

This article presents a study performed to evaluate the fitting, removal, and disposal of contaminated filter cartridges using a flexible containment system.

Safety Evaluation of a Flexible Engineering Control System

by Tony O’Connell, Marie Coggins, Victoria Hogan, and Miriam Byrne

Introduction

A wide variety of industries face significant occupational hygiene and chemical containment challenges due to the increased manufacture of more potent drugs and chemicals. The manufacture and use of potent substances with Occupational Exposure Limit values (OELv) $<1\mu\text{g}/\text{m}^3$ often requires the development and use of containment systems. This may include designs for new manufacturing facilities and the retrofitting of older facilities.

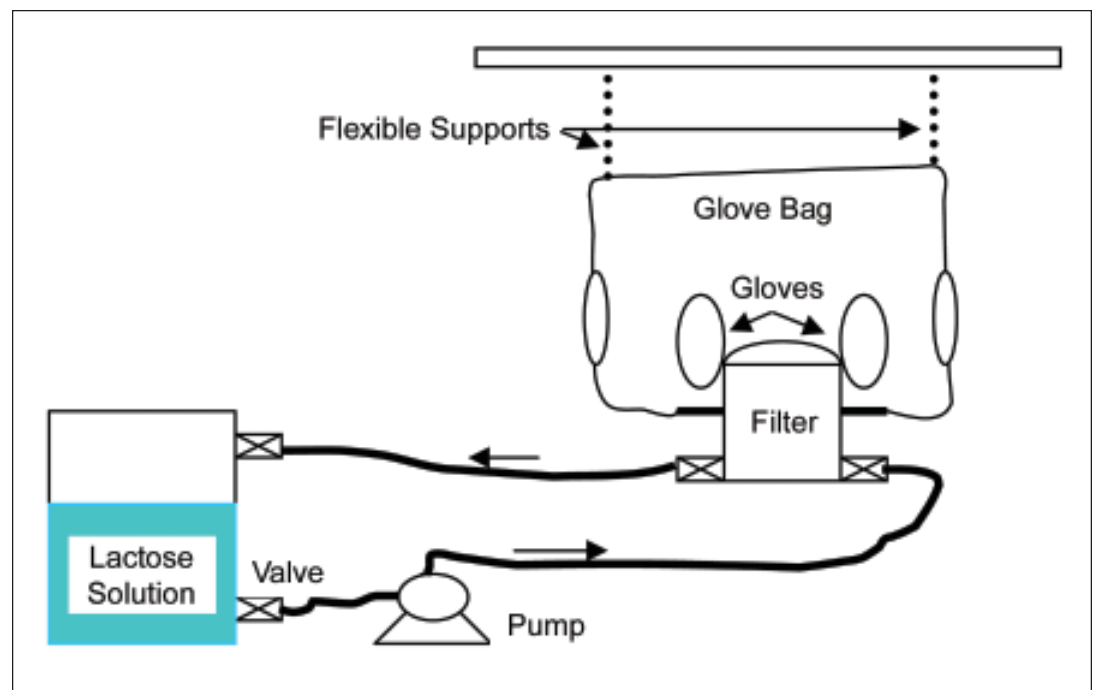
When selecting engineering controls for the management of particulate emissions, the choice of options is vast and selection is usually dictated by performance, suitability, and cost.¹ Total enclosures are commonly used for control of particulates in the chemical and radiation industries,^{1,2} where designs vary from rigid glove boxes to flexible glove bags. Many of the

fixed containment options are expensive; therefore, they are outside the budgets of Small to Medium size Enterprises (SMEs). Due to financial constraints, many SMEs resort to the use of elaborate (and often costly) Personal Protective Equipment (PPE) as their ultimate control measure. Both the use of fixed containment options and PPE can pose challenges to the end user.

A task which often requires the use of exposure control and that is commonly conducted in the chemical and pharmaceutical industries is the filtration of either a liquid or particulate chemical agent. The filtration process for pharmaceutical products is conducted by a variety of techniques; one of the most common types of filters used (for polishing wet products and for trapping dry particulates) is the cartridge filter.

In the majority of filtration operations, the filtration itself, whether wet or dry, is normally

Figure 1. Outline of liquid filtration test rig.



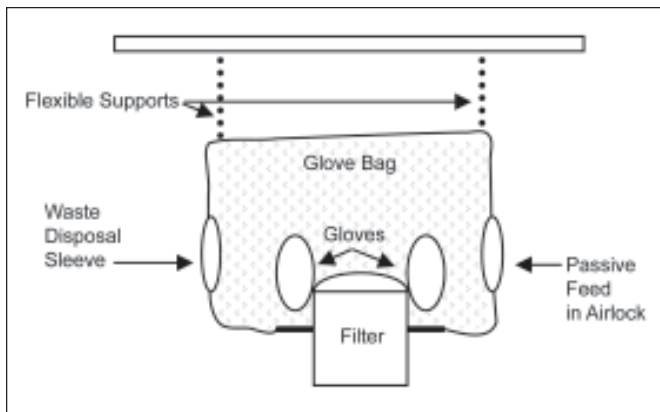


Figure 2. Outline of dry filtration test rig.

conducted under contained conditions; where the cartridges are contained within a secure housing and pose no containment problem while in situ. However, a potential exposure issue may arise when used cartridges are being removed. Traditional containment systems used in this situation include rigid glove boxes, 'dry break coupling,' and/or the use of PPE. The former system always requires considerable capital investment and the latter releases the product into the facility, necessitating further cleaning which again requires the use of PPE.

There is often no or limited occupational hygiene exposure data estimates available for current containment systems. And most of the designs available are for routine manufacturing tasks and not for non-routine activities where the potential occupational exposure risk is often the greatest, e.g., maintenance or emergency activities. The task analyzed in this study includes the fitting, removal, and disposal of contaminated filter cartridges using a flexible containment system. Inadequate containment during this unit operation could result in over-exposures to hazardous substances, expensive decontamination, clean up requirements, and significant product quality concerns.

The Use of Flexible Containment in Industry

A viable alternative to rigid containment systems is the use of flexible containment, e.g., 'glove bags.' Flexible systems aim to provide containment in situ when potential high risk exposure unit operations are being performed. The advantage of using flexible containment systems is that they can be adapted easily to any facility, without modifying equipment and incurring significant capital cost. The flexible containment design also is more ergonomically friendly and is an especially useful containment solution for retro-fitting older facilities. Flexible containment designs also can be continuously used subject to the replacement of attachments such as sleeves.

The following include a number of areas where flexible containment systems are being used successfully:

- filter changing (all types)
- dry powder and liquid sampling
- powder dispensing
- sample handling in laboratories

- removal of equipment from process lines
- dryer vent sock changing
- centrifuge cloth removals
- barriers for inspection of vessels and lines
- seeding process vessels
- powder and liquid charging etc.
- asbestos removal³

These flexible systems are not only a containment solution for the pharmaceutical industry, but are applicable for any industry that requires the containment of products. Flexible containment systems have proved especially valuable in GMP manufacturing environments where there is a risk of two-way contamination.⁴

As pharmaceutical compounds become more potent and pose a greater challenge from a containment perspective, greater efforts are required to assess the performance of a containment device before introduction to the workplace.³ Some have assessed the containment capability of a glove bag in the context of asbestos removal. However, while data from other industries suggest that the containment capability data for flexible systems are directly comparable to rigid systems, these data are company-specific; therefore, they are not widely available. However, there is data to support some exceptions.⁵ It is likely that flexible containment provides other operational advantages apart from containment, e.g., time and labor savings, over rigid systems, but these have not been formally assessed. To redress this, the objective of the present study was to carry out an assessment of both the ergonomic and containment capability aspects of two glove bag designs to be used as the primary containment device for the unit operation of changing product-contaminated wet and dry cartridge filters.

Methodology

Materials

The glove bag designs tested in the study were manufactured from anti-static polyurethane and were attached to the filter housing by means of a clamping arrangement. The first glove bag design was a closed system, the second design had a built in passive 'feed in' airlock and a detachable 'waste disposal' sleeve. Two experimental test rigs were built; one to carry out the safety review of the closed glove bag system on a liquid filtration system, an outline of this test rig is shown in *Figure 1*. The second experimental test rig to complete the safety review on the glove bag with the passive 'feed in' airlock and detachable 'waste disposal' sleeve on a dry powder filtration system, an outline of this test rig is shown in *Figure 2*. In these trials, the glove bags were maintained at normal atmospheric pressure and air was exhausted through a HEPA filter welded to the glove bag.

Using the equipment set up as detailed in Figures 1 and 2, a containment capability survey and ergonomic assessment was complete. A surrogate material, micronized lactose, was selected for the containment capability study, the primary aim of which was to estimate the potential personal exposure level when using the flexible unit to introduce and install new

filters and remove and dispose used contaminated filters. The containment capability study was conducted following documented guidelines.⁶

Experimental Set Up Liquid Filtration Test Rig

5kgs of Lactose was dissolved in 40 liters (8.8 gal) of water at room temperature and re-circulated through a multi stack fluid purification unit. The unit used contained five 10 inch (254 mm) (length) cartridge filters. The closed system glove bag was attached to the filter housing unit. The glove bag was initially primed with 30 new filters to allow for completion of the assessment without requiring further access into the system. The unit operation using the glove bag under investigation had the following distinctive steps:

1. insertion of five new cartridge filters into housing unit
2. circulation of lactose solution through the filter housing unit
3. removal of contaminated filters from filter housing
4. deposition of contaminated filters into 'waste disposal' sleeve
5. fitting of new filters into the filter housing unit

The unit operation was repeated six times. To further challenge the containment capability of the glove bag design after the first trial, the previously contaminated filters were re-used as the new filters for introduction and fitting into the filter housing for successive trials.

Dry Powder Test Rig

The second glove bag design with the built in passive 'feed in' airlock and detachable 'waste disposal' sleeve was used in this set up. A new cartridge filter was inserted into a single 10 inch (254mm) filter housing. The unit operation using the glove bag under investigation had the following distinctive steps:

1. insertion of one new cartridge filter into housing unit through passive airlock

2. distribution of 250g (0.55lbs) of lactose inside the filter housing and working chamber of the glove bag itself
3. removal of contaminated filters from filter housing
4. deposition of contaminated filters into 'waste disposal' sleeve
5. removal of section of 'waste disposal' sleeve containing contaminated filter cartridge
6. fitting of new filter into the filter housing unit

The unit operation was repeated six times. However, the step of removing the contaminated filters from filter housing and their disposal into the 'waste disposal' sleeve was only completed during trials three, four and six. To further challenge the containment capability of the glove bag design, the same glove bag was used for successive trials without cleaning between trials.

Collection of Exposure Data on the Unit Operation Without the Use of the Glove Bag

As no work place data was available on the potential work-place exposure concentrations expected when removing contaminated filters from filter housings, the unit operation filter removal without the flexible glove in place also was studied here using the placebo material. This test was carried out after the test trials were completed, using both the single and the five filter cartridge units without the use of the glove bags.

Lactose Air Concentration Sampling

Personal breathing zone samples were collected from the operator who performed the unit operations. Fixed area sample locations around the filter housing unit, the operator side of the glove bag, were selected after visualization of the airflow in the test room using an air current tester prior to the study. Four area samples were taken at locations 90°, 180°, 270°, and 360° from the filter housing unit at distances of between 2.1 and 2.6 meters (6.8 to 8.53 ft) from the equipment set up. All area and personal samples were collected using glass fiber filters and IOM sample collectors. Samples were collected at an average flow rate of 2 liters/min (0.44 gal/min) and calibrated for flow rate before and after sampling using

Sample Location /Sample Type	Number of Samples	Average Result ($\mu\text{g}/\text{m}^3$)
Area Samples*		
Background 90°, 180°, 270°, and 360° to the filter housing pre trial	4	< 0.04 μg
90°, 180°, 270°, and 360° to the filter housing during trial 1- 6	24	< 0.04 – 0.78 $\mu\text{g}/\text{m}^3$ average = 0.042 $\mu\text{g}/\text{m}^3$
Background 90°, 180°, 270°, and 360° to the filter housing between trial, 1&2, 2&3, 3&4, 4&5, 5&6	20	< 0.04 – 0.85 average = 0.14 $\mu\text{g}/\text{m}^3$
Background 90°, 180°, 270°, and 360° to the filter housing Post final trial 6	4	< 0.04 μg
Personal Samples		
Trial 1 - 6	6	< 0.04 μg
Limit of Detection = < 0.04 $\mu\text{g}/\text{filter}$		
*All area samples were taken operator side of the glove bag.		

Table A. Summary of area and personal sample air concentration data ($\mu\text{g}/\text{m}^3$) for the five cartridge filter housing.

a primary flow meter. Personal samples were taken in the breathing zones of the operator performing the unit operation. Area samples were sampled at breathing zone height to better understand the potential for release of material from these operations into the surrounding test laboratory area. Personal and area samples were run for the duration of the unit operation 10 to 15 minutes and for a minimum of 20 minutes after the unit operation was complete. The unit operation was repeated six times (trial one to six). Background samples were run prior to trial one, between each trial and after the final trial (trial six). Temperature and humidity was measured throughout the study and found to vary from 22.8 to 24.2°C and 49-52% respectively. The air change rate in the test laboratory was measured as 5.1/hour.

Analytical Sample Analysis

Samples were analyzed for lactose by the Institute of Occupational Medicine, Edinburgh, using a validated lactose air monitoring method. One quality control spike (0.68 mg/filter) and one blank sample per 10 actual samples were included in the study. The average recovery of the spikes was 104.7%, within the acceptable range for the analytical method. The limit of detection of the lactose air monitoring method was 0.04 mg/filter.

Real Time Particulate Sampling

Airborne particle counts were obtained using a laser-based particle counter, which sampled a $2.8 \times 10^{-2} \text{ m}^3$ volume of air in one minute, and sensed particles with cut-off diameters of 0.3 μm , 0.5 μm , 0.7 μm , 1.0 μm , and 5 μm . The particle counter was positioned to monitor around the filter housing at a distance of approximately 1 meter from the filter unit. A baseline measurement of particle counts per minute was obtained during a period of approximately 10 minutes prior

to each filter-changing trial, followed by a particle count during each filter-changing trial. Additionally, a count was obtained after the complete survey, comprising six trials, was complete.

Ergonomic Assessment of Operations

In order to assess the ergonomics of the operations involved, the operation was divided into four main tasks:

1. removal of lid from filter housing
2. removal of filters from housing and placement into the waste filter glove sleeve (five filters per change out)
3. filter replacement – from clean glove sleeve into filter housing
4. replacement of filter housing lid

Completion of the task was averaged to be six minutes for all four steps of the operation. This time requirement may vary in industrial practice because it depends on operator experience. Each step of the operation was viewed six times for the assessment to ensure accurate results.

The ergonomic assessment was completed on operations using the five cartridge filter housing unit; an alternative to this filter system is the single cartridge filter housing system. The operations using the single cartridge filter housing unit were not observed; however, some of the findings of this study can be extended to the use of the single cartridge filter housing unit (due to similarities in dimensions, weights, etc. between the two filter systems).

Assessment Techniques Employed

Qualitative Manual Handling Risk Assessment

A qualitative manual handling checklist was used to assess the lifting tasks involved in the operation.

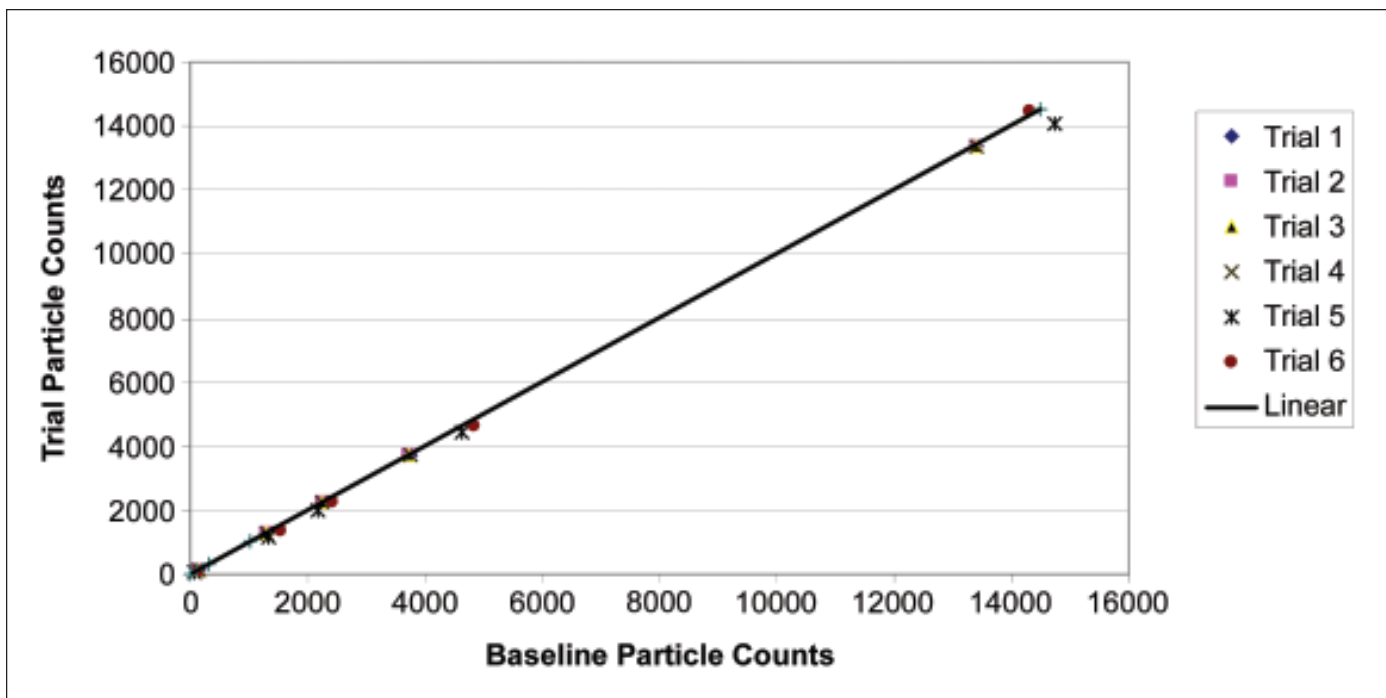


Figure 3. Particle counts vs. baseline counts during dry powder trials.

Location Title	Number of Samples	Average Result ($\mu\text{g}/\text{m}^3$)
Area Samples*		
Background 90°, 180°, 270° and 360° to the filter housing pre trial	4	< 0.04 μg
90°, 180°, 270°, and 360° to the filter housing during trial 1 - 6	24	< 0.04 μg
Background 90°, 180°, 270°, and 360° to the filter housing between trial, 1&2, 2&3, 3&4, 4&5, 5&6	20	< 0.04 μg
Background 90°, 180°, 270°, and 360° to the filter housing Post final trial 6	4	< 0.04 μg
Personal Samples		
Trial 1 - 6	6	< 0.04 μg
Limit of Detection = < 0.04 $\mu\text{g}/\text{filter}$		
*All area samples were taken operator side of the glove bag.		

Table B. Summary of area and personal sample air concentration data ($\mu\text{g}/\text{m}^3$) for single cartridge filter housing.

Baseline Risk Identification of Ergonomic Factors (BRIEF™) Risk assessment of the unit operation - filter change out

The BRIEF™ survey is a risk evaluation method using a structured and formalized rating system to identify ergonomic acceptability on a task by task basis.

Results

Containment Capability Study Results

See Tables A, B, and C, and Figure 3.

Ergonomic Assessment Results

Anthropometric Data

For the purpose of this assessment, the filter housing unit was positioned upon a standard table.

- height of table (top) from floor level = 715mm
- height from table top to top of filter housing = 570mm
- height at which filter housing is opened = 460mm (from top of table)
- working height, i.e., from floor to bottom of elbow = 1170mm

Ergonomic Considerations with Regard to Glove Bag Use

Glove Bag Positioning

The glove bag is suspended from a fixed point by use of flexible supports which allow movement of the bag. The height at which the glove bag is placed is ultimately dependent on the fixed position/location of the filter housing which will vary in industry.

Glove bags are purpose designed for specific pieces of equipment and the operations that must take place. The specific aim of the design is to allow the operation to take place in a contained system, which also is user friendly.

The glove bag sleeves are positioned at the height of the operation (through raising/lowering the bag using the flexible supports). The glove sleeve oval is 330mm in diameter with size 10 gloves fitted as standard. Glove sizes can be changed to suit the user population, e.g., a predominantly female population who may require a smaller glove size.

The efficacy of the glove bag in accommodating all users is dependent ultimately on the positioning of the filter housing unit and any obstructions in the vicinity, e.g., if the filter housing is positioned, e.g., at floor level or above elbow level, providing a comfortable working position may not be possible even with the use of the glove bag. Having to operate with arms in a raised position (i.e., above elbow height level) places a significant level of strain on the person, even for short periods of time). If squatting or kneeling are required, static loading on the muscles or joints of the legs will occur.

Glove Bag Operations

The glove bag is designed to accommodate the operations that must take place at the particular piece of equipment. This design takes into account the range of tools that must be used. The size of the glove sleeves, i.e., diameter will take account of the tool/filter dimensions, the length of the glove sleeves will be determined by the operational constraints.

Glove Bag – Additional Features

A HEPA filter is in place on all bags, minimizing any problems with condensation developing during the operation. The material of construction allows full visibility to the user.

Manual Handling Risk Assessment Results

The following two manual handling operations were assessed:

1. lifting off filter housing lid
2. removing/replacing filters

Both tasks were classified as low risk. The use of the glove bag when completing the manual handling tasks did not pose any additional ergonomic difficulties to the operator.

BRIEF™ Risk Assessment Results

The BRIEF™ risk assessment findings of the operation sub-tasks did identify a number of high risk hand positions; however, these operations are related to the filter housing system and not related to the glove bag use per se. The use of the glove sleeves may affect operations by slightly decreasing



Figure 4. Inserting a new filter into a single cartridge unit using glove bag design.

operator dexterity. The operator may need to increase the grip strength used because of the use of the gloves.

Discussion of Results

Discussion of Containment Capability Results

Table A shows a summary of the lactose air concentration data (mg/m^3) obtained for area and personal samples when using the closed system glove bag design on the five cartridge filter housing unit. All personal samples were non detectable ($<0.04 \text{ mg}/\text{filter}$). Most of the area data also was non detectable ($<0.04 \text{ mg}/\text{filter}$), the average area concentration during the unit operation sampled was $0.042 \text{ mg}/\text{m}^3$. Detectable data obtained for area samples during background sampling post trial one and pre trial two and during trial two and trial six were both less than $1 \text{ mg}/\text{m}^3$. Post trial one a small leak ($< 5 \text{ mls}$) was observed at the connection point of the circulation line and the pump. The leak was dried and the area was covered for the remainder of the test. Detectable lactose concentrations are attributed to this leak and not failure of the glove bag containment features.

Table B shows the area and personal lactose air concentration data (mg/m^3) sampled during the unit operation using the glove bag design with the passive 'feed in' airlock and detachable 'waste disposal' sleeve on the single cartridge filter housing unit. All area and personal data was non detectable ($<0.04 \text{ mg}/\text{filter}$).

Table C shows a summary of the lactose air concentration data for the cartridge filter removal task without the use of a glove bag. An average air concentration value of $308.5 \text{ mg}/\text{m}^3$

and $1535 \text{ mg}/\text{m}^3$ was obtained for the task filter removal from the five cartridge filter housing unit post wet filtration and from the single cartridge filter housing unit post dry filtration respectively.

A comparison between lactose air concentration data obtained for the task filter removal from either the single or five cartridge housing unit with and without the glove bag clearly shows a reduction in lactose air concentration of up to 1000 fold for this task when using the glove bag,

Figure 3 is a plot of particle counts during the dry powder trials versus the background counts before each of the trials. The solid line on the graph is a linear regression line with a slope of unity, which indicates that particle counts in the room during the trials did not exceed baseline counts. A similar pattern was observed during the wet filtration trials (data not shown). In each case, particle counts for respective size cut-off diameters of 0.3 mm, 0.5 mm, 0.7 mm, 1.0 mm, and 5mm were recorded.

Discussion of Ergonomic Results

Completing this task (using glove bag technology) should not present any serious ergonomic risks in the workplace if the filter-housing unit is positioned at a suitable working height and there are no obstructions for the user to deal with, e.g., lack of overhead space etc. In order to provide adequate clearance, the workstation should allow 2030mm from floor to ceiling to accommodate all workers. A standing work position is suitable for this task, as the duration is relatively short. If necessary, a sit/stand option could be provided.

Use of a fixed glove box to provide containment for this operation may be an option. However, there are a number of ergonomic disadvantages associated with the use of fixed containment methods, i.e., the structure and positioning of the unit is fixed. While efforts may be made to accommodate the majority of users, it is not possible to suit all users. Persons in the fifth percentile (i.e., smallest members of the population) and the 95th percentile (i.e., tallest/largest members of the population) may be at risk. The working height at which the structure is positioned and the reach distances allowed by the glove portals also are fixed.

Working in glove boxes requires extended static loading on the shoulders. Extending the arms for more than a couple of minutes can become very tiring.⁷ Grip strength is reduced when gloves are worn.⁸ Therefore, the glove box user may have to overcompensate on grip strength.⁷ It must be noted that most ergonomic problems associated with glove box use are related to the extended nature of glove box operations, and the static loading that occurs at the shoulders. However, the task studied in the present work is very short in duration

Location Title	Number of Samples	Average Result ($\mu\text{g}/\text{m}^3$)
Filter removal from 2 cartridge filter housing unit (post wet filtration)	3	308.5
Filter removal from 5 cartridge filter housing unit (post dry filtration)	3	1535.0
Limit of Detection = $< 0.04 \mu\text{g}/\text{filter}$		

Table C. Summary of exposure data ($\mu\text{g}/\text{m}^3$) for filter removal from the single and the five cartridge filter housing without the use of a glove bag.

and would not have the same ergonomic risk.

The user friendly/ergonomic advantages associated with the use of the glove bag include:

- The height of the glove bag can be raised/lowered to suit the user.
- The user can be positioned as close as is necessary to the equipment in order to complete the operation, as there are no fixed constraints.
- The glove bag hand ovals can accommodate all users, as the reach requirements are not fixed due to any physical constraints. The bag moves with the person, and the glove sleeves can accommodate all arm sizes.
- Glove bags are a cost effective option for retro-fitting older plants and equipment, as they are purpose designed for the piece of equipment and the task requirements.

Conclusion

The lactose containment capability air concentration data (mg/m^3) demonstrates that both glove bag designs, the closed system, and the design with the passive 'airlock' and 'disposal sleeve', are capable of containing the placebo material to $< 1\mu\text{g}/\text{m}^3$. When comparing air concentration data collected for the task filter removal from either filter housing, with and without the use of a glove bag, a significant reduction in lactose air concentration is observed when using the glove bag. The containment capability study concludes that both glove bag designs could be used as an engineering control in workplace situations where containment criteria of $1\mu\text{g}/\text{m}^3$ are required. However, it is recommended that an in-house containment capability study be completed using the material for which the system is intended to contain before use. Future work also should include surface swabs to assess the surface contamination surrounding the unit, and address dermal risk.

The glove bag design allowed the operation to be completed unhindered and is considered a suitable (ergonomically friendly) alternative to glove boxes, dry break coupling, or use of PPE. The glove bag use allows for a range of adjustability, where the needs of a large group of people can be accommodated; therefore, it is a cost effective method of design.

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About the Authors



Tony O'Connell is Managing Director of Containment Service Providers (CSP) Ltd. Prior to establishing CSP in 2003, O'Connell was employed with Eli Lilly S.A. Irish branch for 22 years. While at Eli Lilly, he gained experience in various roles supporting bulk manufacturing before eventually joining the Health and Safety Group specializing in chemical containment. In this role, he gained valuable experience both in designing containment systems for new production facilities and also in retro-fitting old manufacturing facilities to enable new and more potent products to be manufactured. He also has much experience in providing expert advice and training to process engineers in contained material handling design, i.e., raw material dispensing, reactor charging, sampling, filter fitting, and change out, final packaging, and

facility cleaning. In his current role as Managing Director of CSP, O'Connell has been involved in the research of new innovative chemical engineering control technologies.

Containment Service Providers Company Ltd.,
Knocksmall, Dunderrow, Kinsale, Co. Cork, Ireland.

Dr. Marie Coggins holds an MSc from the Department of Biology and Biochemistry, Queens University Belfast and a PhD from the Physics Department NUI Galway. She also holds a certificate of operational competence in Occupational Hygiene with the British Occupational Hygiene Society. She is currently employed as an Occupational Hygiene lecturer at NUI Galway and she also works as a researcher with the Air Quality Technology also based at NUI Galway. Previous to her employment at NUI, she worked as an occupational hygienist in the pharmaceutical industry. She is currently Treasurer of the Occupational Hygiene Society of Ireland and a former member of the Irish Occupational Hygiene Pharmaceutical Forum.

Department of Experimental Physics, National University of Ireland, Galway, Ireland.

Victoria Hogan is a graduate of the Department of Psychology, NUI Galway and the MSc Occupational Health and Ergonomics, National University College Galway. Victoria Hogan is currently working as Occupational Lecturer in the Department Health Promotion NUI Galway. She has several years of industrial experience and is a Registered Safety Practitioner with the Institute of Occupational Safety and Health. Her industrial experience includes heavy manufacturing, pharma-chemical, and local authority. Her research interests include: the impacts of new technology and forms of work on worker health, occupational stress and work life balance issues, occupational health psychology.

Department of Health Promotion, National University of Ireland, Galway, Ireland.

Dr. Miriam Byrne has 14 years of experience in health-related air pollution science. She worked at Imperial College between 1990 and 1998 (and obtained her PhD there) as a researcher on a succession of EU contracts held between the Risoe Laboratory and Imperial College, focused on generating indoor aerosol transport data for radiological risk assessment. She has contributed to more than 40 papers and articles, and her research interests include aerosol deposition on indoor surfaces, aerosol deposition on human body surfaces, skin sampling protocols, indoor aerosol exposure, tracer aerosol detection, indoor-outdoor aerosol ratios, occupational aerosol exposure, compartmental modeling of indoor aerosol concentrations, aerosol penetration into skin, transport of biological aerosols.

Department of Experimental Physics, National University of Ireland, Galway, Ireland. 