University of Oxford
Safety Executive Group (SEG)

SEG GN08 High Containment Facilities

What do we mean by High Containment Facilities?

Biological agents (e.g. microorganisms, cell culture, or human endoparasite), whether or not genetically modified, are classified into one of four hazard groups. Hazard Group 3 agents are able to cause severe human disease and may be a serious hazard to employees. They might also spread to the community, but there is usually effective prophylaxis or treatment available. The physical and procedural control measures for work with Hazard Group 3 agents are significant and these define the workings of a containment level 3 laboratory.

Certain non-endemic animal pathogens are regulated due to the risk they pose to the environment. These pathogens are covered by the Specified Animals Pathogens Order. Specific controls are required to prevent their introduction or spread in the animal community of Great Britain.

Who does this Guidance Note apply to?

This SEG guidance note applies to those departments that operate high containment facilities working with Hazard Group 3 pathogens under the Control of Substances Hazardous to Health Regulations and the Genetically Modified Organisms (Contained Use) Regulations. It will also apply to those working with agents requiring licensing under the Specified Animal Pathogens Order.

What do I need to do?

You must take action to ensure you or others are competent and working appropriately within high containment facilities. The legislative requirements for work in high containment facilities is prescriptive. Risk assessments will also determine specific control measures related to the biological agents being handled.

What is the legislation?

- Control of Substances Hazardous to Health (COSHH) Regulations, 2002
- Genetically Modified Organisms (Contained Use) Regulations, 2014
- Specified Animal Pathogens Order (SAPO), 2008

What are the related SEG briefing notes?

- SEG GN01 *Guide to SEG organisation and operating principles.*
- SEG GN04 *Guide to action-oriented safety*.

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1. Introduction

a) Working practices and controls for containment laboratories are defined in the 'Management and operation of microbiological containment laboratories' and further guidance is provided for working under the Specified Animals Pathogens Order (SAPO) in 'Guidance for licence holders on the containment and control of specified animal pathogens'.

b) Containment Level 3 and SAPO laboratories are subject to regular inspections from the competent authority, the Health & Safety Executive (HSE). Oral and written instructions from HSE inspectors identify specific requirements to improve local containment or control of higher consequence pathogens. To ensure compliance, the University commits to the close monitoring of these facilities by enhancing the inspection regime and improving user competency assessments.

2. Specialist Terms and Acronyms

a) The following definitions apply in relation to this guidance note.

SEG Guidance Note	SEG Guidance Notes are the definitive guidance on safety for those working within the University, which will be reviewed and revised as necessary. They are issued and authorised by the Safety Executive Group (SEG), which has the delegated authority to do this by Council. This SEG Guidance Note supports, and builds upon, the Biorisk Management requirements already set out in University policy statement S5/09. It outlines the following: • Roles and responsibilities specific to the safe operation of high containment facilities. • Inspection requirements specific to high containment facilities. • Training and competency assessment for those working in high containment facilities.

High Containment Facility	High containment facilities include all individual or suites of ACDP & DEFRA Containment Level 3 laboratories and any laboratory where SAPO licensed work takes place.
Managers or Supervisors	A manager or supervisor is defined as the person ultimately responsible for the education, training and day to day activities of those working within a group e.g. principal investigator or group leader.

b) The following acronyms are used within this guidance note.

ACDP	Advisory Committee for Dangerous Pathogens
CL3	Containment Level 3
DEFRA	Department of Environment, Food & Rural Affairs
GMO	Genetically Modified Organisms
HEPA	High Efficiency Particulate Air
HSE	Health & Safety Executive
SAPO	Specified Animal Pathogens Order
SEG	Safety Executive Group

3. Action-Oriented Safety

a) Safety Executive Group (SEG) Guidance Note GN04 'Action-Oriented Safety' outlines the general actions different groups of people are expected to take in order to work safely. These build upon the responsibilities set out in the Health and Safety Management Responsibilities policy statement S2/11, as well as the Supervisor Responsibilities policy statement S1/09.

b) The Biorisk Management safety policy statement S5/09 sets out how biological agents must be handled in laboratories, or clinical and field settings, for legal compliance. The following provides additional standards specific to high containment facilities.

c) The following actions apply to specific groups of people.

i) Heads of Department with High Containment Facilities

(1) Ensure a suitable high containment manager is appointed, following discussion with principal investigators / supervisors.

(2) Ensure a high containment scientific coordinator is appointed, following discussion with principal investigators / supervisors.

(3) Ensure the above information is recorded in the following documents:

- The code of practice for the high containment facility
- The departmental statement of safety organisation

(4) Ensure up to date copies of the above documents are sent to the University Occupational Health & Safety Office.

(5) Ensure there is a reporting line from the High Containment Facility (manager and/or scientific coordinator) to the departmental genetic modification and biological safety committee, for reporting of proposed changes to significant hazards or control measures, as well as overall assurance reporting. This reporting line must also continue to senior management through the departmental safety committee.

ii) Principal Investigators/Group Leaders (i.e. supervisors) of those working in High Containment Facilities

(1) In conjunction with the high containment scientific coordinator, ensure all researchers working under their supervision are evaluated for competence with the pathogens in use before any work commences and on an annual basis thereafter.

(2) In conjunction with the high containment manager, departmental biological safety officer and university biological safety officers ensure that all appropriate notifications for work with biological agents, specified animal pathogens and genetically modified organisms are in place.

(3) Ensure that an approved risk assessment is in place for the work undertaken by the group or individuals working in a high containment facility.

(4) Participate, as required, and provide support to those undertaking inspections or incident investigations in relation to high containment facilities.

iii) High Containment Scientific Coordinators

(1) The designated high containment scientific coordinator should be a principal investigator or senior scientist with experience and knowledge of working in such a facility.

(2) Their role is to provide senior management oversight of the work on behalf of the head of department. This does not replace the functions carried out by supervisors or high containment managers, but enhances the direct link to senior management.

(3) The high containment scientific coordinator's specific responsibilities are:

- To liaise with other supervisors of those using the high containment facility.
- To provide senior management support for the high containment managers and departmental biological safety officers with regards to high containment work.
- To inspect the high containment facility on an annual basis.
- Proactively monitor the safety performance and working practices of those working in the facility and to support supervisors in the continued evaluation of competence.
- To be involved in investigations regarding incidents within high containment facilities.

- To raise issues and concerns to the senior management team responsible for the facility.

- To provide assurance to the head of department with regards to compliance with this guidance note within the high containment facility. Specifically:

    - To provide an annual report to the senior management on the safe use and activities taking place in the facility.

    - To provide feedback to the departmental genetic modification and biological safety committee and departmental safety advisory committees.

- To act as the lead senior management representative during inspections of the facility by the HSE or other enforcing body.

- To ensure high containment user groups are in place and attended, as necessary.

iv) High Containment Managers

(1) The designated high containment manager is likely to be a containment level 3 or SAPO laboratory manager. In some cases, it might be a relevant facility manager or experienced researcher.

(2) The high containment manager should have sufficient delegated responsibility to oversee and direct the safety of those working in the facility on behalf of supervisors.

(3) The high containment manager's specific responsibilities are:

- Ensure the implementation of a laboratory diary to record the outcome of regular checkpoints. These must include, as a minimum, annual sealability checks, annual autoclave validation, annual testing of HEPA filters, annual validation of disinfectants, bi-annual KI-testing and monthly anemometer testing of microbiological safety cabinets.

- Ensure appropriate training processes are in place and that records are maintained.

- Ensure that frequent spill drills are undertaken.

- Ensure that individuals working in the high containment facility have the appropriate level of security vetting.

- Ensure that individuals working in the high containment facility register with Occupational Health for the work they are doing.

- Ensure that an exposure record is in place for all individuals working in the high containment lab and, working with supervisors, ensure there is a process for maintaining this record for at least 40 years.

- Ensure there is a maintained record of observed safety related non-conformities and review this regularly to identify areas for improvement. All near-misses and accidents must be reported on the University's Incident, Reporting and Investigation System (IRIS) and investigated.

- Attend and report to the departmental genetic modification and biological safety advisory committee and departmental safety advisory committee, considering the findings from the items listed above.

- Support supervisors, by ensuring there is a process in place to assess the competence of those working in the high containment facility (see section 6 below for more detail)

- Ensure an annual cross-inspection of their facility by a counterpart high containment facility manager is undertaken and participate in reciprocal cross-inspections.

4. Required Inspections

a) The following inspections and audits are to be undertaken, at least annually:

i) Standard Laboratory Inspection: Undertaken in line with University policy statement S1/07 – departmental safety inspections, ensuring that departmental biological safety officers are involved in inspections of high containment facilities.

ii) High Containment Scientific Coordinator's Inspection: Undertaken by the scientific coordinator on behalf of the supervisors, with specific attention to safety performance and working practices.

iii) High Containment Manager's Cross Inspection: Initiated by the high containment manager and undertaken by a corresponding manager from another facility.

iv) Regular Laboratory Check: Undertaken by the high containment manager; frequency to be determined by risk, but no less than monthly.

v) University Occupational Health & Safety Office Audit: Undertaken by the University Biological safety Officer (or nominated deputy).

5. Required Training

a) All high containment facility workers must be sufficiently trained and competent.

b) The following elements are key to achieving this standard:

i) Ensure workers are suitably trained and competent

(1) All high containment workers must have received suitable training. This includes:

- Completion of the University's Biological Safety Training.

- A documented training record outlining a suitable level of competency for safe working in a containment level 2 laboratory.

- A period of close supervision, with restricted access, whilst training is undertaken in how to safely work in the high containment facility, including training on the codes of practice, standard operating procedures, and safe systems of work arising out of risk assessments. This training must be specific to the facility where the person is working and specific to the organisms the person will be handling. It must also include sufficient knowledge of other organisms or work being undertaken in the facility, to ensure the person is able to maintain their and other people's safety at all times whilst working in the facility.

- Detailed training on what to do in the event of a spillage within the high containment facility.

- Independent access can be given once competence in both safe use of the facility and good microbiological practice in the use of the pathogen(s) can be demonstrated to the satisfaction of both the individual's supervisor and the high containment manager via observation and appropriate examination or testing.

- Out of hours access must only be obtained following an assessment of the risk.

(2) Ongoing competence should be judged by observation of behaviour, compliance with expected standards and checks on documented competency. As a minimum competency will be tested for all high containment facility workers by:

- An annual knowledge test in the form of a written exam and a spill drill.

- A re-examination of competence undertaken after three years. This will take the form of being observed undertaking protocols by the high containment manager (or nominated individual), a spill drill and a written examination to test current knowledge.

- A re-examination of competency when there are extended periods of absence exceeding six months. This will involve first level access training, plus that of the three-year re-examination.

- Access control data should be used to remove access for any worker not entering a facility for more than six months to ensure a re-examination is undertaken.

- Observed procedural or behavioural non-compliances by current workers must be recorded, acted upon and competence re-examined.

(3) New high containment users or visitors that have worked elsewhere, including senior positions, must not be presumed to have the correct competence to work in a particular facility, but must be trained or examined as per new/untrained users.

ii) **Ensure those carrying out training and competence assessment are suitably trained**

(4) High containment managers must attend either of the courses offered in the use of Containment Level 3 laboratories by UK Health Security Agency or The Health and Safety Laboratory and should undertake refresher training every five years.

(5) Supervisors and high containment scientific coordinators may also benefit from the same level of training, but that should be determined by risk assessment. If these individuals are not regular workers themselves within the high containment facilities, they should undergo a degree of instruction from a fellow supervisor or the high containment manager to ensure they can demonstrate their own competence to train or assess others.
