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Selecting the Right Chemical Agent for Decontamination of Rooms and Chambers

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Introduction

Room and chamber decontamination has been done for almost a century now. Most decontamination agents are surface sterilants or high-level disinfectants that only decontaminate the outside of objects and debris. The first step for any room decontamination, independent upon which agent is used, is to clean the room or chamber prior to decontamination. The subject of cleaning, and the steps required, can be the focus of a paper by itself. This paper will discuss the decontamination step with the understanding that the cleaning step removes quantities of bio-burden that exist in a room and prepares the room for the decontamination step.

Before deciding which decontamination method is the best for your situation, it must be acknowledged that all decontamination methods can work based on the following:

1. Good and complete distribution
2. Good and total penetration
3. Sufficient contact time at specified concentration

Any decontamination method requires a complete and thorough distribution of the sterilant or high-level liquid disinfectant to get an effective decontamination. No sterilant or disinfectant will kill what it cannot reach so distribution is essential for a complete decontamination.

Contact time is important. Contact time is a variable length of time dependent upon the concentration of the decontaminating agent used, which states how long the agent must dwell upon the surfaces to achieve a proper level of kill. This time is specified on the products label. The product label is approved as part of an antimicrobial pesticide registration by the United States Environmental Protection Agency (U.S. EPA, 2007). Antimicrobial pesticides are substances or mixtures of substances used to destroy or suppress the growth of harmful microorganisms such as bacteria, viruses, or fungi on a variety of objects and surfaces.

Antimicrobial pesticides have two major uses:

1. to disinfect, sanitize, reduce, or mitigate growth, or development of microbiological organisms
2. to protect objects (e.g., floors and walls), industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime (U.S. EPA, 2006).

Why is antimicrobial pesticide registration important? The registration specifies what level of kill an agent has been tested to and its use instructions for obtaining that level of kill. Simply stated, the Code of Federal Regulation (CFR) says that all products that claim any antimicrobial properties must be regulated. The U.S. EPA regulates the sale and use of pesticides and antimicrobial pesticides under the statutory authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Regulation 40CFR Subchapter E - Pesticide Programs (Parts 150-189).

The Federal Government carefully regulates pesticides to ensure that they do not pose unreasonable risks to human health or the environment, and, as part of that effort, requires extensive test data from antimicrobial pesticide producers that demonstrate as such. EPA scientists and analysts carefully review these data to determine whether to register (license) a pesticide product, or a use, and whether specific restrictions are necessary (U.S. EPA, 2007). Different products have different properties or levels of kill. Table 1 provides the definitions as approved by the U.S. EPA. The different types of antimicrobial pesticides must be looked at, and the selection should be made as to what level of cleanliness is required. Keep in mind that sometimes it may be better to use a higher level of kill (sterilizer) when trying to achieve sanitization due to the simplicity and automation involved in some of the sterilizer methods. For example, when using a sanitizer for cleanliness, it is incumbent upon the person performing the cleaning to reach all surfaces for the specified amount of time. This is not easily achievable and, if automated equipment is available, it may be the method better suited to the environment. Table 2 contains a summary list of the current registrations that achieve sterilization, the highest level of kill.

When performing any decontamination there are issues that must be taken into account. These are listed below. Is concentration monitoring available for the agent selected? This is an important question when using

Table 1

U.S. EPA definitions of levels of Kill (U.S. EPA, 2006)

Level of Kill	Definition
Sterilizers (Sporicides):	Used to *destroy or eliminate all forms of microbial life including fungi, viruses, and all forms of bacteria and their spores.* Spores are considered to be the most difficult form of microorganism to destroy. Therefore, EPA considers the term Sporicide to be synonymous with "Sterilizer."
Disinfectants:	Used on hard inanimate surfaces and objects to *destroy or irreversibly inactivate infectious* fungi and bacteria but NOT necessarily their spores. Disinfectant products are divided into two major types: hospital and general use.
Sanitizers:	Used to *reduce*, but not necessarily eliminate, microorganisms from the inanimate environment to levels considered safe as determined by public health codes or regulations.
Antiseptics and Germicides:	Used to prevent infection and decay by inhibiting the growth of microorganisms. Because these products are used in or on living humans or animals, they are considered drugs and are thus approved and regulated by the Food and Drug Administration (FDA).

Table 2

Current Sterilizer (Sporicides) Registration with U.S. EPA as of January 2006.

Agent	Quantity
Ethylene Oxide	28
Sodium Chlorite (chlorine dioxide)	3
Hydrogen Peroxide Based	8
Other	3
Total	43

gaseous or vapor systems because:

- Paper or cellulose based products react with most sterilants (JSPPTOH, 2004; Jones et al., 1993; Ryan et al., 2006; SAIC, 2005)
- There can be a leak in the dampers or room
- Water absorbs and/or dilutes some sterilants (Wintner et al., 2005; Luftman et al., 2006)

The above issues would cause the concentration in the room to drop and therefore create a possible issue with the decontamination where some areas may not have a complete decontamination.

Does the agent of choice penetrate water? The ability to penetrate water is important since the first step of decontamination is cleaning. When cleaning a room, water is usually involved in the process. If not all of the water is removed from the environment and the chosen agent does not penetrate water, then there will be an area that is not decontaminated.

What are the materials of construction in the room/chamber to be decontaminated? This is important since some materials degrade decontaminating agent concentrations:

- Galvanized metal breaks down VHP (Carlsen, 2005)
- Temperature gradients effect vapor concentrations (Fritz et al., Steris White Paper Document #M1379)
- Cold surfaces cause formaldehyde fall out (Ackland et al., 1980)
- Direct sunlight causes chlorine dioxide to break down (SAIC, 2005b)

What is the size of the room? What is the room configuration? How much large equipment is in the room? These are important questions that can help decide which agent to select. If the room is complex (many lab benches or several rooms connected), gaseous agents might be the best choice. Large equipment blocks the flow of vapors and mists. If the room is simple and empty, then liquid disinfectants (fogging or spray and wipe) might be the choice. Fans aid in the distribution of all agents and more fans are required for the vapors and mists compared to the gases (Shearrer, 2006).

Available Methods

Current room decontamination methods include gaseous systems (formaldehyde and chlorine dioxide),

vapor systems (both "wet" and "dry" hydrogen peroxide), misting and fogging systems, and manual spray and wipe techniques that use a variety of liquid disinfecting or sterilizing agents. Manual spray and wiping, and formaldehyde gassing are by far the primary methods.

Manual Spray and Wipe

Manual wiping involves hand spraying a high-level liquid disinfectant or foam on all surfaces, or wetting a mop/wipe and wiping surfaces to both physically remove organisms and apply a solution to kill organisms. The spraying/foaming method is more likely to reach all surfaces compared to the mop/wiping method since it achieves wider coverage. Benefits of this method are that the equipment and consumable costs are low. The disadvantages/shortcomings of this method are that it's difficult to spray or wipe all surfaces of equipment including corners, crevices, undersides of ventilation grills and the inside of components. In addition, uniform coverage is extremely difficult to achieve, thus in the areas that get less coverage, the decontamination may not be as complete or effective. The liquid disinfectant must also remain on the surface (wet) for the specified amount of time; typically 10-20 minutes for disinfection or up to several hours for sterilization (see Table 1 for levels of kill). When using the spray and wipe or mop method, respirators may be required to protect the user from harmful vapors, or off-gassing. Many liquid disinfectants are acidic or corrosive and require an additional step of rinsing with water to remove corrosive residue. If this step is not completed material corrosion can occur.

Spray and wipe techniques may be the appropriate method to use when spot decontamination is required. It may be the only method available if the in-room process cannot be shut down and the room evacuated, as is necessary for more thorough methods. From a practical viewpoint, it is better to reduce the level of organisms than to do nothing.

Automatic Fogging

Sprayers, foggers, atomizers, and misters are an improvement over the manual spray and wipe technique for entire rooms since the operator is removed from the process; however, it is still limited in its ability to reach all areas. The benefits of the automatic systems are that the human factor is removed from the process, but the human is involved in the placement of the equipment and, if it is not placed in the room correctly, then complete decontamination may not occur. Equipment costs are low compared to equipment costs for gaseous or vapor systems. Foggers or misters typically take a high-level liquid disinfectant and spray a fine mist or very small droplets (5-100 microns) around the room. Because sprays and liquids, even in mist form, are heavier than air, they eventually settle, making contact time an issue. While walls generally get good coverage, the underside or backside of components may remain inadequately covered, leaving areas that are not disinfected or decontaminated. Additionally, any equipment present in the room (racks, tables, or shelving) must be removed since the spray will not reach the backside, or underside of the equipment. Furthermore, spraying in odd-shaped rooms (Figure 1)

Figure 1
Odd-shaped Room

does not get complete or even coverage since the spray does not reach all surfaces. One benefit for the foggers from a safety perspective is that the person is not in the room during the procedure, thereby eliminating human health concerns.

If funding is unavailable for the equipment required for vapor hydrogen peroxide, or chlorine dioxide gas generators, this may be the best option. It may also be the best option when sealing of the room (required for gassing or vapors) is impractical. This is possible since mist does not reach into tight configurations. These methods should only be used when complete kill is not required, when the room can be emptied of obstructions to the mist or droplets and when the room has a straightforward square shape. Fans can help move the mists or fog around, but do not eliminate problems reaching the undersides of components and equipment.

Formaldehyde Gas

Formaldehyde is a very effective method that has been used longer than all of the other "gassing" methods, and is very well understood. The main benefit of formaldehyde is that it is a gas. Gasses offer excellent distribution and penetration in to hard-to-reach areas, but are limited by their inability to penetrate soiled loads or bioburden. It is effective against a broad range of organisms as shown in data summarized by G. B. Wickramanayake (1990) and is low in cost. The major concern with decontaminating rooms, buildings, and vessels with formaldehyde is that it is listed as a potential carcinogen by the U.S. EPA and as a human carcinogen by the International Agency for Research on Cancer (IARC) (IARC, 2004). Additionally, formaldehyde does not penetrate water. Therefore, in the cleaning step, the user must take this into account and ensure that no water is present in the environment, or take care when post exposure cleanup is performed. Formaldehyde dissolves in water forming formalin, which can be an issue.

To do a formaldehyde decontamination, paraformaldehyde powder is heated up using a hot plate (230 deg Celsius) or by boiling Formalin (UK) to release the formaldehyde gas. The amount of paraformaldehyde used is typically 0.3 grams per cubic foot (NSF, International Standard 49 Annex G). This concentration yields a high concentration of 8,000-10,000 ppm. The exposure for a typical cycle is 12 hours for a greater than 5 log kill on most surfaces (Rogers et al., 2004). Once the exposure time has elapsed, the formaldehyde is removed. Removal is accomplished by heating up ammonia bicarbonate to release an ammonia vapor, which neutralizes it and forms the relatively safe by-product of methenamine (Luftman, 2005). The residuals from neutralizing the formaldehyde create another issue. The residuals must be cleaned up and the user must also be aware that formaldehyde may repolymerize at humidities greater than 80% and leave paraformaldehyde residue (Luftman, 2005). Additionally, if the room is complex, or has a lot of equipment, it is extremely troublesome to remove all the neutralization by-product. To minimize the amount of residuals, some users try to use lower amounts of ammonia bicarbonate. This does create fewer residues, but it also has the possibility of an incomplete neutralization. Conversely, some users use larger amounts of ammonia bicarbonate to get all the formaldehyde neutralized, but this causes a lot of residue, which again is difficult to clean up. This is an issue when trying to balance the two.

Formaldehyde is easily scalable to large sizes in empty rooms and rooms filled with equipment by just adding more hot plates to the chamber. Typically, every hot plate has enough capacity for 1000 cubic feet. Formaldehyde does not have issues with large spaces since it is a gas at room temperatures, and therefore is governed by gas laws that state it will evenly distribute throughout the room naturally. Fans do assist in the dispersal and speed up the distribution time.

Hydrogen Peroxide Vapor

Vapor methods using hydrogen peroxide have more benefits compared to misting/fogging and manual wiping methods. Vapor hydrogen peroxide (VHP) is effective against a broad range of organisms is non-carcinogenic and the dry process has been U.S. EPA-approved for small isolated chambers (Steris Corp., 2007; Reich et al., 2004). Vapor is not a mist and is therefore not subject to the gravitational effects that limit sprays, mists, or foams. VHP is generated by heating a 30%-35% solution of hydrogen peroxide (109 deg Celsius boiling point for 35%) until it reaches the vapor phase. This vapor is then delivered to the room.

Although the vapor method is typically easier and better than manual wiping or fogging, it has some drawbacks. Hydrogen peroxide tends to form strong hydrogen bonds between the molecules, limiting its movement in air (Herd, 2005). This makes the placement of injectors and circulation fans extremely critical as presented at ABSA annual meeting in 2006 (Shearrer, 2006). As a vapor, VHP is subject to condensation caused by temperature differentials and differences in thermal masses between objects of different sizes and materials. One way to help the vapor methods achieve better success is to have tighter control of temperature gradients throughout the room. Additionally, VHP does not penetrate water. Therefore, in the cleaning step, the user must take this into account and ensure that water is not present in the environment. Drawbacks aside, the vapor methods have the benefit of removing the human factor where some surfaces might accidentally be missed and it tends to be safer as it allows the operator to be outside the room.

There are two primary systems available that use VHP: one uses a "wet" process and the other a "dry" proc-

ess where visible condensation is avoided. Both generate the vapor in the same way such that liquid hydrogen peroxide is heated up, or vaporized to deliver it to its target. In the dry process, the relative humidity (RH) in the room must be lowered before injecting the vapor. The VHP is maintained below the condensation point to prevent condensation of VHP on the surfaces within the room. If condensation does occur, this can lead to surface damage as seen in earlier studies (Malmborg et al., 2001). In the wet process, the vapor is generated in the same manner, but the RH in the room is not lowered prior to injecting the vapor. This decreases cycle time, but the user must be aware of condensation patterns generated during the cycle development period and try to minimize heavy condensation in particular areas to reduce corrosion. This is usually accomplished during the setup and cycle development. One drawback of the wet method is that when the ambient RH, or the room temperature, is different from when the cycle was developed, the injection rate should be modified to reflect this difference in starting RH levels to keep the condensation constant or repeatable.

Another downside of the system is that if the generator is far from the chamber being decontaminated, then the hosing/piping must be insulated or heat traced and must be kept off the floor or other cold surfaces to minimize condensation in the piping and maximize concentration delivered to the chamber (Bioquell, 2003; Vance, 2002; Steris Corp., 2006). This is the reason that one of the VHP manufacturers places the generator in the room to eliminate the need for heat-traced piping (Bioquell RBDS). Another drawback to VHP is the absorption of VHP into plastics and materials causing extended aeration times (Fritz et al., Steris White Paper Document #M1379; Ryan et al., 2005; Jones et al., 1993; Steris Corp., 2003).

VHP has additional benefits of a short contact time of 1-4 hours, no post exposure cleanup is required (the VHP is catalytically converted or directly vented), and the concentrations are low (720-1500ppm) compared to formaldehyde. VHP is scalable to large sizes in empty rooms, but has trouble with rooms containing equipment or fixtures. The equipment tends to block the flow of vapors and injection points need to be spread out and fans used to help distribute the vapor. It also has issues with large spaces since it exists as a vapor and not a gas. This is a limiting factor with VHP in many scenarios. For example, when the decontamination occurred at U.S. Department of State Mail Annex (SA-32), Sterling, VA, the facility was first emptied of the interior finish and equipment; only the building shell remained the exterior walls (and a few interior structural walls), the slab, the metal sheeting supporting the flat built-up roof overhead, and the metal roof trusses along with the electrical system. The area was then broken into seven zones and decontaminated. During the decontamination, the concentration was not able to be achieved due to the materials in the facility. The facility had to be further broken down to a total of 10 areas ranging in size from 40,000 cubic feet to 100,000 cubic feet as compared to the 14 million cubic feet that were decontaminated at once using gaseous chlorine dioxide (SAIC, 2005c; SAIC, 2005d).

Chlorine Dioxide Gas

Chlorine dioxide (CD), like formaldehyde, is a true gas. Its boiling point is 11 deg Celsius and it is effective against a broad range of organisms, non-carcinogenic, residue-free, and has been U.S. EPA-approved for a variety of chambers including rooms (clean-rooms, holding rooms, surgical suites and procedure rooms) (ClorDiSys Solutions, Inc., 2007). There are many ways to generate CD, but the common method for gas generation is using a safer, dilute 2% chlorine gas, which passes over sodium chlorite cartridges and produces a pure chlorine dioxide gas with no byproducts delivered to the chamber. This is one of the main differences between gaseous CD and liquid chlorine dioxide. With the liquids, acids are used to generate the CD and this liquid is therefore acidic and the source of the issues with corrosion when using liquid CD.

CD is a gas at room temperatures, and is not subject to condensation, or affected by natural temperature gradients found in rooms. Drawbacks of using gaseous CD is that it requires a capital expenditure similar to that of the vapor systems. Direct sunlight should be avoided since is can cause CD to break down and thereby reduce its effectiveness during decontamination and may cause corrosion.

CD has additional benefits of being monitored by a UV-VIS spectrophotometer (similar to the NIR systems available, but not integrated, into the VHP systems). CD is applied in low concentrations (360 ppm to 1800 ppm), has short contact times compared to formaldehyde (0.5 to 2 hours), is non-flammable at use concentration, water soluble and remains in solution as a dissolved gas, and it does not hydrolyze to any appreciable extent (Aieta et al., 1986). Furthermore, no post exposure cleanup is required and it can be directly vented or scrubbed at the end of exposure and the aeration is much faster in CD as opposed to VHP, which lingers around a longer period of time.

CD is easily scalable to large sizes in both empty rooms and rooms filled with equipment. Typically, one generator is required for every 30,000 cubic feet. It does not have issues with large spaces, multiple rooms or equipment filled rooms since it is a gas at room temperatures. As with all gaseous and vapor methods, fans assist in the dispersal and speed up the distribution time.

Conclusion

In conclusion, all the methods can work; what differentiates one method from another is the ease at which each agent can contact the target organism for the prescribed amount of time (Table 2). Gasses provide the best method to do this. They are not influenced by external factors such as temperature or human error. Gaseous methods also get the best penetration and the best and quickest distribution. This would lead one to conclude that gaseous methods are the methods of choice for all room decontaminations. However, this is not necessarily the case (see Table 3 for summary). This is where the decision becomes more challenging. Performing a complete gaseous decontamination of the room may not be needed. The equipment required for gaseous CD and vapor methods is somewhat costly compared to spray bottles, or even fogging systems. Formaldehyde has the benefits of a gas and does not require any capital equipment expenditures, but it requires neutralization and manual wipe down and this can be a time-consuming process. The decision of which method to use should consider the following questions:

- Is the entire room contaminated, or just one spot from a spill on an accessible area such as a work surface?
- What type of contamination is present?
- What is the physical size of the infected area, and what obstacles are involved?

An evaluation of the type of contamination that is present is important to determine if "sterilization" is required, or simply a reduction of organisms. The use of the room also needs to be considered. Contamination of pharmaceutical or medical devices can be potentially hazardous to patients as well as costly for producers and research facilities may have ongoing long-term experiments that can be compromised by an outbreak.

One important final point when undertaking any disinfection, decontamination or sterilization is that all safety measures must be adhered to. All of these methods can be harmful to humans; by definition, a method that efficiently kills or removes the bio-contamination will also be harmful to humans. All methods can be made safer by

Table 3

Summary of Decontamination Agents

Issue	Spray/ Wipe/Mop	Fogging	Formaldehyde Gas	Hydrogen Peroxide Vapor	Chlorine Dioxide Gas
Equipment Cost	Low	Low	Low	Moderate - High[1]	Moderate
Labor Costs	High	High	High	Low	Low
Consumable Costs	Low	Low	Low	Low	Low
Facility Downtime Costs (cycle time costs)	High	High	High	Moderate - High	Low
Corrosiveness	Low - High (agent specific)	Low - High (agent specific)	Low	Low (unless condensation)	Low
Total Cycle Time	1-2 days	1 - 2 days	9 - 15 hours + clean up	4 hours (small) 12 hours (large)	1.5 hours (small) 5 hours (large)
Residues	High	High	High	Low	Low
Concentration Monitoring	No	No	No	Yes (not all equipment have integrated monitoring)	Yes
EPA approvals	Yes (agent specific)	Yes (agent specific)	No	Yes (Isolators & Small Chambers only)	Yes
Scalability	Yes[2]	Yes	Yes	Yes[2]	Yes

[1]Moderate to high due to the equipment for multiple generators for some rooms.
[2]Scalability of these techniques is feasible but the expenditure to scale-up can become cost-prohibitive due to manpower and time required or equipment cost.

taking the proper precautions into account. These precautions include the proper sealing of rooms for foggers, vapors and gasses, the appropriate use of masks or respirators, and the presence of good ventilation for manual methods or thorough neutralization when using formaldehyde.

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Join a Committee

Have you ever considered joining a committee? When you choose to serve on a volunteer committee, you open up a world of possibilities for networking, professional growth, and career opportunities while serving your profession. Volunteer member groups are the backbone of the association because they: serve as a forum for exchange of information; advance the science in all specialties of biosafety; develop guidelines and standards; provide education and training; and link ABSA to many other institutions.

You should explore committees in areas of the profession where you are active or have an interest. There is a great variety; you can be sure to find one of interest to you. Please review the list of committees and identify those areas in which you would like to participate or contact the chair of the committee (www.absa.org/abocommittees.html) that interests you to find out more information about the committee's goals. You are also invited to attend the committee's meeting during our annual conference or at any other time (all committee meetings are open).