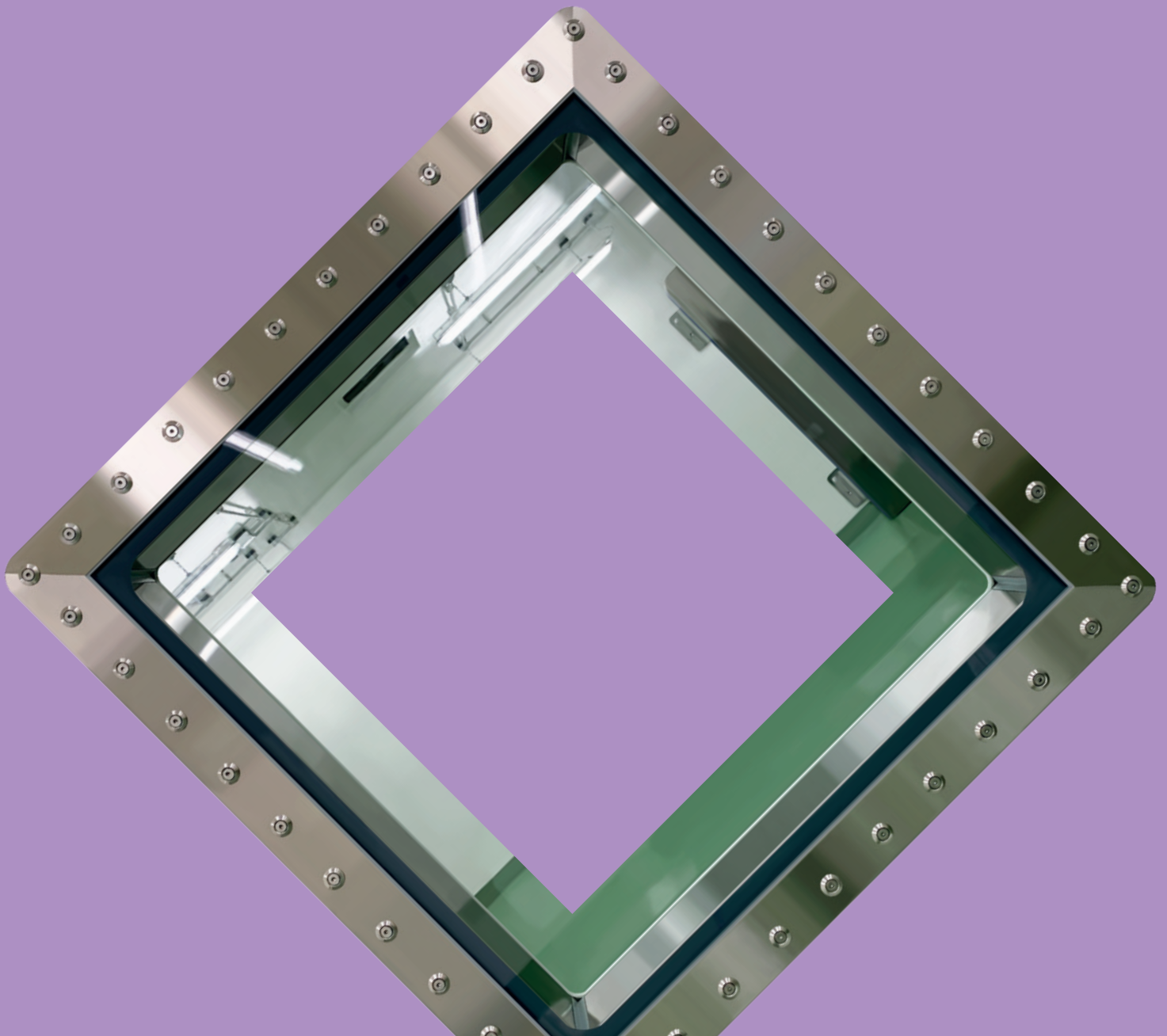


Airtight solutions. A future-focused look at designing for fumigation.

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Airtight solutions.

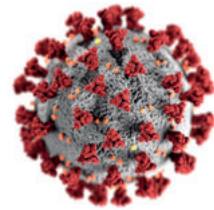
A future-focused look at designing for fumigation.

Fumigation in this context is the process of using a highly toxic gas or vapour to inactivate biological agents within a defined space or setting.

Advancements in gene therapies and bespoke therapeutics, along with the rise in biological containment facilities following the Covid-19 pandemic have resulted in a significant increase in the number of environments that require fumigation inside buildings. This is a trend that is expected to continue as plans are developed to manage future crises.

Fumigating a room can be extremely dangerous and needs to be carefully considered and managed.

“This white paper draws attention to the need to better understand the fumigation process and the implication on room airtightness. Retrofitting or consideration of room sealability late in a design can be dangerous, even life threatening and is often impractical and very expensive. In contrast, consideration of room airtightness requirements early in the design process will help achieve a safe and cost-effective result.”



Covid 19

contributed to a vast increase in the number of environments that require fumigation inside buildings.

Why do we make rooms airtight?

Fumigated rooms need to be airtight for a number of reasons, and this depends on the function and operation of the space. The three primary reasons are:

- 1. To prevent fumigant release to neighbouring areas.**
- 2. To maintain fumigant concentration required for effectiveness.**
- 3. To prevent either the escape or entrainment of biological agents.**

Typical fumigation systems. An introduction.

Introduction.

Whole-room fumigation uses a highly toxic substance in vapour or gaseous form to fill the space to inactivate biological agents. This can be used to prevent transmission of dangerous pathogens or contamination of the work being undertaken within a room.

There are many different types of fumigation systems, and some are more challenging to work with than others as they use different chemicals and create different hazards. For room fumigation sealability, the main issues are airtightness of room envelope construction, material compatibility and the influence of the fumigation process on the pressure differential between the fumigated space and adjoining areas throughout the fumigation cycle.

“The pressure differential between the room being fumigated and the adjoining areas is the driving force of the fumigant potentially escaping. Understanding the fumigation process and how pressure differentials may occur during the cycle is essential for designing effective engineering controls.”

If the fumigant is introduced as a liquid and boiled off in the space, it can create a positive pressure in the room. If the fumigant is flash vaporised and recirculated to the room by an external system then that may have minimal room pressure impact. Fumigation barrier and its seals must be designed to meet the expected pressure differentials experienced during the fumigation process, plus a safety margin.

Fumigation cycle.

To undertake whole-room fumigation, a suitable process must be followed. Some of this process will be manual and some may be automatic, dependant on the system used. We typically see the following steps (full detail overleaf):



PRE-FUMIGATION

- Notify appropriate people of the planned fumigation to reduce risk of exposure and check for any issues that could delay fumigation.
- Visually inspect the fumigation line for any defects and fix, if possible, prior to undertaking fumigation. If the fumigation barrier cannot be fixed, consider an alternative decontamination method or procedure.
- Prepare the room for fumigation including wipe down, opening items for fumigant circulation, and removal or bagging of items that could be damaged by, or absorb, the fumigant.
- Set up and prepare fumigation system.
- Set up biological indicators and/or chemical indicators if required.
- Condition the room environment to increase fumigant efficacy if possible, viable or required.
- Ensure all personnel have evacuated the room and set up warning signs.
- Seal the room, including the ventilation systems and doors.
- If required, set up monitors to detect fumigant in neighbouring spaces, particularly at the entrance doors.
- Select the appropriate validated fumigation cycle or prepare the validated quantity of fumigant.

FUMIGATION

- Introduce fumigant to the room via a fumigation system.
- Fumigant is left in the room at a suitable concentration to meet requirements (dwell time). Dependant on the system, fumigant can be topped up during this time. Some rooms or chemicals will require a circulation system to provide adequate coverage within the space so that all surfaces are exposed to the fumigant.
- If required, some fumigants can be neutralised by introduction of an additional chemical or use of a catalysing system to reduce the overall cycle time, safety risks and environmental impact.
- Purge the fumigant to make the room safe to enter. Consideration of the safe release of the fumigant is essential to ensure that it does not cause harm to people or the environment.

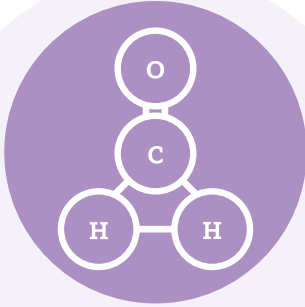
POST FUMIGATION

- Check the concentration of residual fumigant within the room and only open the room if the concentration is confirmed to be at a safe level.
- Dependant on the fumigant, exposed surfaces may require a wipe down to remove any potential residues resulting from fumigation and/or the neutralisation process. Ensure that the room has good air flow in case materials have absorbed fumigant which could be off-gassed.
- Confirm successful validation if biological indicators and/or chemical indicators were used.
- Remove any fumigation equipment and warning signage.
- Put the room back into working order and wait for the conditions to return to normal operation.

Types of fumigant and equipment.

An overview.

There are many types of fumigant and generating equipment. Those shown below are currently the most common. A thorough understanding of the fumigation systems, and the associated risks, must be established to ensure they are fully considered in design, construction and fumigation activities.

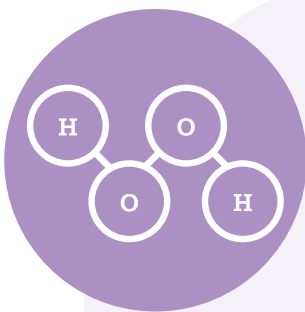


Formaldehyde.

Formaldehyde is typically boiled off within the room being fumigated. This increases the room pressure, in some cases dramatically, unless appropriate engineering controls are provided, such as pressure relief valves.

Other systems introduce formaldehyde by injecting the vapour into the room through a pipe. This is called an open loop system as the equipment does not recirculate the vapour. A closed loop system would recirculate the vapour and room air.

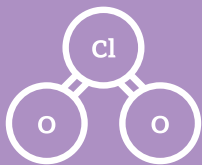
Neutralisation of formaldehyde is possible by using ammonium hydroxide to shorten the fumigation cycle and eliminate the discharge of formaldehyde into the atmosphere.



Hydrogen Peroxide.

Hydrogen peroxide fumigation systems can be closed loop or open loop depending on the equipment utilised and suitability to the application. Some hydrogen peroxide systems require the room to be conditioned to a suitable temperature and humidity.

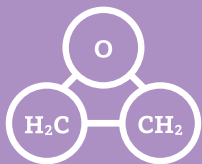
Hydrogen peroxide fumigation is sometimes described as a lazy fumigant as it is not as penetrating or seeking as other fumigants. This is due to the vapour being heavy and dropping out of the air. To overcome this, hydrogen peroxide fumigation systems often incorporate blowers to recirculate the vapour in the room to help distribute the fumigant.



Chlorine Dioxide.

Chlorine dioxide is a yellow-green gas with an odour similar to chlorine. Due to its gaseous nature, it has very good distribution, penetration, and sterilisation abilities.

The room being fumigated should be conditioned to have a suitable relative humidity level. Chlorine dioxide is an open loop system that injects the fumigant into the room.



Ethylene Oxide.

Ethylene oxide is a true gas and a highly effective sterilising agent. Being a true gas, ethylene oxide will completely fill any area it is injected into and has excellent penetration properties.

A major drawback of using ethylene oxide is its explosivity. For this reason, ethylene oxide must only be used in a vacuum steriliser, making room decontaminations highly hazardous.

Chemical Fogging.

Applying chemical disinfectants to rooms as fogs or mists is an alternative method to fumigation used in some industries, but with limited uses in biocontainment.

Fogging creates a disinfectant aerosol that is sprayed in the room, typically by fixed nozzles, to decontaminate surfaces. Material compatibility will vary dramatically with the chemical and concentration used. Newer systems electrostatically charge the chemical during aerosolisation to improve the application as the spray is attracted to surfaces.

Disinfectants dispersed by fog may not result in even application to all surfaces and hidden or 'shadowed' surfaces may not be disinfected.

Sealability standards. Latest guidance.

Airtightness requirements and guidance for fumigable spaces have been developed around the world. Most of these standards are for biological containment laboratories where room sealability not only mitigates fumigant leakage but also contains biological agents, the release of which may have significant political, economic, human health and animal health consequences.



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A risk assessment should be the first step in establishing the criteria for use of fumigant in a facility and may indicate the need for stricter requirements than those set in local, national or international standards. The context of these standards should be reviewed to understand how they apply to the facility. For example, whether the selected fumigation process is going to generate pressure differentials greater than the standard or guidance considers.

Standards & guidance

An overview of current documents is provided below. Please note that this list may not be current at time of reading and the latest standards should always be referred to.

Document	Test type
Australian AS/NZS 2243.3 – 2010 - Safety in laboratories - Part 3: Microbiological safety and containment*	Quantitative constant flow test
Canadian Biosafety Standard (CBS) – 2nd Edition	Select low containment and all high containment laboratories, qualitative test High containment (CL3-Ag & CL4) Quantitative pressure decay test
USDHHS/CDC/NIH – Biosafety in Microbiological and Biomedical Laboratories – 6th Edition, USA	Referencing USDA ARS Facilities Design Standards 242.1
USDA ARS 242.1 – 2012 – ARS Facilities Design Standards, USA*	BSL3-Ag quantitative pressure decay test CL3-Ag in greenhouses quantitative constant flow
World Health Organization – Laboratory Biosafety Manual – 4th Edition	Not defined
ANSI/ASSE Z9.14 – 2014, USA	Qualitative methodologies
'Sealability of Microbiological Containment Level 3 and 4 Facilities' and Health and Safety Executive, UK	Gives examples of qualitative methods as well as referencing Canadian Biosafety Standard
'Management and operation of microbiological containment laboratories' Advisory Committee on Dangerous Pathogens (ACDP) – 2018, UK	Gives examples of qualitative methods as well as referencing Canadian Biosafety Standard
VDI 2083 Cleanroom technology Tightness of containments, Classification, planning, and testing – 2018 Germany	Quantitative constant flow test with varying criteria dependant on airtightness class

*NB These guidelines are currently under review for a future update.

Quantitative tests typically include constant flow at a fixed pressure differential, or pressure decay testing.

Qualitative test methods typically include soap bubble testing, smoke pencil testing, or audible leak detection methods but other less common methods are sometimes used e.g. traceable gas or non-toxic simulated fumigation.

Many clients who undertake fumigation regularly will have their own testing standard based on their risk assessments and testing requirements.

Assessing the risks. An approach.

When designing fumigated rooms and before developing fumigation protocols, the risks should be suitably identified and managed. Many organisations around the world have methodologies to assess and control risks and the reader should identify local requirements prior to undertaking any risk management process.

This document is focused on the design for airtightness of fumigated spaces and does not elaborate on other risks associated with fumigation.

It is important for the designers to understand the fumigation process and preferably to be involved in the associated risk assessment. This will support the 'Why & How' of risk mitigation and identification of control measures.

To assess the risk(s) we would typically follow a risk management process, including the following steps:

- consultation
- identification of hazards
- assessment of risk
- identification of appropriate risk control measures
- implementation of the control measures
- monitoring
- regular review

We summarise each step further below.

1. Consultation.

In this step the designers should develop their understanding of the fumigation process and procedures being proposed for the room through consultation with relevant parties, including the client and end users, safety representatives, facilities management representatives and other design team members. This will enable the identification of hazards in the next step of the risk management process.

Consultation is required to take place during all stages of the risk management process to:

- help establish the context
- ensure that all hazards are adequately identified
- bring different areas of expertise together for analysis of risks, and
- enhance appropriate change management during the risk management process.

The consultation should consider items such as; how the room is sealed; how airtight the room envelope construction is; how the fumigant is introduced to the room; what type of fumigant; whether a proprietary fumigation system will be used; the peak concentration of fumigant; how surrounding areas will be used; whether the room can be accessed to prepare for fumigation; how doors will be prevented from opening; the extent of the fumigation barrier; what happens in a fire or other emergency situation; whether there are any substances or materials likely to be in the room that can react with the fumigant; and so on.

2. Identification of hazards.

Dependant on the type of facility and activities in the building, a formal method of identifying hazards may be required. For most assessments of airtightness and fumigation sealability requirements, an informal process is used.

Identifying who or what might be harmed by a release of fumigant and how they can be harmed is key to this step. Risks to people or samples in neighbouring spaces must be considered.

Identifying the extent of the fumigation barrier is also key. The fumigated area may consist of a single or cluster of rooms. Ductwork can often extend the barrier past the wall, floors, or ceilings of the room and as such should be considered as part of the fumigation barrier up to the point of the damper or device that stops the fumigant. It is worth noting that fumigant can escape up and down as well as to neighbouring rooms on plan and, therefore, fumigation barrier shall be considered in three dimensions.

“Understanding the potential dynamic differential pressures between the fumigated space and neighbouring spaces throughout the whole of the fumigation procedure (including fumigation introduction and the deactivation or purging of the fumigant) is vital, as this is the driving force behind the potential escape of the fumigant.”

The context of the laboratory is also a significant factor in understanding hazards. A new state-of-the-art building in a capital city with generous funding and an experienced team will be different to an emergency response field laboratory. As such the type of laboratory facility, location, available resources as well as human factors such as legal, cultural, and socioeconomic circumstances, should be considered.



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Assessing the risks. An approach.

CONTINUED

3. Assessment of risk.

The majority of risk assessments utilise a Risk Assessment Matrix to identify and classify hazards from low, medium, or high when considered against the likelihood and consequence.

Each project should use a risk evaluation/assessment method that best meets their unique needs, including appropriate scoring methods and definitions of the parameters. In higher hazard environments risks may be assessed by quantitative numerical methods or hybrid (semi-quantitative) methodologies.

Acceptable and unacceptable risk criteria will vary on every project dependant on the institution, the facility, the team, the location, the requirement for the facility, etc. They should be established before starting any risk assessment classification.

For each of the hazards identified, the likelihood and consequence should be assessed and then the overall initial risk of the process classified. If there are unacceptable risks it should be considered whether they can be controlled, or whether the work should proceed at all.

4. Identification of appropriate risk control measures.

“When considering risk control measures, the context of the facility is a key driver as this will dictate how control measures are considered and if they are practical. For example, a facility with a very short lifespan is likely to have a different solution to one that has a 50-year design life.”

Consideration should be given to understanding if there are sufficient resources to obtain and maintain the proposed risk control measures in an effective and sustainable manner throughout the life of the facility.

Local or international regulations and guidance should be considered and reviewed for compliance and/or derogation should they not be sufficient or applicable to the facility.

When identifying control measures, understanding how they will work in practice is essential. Potential control measures should be discussed and agreed with the users to ensure there is a good understanding of how they will be integrated into the Standard Operating Procedures and training provided for fumigating the space safely. Other considerations include whether the control measure adds a risk or relies on a management step that could easily be missed.

By reviewing the neighbouring spaces for the impact of a potential fumigant leak at peak concentration, we can consider control measures to mitigate the risk. These could be engineering controls to maintain pressure differential and/or dilution rates, or management controls such as restricted access, monitoring, or most likely a combination of these controls. Once control measures have been identified, the residual risk should be reviewed and verified if acceptable. A sensitivity review and a simple failure analysis will support understanding of whether the proposed solution is robust.

5. Implementation of the control measures.

When implementing control measures for fumigation sealability, it is key to have the measures agreed and communicated with all relevant stakeholders so that they know the solution and management procedures in depth. This is relevant for operational and maintenance procedures as well as any emergency response. All operational and maintenance personnel must be trained in all procedures and have regular refresher training.

When a control measure is implemented, it must be confirmed that it is performing within agreed parameters. As such, the control measure should be tested at the time of installation and then on a regular periodic basis. For fumigation sealability this is typically completed by testing to agreed airtightness requirements as well as undertaking regular visual inspections. Sometimes, non-toxic simulated fumigations are also used to confirm the integrity of the fumigation barrier.

6. Monitoring.

Once the sealable facility for fumigation and all control measures are in place, monitoring procedures provide assurance that they are being maintained in a safe, operational manner. Monitoring activities should consider engineering control measures as well as the processes, personnel and equipment used. Lessons learnt should be established from incident reports and investigations that may identify improvements.

7. Regular review.

A regular review cycle should be established to assess processes, personnel, equipment, incident reports and test results from sealability testing or fumigation efficacy testing. This review should consider the facility and equipment life expectancy and resilience, potential degradation of fumigation barrier performance over time, personnel succession planning, training plans and if there are any single points of failure in any systems.



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Integrated barrier system. Considered design.

To make a room airtight there must be a sealed barrier provided to all faces of the room. The greatest proportion of this barrier consists of floors, walls, and ceilings, typically constructed of monolithic substrates with specialist coatings or proprietary panel systems.

The selection of the right barrier material requires an understanding of the frequency of fumigation, type of fumigant, delivery system to be used, the operational model that the fumigated space will function under, and the expected life of the facility.

Vulnerability of the containment barrier typically occurs at junctions of dissimilar materials, services penetrations or where the containment barrier (or its substrate) fails or has been damaged. All these conditions must be carefully detailed and some basic principles apply to how to form these junctions. Continuous and permanent joints (e.g. welded), overlapping materials with a compressed gasket, and proprietary services penetration seals are preferable to butting together with a thin edge of sealant. Where a coating system forms the airtight barrier, overlapping the different barrier elements—floors, walls, ceiling, embeds, and opening frames—with the coating will ensure an airtight junctions as long as the materials are compatible.



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“The containment barrier needs to fully integrate with any item that penetrates through it such as doors, windows, lights, pipes, cables, ducts, to provide the seal. These penetration details need to enable a robust, reliable, and cleanable solution.”

Interfaces and details need to be comprehensively considered early in any project as they can impact setting out and space planning of fumigated spaces in significant ways. Wall or floor coving near a cable penetration that requires a flange seal will need to be spaced out to consider tolerance and minimum dimensions, allowing application of containment coating and seal. The ability to inspect and test the fumigation barrier also needs to be considered when designing and setting out the containment barrier components.

Highly airtight components are often specialist items that cannot provide multiple functions and therefore reviewing the fumigation barrier against other performance requirements such as fire, security, acoustic, etc. is very important. Any item that is intended to meet multiple requirements might not exist or may not have been appropriately tested and certified. Therefore designing out multiple requirements is good practice.

Conclusion.

Our key takeaways.

The importance of understanding and defining the airtightness requirements relevant to fumigation and room sealability early on in projects cannot be overstated, and the key takeaways from this paper include:

- It is important for designers to understand the fumigation process.
- Identifying who or what might be harmed by a release of fumigant and how they can be harmed is key.
- When considering risk assessment and control measures, the context of the facility is an important driver as this will dictate how control measures are considered and if they are practical.
- Relevant airtightness criteria should be defined as part of the risk assessment early in the design process.
- Identifying the extent of the fumigation barrier early in the design process is key.
- Construction should be appropriate for the selected airtightness requirements with consideration of testing methodology and foreseeable failure conditions.
- Room sealability performance should be tested in accordance with the relevant criteria during construction and then on a regular periodic basis during operation.
- Consideration should be given to the ongoing maintenance of the risk control measures in an effective and sustainable manner throughout the life of the facility.

About the authors.



Andrew Somerville.

Andrew is a Director and the Science & Research sector head at Hoare Lea. Hoare Lea is an award-winning engineering consultancy with a creative team of engineers, designers, and technical specialists. It provides innovative solutions to complex engineering and design challenges for buildings.

Andrew is an engineer who has worked in Science & Research for more than 25 years and has been involved with major projects that positively impact people, their health, and quality of life. Andrew leads dynamic project teams, promoting multi-discipline approaches to design, as well as incorporating scientific methodology. As a champion of simplicity and adaptability of design, he is one of the leading voices in the science & research construction industry.



Shem Sacewicz.

Shem is a senior Associate and Laboratory Architect at HOK London office with 20 years of experience of working on science projects from inception to completion in the UK, Europe, and Asia. He has a particular interest in and has developed practical knowledge of bio-containment at all containment levels as well as designing for highly collaborative and interdisciplinary research. He is an expert at complex space planning, responding to scientific, operational, and regulatory requirements and based on collaborative engagement with scientific users and regulatory bodies. Shem has worked with a number of government, commercial and academic clients across a broad range of projects.

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