



Containment

Good Practice Guidance on controlling exposure to chemicals that cause platinum sensitisation

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1. Glossary

Airlock	An airlock is a closed area with two or more doors situated between different rooms with varying levels of cleanliness. Its purpose is to control the airflow between these rooms when people or items need to move between them. Airlocks are used to maintain proper air quality and cleanliness during transitions.
ALARP	'As low as reasonably practicable'. Controlling the level of exposure to a chemical to a level that is as low as is reasonably practicable, considering the risk and the effort, time, cost and resources needed to decrease that risk.
Butterfly valve	A round disc with the same width/diameter as the pipe it's in. It can turn 90 degrees, either allowing liquids or powders to pass or stopping the flow. (See Controlling exposure to chemicals that cause platinum sensitisation: A visual guide).
Containment	1. Keeping hazardous materials within equipment (tanks, drums, pipes, etc.) so there is no release into the workplace. 2. Keeping materials within their designated work area to avoid transfer to other work areas or releases into the environment.
Cross-contamination	Contamination of a material or of a product with another material or product.
Dedicated	A dedicated facility, suite or plant is used solely for the manufacture of a single product. This prevents the possibility of cross contamination from other materials or products left over after cleaning.
Engineering controls	The systems installed to provide containment.
Facility design controls	These are additional controls, also called tertiary or environmental controls. They are separate from the main secondary system and stop materials from escaping into other parts of the facility. They involve containment rooms with airlocks, dressing and undressing areas, and air pressure systems to prevent airborne leaks. They are used in case the primary or secondary systems fail, or for managing spills.
Factory acceptance test	Checking and testing equipment or parts to make sure they work correctly. This is done by the equipment manufacturer at their factory and documented to ensure equipment quality. (See page 16).
Hazard	A hazard is something that can hurt people or the environment. In this guide, it refers to the harm that can come from using a chemical substance due to its dangerous properties.
Hierarchy of controls	A system of grouping exposure control methods from the most to the least effective. When controlling a hazard, the most effective control that is practicable should be used.
Isolator	A sealed enclosure, such as a glovebox, where work is done and the chemicals stay contained within the enclosure.
ISPE	International Society of Pharmaceutical Engineers.
LEV	Local Exhaust (Extract) Ventilation. A system that pulls in air in the immediate vicinity of a source of contamination/pollution and transfers it away from those working in the area. (See Controlling exposure to chemicals that cause platinum sensitisation: A visual guide, and Local Exhaust Ventilation: Good Practice Guidance on controlling exposure to chemicals that cause platinum sensitisation).
OEB	Occupational Exposure Band.
OEL	Occupational Exposure Limit. The two most common types of OEL are: • short-term exposure limit (STEL), typically 15-minute exposure limit; • long-term exposure limit (LTEL), which is typically an 8-hour exposure limit

PPE	Personal Protective Equipment. Items such as a hard hat, safety harness, ear-muffs or reinforced boots worn by people to protect themselves against workplace hazards. In the context of this guide, PPE refers to items such as gloves, goggles, coveralls, airo suits, and respirators that protect the wearer against chemical hazards. PPE should be worn where it is not reasonably practicable to adequately control risks by other means (see Hierarchy of Controls) (See separate guidance on PPE). ¹
Primary containment	Equipment, such as a glovebox, that keeps material inside and stops it from getting out into the workspace. It uses sealed containers or safety biological cabinets and safe procedures.
Primary system	The main way to control exposure is by keeping hazardous materials contained within the processing equipment where they are produced, transferred, and stored. This involves using things like process vessels, pipework, clean-break couplings, isolators, intermediate bulk containers, etc.
Risk	In chemical control, risk is the combination of hazard and exposure. The greater the hazard or the level of exposure, the greater the risk. Exposure depends on things like the amount and type of material being handled, the process used, how often it's handled, and the equipment and procedures used. If there is no exposure, there is no risk.
RPE	Respiratory Protective Equipment. RPE is a type of PPE that prevents breathing in harmful chemicals. RPE can range from simple filters over the mouth and nose to self-contained breathing apparatus. (See separate guidance on RPE).
SAT	Site Acceptance Test. (See page 16).
Secondary containment	A means of controlling residual risks in the event of the failure of a primary control system. For instance, a glove-box is a main safety control for handling dangerous powder. If you use it inside a down-flow booth, it gives added protection if the glove-box has a problem.
Separated	A place that's kept apart from another place, often with special barriers or devices.
Substance	A chemical element or one of its compounds, including any impurities.

2. Introduction



Containment is a system of specialised equipment that either stops chemicals from being released into the workplace so there is no exposure to workers, or which keeps chemicals within a specific work area and stops them from entering other work areas or the environment.

This booklet provides guidance on the selection, use, and monitoring of containment solutions. A glossary of terms is provided at the end.

Different types of containment are also described in the following separate guidance:

- Controlling exposure to chemicals that cause platinum sensitisation – a visual guide
- Local Exhaust Ventilation

There is a process to follow to effectively select and manage containment approaches comprising of the following steps:

1. Identify and classify hazardous materials used in the workplace

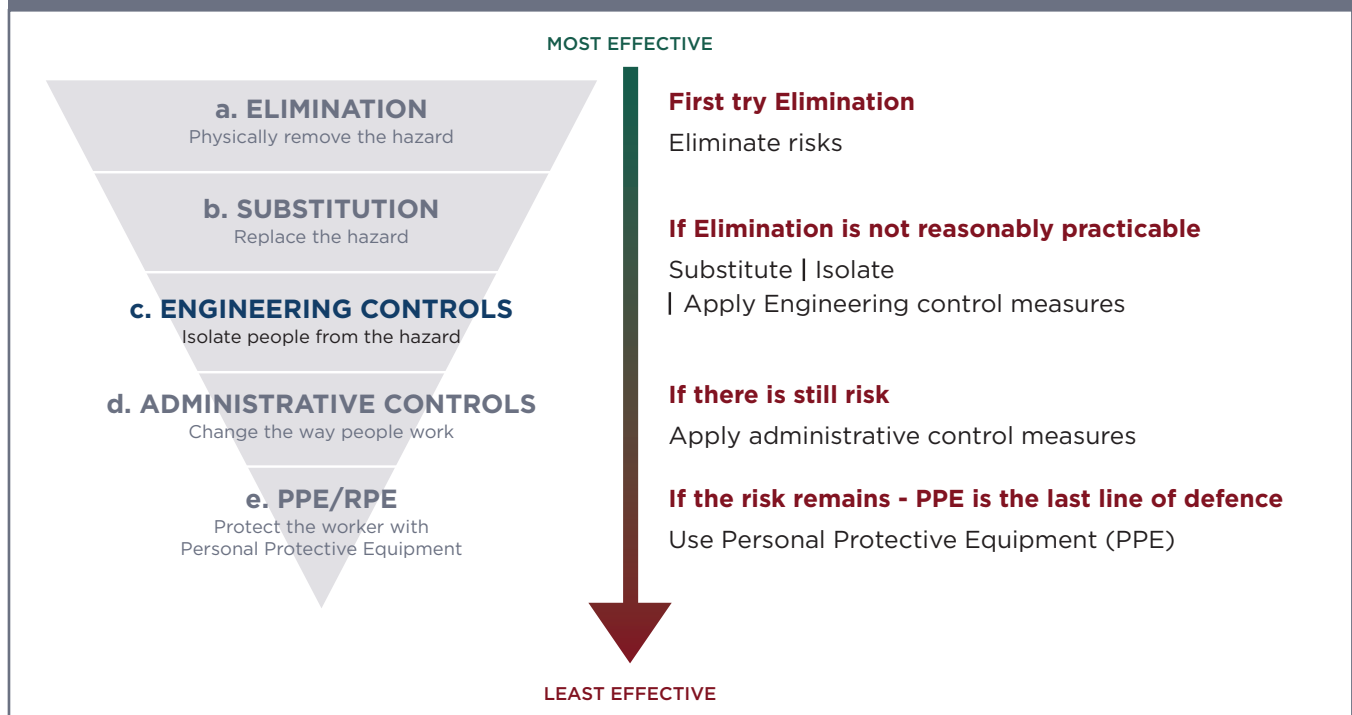


2. Perform a risk assessment where chemical substances that are hazardous to health are used

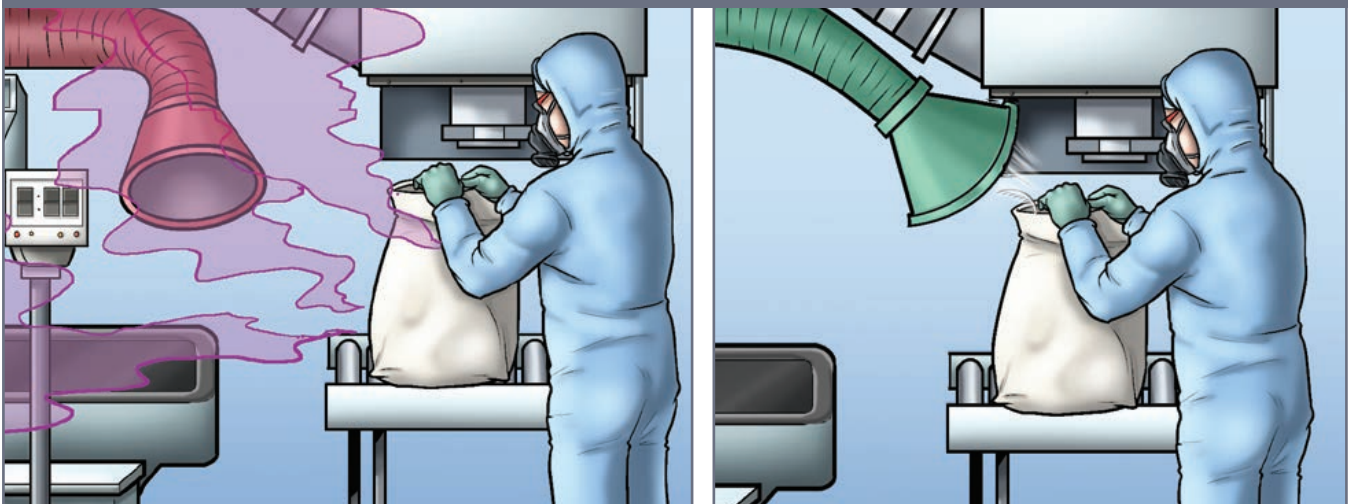


3. Reduce the risk of exposure to hazardous substances by using the hierarchy of controls listed below:

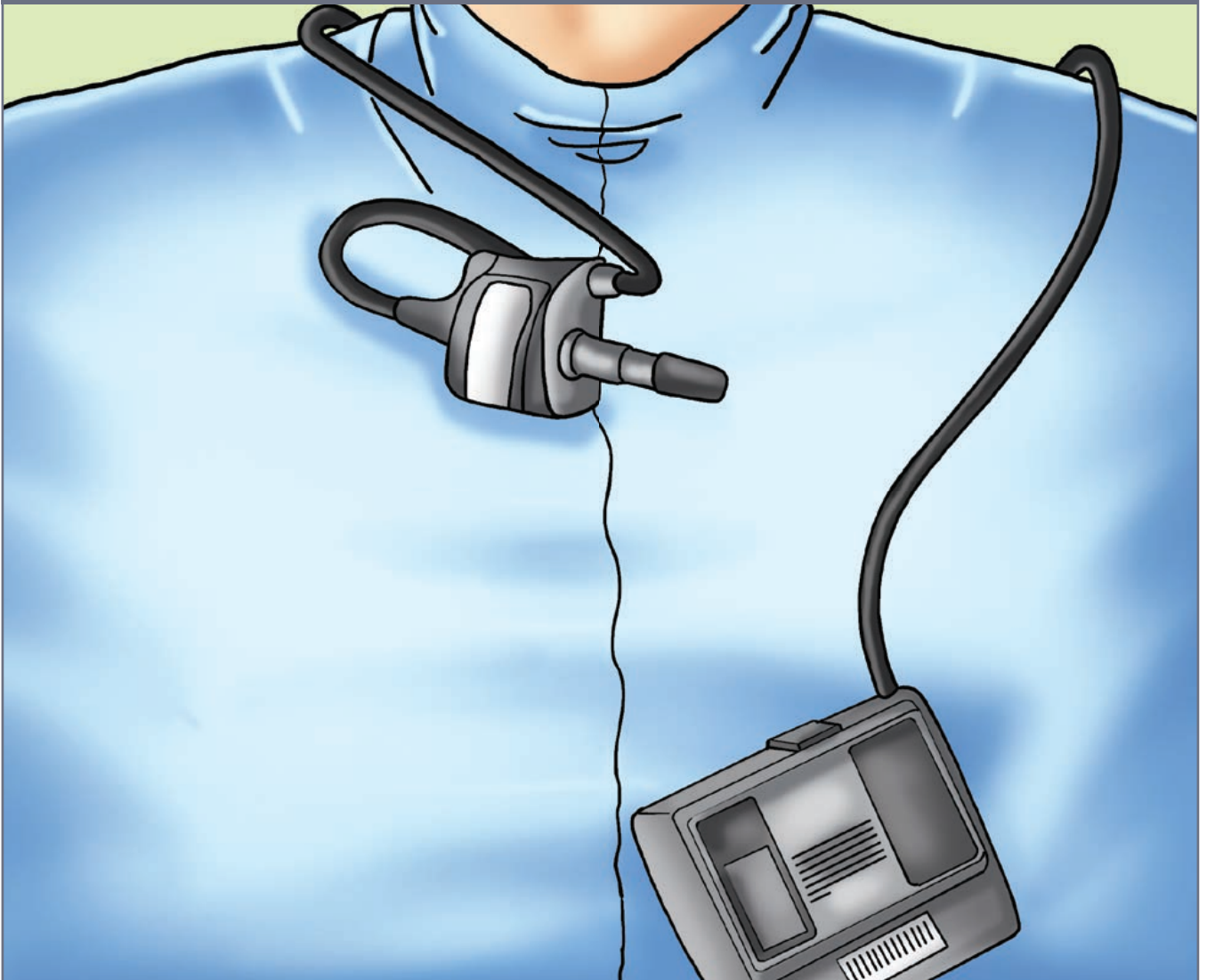
- a. **Elimination:** change processes so the hazardous substance is not needed
- b. **Substitution:** replace the hazardous substance with a less hazardous substance or a less hazardous form of the substance. For example, use wetted material or a slurry instead of dry powder to reduce material getting into the air
- c. **Engineering controls:** enclose and isolate hazardous materials or processes to prevent exposure of workers
- d. **Administrative controls:** Implement rules or procedures (e.g. warning signs and staff rotation) to reduce exposure of workers
- e. **Personal Protective Equipment:** After applying the other controls, if there is still a risk, PPE should be used as a last resort to protect workers



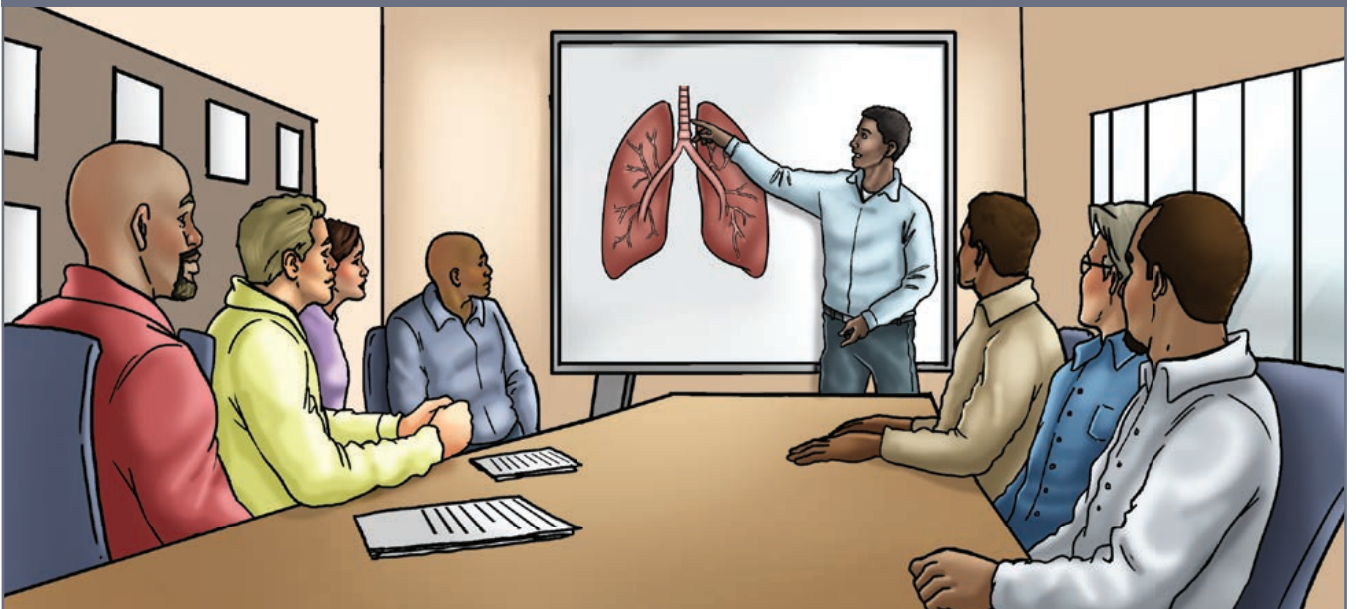
4. Ensure that control measures are used correctly and adequately maintained.



5. Monitor exposure and carry out health surveillance, where necessary.



6. Inform, instruct and train employees about the risks and precautions needed.

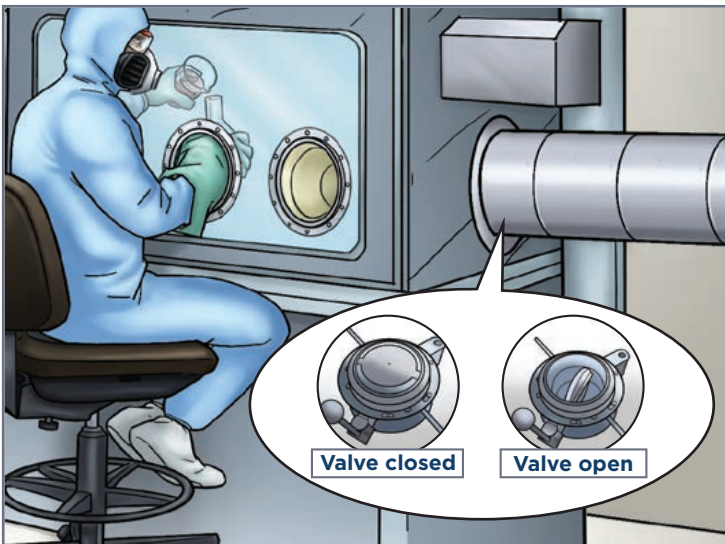


Primary containment



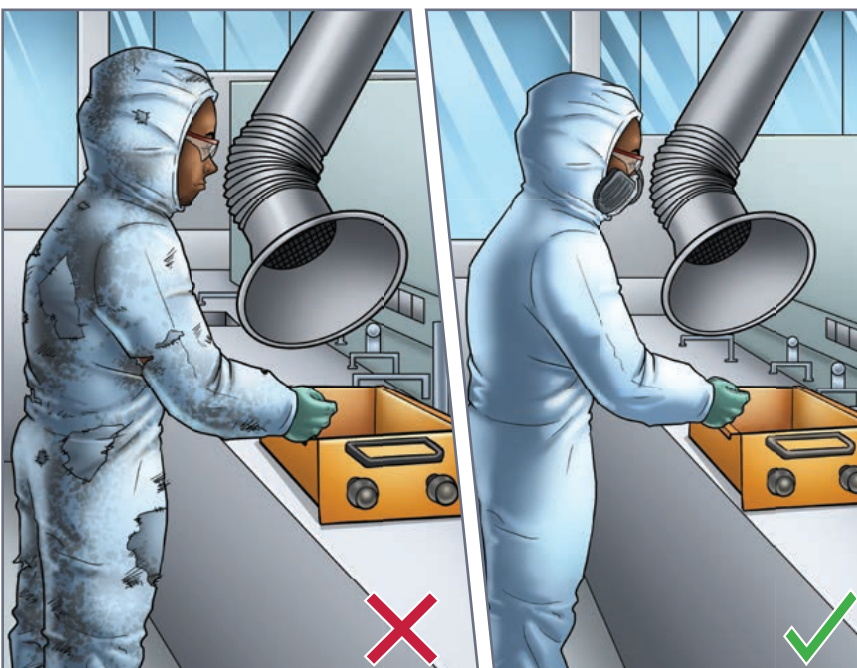
Primary containment is the system of equipment such as reaction vessels and pipes, and potentially also other items such as isolators, intended to contain the hazardous chemicals. If properly designed and used, primary containment may adequately prevent material getting out into the workspace.

Secondary and Tertiary Controls

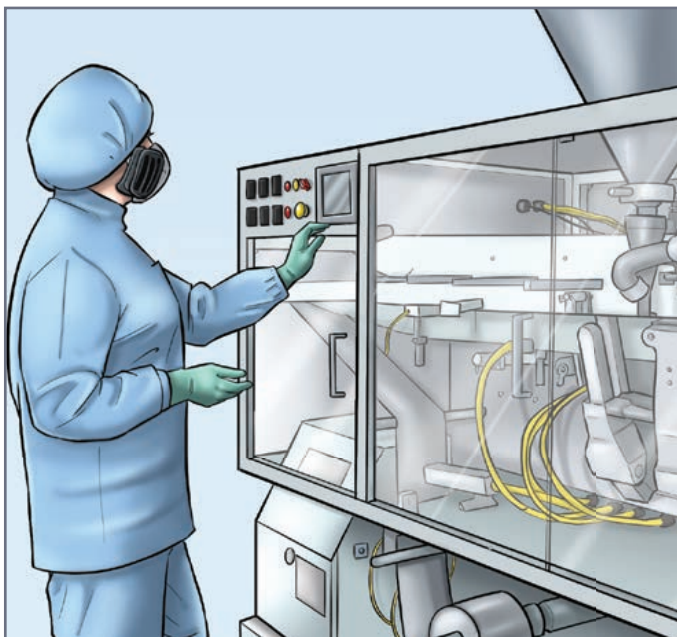


In some cases, primary containment controls are not enough to effectively reduce the risk of exposure and additional protective measures are required.

For example, a second layer of control or elements built into the design of a building or process area, such as a split butterfly valve (primary containment) that is then surrounded by an isolator under negative pressure (secondary containment).



Personal Protective Equipment (PPE) (tertiary control) can be used as a control. PPE is the least effective control and can fail for numerous reasons, such as employee behaviour, which can reduce the efficiency of PPE.

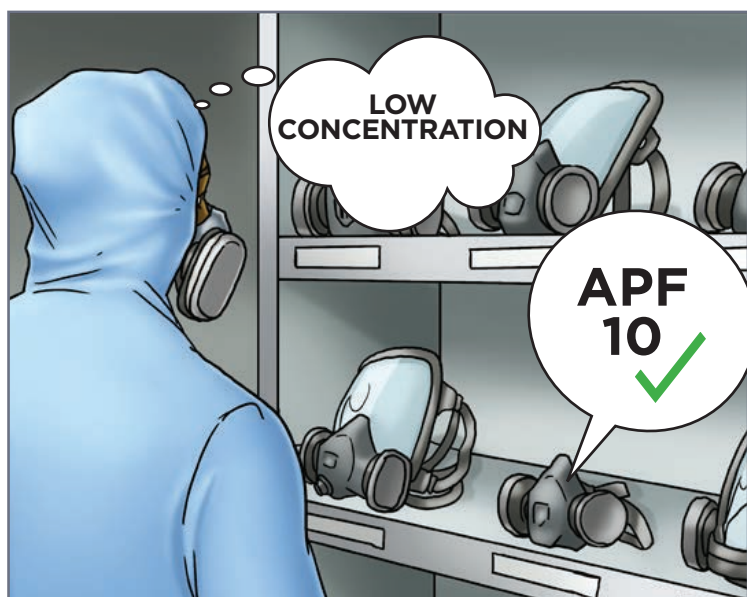


This is why, under normal day-to-day operations, PPE must not be the only or the primary control option; it must be used in conjunction with other primary or secondary layers of containment or control.

PPE will be required for some maintenance and engineering tasks, but other controls need to also be selected and used with it, such as procedural control measures (safe operating procedures and permits), as well as the potential to use basic engineering controls.



Only in certain circumstances, such as emergency situations, can PPE be used as the main control - usually to escape an area that has become too dangerous to stay in.



Types of PPE to consider can be found in the **IPA RPE good practice guide** and the **IPA PPE good practice guide**, which covers different types of PPE, how to select, use, maintain and safely remove and clean PPE while working in environments where sensitising PGMs are present.

3. Risk Assessment and Project Planning

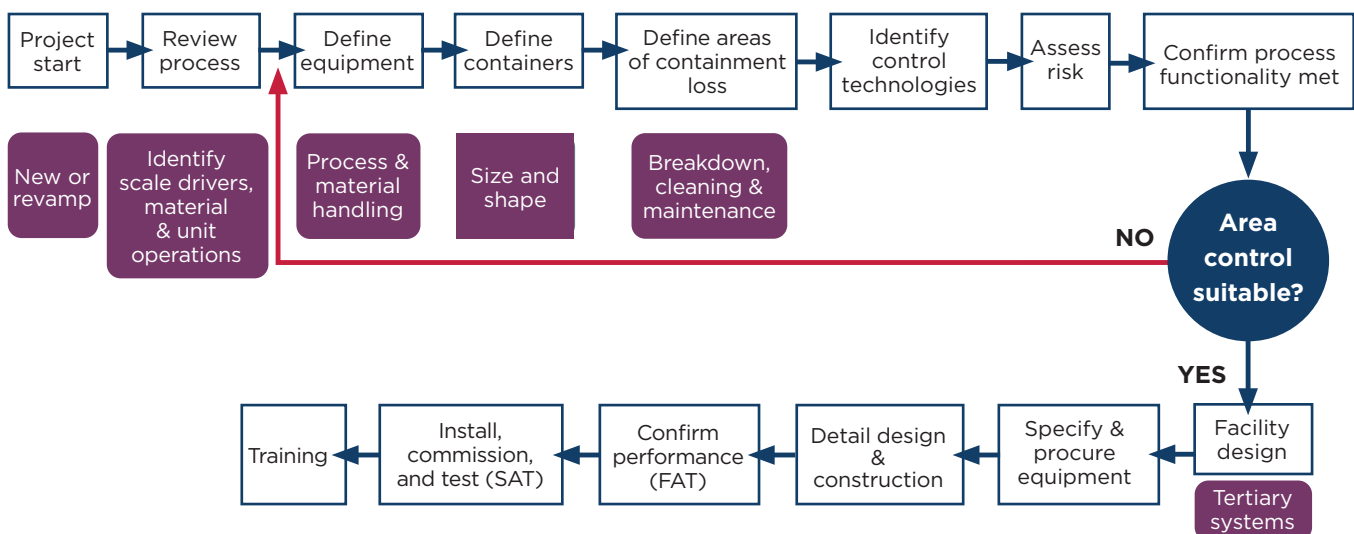


The first step is to begin with a risk assessment. This assessment should be conducted by a suitably qualified individual who clearly determines if there are any health hazards present and where potential exposure might happen. The goal should be to eliminate these hazards whenever possible.

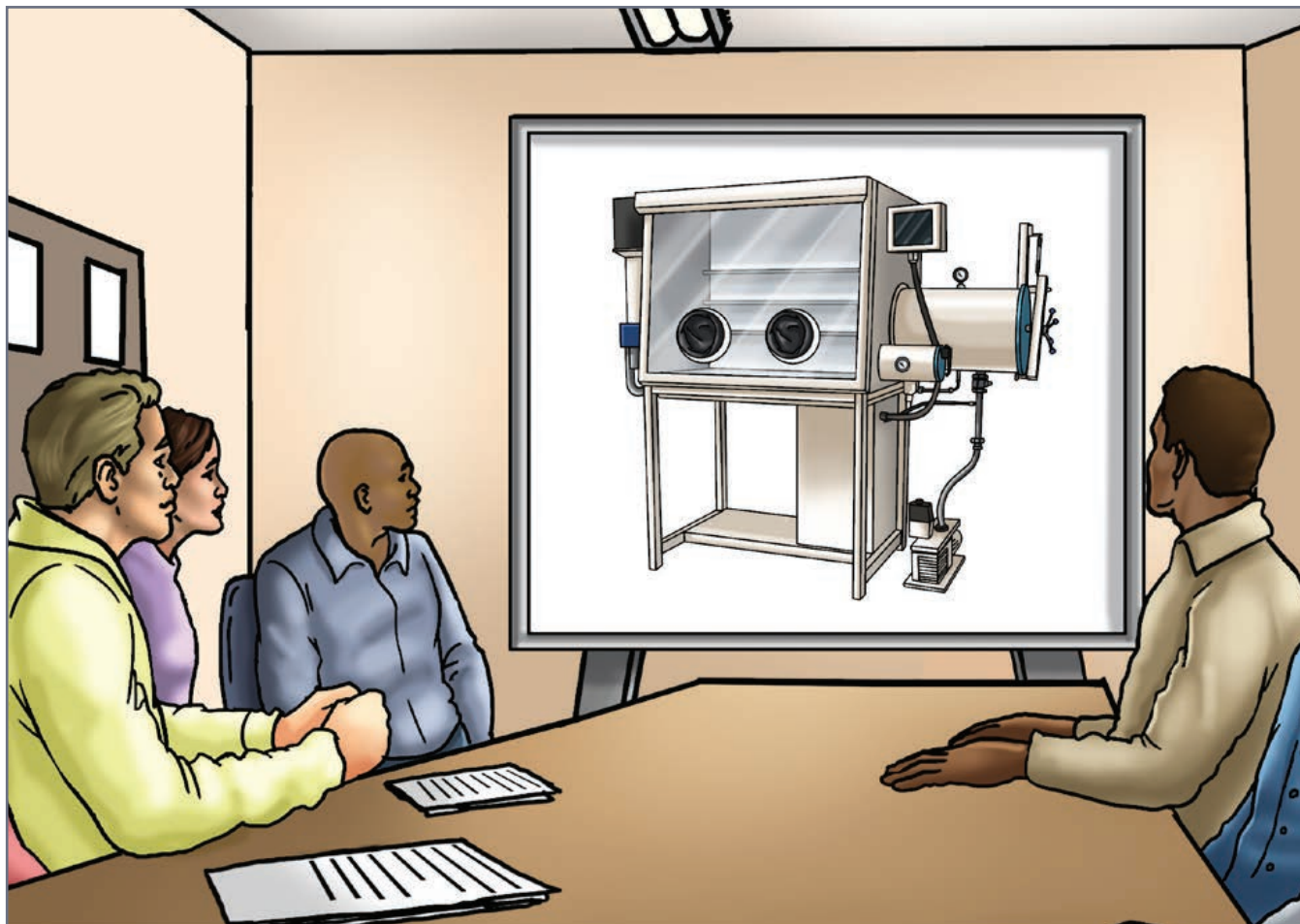
If elimination isn't feasible, the risk assessment is used to identify exposure controls and minimise harm.

4. Foundations of Basic Design

The flowchart below outlines the sequence to assess, identify, confirm and test the suitable containment and control choices for a new chemical or a change to an existing process.



The first step involves reviewing the process details to identify key factors, such as:



- Whether the equipment will be used for a single product or multiple products
- Manufacturing scale (volume of products)
- Length of production runs (single or multiple batches)
- Characteristics of the raw materials, intermediates, and products (including their composition, physical state, flow properties, particle size, moisture content, volatility, sensitivity to light/heat/oxygen, corrosiveness, etc.)
- Unit operations
- How much of the process can be automated
- Critical cycle or transfer durations (e.g., adding reactants to a reactor)
- Fire, safety, and health risks associated with materials (explosion risk, flammability, health effects, Occupational Exposure Limits, or Occupational Exposure Band targets - see next section)
- Turn-around time, especially in a multi-product facility

5. OELs/OEBs/CPTs

Occupational Exposure Limits (OELs)

OELs are limits of exposure intended to either prevent or minimise the chances of both short-term and long-term health risks. For powders, OELs are usually expressed as concentrations in the breathing zone air, measured in milligrams, micrograms or nanograms of material per cubicmetre of air (mg/m^3 , $\mu\text{g}/\text{m}^3$, $\text{ng}/\mu\text{m}^3$).

OELs are typically established by governments or regulatory agencies, but companies may also establish their own OELs for chemicals that do not have a legal OEL.

No controls in place. Above OEL.



Not using correct controls. No RPE.



Correct selection of controls. Below OEL



Occupational Exposure Limit (OEL) is the most common name used to describe legal limits of occupational exposure to chemicals, but some countries may use a different name or acronym. OELs are set based on the toxic effects of chemicals. They do not consider physical hazards like flammability or reaction hazards.



VS



Occupational Exposure Bands (OEBs)

If there is no legal OEL for a chemical, and there is not enough known about the chemical's hazards for a company to establish its own precise OEL, it may be possible to assign it into an Occupational Exposure Band (OEB).

There is no harmonised set of OEBs used by all companies, but below is a common example.

Exposure Control Band	Exposure Control Target (airborne concentration range)
A	Dust: >1 to 10 mg/m ³
	Vapour: >50 to 500 ppm
B	Dust: >0.1 to 1 mg/m ³
	Vapour: >5 to 50 ppm
C	Dust: >0.01 to 0.1 mg/m ³
	Vapour: >0.5 to 5 ppm
D	Dust: <0.01 mg/m ³
	Vapour: <0.5 ppm
E	Specialist advice should be sought in each case from a qualified EHS adviser

Containment Performance Targets (CPTs)



A Containment Performance Target (CPT) is the concentration of a hazardous chemical in workplace air that a company wants to achieve through the use of containment controls to protect worker health. Sometimes the CPT will be the OEL, but it is common practice for the CPT to be lower than the OEL – often 50% or even 10% of the OEL. A CPT is focussed on equipment and a process and not the whole workplace like an OEL. The CPT is an important piece of information when talking to suppliers of processing and containment equipment.

It is important to know the CPT before designing a work area and selecting the appropriate containment options. Testing should be performed to confirm the containment controls are effective and exposure levels are below the CPT. When integrating containment and control measures into a safe work process, determining a CPT for each piece of equipment is advisable for comparison purposes.

OELs, OEBs, and CPTs guide the selection of containment control options. Once in place, levels of the chemical in workplace air can be measured and compared against the OEL/OEB and CPT to confirm the containment controls are sufficient to protect worker health. This testing should be performed by a suitably qualified industrial/occupational hygienist.



6. Process Equipment and Containment Technology Selection

Once the chemical process is reviewed and the process equipment is defined, the next step is to choose the appropriate containment technology. Alternatively, evaluation of containment options may happen alongside or even before the process equipment is defined. Several factors should be considered before finalising the containment technology choice, including:

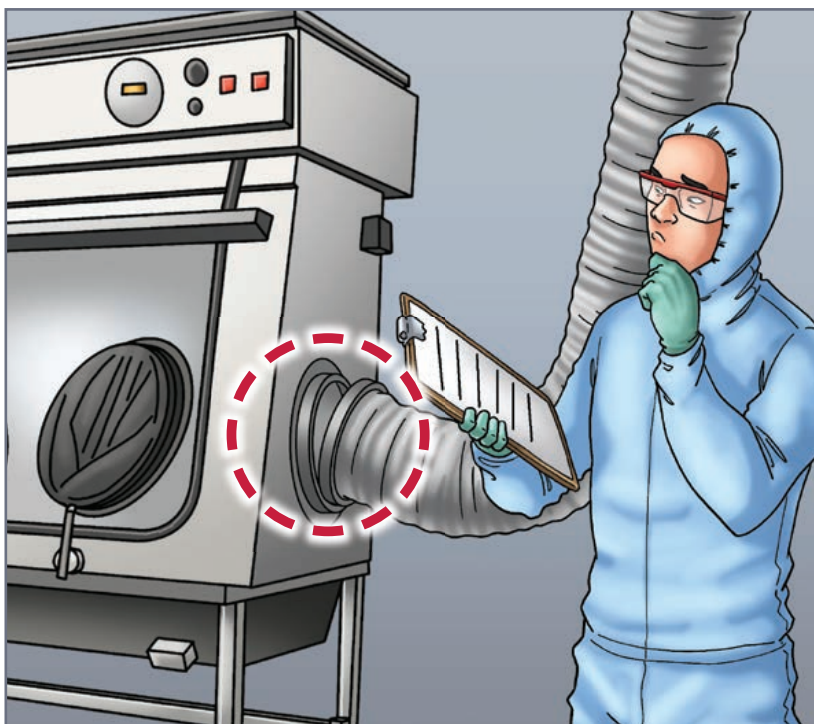
- Manufacturing scale
- Types and sizes of containers being used
- Compatibility with existing infrastructure
- Deciding between disposable or reusable isolators
- Ease of cleaning
- Cleaning methods and materials
- Managing waste
- Automation needs
- Transportation and tracking requirements
- Ergonomics
- Both primary and secondary containment
- Budget for both initial and long-term/life cycle costs



7. Identifying Containment Loss Points

A crucial aspect of the risk assessment is predicting “containment loss” or places where exposure or emissions might occur. Recognising these spots within the process helps shape your containment and control plan. Here are some examples where such exposure might occur:

- Sampling input materials
- Measuring out input materials
- Adding materials from containers to equipment
- Sampling processed materials
- Removing remaining/residual materials
- Transferring materials from equipment to containers
- Dealing with breakdowns or unforeseen situations
- Routine maintenance tasks
- Cleaning equipment
- Cleaning reusable containers
- Disposing of waste
- Venting and emergency situations



To improve containment, the process design should minimise transfers by optimising the arrangement of unit operations, building layouts, and room setups, whenever feasible.

8. Considering Ergonomics

Another critical aspect to include in the process steps, equipment design and selection of containment technology is ergonomics. Ergonomics is the study of how people interact with their work environment. It considers how workers can do their job comfortably and efficiently, avoiding health issues like musculoskeletal injuries.



When specifying containment equipment that involves manual actions by operators, it's crucial to conduct an ergonomic assessment during the early design phase. Many suppliers offer interactive 3D or virtual reality computer aided design (CAD) models that can be very useful for evaluating the ability to operate and maintain the equipment in the workplace. They may create a prototype of the equipment to show its working or a computer simulation.

The engineer should assess the following factors:



1. Operator's required reach



2. Clear vision of operations



3. Dexterity needed for tasks



4. Weight to be handled



5. Comfortable posture during manipulations

6. Material transfer in and out of the system



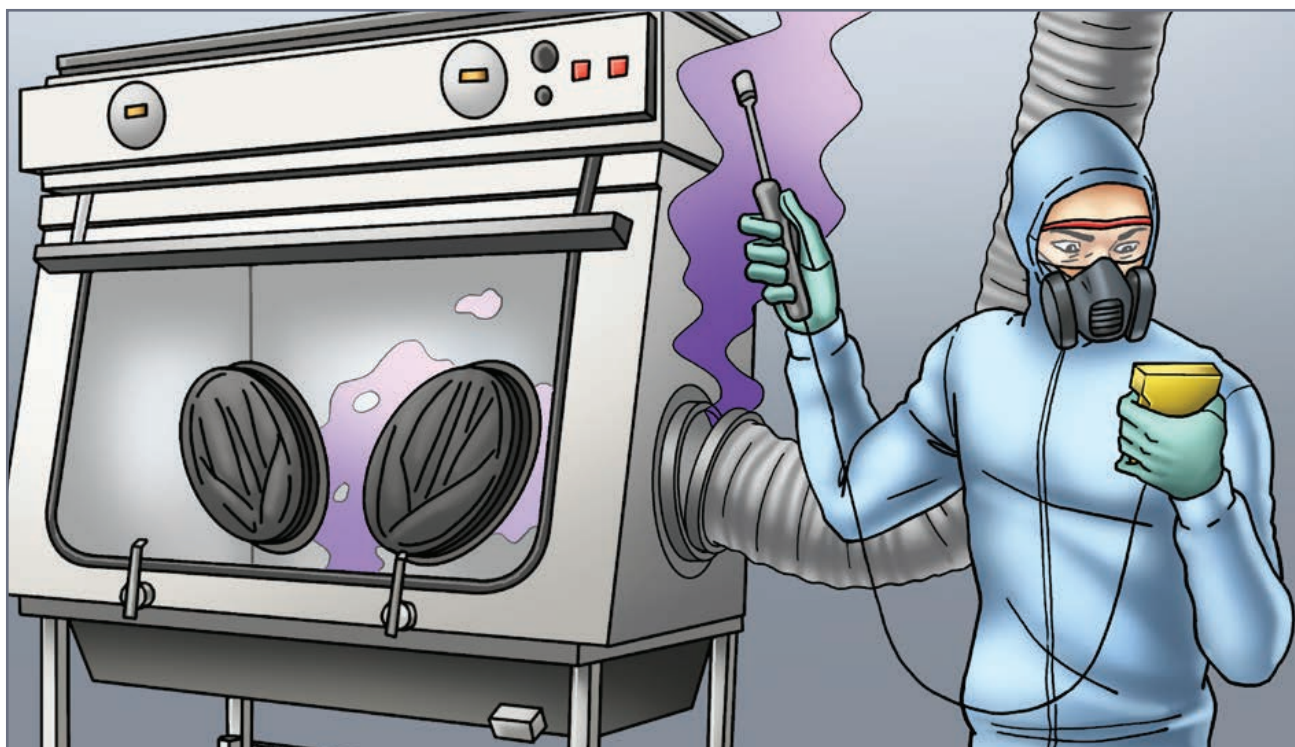
Whenever possible, ergonomic evaluations should involve multiple personnel to account for variations in height and reach. This also ensures operators understand and contribute to the design process, increasing the likelihood of them accepting the final design. When necessary, seek assistance from a qualified ergonomist or industrial hygienist for additional support.

9. Containment testing

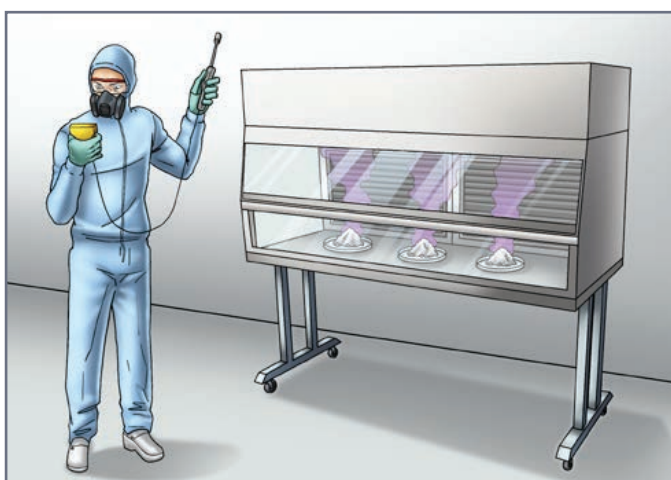
In order to consistently assess containment effectiveness, you must follow a structured testing process. The International Society of Pharmaceutical Engineering (ISPE) offers a valuable guide, “ISPE (SMEPAC) Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment,” which is commonly used in the pharmaceutical sector. It’s advisable to use this guide to evaluate containment performance and engage a competent industrial/occupational hygienist for testing assistance. This helps you devise a sampling plan, including the number and location of samples.

It is good practice to test the effectiveness of containment equipment before installation, after installation, and during use:

- 1. Factory Acceptance Tests (FAT):** The manufacturer/supplier of the containment equipment tests the equipment before it is delivered to a client. Specify desired airborne exposure levels and suitable Containment Performance Targets (CPTs) in the specifications. During FAT, equipment suppliers follow approved test plans and specifications while the client observes, confirming the system’s readiness for installation and site testing. Consider practical airborne monitoring during FAT using non-hazardous surrogate chemicals to align with the ISPE guidance. These tests could also include pressure testing, seal checks, smoke testing, as well as surrogate sampling. A competent industrial/occupational hygienist should be used to help set FAT and also SAT testing.

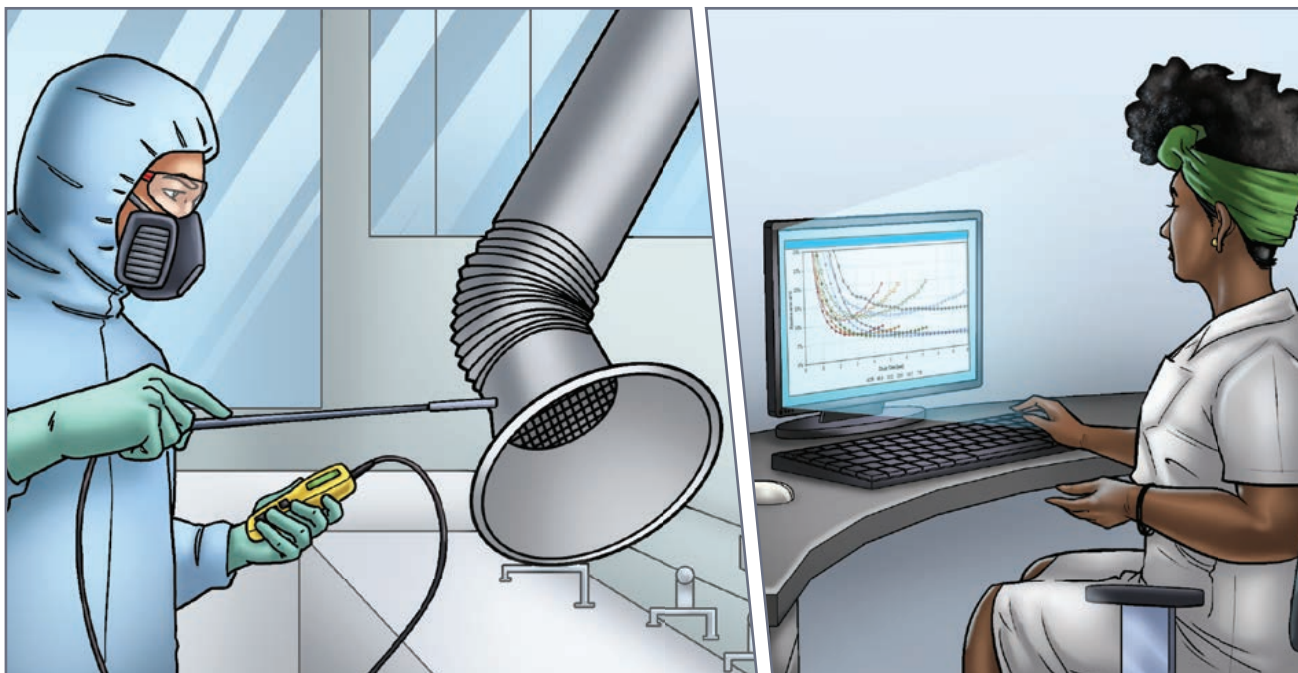


- 2. Site Acceptance Tests (SAT):** After installing the equipment at the site, testing is performed (airborne particulate sampling) to provide real-world data under actual conditions – and confirm the equipment meets the supplier specification. A non-hazardous surrogate chemical may be used to determine if the equipment meets the CPT. This comprehensive approach helps assess the equipment’s effectiveness and build an accurate worker exposure profile. This will guide whether additional control strategies are necessary, such as layered controls or Respiratory Protective Equipment (RPE).



Containment testing (continued)

- 3. Operational Testing:** Once containment equipment is in use, regular testing should be performed to confirm its performance over its lifespan. Test protocols can be integrated into routine industrial hygiene programmes.



The specifics of exposure monitoring, including type and frequency, should be planned as part of the facility's exposure monitoring program with input from a knowledgeable industrial hygienist. Regulatory authorities might also require testing of control measures as part of complying with Environmental, Health, and Safety (EHS) regulations.

Some companies are adopting real-time monitoring to assess process and control performance. This monitoring helps gauge direct exposure, detect control failures or system issues, and identify increased airborne particulate levels that might indicate containment breaches.

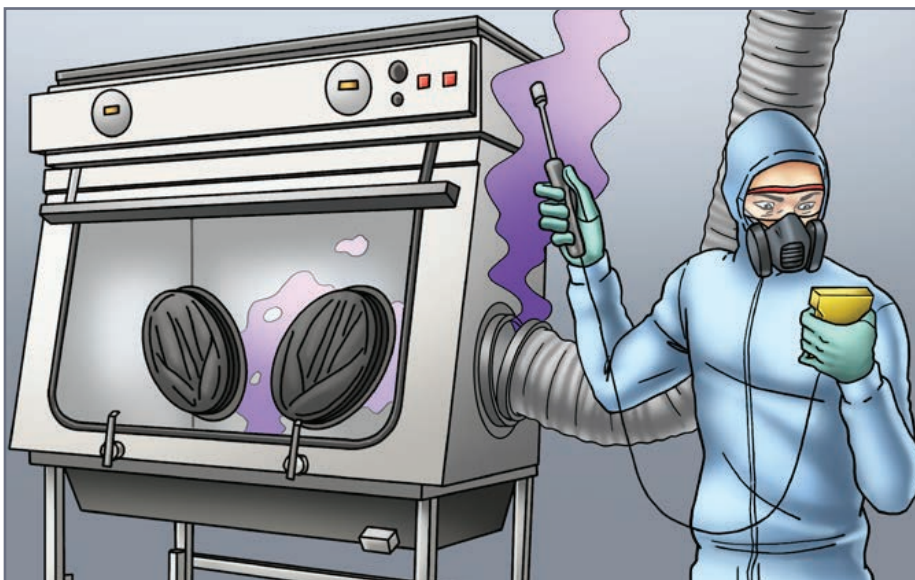
Testing using surrogate chemicals

When evaluating containment effectiveness during FAT and SAT, consider using a surrogate material that is similar to the original substance (e.g. similar size particles) but is less hazardous. However, be cautious when evaluating test results from surrogate materials, as differences in properties like flow, particle size distribution, and dustiness can impact the results.

If it is not possible to use a suitable surrogate material, extra caution and control measures are necessary when testing containment equipment using the hazardous chemical.



Involving operational staff during Site Acceptance Tests (SAT) can aid in training.



Operational testing of equipment containing the actual process material (hazardous chemical) should follow correct methods and a competent person such as an industrial/occupational hygienist should be used.

Managers, superintendents, operators, engineers and industrial hygienists all have duties to perform to ensure containments work as they should (capture and collect harmful particulates). This document includes lists of inspection and verification questions for each of these job roles that will help to ensure containment systems are appropriately selected, designed, installed, operated, and maintained.

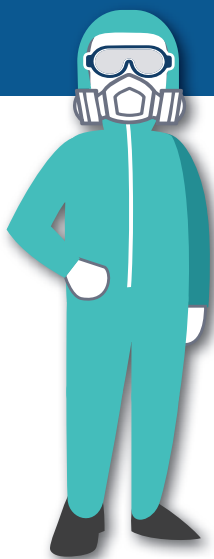
Managing Containment as a Critical Control

Audit Questions

This section provides example lists of 'Go/No Go' questions that could be implemented as part of job risk assessments and operational documents to help manage Containment as a critical control for controlling exposure to chemicals that cause platinum sensitisation. Example lists of 'Go/No Go' questions are provided for Operators, Superintendents, Maintenance/Engineering, Industrial/Occupational Hygienists, and Project Managers/Project Engineers/Project Contractors responsible for installing new equipment and processes. Please refer to the list of questions for the role that most aligns with your role and responsibilities. The question lists are intended to verify that appropriate systems, processes and checks are in place to ensure Containment as a critical control is effective. This includes empowering workers to stop work or not begin a task if a problem is identified.

These question lists are provided as examples. Implementation of such a scheme and the specific questions that would be most appropriate may differ between different companies and sites. Questions should be appropriate and understandable to their target audience and ideally be binary ('Go/No Go'). In implementing such a scheme, consideration should be given to when and how often it is appropriate to ask and answer individual questions. For some questions, such as those relating to checks performed by Operators, it may be appropriate to ask and answer the question each time before commencing a task that uses the critical control to help control exposure to chemicals that cause platinum sensitisation. For other questions, it may be more appropriate to schedule them for daily or weekly checks, while others, such as most of the questions intended for Managers, would be more suitable for attention perhaps quarterly or annually.





Operators

How to use this guide:

- Review each critical control's effectiveness, at their specified frequency, using the questions below.
- If you answer NO to any of the questions, immediate action must be taken to inform your line management to find a suitable temporary fix or permanent solution.

1. Availability

Do I protect myself from becoming ill from work by following procedures and using the provided equipment and controls properly?

YES

NO

2. Risk assessment

Has a risk-based process been carried out to determine exposure risk?

YES

NO

3. Inspections and maintenance

Do you check containment and control equipment as part of your start up and shutdown procedures?

YES

NO

Are checks recorded in a log sheet or log book to provide valuable records/track trends of how the equipment is working?

YES

NO

Do you perform the following tests:

- Visual inspections for damage?

YES

NO

- Simple air flow/velocity checks?

YES

NO

- Check if visual gauges are within specification/showing any problems?

YES

NO

Do you check to see if equipment is kept clean to help maintain its function?

YES

NO

Do you raise any concerns with your line manager?

YES

NO

Do you report any defects/faults so that maintenance teams can perform repairs outside of the planned maintenance window?

YES

NO

Superintendents



How to use this guide:

- Review each critical control's effectiveness, at their specified frequency, using the questions below.
- If you answer NO to any of the questions, immediate action must be taken to inform your line management to find a suitable temporary fix or permanent solution.
- Communicate this Good Practice Guidance and Audit Questions to Operators and other relevant staff and contractors.

1. Training

Has information, instruction and training been provided to employees to help them understand why it is important to use containment and control equipment properly and as required by operating procedures?

☐ YES☐ NO

2. Assurance

Have simple first line assurance checks been done on the following aspects of containment and control?

- Appropriate use by the actual users of the equipment?

☐ YES☐ NO

- Checks carried out by departmental staff and external service providers?

☐ YES☐ NO

- Compliance of use by users?

☐ YES☐ NO

- Completion of training?

☐ YES☐ NO

Are defects, checks and maintenance activities reported on to help manage the appropriate use and continued function of containment and control measures?

☐ YES☐ NO



Maintenance/Engineering

How to use this guide:

- Review each critical control's effectiveness, at their specified frequency, using the questions below.
- If you answer NO to any of the questions, immediate action must be taken to inform your line management to find a suitable temporary fix or permanent solution.

1. Inspections and maintenance

Is planned maintenance being carried out for containment and control equipment?

YES

NO

Are defects being reported, via regular checks and inspections, by users and staff?

YES

NO

Where defects are identified, are improvements to containment and control options (safety critical) acted on as soon as possible?

YES

NO

If a piece of equipment is waiting to be repaired, is the process taken offline to prevent increased risk of exposure?

YES

NO

Is the following types of data collected?

- Velocity or flow measurements across all points of LEV systems?

YES

NO

- Pressure readings from key parts of an extraction system, such as before and after the fan and in the main ductwork?

YES

NO

- Indicative visual inspections of equipment?

YES

NO

- Assurance results from line managers?

YES

NO

Is data gathered by maintenance teams, users and external providers to provide a picture as to the health and status of the containment and control equipment being used on site?

YES

NO

Are trends used to help predict failures before they happen?

YES

NO

Industrial/Occupational Hygiene (IH)/EHS



How to use this guide:

- Review each critical control's effectiveness, at their specified frequency, using the questions below.
- If you answer NO to any of the questions, immediate action must be taken to find a suitable temporary fix or permanent solution.
- Communicate this Good Practice Guidance and Audit Questions to all relevant staff, including Managers, Superintendents, Operators, and Maintenance/Engineering.

1. Training

Do we provide training to users, supervisors, maintenance teams, project teams, as well as senior managers, so they gain an awareness and understanding of the need, use and ongoing management of key containment and control equipment?

☐ YES☐ NO

2. Assurance

Do we provide a more technical form of assurance by providing detailed insight into the operation and continued maintenance of key pieces of containment and control equipment?

☐ YES☐ NO

Do we provide a detailed assessment of extraction systems?

☐ YES☐ NO

Do we arrange and carry out exposure monitoring of users to help validate controls by showing the exposures are below targets and limits?

☐ YES☐ NO

Do we provide support containment performance testing of key equipment during commissioning and ongoing maintenance?

☐ YES☐ NO

Do we provide a non-biased assurance program of the operation of the overarching EHS management of the facilities?

☐ YES☐ NO



Project Managers/Engineers/Contractors

How to use this guide:

- Review each critical control's effectiveness, at their specified frequency, using the questions below.
- If you answer NO to any of the questions, immediate action must be taken to inform management to find a suitable temporary fix or permanent solution.

1. Planning

Do you engage with your SMEs (e.g. ventilation engineers) during the design stage to set containment and control strategies for a project, instead of trying to retrofit later which will increase costs and risks?

☐ YES☐ NO

Do you engage with IHs and other SMEs (e.g. ventilation engineers) to help with risk assessment, choosing strategies and supporting equipment lists?

☐ YES☐ NO

If you work on a gated project management system, do you seek SME sign off at relevant gates of the project (e.g. Gate 1 for design, Gate 3 for embedding and Gate 4 for sign off)?

☐ YES☐ NO

Do you reach out to IHs when you need testing and/or measurements at certain points of the project, such as:

- When performing risk assessment and containment/control strategies?

☐ YES☐ NO

- For advice for Factory Acceptance Tests (FAT) at vendor sites?

☐ YES☐ NO

- When performing containment performance testing or Site Acceptance Tests (SAT) at your own site?

☐ YES☐ NO

- For continued support in setting up exposure monitoring to hand over to operations for completion?

☐ YES☐ NO

- When signing off health statements, risk assessment results, control strategies, etc.?

☐ YES☐ NO

10. Additional Resources/Reference List

- HSG53. The selection, use and maintenance of respiratory protective equipment. HSE Books (1998), ISBN 0717615375.
- HSG258. Controlling airborne contaminants at work. A guide to local exhaust ventilation. HSE Books (2008) ISBN 9780717662982.
- IChemE 2002 Containment systems: a design guide. Institution of Chemical Engineers (IChemE) 2002, ISBN 0852954077
- Industrial Ventilation – A manual of recommended practice by the American Conference of Governmental Industrial Hygienists (ACGIH).
- ISPE surrogate sampling (ISPE (SMEPAC) Good Practice Guide: “Assessing the Particulate Containment Performance of Pharmaceutical Equipment” is commonly used in the Pharmaceutical industry 2014 (<http://www.ispe.org>).
- Reference the IPA Chapter 9 Control Measures and Management systems doc 2022
- “Controlling exposure to chemicals that cause platinum sensitisation: a visual guide”

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