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AGS Glovebox & Isolator Annual Conference & Expo
July 27-29, 2015
Town and Country Resort and Conference Center – San Diego, CA
Conference Info on pages 12/13

Retrofit Gloveport Cover and Security Device
By: Jon “Rick” Hinckley, LANL Glovebox System CSE - page 8
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Change is inevitable. Change is certain. We learn early in our careers that change can be good. Change brings out innovations that might once have been overlooked and change urges us to take the risk when otherwise the opportunity is lost. We also learn that change can be challenging and agonizing, especially if the change is beyond your control or beyond your comfort zone. Change has been an unexpected, but very positive focus of my life this past year. I found myself frequently rethinking Benjamin Franklin’s quote “Nothing is certain except death and taxes” and needed to adjoin “and change” to that adage as well – however - death still cannot get any worse!

The constant world of change ushers in the 29th year of the American Glovebox Society’s presence in the technological world of containments, isolators, clean rooms, hot cells, incubators, radio-pharmacy systems, radioactive gloveboxes and custom enclosures that have changed the world in another very positive way. I must admit, over my 25 years of involvement with the AGS, I have looked forward to the opportunity that would allow me to serve as your president and continue the mission of the society. From my perspective, the AGS is the preeminent technical educational association to promote safety and quality of glovebox/isolator designs, communicate factually and accurately the knowledge in our field, produce technical standard and guideline documents to continue the superiority of applications in our expertise and disseminate specialized knowledge in the field of isolator/glovebox systems. I will do my best to continue the tradition of that mission.

Since the origins of the AGS were from the nuclear realm, our challenge as a society has been the cross discipline outreach to our related and important fields of pharmaceutical, radiopharmaceutical, health/medical services, and science/research laboratories and having these fields share and learn from our mutual expertise. Many of us have worried ourselves in that if we try to come up with the complete list of every application involving a glovebox that is “not nuclear” and we leave an application out, then somehow the AGS is not friendly to that “ousted’ application. Aside from being not true, I do not see it that way. Part of our responsibility as an AGS member is to actively seek all opportunities and expose them to the advantages and benefits the AGS can offer. This is a strong basis of what grows our society. I say this primarily because my career changes in recent months have me working in an industry that is not associated with glovebox activity at all – oil and gas. There are highly toxic and, as result, potentially practical applications for enclosures within an oil and gas world – be it upstream or downstream. Hydrofluoric acid systems are standard in some refineries and beneficial containments, albeit not in the traditional sense of early AGS origins, could provide an economic advantage. My goal is to reach out and capture the opportunity. Change is there if you just look for it.

In closing, I am happy to announce our 2015 conference is in San Diego, California from July 27 through the 29th. This is a great family friendly location. I am also happy to introduce our theme for the 2015 conference: “Equipment Integration – Featuring: Design, Ergonomics, Fabrication, Safety, Protection.” We are planning for the 2015 conference to be dynamic and exciting in this great venue. Your Officers and Board of Directors are busily working on building this conference into a technical force shaped by YOU – the membership – based on your feedback and participation in 2014. Please stay connected with the AGS on our website and Twitter. Partake in our Standards Development Committee – the most direct and beneficial way to involve yourself with our society. Continued success and please be an avenue for change.

Regards,
Scott Hinds P.E.
AGS President 2014-2015
This year’s annual conference in Miami Florida ushered in the second year of the new conference format and proved to be a success with very positive attendance. Commanded by the leadership of Paul Contreras, our conference rolled in with the Miami waves and presented three days of great technical discussion. Over 20 vendors displayed their company knowledge and expertise while live “tweets” scrolled the video screen for the first time in the exhibit hall. Opening ceremonies were on Monday morning followed by the keynote address by John Eschenberg who presented an exacting picture of the Uranium Production Facility and the future of the nuclear legacy. This was followed by our Focused-Topic and Fundamentals training and completed by the Los Alamos National Laboratory “hands-on” demonstrations.

Tuesday provided great technical papers as well as the vendor demonstrations by Carl Fink of CTL, Kelsey Bondelid of Edgen Murray, Stacey Raben of Oregon Iron Works, and Craig Johnson of Walker Barrier Systems. The panel discussion was on Glovebox Safety. Wednesday round out the outstanding technical papers and welcomed the always popular – interactive competition case study. Closing ceremonies turned the presidency over to Scott Hinds – who will lead the conference in 2015 in Sunny San Diego, California.

Surfs up – dude!!

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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 ½" 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).

For questions or inquiries about the Retrofit Gloveport Cover & Security Device, contact the following people at LANL:
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The basic concept of gloveboxes has been applied in a number of different configurations to meet the needs within healthcare. The term isolator has been adopted as well as terms such as restricted access barriers. The concept of using an isolator in pharmaceutical and hospital applications was only a far out thought twenty five years ago.

The spectrum of those involved in healthcare range from basic research to delivery of medications and medical devices that improve the quality of life. Private companies, universities and government agencies are involved in research attempting to discover new and novel compounds and devices. Within this spectrum their search explores the basic body chemistry that allows living organisms to exist on planet Earth. It is not restricted to human beings but also includes plants and animals.

Basic research has benefited from the use of isolation technology by allowing work to occur in more completely controlled environments. Environments can be created that are inert, free of contaminates and have a range of temperature or humidity conditions.

Sterility

The original concept for the use of isolator was developed by the pharmaceutical industry working with FDA through the “BUGS” (Barrier Users Group) as an idea to improve the sterility assurance of aseptically filled parenteral products. Typical isolators used for creating an aseptic environment are positive pressure and are described in the 2004 FDA guidance for aseptic filling. The document identifies two types of isolators open and closed with definitions of each isolator.

Isolators can only provide a contained internal environment and must be supported by a means of decontamination of viable organisms and particulate filtration of the internal air to create an aseptic environment. Typically HEPA filters are used but ULPA filters are employed to filter any particulate that is generated by activity inside the isolators and well as filter any incoming air source. Decontamination is the activity of killing living organisms that may be on surfaces and in the air circulating in the isolator. Different techniques are used to decontaminate from automated systems employing vapors and aerosols to a simple spray down of surfaces. The effectiveness of the decontamination is directly related to the sterility assurance level of the product delivered to the patient.

Decontamination should not be confused with cleaning which is removing materials from surfaces. Cleaning surfaces does not mean the interior of an isolator is decontaminated. Surfaces and the air inside the isolator may be clean and still harbor organisms.

The reality is that all living organisms are under constant attack. Attacks come in many forms including aging, disease and accidents. To prevent or repair damage created by these attacks a number of drugs and devices have been developed. An important example is vaccines for smallpox and polio that have prevented the spread of these deadly organisms that have killed millions of people.

Products intended to help prevent illness can create even greater problems for patients if contaminated with organisms that can lead to infection. The majority of injectible drugs called parenteral dosage forms are produced by aseptic processing and are not sterile. The sterility assurance level describes the probability of the contents of a single vial being sterile with the probability of one in one million considered sterile. The use of isolators in pharmaceutical manufacturing compared to conventional cleanrooms containing an ISO class 5 air quality filling environment has increased the sterility assurance level of aseptically filled parenteral drugs from a potential of one vial in one thousand to one in one hundred thousand. This was a major step forward in patient safety in drug manufacturing.

As drugs move through the steps to ultimately be administered to the patient many require additional manipulation. For parenteral drugs stability in liquid form has limited shelf life and is manufactured in powder form to increase shelf life. A critical step in the pharmacy is to add sterile diluents which allows the drug to be placed in the patient’s blood stream. The term compounding is used to describe this activity which occurs in pharmacies in hospitals, outpatient settings and compounding pharmacies that contact prepare medications. Until recently compounding of sterile drugs occurred in open faced HEPA filtered engineering control devices.
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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:

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 enter 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 qualities (grams to single kilograms) are being manipulated it is critical to protect personnel. In many cases
controlled banding is used by placing the new compound in categories based on a risk assessment of similar compounds and the limited data available.

In pharmacy applications laminator flow workbenches for preparing IVs and biological safety cabinets for preparing antineoplastic 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 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.

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.
Leak Test
Establishes requirements for leak testing gloveboxes and other enclosures (and their appurtenances).

Gloves
Establishes requirements for procuring gloves to be used on gloveboxes.

Fire Protection
Establishes fire protection requirements for the design, operation, and maintenance of gloveboxes, isolators, and their appurtenances serving as barriers to protect the worker, the ambient environment, and/or the product.

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<td>GUIDELINE FOR GLOVEBOXES THIRD EDITION (AGS-G001-2007) Contains over 150 pages of established and proven practices compiled by experienced industry professionals. Covers areas of glovebox technology from conception to installation, operations, and maintenance.</td>
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<td>STANDARD OF PRACTICE FOR THE DESIGN &amp; FABRICATION OF NUCLEAR APPLICATION GLOVEBOXES (AGS-G006-2006) Establishes requirements for the design and fabrication of nuclear application, negative-pressure gloveboxes used for the operations that involve radioactive materials that emit low-penetrating ionizing radiation.</td>
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<td>Online Ordering Available at: GloveboxSociety.org</td>
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