CWA 15793 standard on laboratory biorisk management but encompasses the differences between standard high containment laboratories and facilities used for terrestrial HCFAFs. The main 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.

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Appendix 1. Attendees

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Xavier Abad: IRTA, Spain
Stéphane Abrioux: INRA, France
Frédéric Lantier: INRA, France
Martin Groshup: FLI, Germany
Wendy Shell: AGES, Austria
Laurent Mostin: SCIENSANO, Belgium
Miroslaw Polka: PIWET, Poland
Martje Fentener van Vlissingen: Erasmus MC, The Netherlands
Ghislaine Le Gall-Reculé: ANSES, France
Keith Ballingall: MRI, Scotland
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This is part of a series of guidance documents produced by the VetBioNet (an EU Horizon 2020 project). There are various international and national standards in place for undertaking infectious work in animals with pathogens that require high containment facilities. These VetBioNet guidance documents are intended to be used as examples of how to achieve best practice in the managerial interpretation of these standards.

Best practice for facility management, including emergency response and planning

This document deals with the day to day facility management of a high containment farmed animal facilities (HCFAFs). Information on design, commissioning and decommissioning are contained in other deliverables from work package 3 (Best Practices for biosafety, biosecurity and quality management in HCFAFs.)
The management of HCFAFs can be divided into 3 elements

4) Staff: The organisation of roles, responsibilities, authorities and ensuring they are performed correctly by competent staff so work can be delivered within biorisk management system. This includes any contractors who are used to provide specialist services such as engineering.

5) Maintenance: The upkeep of the physical elements of the building, as well as fit and finish this includes ensuring the complex mechanical, electrical, drainage (inc. effluent treatment) and building management and other electronic systems maintain their performance levels to ensure biosafety and biosecurity of operation of HCFAFs.

6) Planning: The processes which the organisation goes through to ensure that all the elements of the biorisk management programme are co-ordinated so it can deliver work in a biosafe manner. This includes coordinated planning of emergency response and contingency planning.

1) <u>Staff</u>:

There is a lot of detailed guidance out there about role, responsibilities and authorities of Top management, Senior management, Biorisk management advisors and committees and Scientific management (e.g CWA 16393 –Laboratory Biorisk management – Guidelines for the implementation of CWA 15793 and ISO 35001 Biorisk management for laboratories and other related organisations).
However, guidance is limited about facilities managers and what is there is out there is focused on a normal high containment laboratory not HCFAF where the animal room is the unit of primary containment rather than a microbiological safety cabinet in a laboratory. The other complicating factor in HCFAF is that animal experiments once started should be completed for ethical reasons, therefore there is the additional challenge of not being able to stop or interrupt experiments and to maintain environmental safety similar to a normal high containment laboratory.
Under the NADIR, the predecessor project to VetBioNet, the role of the Building Officer was described as an example of way of getting a single point of control in an organisational structure. (Guidance Produced by NADIR and available on International Veterinary Biosafety Work group website and is reproduced in Appendix 1)

The Building Officer of a HCFAF is a member of staff who manages the operation of the facility on a day to day basis to ensure the delivery of the animal work in a biosafe manner. This role also includes acting as a contact and co-ordination for facility management staff such as engineers as well as the scientists and animal care staff who deliver animal experiments.
Facilities management staff are often in a different managerial chain to the scientists and animal care staff who work in the unit. Also facilities management can be contracted out and the amount of work contracted out can vary, from an in-house team

just contracting out specialist tasks to all maintenance being done by a sub-contract facilities management company, who further sub-contracts specialist tasks. There is a lot of discussion about the merits and de-merits of each approach. For the purpose of best practice, no matter how much or little is contracted out, the institute licenced to operate the HCFAF is ultimately responsible for its biosafety thus must have the skills and knowledge to ensure that work contracted out is undertaken to meet the institutes biosafety management programme and legislative standards. Therefore, if the facilities management is contracted out, it is best practice that the institute retains an "intelligent customer" function that understands the engineering in HCFAFs, their particular biosafety challenges and the relevant legislation controlling biosafety. These staff should

f) Have input into the performance criteria of the contractor in the contractual agreement
g) Have the ability to audit the work done by the contractor and have the power of censure if work is not done to the appropriate standard
h) Undertake inspections on the condition of the facility and the performance of its mechanical and electrical components to ensure the maintenance regime undertaken by the contractor is effective and is allowing the HCFAF meet the appropriate standards, as well as running performance tests as needed
i) Ensure that records are kept on the original building design, specification and commissioning, operation manuals and ensure there is a recorded change control process for any modifications
j) Provide a safe working environment for contractors, in particular taking into account what installations need to keep running.

2) <u>Maintenance</u>

There are four maintenance strategies, each of which has its own advantages and disadvantages and in the maintenance of HCFAFs a combination of strategies maybe used

5. Reactive maintenance: This is often referred to as "run until breaks" strategy. The International Facility Management Association (IFMA) describes this strategy as "corrective action taken upon failure or obvious threat of failure". This strategy can lead to unpredictable failures so fails to embrace and aspect of risk management, and thus should only be used as a strategy in HCFAFs for equipment that is not critical to the biosafety, biosecurity or animal welfare.

6. Preventive Maintenance: This strategy is designed to extend the life span of equipment and to increase reliability. IFMA describes it as "the periodic and planned actions taken to maintain and extend its life and performed before equipment failure or to prevent equipment failure". This is very common form of maintenance which is performed according to pre-determined time interval, number of utilisations or total hours used. For HCFAF the setting up of maintenance schedules allow for greater predictability in determining when the HCFAF or part of it will be unavailable, as well as giving more predictable costs and ability to minimise downtime by arranging parts and labour ahead of time (typical preventative maintenance plan for a HCFAF is given in Appendix 2). However preventative maintenance plan does not consider the current

condition of all the parts in the equipment, so the risk of failure of these other elements is not considered. However, the condition and wear rate can change if equipment is not used in ideal conditions established by the manufacturer or when the equipment gets older. Therefore, this is a weakness in this approach in maintaining HCFAFs, particularly older HCFAFs

7. Predictive Maintenance: This is the use of measurements to quantify the level of degradation with in a piece of equipment or system. IMFA definition is “maintenance consisting of activities involving continuous or periodic monitoring and diagnosis to forecast component degradation so as needed maintenance can be scheduled”. The primary difference between this and preventative maintenance is the method of determining when a piece of equipment needs to be replaced. The disadvantage for HCFAFs is that with the animal room being the primary containment and experiments having predetermined schedules, there will be clash if predictive maintenance is required during the experiment. This strategy would be appropriate to older systems where there is an increased risk of failure as it tries to predict timescale of deterioration and need to replace or where there is sufficient level of redundancy of plant and equipment therefore designed into to allow partial shutdown for maintenance but that operating parameters within the facility are maintained

8. Reliability Centred Maintenance: NASA the US Space Agency defines reliability centred maintenance as “the process that is used to determine the most effective approach to maintenance”. It seeks an optimal mix of Predictive, Preventative and Reactive approaches by taking a holistic system approach to determine relative risk, recognising that some equipment is more important than other and some failures will not compromise safety and security. Many organisations suggest flow charts and questions for determining this schedule. Below is an example from the Whole Building Design by the National Institute of Building Sciences (Pride 2010);

    e) What does the system of equipment do? what are its functions?
    f) What functional failures are likely to occur?
    g) What are the likely consequences of these functional failures?
    h) What can be done to reduce the probability of failure(s), identify the onset of failure(s) or reduce the consequences of the failure(s)

This is thought to be the strongest maintenance strategy for HCFAFs as it considers the use of equipment in the entire system and encompasses the advantages of the other 3 strategies where appropriate.
The balance of the elements of reliability centred maintenance will change over time. There is an increased risk of mechanical failure as equipment gets older, so with HCFAFs maintenance of whole systems may move from predictive to preventative to

a) minimise risks of failure during experiments (when containment needs to be maintained)
b) address the inability to get parts due to age of equipment
c) allow upgrading to meet new standards/improve performance

The replacement of whole systems will take the whole of a HCFAF out action or part of it (dependent on original design) for a considerable period of time. Therefore, a significant planning effort needs to go into this, to manage research projects whilst the facility is unavailable, establish contingencies for on demand work which cannot be stopped and project manage the process so the facility is down for the minimum period of time.

3) Planning

The routine planning involved with HCFAF should encompass

d) The organisation of experiments so that they are biosafe and the facility is used efficiently
e) The integration of the experimental programme with the maintenance programme
f) The emergency response and contingency planning (Guidance Produced by NADIR and available on International Veterinary Biosafety Work group website is reproduced in Appendix 3)

Document History

Produced by APHA (Hugh Simmons) May 2019

Reviewed and comments Erasmus MRC (Martje Fentener van Vlissingen) and AGES (Wendy Shell) June 2019

Appendix 1

BEST PRACTICE

This is part of a series of guidance documents produced by the NADIR FP7 project. There are various international and national standards in place for undertaking infectious work in animals with pathogens that require high containment facilities. These guidance documents are intended to be used as examples of best practice in their managerial interpretation. They are based on one national situation but the principles particularly of clear lines of responsibility and ensuring competence of individuals working in this environment, in the areas outlined can be interpreted across all institutes in this field.

High Containment Facilities
Building officer – Guidance Notes

Contents

INTRODUCTION

1.1. A Building officer (BO) for a high containment facility is a member of staff who manages the operation of the facility, assesses competence of staff as well as acting as a contact point for staff, engineers or others working in the facility.

1.2 Some facilities also require a deputy building officer as decided by local management. In these situations, they must work as a team to ensure that all the responsibilities and duties are carried out. This document refers to the building officer but the content will also apply to the deputy where applicable.

1.3 Employment grade or seniority is irrelevant in who can be a building officer but the post holder must have enough standing and respect within their workgroup/department for their advice to be acted upon.

1.4 The Head of Department must ensure that the necessary resources are available to enable the building officers to complete their training and subsequently carry out their duties.

1.5 Where the roles and responsibilities are not carried out by the Building Officer or their deputy this must be documented locally and a system in place designating who is undertaking them and the building officer should check that they are completed.

1.6 Those officers with overall responsibility for Biosafety and Health and Safety in the organisation will maintain an update list of building officers and deputies.

1.7 The line manager of the building officer has the responsibility to ensure their duties are completed.

TRAINING

2.1 To carry out the functions of a Building officer the nominated person must undergo suitable training **before** undertaking these duties.

2.2 The Building officer must first complete training within containment and is assessed as competent to work unsupervised (this training is mandatory in a lot of partner countries)

2.3 The building officer must then undergo further training and shadowing with an existing building officer of a similar containment facility and be signed off in their training records as competent for this role.

2.4 The extra key criteria for a building officer to be competent in are:

- Management and supervision of employees
- Training of employees and competency assessment

- Knowledge of facility including air handling systems and other containment controls

- Use of Building Monitoring System (BMS)
- Alarm response
- Building Fumigation procedures – including set up and post purge testing
- Use of Equipment Monitoring System (EMS)
- Sealability testing
- Contingency procedures for building plant or equipment failures
- Spillage clean up procedures
- Familiarity and understanding of relevant legislation relating to the pathogens being worked with
- Knowledge of planned preventative maintenance (PPM) schedules and requirements
- Reviewing and signing off as fit for purpose testing and calibration certification
- Carrying out contingency drill exercises
- Requirements for ad hoc monitoring of employees within the facility and any required subsequent action to be taken.
- Decommissioning knowledge to ensure the facility or equipment contained within it is safe for maintenance work or removal

2.5 Building officers must undertake formal continuous professional development once a year, minimum the half day.

BUILDING OFFICER RESPONSIBILITIES

3.1 The building officer is responsible for:

- Ensuring the facility is compliant with relevant containment legislation.

- For animal containment facilities they must ensure that the facility is compliant with relevant animal welfare legislation (EU Directive 2010/63/EU).
- Ensuring the equipment within the building is functional and well maintained, according to schedule in the Building Operation Manual.

- Updating the Building Operation manual with those responsibilities for Biosafety and Health and Safety in the organisation.
- Checking staff have completed the pre-entry checklist prior to entry into the facility for the first time.
- Training and supervising staff and visitors and assessing staff competency prior to independent working.
- Liaison with the institutional management of Biosafety and Health and Safety on issues relating to their facility.

- Assisting with inspections and audits and monitoring actions arising to closure.
- Liaison with the engineering maintenance and support of the facility (Facilities Management provider) and external contractors to ensure repairs, maintenance and calibrations are carried out.
- Organising and carrying out contingency drills as per local schedule.
- Provide expertise in the event of an accident or near miss within the facility or associated area and ensuring prompt reporting.
- Monitoring and controlling access to the facility.
- Authorisation of the entry and exit of equipment.
- Authorisation of the removal of inactivated material from the facility.
- Maintaining an out of hours contact list.
- Arranging for suitable cover for periods of leave.
- Ensuring adequate First Aid and Fire warden coverage for their facility.
- The correct storage and use of chemicals, gases and any other substances hazardous to health or damage to the facility due to fire, explosion or corrosion.
- Writing and reviewing standard operating procedures (SOPs) and undertaking risk assessments as required.

Maintaining documentation relevant to any of the above.

BUILDING OFFICER DUTIES

Provision of information, instruction, training and assessment

4.1.1 The building officer will provide suitable and sufficient information, instruction and training to all staff using the facility. They will also carry out assessments on staff who have completed the prerequisite supervised period and wish to work independently.

This will include:

- Induction to the facility and training of new staff.
- Check staff have completed the pre-entry checklist prior to entering the facility for the first time and therefore have all the correct health clearance, security clearance, personal protective equipment (PPE) and respiratory protective equipment (RPE) fitting and have read and understood all relevant documentation.
- Continuing and/or refresher training on using the facility for all staff.
- Carrying out, at periods determined locally, contingency drills within the facility and recording staff attendance.

4.1.2 The building officer will carry out a formal assessment on every member of staff who has completed the supervised period, prior to them working independently. The assessment report should be copied to both the individual and their line manager.

4.1.3 Following any changes in working practices (e.g. new buddy system) the building officer will implement the new systems, provide training to staff and assess competence if required.

4.1.4 The building officer will carry out ad hoc monitoring of staff working in the facility and report any concerns to line management. This includes monitoring compliance with institutional policies, SOPs and Risk Assessments.

4.1.5 The building officer will ensure there is adequate and suitable signage including fire action notices, first aiders contact list and biohazard signs.

Maintenance of equipment

4.2.1 Ensuring servicing and calibration is carried out on all safety critical items (as described in the Building Operating Manual):

- Microbiological Safety Cabinets (MSCs) and Biological Safety Cabinets (BSCs)
- Laminar flow cabinets
- Isolators (and individual ventilated cages)
- Autoclaves
- Airlocks (as other critical barrier device)

4.2.2 Arranging for the removal from service and repair of any broken or unsafe equipment within the facility.

4.2.3 Ensuring portable appliance testing (PAT) is carried out.

4.2.4 Arranging for the correct decontamination and disposal of old equipment. Providing certificates of decontamination for individual pieces of equipment prior to them leaving the facility.

4.2.5 Arranging for large equipment to be transferred into or out of the building and sealability testing to be carried out subsequently.

4.2.6 Registration of all new equipment on local databases.

4.2.7 Responding to equipment alarms (including out of hours).

Building maintenance

4.3.1 In liaison with FM provider ensure the following is completed to schedule (as described in the Building Operating Manual):

- HEPA filter testing and validation

- Effluent Treatment Plant (ETP) PPM (planned preventative maintenance)
- Heating Ventilation and Air Handling Unit (HVAC) PPM
- Back-up generator PPM
- Any legislatively required water testing
- Routine daily plant room checks
- Sealability testing (annually for category 3, six-monthly for category 4)
- Alarm systems PPM
- Laboratory gases system(s) PPM
- Intruder alarm PPM
- BMS calibration
- EMS calibration
- Fire risk assessment
- Calorifier PPM
- Uninterruptible Power Supply (UPS)

4.3.2 Raise any outstanding items to the FM provider and if not resolved with those responsible for Biosecurity, Health and Safety in the organisation.

4.3.3 Carry out according to schedule (as described in the Building Operating Manual):

- Emergency lighting tests
- Fire alarm tests and fire panel checks
- Eye wash and shower station flush outs (if in place)
- Checks on interior building fabric and furniture (for damage or wear and tear)

4.3.4 Carry out fumigation or decontamination of facility in accordance with local procedures as required for building or plant maintenance.

4.3.5 Capture data required for any safety performance indicators (SPI) (HSE Safety Performance Indicators) relating to building, plant and safety critical items.

4.3.6 Respond to building alarms and report incidences to the FM provider. Follow up to ensure repairs are carried out satisfactorily.

4.3.7 The building officer will complete the Permit to Work documentation supplied by the FM provider.

Emergency scenarios

4.4.1 If there is an incident within the facility (e.g. spillage, HVAC failure, accidents, incidents, fire alarm) the Building officer should do the following:

- Ensure the correct contingency procedure is followed
- Coordinate any evacuation

- Prevent unauthorised access to the building
- Clean up any spillage and decontaminate the building according to local procedures
- Liaise with those responsible for Biosafety, Health and Safety in the organisation
- Arrange urgent attendance from the FM provider in the event of equipment failure or alarms
- Assist with the investigation and provide input into the incident report form
- Ensure actions identified from the incident are completed
- Communicate lessons learnt and modify the contingency SOP if it is necessary

Safety inspections and audits

4.5.1 The Building officer will participate in the annual safety inspection of their facility. They may also assist in carrying out inspections in other similar containment facilities.

4.5.2 The Building officer will be required to assist in any audit of their facility by those responsible for Biosafety, Health and Safety in the organisation. It is considered best practice that these have to be done at least annually for Biosafety Level (BSL) 4 or bi-annual BSL 3.

4.5.3 The building officer will monitor actions through to completion and assist in the implementation of any changes in procedures or documentation. They will also ensure the changes are communicated to staff and carry out training or assessment if necessary (see 4.1.3).

Documentation (e.g. Risk Assessments, SOPs, logbooks)

4.6.1 The building officer will ensure that documentation relating to the use of the building is accurate and up to date.

4.6.2 Where they are not the author of the SOP or risk assessment they will raise any anomalies or omissions to the relevant author.

4.6.3 They will monitor logbooks to ensure they are completed.

4.6.4 The building officer will ensure the following SOPs are in place and reviewed as necessary (i.e. every two years, following a change in procedure or legislation and following report of an accident or near miss):

- The receipt and unwrapping of incoming pathogens and genetically modified organisms (GMOs)
- The handling of pathogens and GMOs *in vitro* and *in vivo*
- The disposal of all waste from the Animal facility
- The disposal of surplus pathogens and GMOs
- The storage of pathogens and GMOs
- Emergency procedures and arrangements
- Transfer of infectious and non-infectious material from a Containment Area of a Laboratory/Animal facility
- Entry into and exit from the containment facility
- Inactivation, storage, collection and transport of waste
- Disinfection and decontamination, both routine and non-routine, following the loss of containment, if appropriate
- Operation and maintenance of equipment and infrastructure critical for containment, and other equipment that may impinge on the functionality of this equipment
- Inoculation, maintenance and disposal of deliberately infected animals

4.6.5 The SOPs listed above and Risk Assessments relating to the pathogens are peer reviewed by the prior to their implementation and following any amendments.

4.6.6 Provide building specific fire risk information to the emergency services as required.

4.6.7 If there are animals into the building it should be necessary to provide specific information about how to act with them in case of emergency

Safety of visitors (including contractors)

4.7.1 The building officer will ensure that any visitor or contractor entering the facility whilst it is operational:

- Has completed the pre-entry checklist
- Has signed the declaration regarding avoidance of contact with susceptible species.
- Is escorted into and from the building
- Is supervised by an authorised member of staff at all times during the visit
- Provides written confirmation they will comply with all relevant SOPs and risk assessments

4.7.2 The building officer will ensure that any visitor or contractor entering the facility whilst it is non-operational:

- Is escorted into and from the building
- Is supervised by an authorised member of staff at all times during the visit

4.7.3 Any visitor who needs to work unsupervised in the facility must undergo the same competence assessment as a member of staff and participate in the contingency drills

Access to the facility

4.8.1 The building officer must review who has access to the facility on an **annual basis** as a minimum. Authorised access may be by electronic swipe card, PIN access or other appropriate means.

4.8.2 The building officer is responsible for authorising access to the facility and giving approval to the issuer where swipe card system is managed centrally. They will also arrange for staff to be removed from the system when they leave or no longer require access.

REFERENCES (from the UK, other sources national sources across the EU)

5.1 Biological agents: The principles, design and operation of Containment Level 4 facilities (ACDP).
ACDP Containment Level 4 guidance

5.2 The management, design and operation of microbiological containment laboratories (ACDP).
ACDP Containment Levels 2 and 3 guidance

5.3 Working safely with research animals: Management of infection risks (HSE).
HSE Animal Research guidance

5.4 A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000 (HSE).
HSE GMO (CU) guidance

Document History

Produced by AHVLA (Hugh Simmons) Sept 2012

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Additional review and comments by Erasmus MRC (Martje Fentener van Vlissingen) and AGES (Wendy Shell)

Appendix 2. Typical Preventative Maintenance for a HCFAF

Plant	Description	Frequency
AHU	Maintenance	6 Monthly
	HEPA testing	6 Monthly
	Supply and Extract Interlock testing	6 monthly
	Internal beacon test	6 monthly
	External beacon test	6 monthly
	Louvres and grills maintenance	6 monthly
ETP and drainage system	Validation and calibration	Annually
	Servicing / maintenance	Quarterly
	Vent filter testing / replacement	As required but annually as a maximum
	Cleaning of sensor shields	6 monthly
	Drainage and plumbing maintenance	6 monthly
Lighting	Internal lighting maintenance	Annual
	External lighting maintenance	Annual
	Emergency lighting Flick Test & Maintenance	Monthly
	Emergency Lighting Full Discharge Test	Annually
Fire systems	Maintenance	25% each quarter
	Fire Extinguisher maintenance	Annually
	Fire Risk Assessment	Annually
	Fire damper maintenance & drop test	Annually
	Test emergency escape doors	6 Monthly
	Fire Alarm Cause and Effect Test	6 Monthly

Plant	Description	Frequency
Autoclave	Servicing and maintenance	Quarterly
	Calibration and validation	6 monthly
	Statutory inspection	18 months +
Generator	Servicing and run-up On-load Test	Monthly
	Simulated Power Failure of Generator (4 hour load test)	6 Monthly
Sealability	Containment area sealability	6 monthly
Access systems	Access Maintenance	6 monthly
	Intruder Alarm Maintenance	6 monthly
	Interlock testing	6 monthly
	PIN code change	6 monthly
Calorifier	Maintenance	Quarterly
	Statutory inspection	Annually
	Internal inspection	Annually
Electrical	PAT testing	Annually
	Maintenance	Annually
	Distribution Board Testing and Inspection	Annually
	Microwave leak test	Annually
BMS and Magnehelic gauges	Maintenance	Quarterly
	Calibration of Pressure, Temperature and Humidity sensors	Annually
	Critical alarm relay to gatehouse	6 Monthly
	UPS maintenance	6 monthly

Plant	Description	Frequency
Steam	Pump maintenance	Quarterly
Water	Maintenance (pipework, storage tanks)	
	Cold water booster set maintenance	
	Risk assessment	
	Sampling	
	Hose and shower clean	
	Hot water pressurisation unit maintenance	
Compressed air	Maintenance	Monthly
	Maintenance	Annually
Chiller	Maintenance	6 monthly
	Statutory inspection	Annually
Panic Alarm	Alarm testing	6 monthly
Break-out Panels	Inspection and sealability testing of rubber seals	6 monthly
Miscellaneous maintenance	Heating pumps maintenance	6 monthly
	Heat exchanger maintenance	Quarterly
	Air conditioning maintenance	6 Monthly
	Asbestos management	Annually

Appendix 3

BEST PRACTICE

This is part of a series of guidance documents produced by the NADIR FP7 project. There are various international and national standards in place for undertaking infectious work in animals with pathogens that require high containment facilities. These guidance documents be examples of how these can be practically interpreted

Emergency Procedures and Contingency Planning in Containment Facilities

1. INTRODUCTION

This Best Practice document describes the minimum requirements for dealing with events of certain major accidents within Containment Level 3 (CL3) animal facilities

2. EMERGENCY PLANS AND PROCEDURES

2.1 Regulations and good practice require plans to be in place to deal with accidents or incidents involving CL3 Animal Facilities. There needs to be procedures to be in place for responding to serious and imminent danger, e.g. fire or containment failure, to protect the health and safety of staff and minimise the impact on biosafety of the experiment and welfare of the animals. Risk assessment must identify all the readily foreseeable incidents to be covered by the procedures.

2.2 Emergency procedures must contain arrangements to ensure that the emergency services have sufficient knowledge of the risks within the facility.

2.3 The emergency plans and procedures must also document additional procedures if the incident occurs out of hours and/or when a member of staff may be lone working.

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3 STANDARD OPERATING PROCEDURES (SOPs)

3.1 SOPs must be in place and include the following:

- Procedures to be followed (refer to 3.3)
- Identifying the roles and responsibilities of staff in the management of the response to the emergency, including the first point of contact
- Training requirements
- The safety equipment and PPE to be used
- Arrangements for liaison with emergency services (if required)
- Drill frequency and minimum attendance requirements (to work unsupervised in the unit)
- Accident/incident reporting and investigation arrangements
- First aid arrangements including occupational health and post exposure prophylaxis (if appropriate)

3.2 All facilities must have documented within an SOP procedure in the event of the following:

- Fire (actual and alarms)
- Power failure - prolonged (both mains and back-up generator failure)
- Power failure - mains (generator back up working)

- Spillage outside of primary containment (primary containment is generally the room in CL3 farm animal facilities)
- Spillage inside of primary containment
- Failure of primary containment
- Physical facility and equipment failure, including control system failure (e.g. ventilation system)
- Alarms e.g. Air pressures, effluent treatment plants (ETP)
- Environmental release from failure of decontamination, disinfection or sterilisation process
- Accident or illness to a person that results in the need for evacuation
- Escape of an animal deliberately infected
- Fumigation vapour release, if applicable
- Others as dictated by local procedures e.g. chemical spillages, flood

Appendix 4: VetBioNet Partner example of Emergency Procedures and Contingency Planning in a HCFAF undertaking aerially infectious high containment work

1. PROCEDURE/METHOD

1.1 Roles and responsibilities of individuals during an emergency, including the first point of contact

1.1.1 The first point of contact for any emergency will be the High Containment Building Officer (HCBO) or their deputy. The HCBO will then liaise with the Biosafety Office and departmental senior management along with other key personnel including the other safety professionals with responsibilities in this area and Facilities Management Provider (FMP) engineers, Scientific staff, and Emergency services personnel as to how to proceed.

1.1.2 For any emergency occurring out of normal working hours, the security gatehouse or central security control room must follow the out of hours on-call procedures and the relevant people will be contacted that way.

2 Fire

IF YOU DISCOVER A FIRE – RAISE THE ALARM AT THE NEAREST CALL POINT WHILST EVACUATING THE BUILDING.

2.1 When the fire alarm sounds at the security gatehouse, during normal working hours, security will call the nominated departmental manager responsible or their deputy The nominated person or deputy will then provide assistance to the HCBO.

2.2 For out of hours Security will call the departmental On Call Officer.

2.3 When the fire alarm sounds, staff working outside of containment (i.e. in the office or outer corridor), are also trained to contact the nominated departmental manager then check the location of the fire (see 2.4).

2.4 The fire panel located will indicate the location of the fire sensor that has been set off. If the sensor is in one of the animal rooms or the suite corridors, investigations can be made via the observation corridor or the CCTV system to determine if the fire is genuine or a false alarm.

2.5 If during the evacuation process it has been determined and there is sufficient evidence that it is a false alarm, then the evacuation process will cease and staff notified either by telephone in the suite corridor or by the observation windows.

2.6 If it’s a false alarm ring to inform Security (who monitor alarms)

2.7 Staff working within the suites must **ALWAYS** assume the alarm is a genuine fire and must immediately begin the evacuation procedures 2.8 – .2.17 upon hearing the fire alarm.

Evacuation procedure - Containment Suites

2.8 **Appendix 1 shows all possible fire exit routes from the containment suites.**

- On hearing the fire alarm, immediately cease work.
- Leave any materials or samples in the animal room. Secure animal caging, remove outer gloves in the animal room and exit the room
- In the ante-room, remove your Wellingtons, outer suit, and gloves. DO NOT SPRAY DISINFECTANT. DO NOT REMOVE YOUR RESPIRATOR. Put on clogs before exiting the room. **If a fire is visible, evacuate immediately with all personal protective equipment (PPE) and respiratory protective equipment (RPE) on.**
- In the suite corridor, go to the nearest changing rooms, remove your respirator and exit through the shower cubicles. **DO NOT SHOWER.** If the route to the changing rooms is blocked exit through the break-out panel, refer to 2.13.
- The nominated fire warden in the suite must take with them the entry / exit book for roll-call once everyone is evacuated.
- A physical sweep of each room will be quickly made by the fire warden(s), starting at the rooms furthest away from the fire exit.

The sweep will be done by assessing changing area (for evidence of staff have changed into the room) and looking through the window into the room. Under no circumstances will the fire warden re-enter the suite to do the room sweep. If he/she is not in the suite at the time of the fire alarm, then the sweep will be done via the observation corridor windows on the way out of the building.

2.9 If exiting through the female changing rooms, open the fire escape door leading into the observation corridor and exit the building via the nearest fire escape.

2.10 If exiting through the male changing rooms, exit through the double doors of the air lock and proceed through the nearest fire exit. – see Appendix 1.

2.11 Make your way to Emergency Contingency Box Point at the designated Fire assembly point. As evacuees will not have had time to wash their hands nitrile gloves are in the contingency box to prevent potential contamination by touching A disposable boiler suit are in the box to put over scrubs and overshoes for similar reasons. Staff will wait by the box for instruction on decontamination.

2.12 The key to the emergency contingency box is held within a coded key press located outside of the building. The pin code for the key safe is given to

authorised and identified personnel only.

Emergency contingency box

OR

2.13 If smoke/fire is observed from the autoclave or shower area then staff must:

- Pull the breakout panel cord (see below) and push out the breakout panel and move the panel safely to the side of the exit.
- This will take you out to the observation corridor and you must exit via the nearest fire exit as instructed by the nominated fire warden. – see Appendix 1.


Breakout panel pull cord

- Exit to the Emergency Contingency Box at the designated Fire Assembly point Put on nitrile gloves, a disposable boiler suit and overshoes, and wait for further instruction.
- The building fire warden will take the roll call.

2.14 Decontamination and emergency showering for evacuated staff will take place in a building of equivalent biosafety standard. (A pass for the clean side of the building is held inside a coded key press located inside the contingency box. *For facilities with only one building a risk assessment should be undertaken on the pathogen and type of work being done and*

contingency arrangement put in place.

The route walked by the evacuees will be decontaminated using the validated disinfectant administered using the watering can locate in the Emergency box. The disinfectant and water are also located in the emergency box.

3 Power failure – prolonged (mains and generator failure)

3.1 All containment buildings are designed and engineered with contingencies to prevent the loss of negative pressure and restore normal function as soon as possible (i.e. in the event of mains power failure there is a hard change to dedicated generator). In the unlikely event of loss of power, the following procedures must be adopted.

3.2 If there is no power to the entire building, it is assumed that there will be no lighting apart from emergency lighting. This will indicate to staff that the generator is also not working and that they must follow the procedure outlined below.

3.3 If personnel are in an infected room:

- Exit the room as soon as practicable using the normal procedure for disinfection
- They **MUST** keep your RPE on until entering the changing room.
- RPE must be removed just before stepping into the shower cubicle.
- Once everyone is in the changing room, tape up the door between the corridor and the changing room.
- Shower out of the containment suite for 3 minutes *(standard)*
- The last person through the showers must tape up both all shower doors upon exiting the suite.
- Signed and dated notices must be put up on all entrance doors to the suite stating that there must be no admittance to the suites until further notice.

.3.4 The FMP must be contacted

Those working with the FMP engineer responsible for the building must be the HCBO or their deputy, a member of the Biosafety department and a senior member of departmental management .

3.5 Out of hours the HCBO will be alerted by the On Call Officer.

a. Power failure – mains (generator back up working)

3.6 When there is a power failure and the generator does kick in then it is unlikely that it will affect air handling.

If the switch over from mains to generator does affect the air handling units and there has been a loss of negative pressure gradient then staff inside animal rooms will be alerted to this by an audible alarm and the pressure indicator light above the door will change from green to red (see appendix 2 for beacon instructions).

3.7 **STAFF MUST MAKE THE AREA SAFE** and leave the animal room following normal procedure for disinfection

- Keep the RPE on until entering the changing room.
- RPE must be removed just before stepping into the shower.
- Shower out of the containment suite following normal procedure

3.8 The FMP must be contacted as must the biosafety office and departmental management. Those attending must be the FMP engineer responsible for the building, the HCBO or their deputy, the biosafety officer and a senior member of departmental management who will decide what further action is to be taken.

3.9 Out of hours the HCBO will be alerted by the On Call Officer.

b. Air handling failure

3.10. Loss of air handling will be transmitted to the security gatehouse who will inform nominated departmental management. Any staff in the facility office will also be alerted by the BMS computer going into alarm.

3.11 The FMP must be contacted and departmental management. Those attending must be the FMP engineer responsible for the building, the HCBO or their deputy, a biological safety officer and a member of senior management who will decide what further action is to be taken.

3.12 Out of hours the security gatehouse will follow ASU on-call procedures and the relevant people will be contacted via those methods.

3.13 Staff working inside infected animal rooms will be alerted to an air handling failure by an audible alarm and the beacon above the door will change from green to red.

- They **must** remain inside the room until contacted with instructions.
- Seal all open sample or inoculum containers and secure the animals.
- Not create any aerosols by moving waste or bedding around.
- Unless just a transient failure, staff must wait for 30 minutes to after air flow is restored. For staff working out of hours or lone workers, follow 3.15.

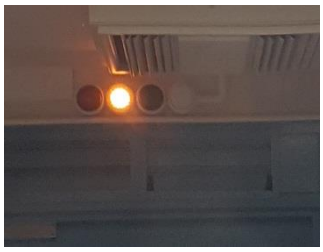
3.14 Staff will be contacted via the telephone or the observation window by the HCBO or senior departmental management. If the problem can be rectified quickly then staff must remain inside the infected room so as not to breach containment.

3.15 Unless air handling failure was transitory wait 30 minutes before exiting normally. If FMP consider there will be an on-going loss of air handling then staff will evacuate the room following the prescribed procedure for disinfection as normal but keep your RPE on until entering the changing room.

3.16 The anteroom door must be sealed on exit with PVC tape and personnel must shower out of the containment suite as usual.

Loss of air handling in different area.

3.17 Loss of air handling in an animal room other than the one you are working in will be indicated by an audible alarm and an orange beacon.



- If the orange beacon illuminates whilst working then you must stop work and exit the room following the prescribed procedure for disinfection as normal, but keep your RPE helmet on whilst entering the corridor.
- The affected room will be indicated by a red light illuminated above the door

- Seal the affected room door with PVC tape and exit the suite, removing your RPE in the shower area.

3.18 Signed and dated notices must be put up on all entrances to the containment suite clearly stating:

NO ENTRY TO THE CONTAINMENT SUITE UNDER ANY CIRCUMSTANCES.

These signs may only be removed once the problem has been rectified and the negative air pressure fully restored.

3.19 The HCBO or their deputy, a biosafety officer, the senior scientist for the affected projects and a senior member of departmental management will decide what further action is to be taken.

c. ETP failure

3.20. If there is a failure of any part of the ETP process, the BMS computer will go into alarm, the security gatehouse will be notified and a blue flashing audible beacon will sound outside the entrance to the building and the plant room. If the ETP is in alarm prior to working, DO NOT enter the containment suites and inform the Building Officer or Deputy.

3.21 The ETP serving the building is fitted with a secondary independent verification system and compliance with the parameters for each cycle must be verified by both systems prior to release to foul sewer. If for any reason the ETP fails to reach any set parameters for a cycle, then the cycle is restarted from the beginning. Data for each cycle is stored for at least 12 months on a dedicated EMS for the ETP and this data is reviewed as part of the Safety Performance Indicators (SPIs).

3.22 In the event of the heating tank failing, all current animal work will continue however water usage will be kept to a minimum and no infected water will be put down the drains in the rooms but instead decontaminated in sulo-bins, which will remain in the room, until the problem is rectified.

3.23 No further animal work will begin until the problem is rectified.

High level alarm

3.24 The high level alarm is activated when the holding tank is almost at full capacity and all other tanks are full. Staff will be alerted to this by the Blue beacon (located on the outside of the building) flashing and an audible alarm will sound for the first 30 seconds.

Staff working inside the building will be alerted to the high level alarm by the beacon in the animal room turning amber (see appendix 2)

- Staff must immediately cease work and make safe their work area.
- **DO NOT PUT ANY MORE WATER DOWN THE DRAINS EXCEPT WATER USED FOR SHOWERING OUT OF THE SUITE.**
- Decontaminate out of the animal room following the normal procedures.
- Shower out of the suite, ensuring the shower lasts at least 3 minutes.

In the facility design there is enough capacity in the holding tanks for up to 12 people to shower out of the containment suite before the high-high alarm is triggered and the water is shut off.

High-High level alarm

3.25 If water is continuing to flow into the holding tank, the high-high level will eventually be reached. This is indicated by the red beacon (see appendix 2). This will cause ALL water to the building to be shut off to prevent contaminated effluent from the ETP holding tanks backing up the drains. If staff discover the water supply to the suite has been shut down (lack of animal drinking water, no shower water) then they will follow the procedures outlined below:

- Staff should call the HCBO or FM using the suite telephone and explain they cannot currently shower out.
- If staff have not had the full 3 minute shower, put on a boiler suit on exiting the suite, and use the contingency shower (see 2.14)
- It is necessary to ensure animals in the facility have water to drink. A lot of drinking systems have reservoirs of water which to cover a period of time. If these are not present or have run out water should be contained in, with personnel exiting as above.

3.26 Drinking water for animals will be obtained from other animal facilities.

d. Spillage outside of primary containment

3.27 Any pathogen brought into the building is contained within a primary container, plastic bag and bio bottle. Even if dropped, it would be very unlikely that there would be a pathogen spillage outside of containment.

Any samples arriving at the front door incorrectly packaged will immediately be placed inside a secondary container for transport to the containment suite, to prevent spillage during transport. Nitrile gloves must be worn for this task. The Building will be evacuated of all non-essential personnel during transfer to the containment suite.

3.28 **The bio bottle containing the pathogen is never opened until inside the animal room of the suite.**

3.29 In the unlikely event that samples entering the containment suite are incorrectly packaged and either leak or break during transport from changing area to animal room, resulting in a pathogen spillage, the following process must be followed

- Do NOT attempt to clean up the spillage immediately
- Move away from the spillage and into the change area – if spillage occurs in the shower area then use the other showers (i.e. if spillage is in male showers, please use the female showers)
- Shower out of the containment suite and inform the HCBO or deputy of the incident.
- The HCBO or nominated deputy will enter wearing full RPE and PPE obtained from outside of the containment suite
- The spillage will be decontaminated using a validated disinfectant for the prescribed contact time
- Absorbent material will be placed over the spillage. The validated disinfectant will then be poured on top of the absorbent material and left for the prescribed contact time. The absorbent material will then be placed inside a plastic bag, sealed and then placed inside a steri-box bin which will be removed by autoclaving.
- A 'DO NOT ENTER' sign will be put up on both changing room doors during this process to prevent personnel entering without the required RPE. The signs will be removed once the spillage has been cleared up and sufficient air changes have occurred.

e. Spillages inside of primary containment

3.30 Any pathogen brought into the building is contained within a primary container, plastic bag and bio bottle. The bottle is only opened once inside the animal containment room where everyone must be wearing the PPE and RPE appropriate for the pathogen so they are protected if there is a spillage.

3.31 The spillage will be decontaminated using a validated disinfectant for the prescribed contact time

3.32 Absorbent material will be placed over the spillage. The validated disinfectant will then be poured on top of the absorbent material and left for the prescribed contact time. The absorbent material will then be placed inside a plastic bag, sealed then placed inside a steri-box bin which will be removed for autoclaving following the normal procedures.

3.33 If a pathogen spills onto your protective clothing during inoculation of animals then the following procedure must be used.

- Wipe up spillage with absorbent material soaked in a validated disinfectant which is then discarded as in 3.33.
- The prescribed validated disinfectant must then be poured over the affected area of clothing and wait the prescribed contact time.
- Exit the room following prescribed decontamination procedures.
- Once in the ante-room, remove the contaminated item of clothing (neoprene) and leave to soak in the bath of validated disinfectant for the prescribed contact time
- Put on new, clean, protective clothing and re-enter the room following the prescribed procedure.

f. Unconsciousness / Immobile casualty

It is important for staff to remember that if they start feeling unwell whilst working in containment, they must notify someone and exit the containment suite following the prescribed decontamination procedures

3.34 If staff are working with someone who suddenly collapses, or is seriously injured, or if they discover someone who has collapsed or been seriously injured, the instructions below should be followed.

- During normal working hours, go to the nearest phone and dial the departmental office emergency line (to office always manned during working hours)
- Trigger the implementation the Man Down action sheet (see Appendix 3).

3.35 The interlocking doors into the containment suites can be overridden in the event of an emergency, to allow stretchers to easily be bought in and out of the unit.

Under normal operation, the key is locked in the ‘normal operation’ position. To override the interlocks, turn the key to the ‘door override unlocked’ position.

g. Security breach / Intruder

3.36 There are many layers of security that mean an intruder should not be able to gain access to the containment area of the building

3.37 Staff should undergo annual contingency training on the topic of intruders and security breaches and are trained to challenge unauthorised personnel and report anyone acting suspiciously to departmental management and security. This includes the following instruction

3.38 On finding an unauthorised person **only challenge them directly if you feel safe to do so.** Politely ask their name and reason for being in the building. If the reason given is not justified and no evidence of authorisation is given, and you feel safe to do so, ask the person to accompany you to see the HCBO or their deputy.

3.39 If you witness any suspicious activity from either staff, visitors or FMP/contractors immediately inform the HCBO or their deputy.

h. Procedure if FMP staff discover a leak/spillage in the ETP area

3.40 If an FMP engineer, or contractor, discovers a leak, or potential leak from the ETP, they should immediately follow the procedure set out below.

- Do NOT attempt to clean up the spillage initially
- Vacate the immediate basement area and go to the ‘dirty lobby area’
- Use the phone to call out and alert FMP and the HCBO or Deputy to the problem.
- **Do not re-enter the ETP area without informing the HCBO and without RPE/PPE.**
- Remove your contaminated work clothes in the ‘dirty lobby’ area to be decontaminated or disposed of.
- Put on spare work clothes in the ‘clean lobby area’ and report to the HCBO or deputy who will inform senior FMP management,

biosafety officer to determine further action to be taken.

3.41 Before entering the ETP area to facilitate the decontamination process, a different (2nd) FMP engineer must speak to the HCBO or there Deputy to find out what PPE and or RPE is required.

3.42 The clean-up procedure is as follows:

- An engineer will enter the basement into the changing area and put on scrubs, then go through the shower area where they will put on the prescribed PPE/RPE before entering the ETP area.

- Decontaminate the spill using absorbent material or pad(s) and the prescribed disinfectant found in the spill kit provided. The absorbent material/pads are then placed into a clear bag which is then sealed by tying the neck

- The area is then covered with a prescribed disinfectant and left for prescribed contact time before being cleaned up using more absorbent material/pads.

- All absorbent material/pads are placed into a double yellow bagged Steri-box bin which is then sealed, surface decontaminated and taken into the facility for autoclaving.

- The engineer can then investigate the cause of the leak/spillage and take the necessary steps to stop it.

- **Upon exiting, the engineer will**
- Spray down the microchem suit with 1% Virkon S solution before removing it and placing it into a clear plastic bag.
- Wipe the Pureflo helmet with 70% Ethanol using paper towel.
- Remove outer gloves and place into the clear plastic bag containing the microchem suit.
- Seal the clear plastic bag and place inside a second plastic bag and seal
- Place double bagged PPE into a sulo bin. Seal and take into the facility to be autoclaved.

3.43 **Leak Detection**

If leak detection in the basement is activated, IFM staff should **NOT** go down into the basement to investigate before informing the HCBO and putting on all the required PPE and RPE. They should then follow 3.44 – 3.42

i. Loss of other Utilities

Steam

3.44 In the event of steam failure, the following equipment will be inoperable

- Autoclave
- ETP
- Humidity / Temperature controls to the HVAC

Both the ETP and Autoclave will ‘fail safe’ however, they will both need to be re-started once steam becomes available.

3.45 Emergency showers are located in each suite to enable staff to shower out of containment using warm water however, once the ETP holding tanks are full, no further ETP cycles can be run until steam is restored.

3.46 Discussion between departmental management, the biosafety officer and Scientific study leaders what actions are needed to allow current projects to be completed or whether they have to be terminated.

Water

3.47 In the event of water shut down to the building – see section 4.6.6.

3.48 In the unlikely event of a prolonged water shut down will result in termination of all studies.

In the event of site-wide water shut down, discussion would be had between departmental management, the biosafety officer and Scientific study leaders to determine the course of action based on expected duration of water loss.

4 TRAINING REQUIREMENTS

4.1 Emergency evacuation drills and walk through demonstrations of all contingency plans must be carried out by the HCBO or their deputy every 6 months during the buildings bi-annual maintenance shut down.

4.2 All staff using the building will be required to attend these drills at least once a year and all training will be recorded in their training record.

4.3 All staff working unsupervised in the building must have undergone a minimum of 40 hours supervised training at high containment and must have been assessed by the HCBO as competent to work unsupervised in the building. This is captured in individuals training record.

4.4 Any staff not signed off as competent to work unsupervised must be accompanied by a trained, competent member of staff at all times.

5 ACCIDENT REPORTING AND INVESTIGATION

5.1 Immediately report accidents, incidents and near misses to the biosafety officer by email or telephone. Other people to be notified will be organisation specific :

5.2 Any incident that has or potentially could have involved the accidental release of a high containment pathogen and/or genetically modified organisms must be reported to the Biological Safety Officer by the quickest practicable means as soon as possible.

6 ARRANGEMENTS

a. First Aid

6.1 As a minimum, the facility should have :

- A suitably stocked first aid container in each containment suite and one located outside of containment.
- A qualified first aider who has the necessary health clearance and is competent to enter the facility unsupervised.
- Information on first aid arrangements, including contact details, displayed in prominent areas.

b. Fire Wardens

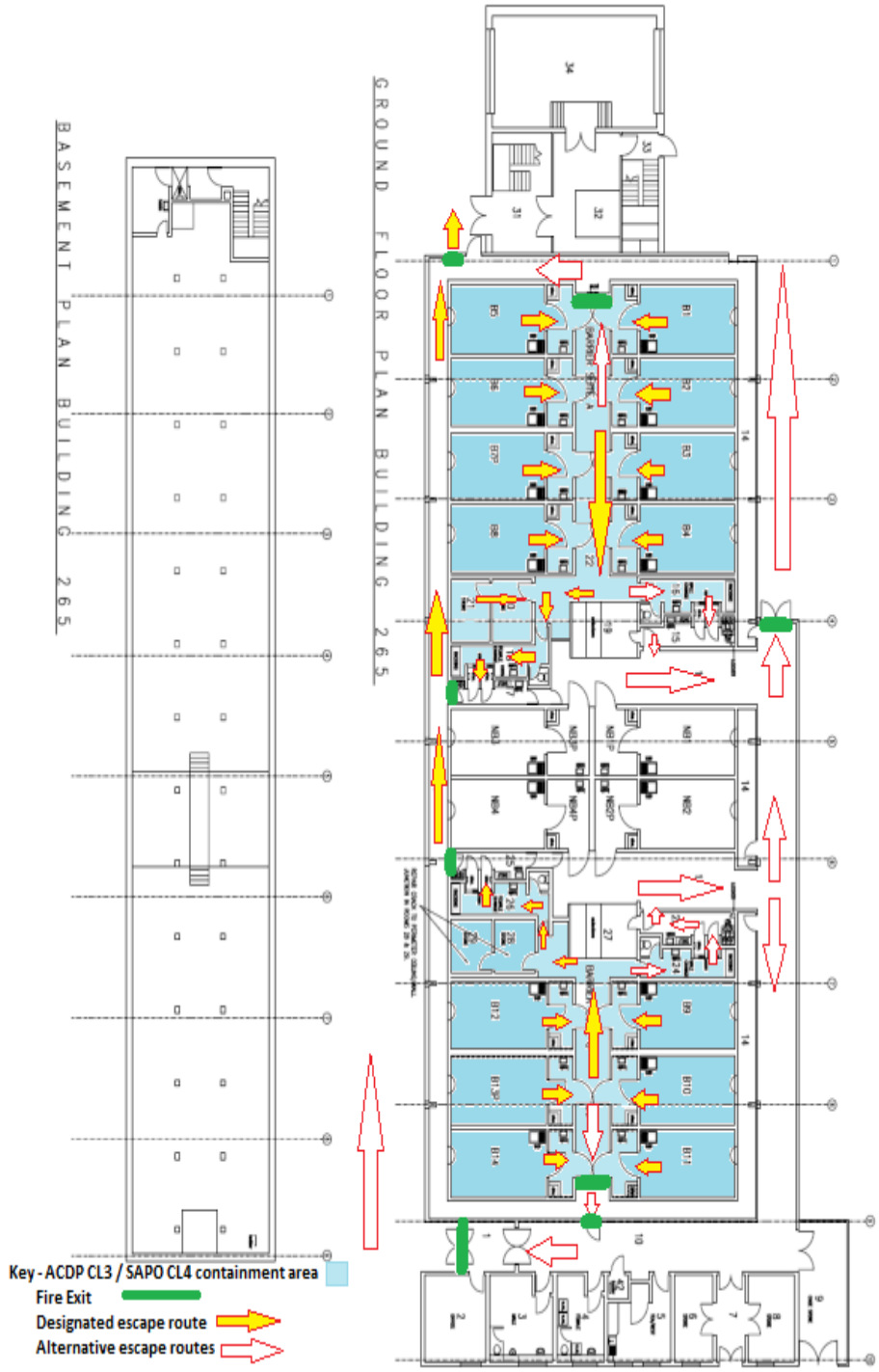
6.2. The facility should have a fire warden.

c. Spill Kits

6.3 The facility should have spill kits prescribed for the pathogens being worked with and chemicals used and these are located in each suite and outside of containment next to the chemical store.

Appendix 1

Example: Fire escape routes for staff working in containment Suites shown in blue



Appendix 2

ALARMS in Animal rooms

GREEN

All OK – carry on working ☺

AMBER

Cause 1) – AHU failure in another animal room or corridor within the Suite – **ACTION -** decontaminate out following normal procedures. Keep RPE on into corridor until cause of the alarm is identified and rectified (i.e affected door taped)

Cause 2) – ETP Common or High level alarm. **Action** – Decontaminate out following normal procedures, keeping RPE on until the corridor. IF all lights above the animal rooms are green (indicating no loss of pressure) then this signifies an ETP high level alarm and RPE can be removed. Shower out of the suite immediately.

RED

Cause - AHU failure in this room. **ACTION**: - Remain in the room and use the telephone to seek assistance. If the problem is not rectifiable within 30mins, or you cannot contact anyone, begin to decontaminate following normal procedures, leaving your RPE on into the corridor. Tape up animal room door behind you.

NOTE: - Red beacon also indicates an ETP 'HIGH HIGH' alarm. Assume all RED alarms are AHU unless preceded by AMBER (in which case you will be out anyway – see above)

FLASHING AMBER / RED

Cause – Multiple failures of plant. Each time a new alarm is generated, the beacon will flash for 30 seconds to indicate a new problem. In any flashing beacon, or Red + Amber beacon scenario, decontaminate and exit the room following the normal procedures, leaving your RPE on until the shower area, shower out and seek further advice from HCBO or deputy.

Appendix 3: MAN DOWN STAFF ACTION SHEET

Inform departmental office of situation, location and containment information and whether a first aider in attendance.

Departmental Office actions: in priority order

1) *If not already in attendance* find a suitably health cleared first aider who is able to immediately attend the area.

2) Contact emergency services giving situation, location and that injured party is in containment

3) Inform the security that emergency services are expected (repeat location and containment information)

4) Ensure the Building Officer or other staff familiar with the building and current biosafety requirements are in place to meet the emergency services and brief them on biosafety requirements for entry. Keep departmental office informed of progress.

5) Inform the departmental management and safety/biosafety officer*

*safety/biosafety officer will undertake a root cause analysis investigation, write a report of incident and any lessons learnt.