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Mobile Biosafety Level-4 Autopsy Facility—An Innovative Solution

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Abstract

Recent threats of bioterrorism, outbreaks of previously unknown infectious diseases such as Severe Acute Respiratory Syndrome (SARS) and the reemergence of diseases like the Avian Influenza are very real and have caused serious concerns not only for the world-at-large, but also for many authorities. This is an even greater concern for the forensic community as they are generally ill-equipped to deal with highly infectious pathogens due to chronic under funding and administrative constraints. The cost for building a Biosafety Level 4 (BSL-4) facility is exorbitant; such a facility is also very expensive to operate and maintain. Given the state of funding for most Forensic Centers and Medical Examiner Facilities in the world, having a high containment BSL-4 facility just to carry out autopsy work is highly unlikely.

In the course of dealing with the SARS outbreak in Singapore in 2003, the Centre for Forensic Medicine (CFM) of the Health Sciences Authority, together with its strategic partner, Acre Engineering, developed an innovative solution that would meet the requirements set out for a BSL-4 Mobile Autopsy Facility. This was completed at a fraction of the cost and in less than half the time spent building such a facility de novo. This paper therefore sets out to present an innovative solution to meet the need for an autopsy facility equipped to BSL-4 standards that can be mobilized and deployed at short notice to conduct autopsies on highly infectious cases at distant locations. In particular, it addresses the engineering and facilities components of the solution.

Background

Presently, very few nations are equipped with standard BSL-3 or BSL-4 autopsy facilities as such units are expensive to build, operate and maintain correctly. These existing contingency facilities are normally housed in permanent or semi-permanent structures and cannot be moved to distant locations to deal with emergencies involving BSL-3 or BSL-4 hazards. While "portable morgues" in the form of palletized mortuary supply systems organized by the U.S. federal government department under the Disaster Mortuary Operational Response Team (DMORT) are available, they have no capacity for biosafety stringency, or for microbiologic diagnosis (Nolte, 2003). The lack of a mobile autopsy facility poses a very real problem in that bodies infected, or suspected of being infected with RG-3 and RG-4 agents, cannot be autopsied in remote locations where such practice is most required. Nolte, Taylor, & Richmond (2001), addressed this problem when they were evaluating the status of Autopsy Facilities in the United States in their study of "Autopsy Biosafety" in 2001. They recommended that "a mobile containment autopsy facility constructed to operate at Biosafety levels 3 or 4 might be useful in providing autopsy support to jurisdictions with inadequate facilities when they are confronted with contagious or toxic cases."

At the height of the SARS outbreak in Singapore in 2003, the need for developing a solution that would meet the requirements set out for a BSL-3 or 4 mobile autopsy facility became very apparent and pressing. The challenge was to meet the need for providing appropriate facilities for autopsies, or for examination of contaminated bodies at a BSL-3 or 4 level setting; to do so at a fraction of the cost and in less than half the time required for building such a facility in the conventional method.

Autopsies and Biosafety Levels

While researchers in academic, corporate and government facilities typically work in well-designed, biological containment environments with known agents (Hartman, Ellis, & Mohr, 2005), Medical Examiners face the danger of encountering unknown threats from mass casualties, or even from a single entity when performing autopsies.

"An autopsy is a systematic examination of a dead body" (Nolte et al., 2001). This process might subject the Medical Examiner and staff to a wide variety of infectious agents including bloodborne and aerosolized pathogens such as Human Immunodeficiency Virus (HIV), Hepatitis B and C viruses, *Mycobacterium tuberculosis*, SARS and other serious pathogens. Other hazards include toxic chemicals (e.g., formalin, cyanide, and organophosphates) and radiation from radionuclides used for patient therapy and diagnosis. However, Nolte et al., (2001) noted that, "these risks can be substantially mitigated through proper assessment, personal protective equipment, appropriate autopsy procedures, and facilities design."

Biological safety levels have been clearly established for biomedical and microbiological laboratories (U.S. Department of Health and Human Services, 1999). Should the same levels and principles be introduced to autopsy facilities now? Safety guidelines for autopsy personnel indicate that any autopsy can potentially result in exposure to a biological hazard classified as RG 2, 3, or 4. Nolte et al. (2001) concluded that the biosafety principles that have been developed for clinical laboratories, biomedical research laboratories and animal facilities could be broadly applied to autopsy facilities. The Biosafety levels are:

1. BSL-2 provides personal protection against the majority of bloodborne pathogens. BSL-2 associated practices form part of the standard hygienic procedures and precautions applied to normal medical operations within healthcare facilities.
2. BSL-3 procedures provide protection to healthcare participants in an environment of risk to harmful agents spread by aerosols such as *Mycobacterium tuberculosis*, rabies and *Yersinia pestis*. BSL-3 principles are suitable for work with indigenous or exotic agents that can cause serious or potentially lethal disease as a result of exposure by the inhalation route.
3. BSL-4 containment conditions are required when operators may be exposed to dangerous and exotic agents, which pose a high risk of aerosol-transmitted exposures to agents causing life-threatening diseases for which there are no prophylactic or post-exposure treatments.

As the case in hand is to design and build a BSL-4 Mobile Autopsy Facility, it is imperative that in order to achieve the appropriate "personnel" protection from biohazards at BSL-4 level during such autopsies, an understanding of the risks and hazards faced by autopsy practitioners be addressed.

Risks and Hazards Faced by Autopsy Practitioners

Autopsy-transmitted infections may occur after direct cutaneous (percutaneous) injury, contact with droplets, or after aerosol exposure (Nolte et al., 2001). The risk of sustaining an occupational infection caused by exposure is high for bloodborne pathogens such as those from HIV-infected bodies (Nolte et al., 2001). Autopsy personnel are particularly at risk due to the nature of work performed on infected bodies, and the high frequency of percutaneous injury through use of autopsy machinery and utensils. The risk of infection is exacerbated by the high seroprevalence in certain autopsy infectious populations. In the past, autopsy personnel have died of autopsy-transmitted Marburg, Ebola and Lassa Hemorrhagic Fever Viruses (Nolte et al., 2001). A significant route of transmission in the autopsy environment is by aerosols. Infectious aerosols are composed of airborne particles approximately 5-10 microns in diameter, which can remain suspended in air for long periods of time. When inhaled, the particles traverse the upper respiratory passages and pose a significant risk for autopsy personnel.

Many tools used in autopsy contribute to the generation of in air suspended infectious particles, and it is known that all autopsies generate potentially infectious aerosols. For example, *Mycobacterium tuberculosis* is the prototypical organism transmitted by autopsy-generated aerosols. However, these aerosols can also potentially transmit other infectious agents, including rabies, plague, legionellosis, meningococcemia, Q fever and anthrax. Personnel are also at risk of inhaling volatized acids and converted salts such as hydrocyanic gas unless they work in a containment area that is totally air-exhausted and air-conditioned. Autopsy personnel may also be exposed to radioactive materials in a body from diagnostic procedures (Nolte et al., 2001). Based on their work environment, autopsy practitioners are at a significant risk of contracting an infection unless the appropriate biosafety practices and procedures are observed during autopsies. Practitioner infections are most common in instances where autopsies are performed in remote and primitive locations. There are, therefore, numerous situations where it is desirable to temporarily deploy mobile facilities in a responsive fashion. Certain situations, such as after a natural disaster, or a terrorist attack involving human casualties, optimally require facilities capable of providing autopsy services in environments that meet BSL-3 and or BSL-4 practices. Again these are clear indicators justifying the need of proper facilities.

General Considerations for the Development of a Mobile BSL-4 Autopsy Facility

While the need for the development of a mobile BSL-4 Autopsy facility has become very real and pressing, due consideration must also be given to the cost and time for the construction of such a facility. Grantham (2000) stated that the idea of the modular or mobile BSL-2 or -3 laboratory was developed when he was part of a design team for a "Stick-built" (normal construction) facility. He added that "the Stick-built facility required three years for completion from the design phase through occupancy and was very costly to construct," whereas, "the modular/mobile concept permits delivery and commissioning of a laboratory within five to six months of initiation with substantial cost reductions compared to a traditional facility."

This reasoning supports the case at hand. Apart from the time and cost setback that is typical of a "Stick built" facility, the consideration of building a facility that is mobile and remote from the main building (that houses the facility) has also given rise to other advantages in the construction and operation of such a facility. These are:

1. The "Box-in-Box" concept of the containment enclosure is easier to achieve; the choice of materials for construction is no longer limited to concrete, bricks and mortar. Materials such as stainless steel and other metals can be considered. This eliminates curing and shrinkage problems associated with concrete work. Also, problems related to "envelope integrity" are reduced.
2. The layout of the facility is less restrictive as compared to having to build the facility within an existing building; there are fewer problems with negative room pressure and air change requirements.
3. Services such as the supply and exhaust air systems, the waste water system, the electrical and back-up power systems, breathable air systems, and decontamination system will be remote and/or independent from the main building. This eliminates the problems of having to isolate these systems from the systems in the main building and prevents cross-contamination between different zones.
4. Plant room and interstitial space issues are reduced.

These advantages indeed support the case for a mobile facility.

Design Concept

The design, development, integration, and validation of this type of a mobile/modular facility therefore requires the evaluation of state-of-the-art, highly technical, emerging technological trends and the selection of appropriate novel technologies based on a variety of criteria such as engineering, risk assessments and logistical requirements (Heyl, Henry, & Reutter, 2005).

Consequently, the requirement is to design and build a "remote" mobile facility that permits the conduct of a full and comprehensive autopsy on an adult deceased human individual suspected to be infected by Risk Group 4 organism by three operators: a Medical Examiner (Forensic Pathologist) and a Mortuary Technician in positive pressurized suits monitored by a third individual in an outside command and control room. The facility is to be designed and built to meet BSL-4 criteria as outlined in the CDC-NIH Guidelines: "Biosafety in Microbiological and Biomedical Laboratories," (U.S. Department of Health and Human Services, 1999).

The CDC-NIH Guidelines are "deliberately flexible and simple without losing sight of the important basic requirements for biocontainment applicable in most circumstances" (Fischer-Hoch, McCormick, 2004) and can be used as a basis for design. The fundamental principles rest on the universal concept of BSL-4 biocontainment, that is:

1. The operator must be protected from the agent by an airtight, impermeable layer at all times.
2. The environment must similarly be protected by an airtight, impermeable layer at all times.

After evaluating the criteria for a mobile/analytical laboratory facility from the engineering and logistical perspectives and also evaluating the requirements of a BSL-4 autopsy facility, the design for the solution was eventually based on the following key concepts (Figure 1):

1. BSL-4 positive air suit system with redundant breathable air supply to protect Medical Examiners and staff from exposure to BSL-4 hazards.
2. "Box in Box" containment concept with a total of 3 containment layers.
3. Fully mobile capability—ready for probable air lift slung under a helicopter, land deployment via flatbeds and/or rail and by sea and requiring only a source of water supply and the availability of a sanitary sewer.
4. Quick deployment to location with short set-up time.
5. Simplified maintenance required.
6. Lower holding and maintenance costs.

Technical Specifications

The mobile containerized BSL-4 autopsy facility comprises a set of two 40-foot 9-1/2 foot high-refrigerated containers (Figure 2), (Illustration 1).

Container 1—(the Autopsy Container), which houses the main autopsy suite, is lined with an internal stainless steel shell giving it the "box-in-box" property. It also houses the changing room, the pass-through decontamination chamber (Figure 4), (Illustration 3) and the personnel decontamination shower.

Container 2—(the Support Container) houses the support control and monitor room (Illustration 4) and ancillary engineering systems (Figure 2). The following systems are also incorporated:

1. Autopsy table system incorporating a mobile trolley with a docking station and a downdraft dissection table (Figure 3), (Illustration 2).
2. Ventilation system with gas-tight interlocking doors, negative pressure crossing different zones and a high rate

Figure 1

Physical and operational layout of the mobile BSL-4 Autopsy Unit.

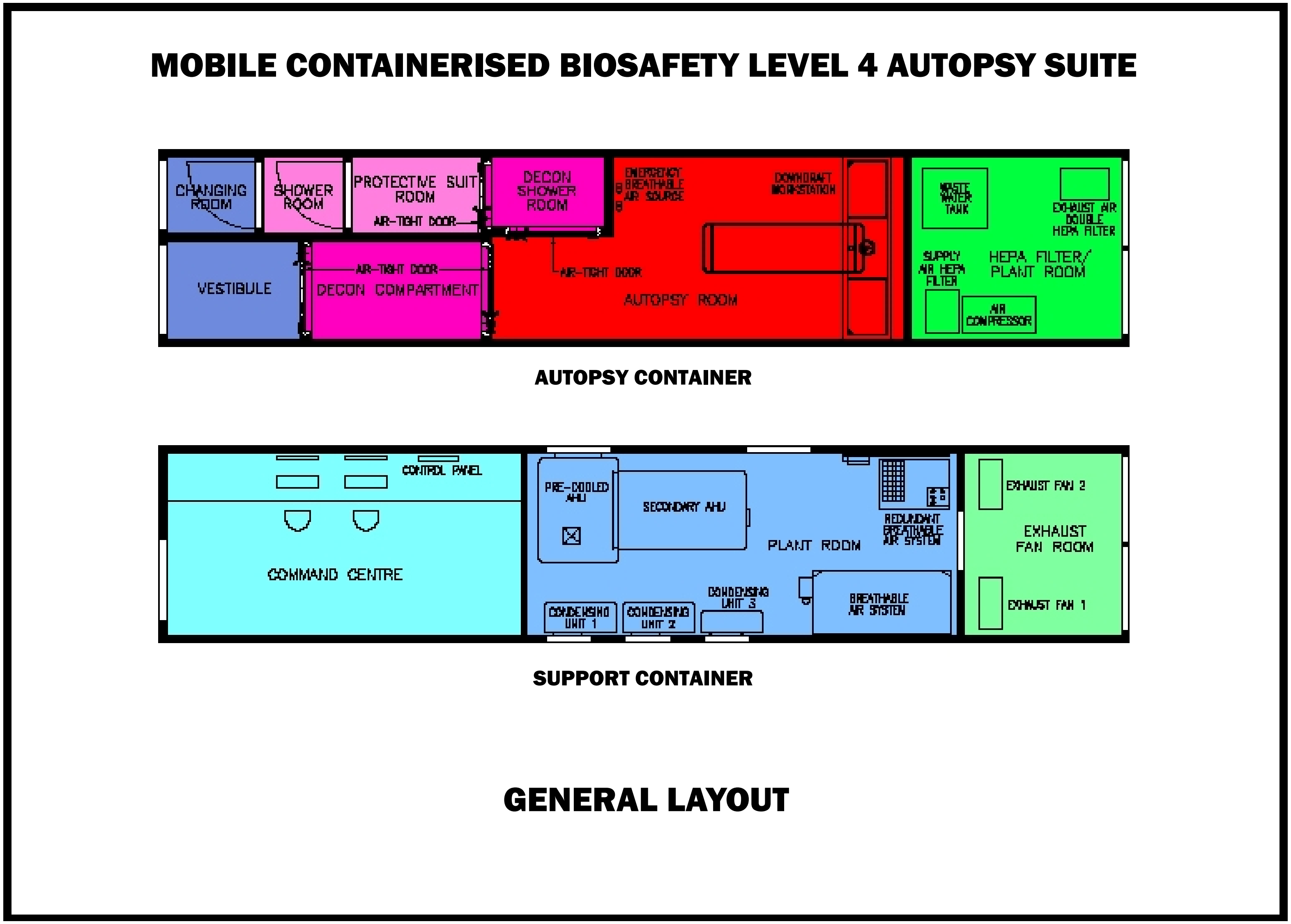


Illustration 1

"3D" Rendition of the General Layout of the Mobile BSL-4 Autopsy Facility

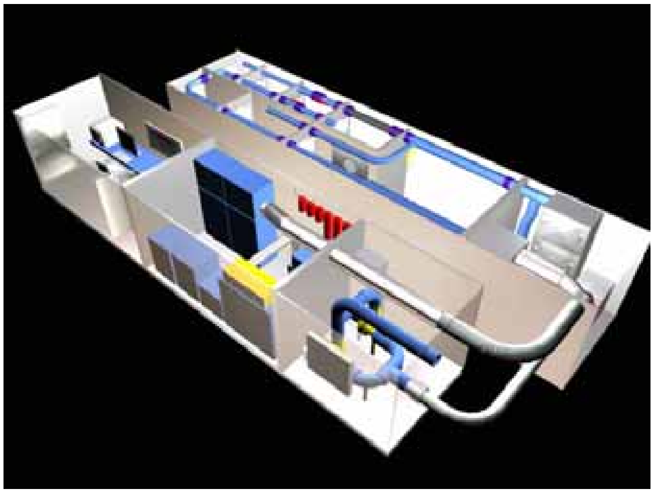


Illustration 2

"3D" Rendition of the Main Autopsy Suite with the Mobile Trolley

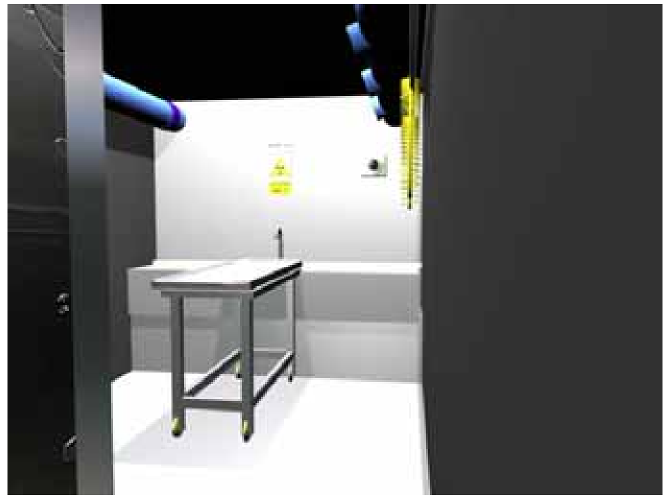


Illustration 3

"3D" Rendition of the Autopsy Suite and the Pass Through Decontamination Chamber

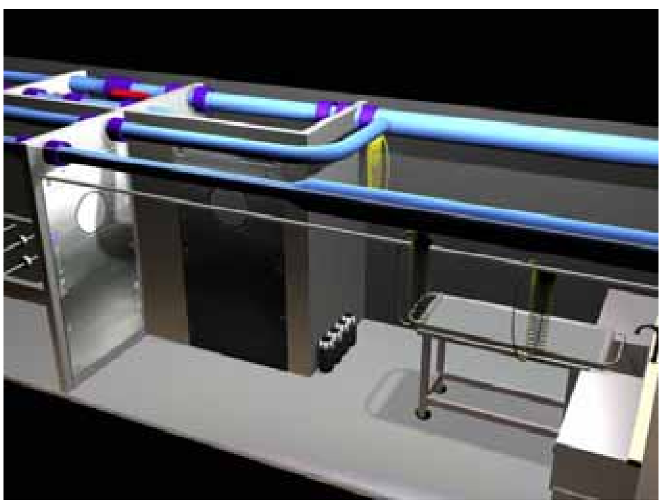
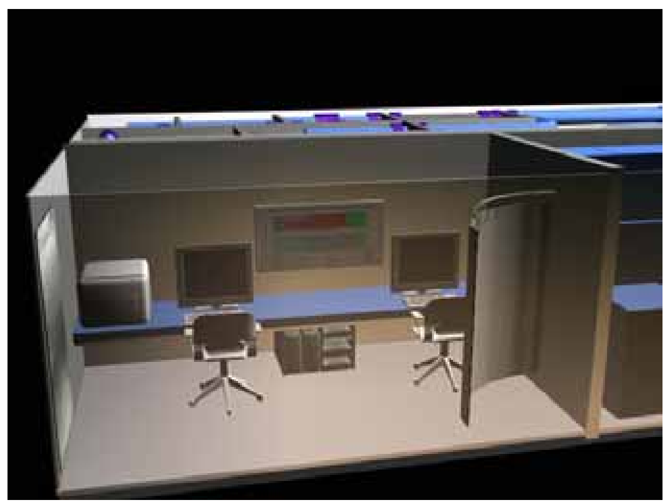


Illustration 4

"3D" Rendition of the Control Room



of air exchange.

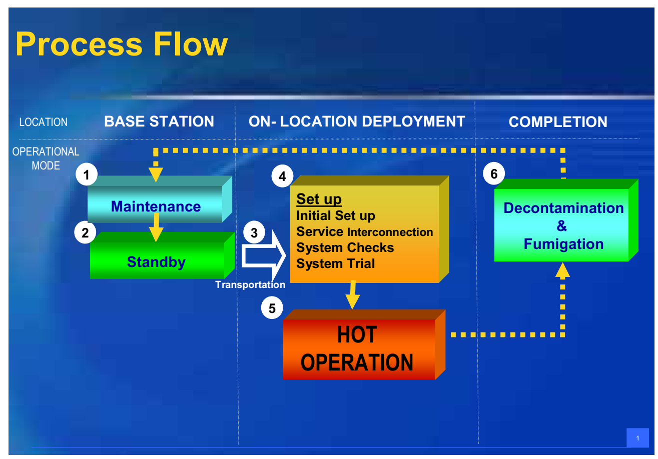
3. BSL-4 suit system for operators with pressurized clean breathable air supply.
4. Atomized chemical decontamination spray.
5. Comprehensive decontamination system in conjunction with biosafety and biocontainment protocols and procedures which include:
    a. Air—HEPA (double) filtration and UV cleaning of exhaust air before leaving Container 1 and subsequent discharge into the environment
    b. HEPA filtered supply air to the autopsy room
    c. Carbon filters in the exhaust system
    d. Bubble-tight isolation dampers complete with ports for the insertion of decontamination equipment
    e. Liquid waste treatment system by chemical decontamination and heat treatment before discharge
    f. Solid waste treatment system by chemical decontamination and physical containment prior to further processing
    g. Body bag decontamination system by chemical decontamination and physical containment; Bodies are cleaned/washed and decontaminated before being enclosed in a sealed (first) body bag. This body bag is then decontaminated on the outside and enclosed in yet another (second) body bag. The second body bag will then be decontaminated before being passed to the decontamination chamber
    h. Exit point automatic decontamination system—bodies (in double body bags) are passed through the

Figure 2
Outside view of the mobile BSL-4 Autopsy unit (Support Container)

Figure 3
Main autopsy room with movable autopsy table

Figure 4
Pass Through Decontamination Chamber

Deployment Process



decontamination chamber for the final decontamination process by cremation. Autoclaving may not be suitable for the decontamination of human cadavers. All infectious materials such as samples will be placed into sealed, autoclavable transportation containers and decontaminated before being removed from the autopsy area through the decontamination chamber. They may exit together with the body on the body tray

i. Chemical decontamination showers for operators in suits

j. Fumigation system applied before movement of the unit.

1. Other support systems:
   a. Air conditioning system (with redundant capacity)
   b. Personnel safety monitoring system
   c. Personnel shower facilities
   d. Lighting system
   e. Communication system
   f. State-of the-art programmable logic control system
   g. Electrical and control engineering subsystems
   h. Self-sufficient power generator
   i. Standby portable breathable air systems
   j. Manual decontamination system (in case of system failure)

1. The two containers are at base station in maintenance mode. This is where the containers are cleaned and serviced. General maintenance/modification/system testing may be carried out

2. On a standby mode, the containers are ready for transportation. All services must be functional/operational but not connected.

3. When called out for operation, the containers are transported to location
4. On a set-up mode, services will be interconnected and systems checked before going into operations
5. In operation mode, the containers are ready for autopsies.
6. At the end of the operation, the containers will be put through a decontamination and fumigation process before they are sent back to base station. The units will not need to be decontaminated in between autopsies, but will be decontaminated after the completion of deployment just before transportation back to base station.

Conclusion

Our mobile autopsy suite is designed and constructed to be completely and fully containerized. It is capable of being deployed worldwide on short notice, deliverable by air, land, or sea. It requires a relatively short time for deployment; the risk of contamination from bodies having to be transported out of the "hot zone" for examination purposes is greatly reduced. Also, given the size of the unit, decontamination and fumigation is easier and cheaper. There is a tremendous reduction in overall cost as both construction and maintenance cost can be shared by many different parties/agencies. Perhaps the greatest advantage of the solution is the considerably shortened construction time. It can be constructed in less than one year.

Other Notes

The original idea for a mobile containerized BSL-4 autopsy facility was generated in March 2003. Preliminary design with a mock-up model was completed in May/June 2003. In October 2003 an international patent was filed securing the intellectual property.

The construction of a prototype started in May 2005 and was completed in November 2005. It is presently being tested and commissioned with a goal to have it validated in November 2006.

Acknowledgements

The authors would like to thank Dr. Gordon Abraham, CSIRO, Geelong, Australia for his advice and support and the staff of the Public Health Agency of Canada at the Canadian Science Centre for Human and Animal Health for their much-appreciated assistance.

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