

Retrofit Gloveport Cover and Security Device

8" Gloveport Ring (aka. Sergeant Gloveports)

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Figure 1.

HISTORY

The world of glovebox work in the areas of science and manufacturing is in a consistent state of flux due to the inherent nature of changing missions. These rapidly changing work environments result in almost continuous regulatory changes within the codes and standards in order to maintain worker and environmental safety; one such example is the area of fire protection. The past decade has seen a strong regulatory emphasis on such issues as combustible loading, fire mitigation, and fire migration for gloveboxes. However, gloveboxes designed and manufactured prior to these regulations are not always easy to update or retrofit to accommodate new requirements and stay compliant. In the area of Fire Migration, the recent fire protection codes and requirements (DOE 1066/AGS-G010, and NFPA 801) have added, among other things, statements like this: "Gloveports not used within 60 days shall have... non-combustible gloveport covers installed" (AGS-G010). For older style gloveport rings, it has proven to be a challenge to meet this requirement and keep the needed functionality for the gloveport. The more recent "push-through" gloveport designs can easily accommodate the new port cover requirement because of features that are an inherent part of those designs. In order to meet the challenge of retrofitting gloveboxes to meet the requirements, the following solution was developed;

BASIC DESCRIPTION

One of the main challenges in designing retrofits for gloveboxes is the varied design configurations inherent to the hardware, as well as the various historical and current operations in a given glovebox. Simply finding a place to affix any type of retrofit equipment to the glovebox shell is one of the biggest engineering challenges in the design process; not to mention ergonomics and radiological control. The older style gloveport rings consist of rolled and welded sheet metal strips (1/8" thick by approx. 1 1/2" wide) that

get welded to a glovebox opening to form a lip or ring (typically 8" diameter) onto which a glove is affixed using a rubber band and a standard stainless steel hose clamp around the periphery. The port cover design is an assembly of several pieces including a mounting ring, a clamping ring, a cover plate, and miscellaneous hardware. The mounting ring and the clamping ring go together to form the ring subassembly which is first affixed over the gloveport lip and the hose clamp by tightening four set screws. Once the ring subassembly is fully clamped around the gloveport, the cover plate piece is installed into the ring subassembly. The cover plate is turned clockwise approximately 20° and secured in place using the locking mechanism on the front of the cover plate. Beyond the basic functionality of the cover assembly; the other factors mentioned above were all considered in the design. The current solution took into account ease of use, glovebox worker ergonomics, radiological control, and of course cost. For fire migration controls the current codes do not require that the port covers seal the port in the event that a glove is consumed; these covers simply provide a fire barrier.

DESIGN FEATURES

Ease of Use

The ring subassembly is designed to be semi-permanent, so the cover plate can be easily removed and replaced in a few seconds. Aluminum helps to keep the weight minimized and also meets the requirement of being a non-combustible material. The ring subassembly need only be removed during glove changes.

Ergonomics

The "Gloveport Cover and Security Device" is fabricated from aluminum for ergonomic, as well as economic, reasons. While it would be impossible to have zero impact on the worker's range-of-motion, the ring is designed to minimize the impact on range-of-motion for the glovebox worker to the point of being negligible.

Glove-Clip

A glove-clip is affixed to the inside face of the cover plate. (Figure 1) This allows the glove to be rolled into a cylinder and placed into the clip to meet the requirement from NFPA 801 to tie gloves outside the glovebox when not being used. Obviously the gloves cannot be outside the glovebox when a cover is in place. However, the clip does meet the intent of the requirement by keeping control of the glove which mitigates the potential for it to get into hot equipment or to keep it as far away from a fire in the glovebox as possible. Other options for keeping a glove in check are always being explored, but for right now, past solutions, like a hole through the cover just defeats the functionality as a fire barrier.

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Security

The ring subassembly is affixed with tamper-resistant set screws that require a special wrench to remove. This special wrench can be treated as a controlled item if need be. As an optional feature, the locking mechanism is designed to allow a tamper indicating device, or "TID", to be affixed so the port can be secured in the locked position and the installed ring subassembly can have tamper indicating tape or similar to mitigate security or radiological-based control issues. Any operations that need access restricted, or tracked, can benefit from this feature.

Radiological

The cover plate was designed to be a simple flat plate. This was not only done to help keep manufacturing costs down, but also to be easily modified to add shielding material. The shielding can be added as an encapsulated module, or simply as sheet material cut to the appropriate shape (cookiecutter style).

INSTALLATION

The ring subassembly (in figure 2) fits over the stainless steel hose clamp that holds the glove in place on the perimeter of the gloveport; ensure that the cutout in the ring is positioned to clear the band clamp screw (in figure 4). The four (4) tamper-resistant set screws (in figure 4) are tightened, starting away from the ring cutout, in order to press into the flexible band that, in turn, tightens around the hose clamp; thereby affixing the ring subassembly to the gloveport. In order to secure the glove away from the inside of the glovebox, the glove is pulled out, folded/rolled and placed into the Glovebox Glove Holding Clip (in figure 3). Then the user can align the Cover Pins (in figure 3) with the Cover Pin Channels (in figure 5), insert the pins into the lead-in points and turn the cover clockwise approximately 20°. To secure the cover plate in place, turn the Locking Mechanism Screw (in figure 6 and 7) until it is seated sufficiently in the cavity in the ring (in figure 5). In order to secure the port, a "TID" can be run through the holes in the Locking Mechanism Screw and the Locking Mechanism anchor hole (in figure 7). ♦

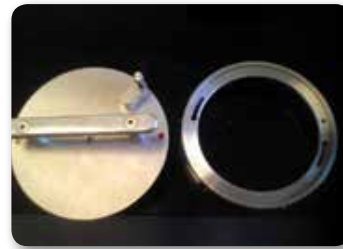


Figure 2.



Figure 3.



Figure 4.



Figure 5.



Figure 7.



Figure 6.

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PICTURES OF INSTALLED GLOVEPORT
COVER AND SECURITY DEVICE



Figure 8.



Figure 9.

In 2004 United States Pharmacopeia (USP) introduced a standard (General Chapter <797>) requiring pharmacies compounding sterile preparations to provide facilities to improve the sterility assurance level of these preparations. Patient deaths in several states were the driver behind the need for a national standard. Although the standard, which was reissued in 2008, is technically enforceable by FDA, the enforcement is state by state through pharmacy boards.

A major product contamination occurred in an outsourcing compounding pharmacy in 2012 resulting in close to fifty deaths and over seven hundred people injured. The magnitude of the impact on human life from these contaminated preparations prepared in a single pharmacy brought compounding of parenteral preparations into the national spotlight. In 2013 the United States Congress passed the Drug Quality and Security Act that increased to right of FDA to regulate compounding pharmacies by dividing enforcement responsibility between FDA and state boards of pharmacy. In addition to direct enforcement of those classified as compounding pharmacies the FDA also stated that they would work with state boards of pharmacy to assure that facilities where sterile products are being compounded meet expectations.

The 2008 version of USP <797> focused on conventional engineering controls. Not a single time in the standard is the term “sterility assurance” used. Isolators are mentioned but the superiority of the technology is not recognized as it is by FDA in the manufacturing of the drugs. The efforts of pharmaceutical companies to produce a higher level of sterility assurance through isolations technology is less effective than it could be for the patient because of the risk of a higher level of microbiological contamination at the compounding step in the delivery of the drug using convention technology of cleanrooms and open faced ISO class 5 environments.

Containment

Isolators like their cousins, gloveboxes in the nuclear industry play an important role in contamination control in the pharmaceutical, biotechnology and medical device industries. Typical containment applications of the technology use a negative pressure environment as a secondary level of personnel protection. The isolators act as a barrier around the product manufacturing operation reduce the need for individuals to wear PPE (personal protective equipment) while working with potent drugs and have become almost a necessity as the drug exposure levels of new compounds has become lower and lower.

Targeted therapy and new classes of drugs has caused the amount of drug causing an adverse effect to drop into the nanogram per cubic meter of airborne concentration range. Such small quantities are beyond the safe handling capabilities of open faced engineering controls such as down flow booths or Class II biological safety cabinets.

All pharmaceutical compounds are potent because they are intended to cause an effect on the person taking the medication. The effect can be either reversible, non reversible or toxic. Safety factors are used to lower the exposure limit based on the impact of the exposure on the person. Levels of acceptable exposure to an individual in the workplace is described in a number of terms. The permissible exposure limit (PEL or OSHA PEL) is a legal limit in the United States for exposure of an employee. There is also a short-term exposure limit (STEL) is designated by “ST” preceding the value which reflects the fact that high levels of exposure for a short period of time may have a significant impact on the health of the individual.

The basic premise of exposure limits is that they represent a level of exposure that will not have an impact on a health individual if exposed to that level for eight hours per day in the workplace.

The level of exposure effect on individuals is primarily a function of three things:



Manual Filling and Weighing Isolation System.

1. The route of entry into the body
2. The concentration of the potent compound in the environment
3. The duration of exposure

The four routes of entry into the body are skin absorption, ingestion, inhalation and injection, with the ability of the compound to impact body function playing an important role on impact to the person. Direct injection into the blood stream bypasses the body safeguard and is the most likely to have an effect. Inhalation through the nose and mouth allows the compound to entry the body blood stream by passing through the lungs. Ingestion offers some level of protection as the compound is exposed to the stomach acids and only adsorbed through the intestines into the bloodstream. Dermal adsorption is through the skin and entry through the skin is 10 times less likely.

Areas of pharmaceutical applications of isolation technology range from research, development of compounds, formulation, packaging and laboratory testing of the compounds. Active Pharmaceutical Ingredient (API's) represents the greatest challenge because this is the most concentrated form of the drug. As the drug form is developed an excipient or inactive substance is added to the formulation thus reducing the airborne concentration of the drug.

An additional risk factor in research, development and formulation is at this stage of product development the compound and its effects are not totally understood. This level of uncertainty results in increased exposure precautions. Even though only small quantities (grams to single kilograms) are being manipulated it is critical to protect personnel. In many cases

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controlled banding is used by placing the new compound in categories based on a risk assessment of similar compounds and the limited data available.

cabinets used to compound antineoplastic drugs.

Currently USP <797> allows for either ISO Class 7 cleanroom or the use of an isolator not located in a cleanroom. Hazardous drugs can be compounded in either a Class II biological safety cabinet or an isolator.



Tray Open - Hood Modification

In pharmacy applications laminar flow workbenches for preparing IVs and biological safety cabinets for preparing antineoplastics compounds were the main line of engineering controls used to protect compounded preparations and workers twenty five years ago.

Pharmacy isolators were introduced in England in the early 1990s. The first isolators in the United States began appearing in the mid to late 1990s. USP <797> has adopted the terms CAI (compounding aseptic isolator) and CACI (containment aseptic compounding isolator) to differentiate between isolators used for compounding non-hazardous and hazardous preparations. The primary difference between the two is the pressurization with the non-hazardous being positive pressure and the hazardous being negative pressure. Pressurization has been a means of secondary containment. Studies ("Exposure to Antineoplastic Drugs in Two UK Hospital Pharmacy Units") have shown no difference in exposure levels between hazardous drugs prepared in positive and negative isolators. The same study did show that the use of isolators significantly reduces exposures compared to Class II biological safety



Single Isolator

Conclusions

There are two levels of conclusions that can be reached based on the use of gloveboxes and isolators. The industry and healthcare comparisons are noted below.

The between industry comparison of isolators to gloveboxes is centered on what each is trying to achieve with the use of engineering controls. Gloveboxes are primarily for protecting people and environment from nuclear exposure and has extensive challenges. Radiation can pass through solid barriers and requires a much more robust use of materials. It has the advantage of immediate feedback in terms of presence of contamination. Isolators are used for both protection of the product and personnel protection which at times create a conflicting pressurization strategy.

Both applications of controlled environments can learn from one another with a very important area being the extensive work that has been conducted on ergonomics with isolators.

Within healthcare the contrast between the segments of the industry that manufacturers of products and those that compound the final dosage represent a dangerous gap in protection of the patients receiving the final drug form. Engineering controls have moved far beyond the 1980's and advances in isolation technology offer greater benefits to patients, personnel and the environment. To remove the barriers organizations such as NIOSH and USP must move forward with current technologies such as isolators and decontamination.

What does the future hold? The future lies in the support of advanced technologies. The FDA set the example twenty five years ago by embracing isolation technologies to improve patient safety.

Borrowing ideas much like the pharmaceutical industry did from the nuclear industry a number of years ago has resulted in both a safer workplace and improved sterility assurance of medications. The concept of isolation technology and its superiority over open face engineering controls has proven itself. ♦