

Spore News

Volume 9, No. 2

Medical and Lab Waste Monitoring

by Russ Nyberg and Annette Bojanski, M.D.

Improper disposal of medical and biological waste poses a significant risk to both waste handlers and to our environment, and is often closely monitored by regulatory agencies. Consequently, individuals treating this waste strive to ensure that items are properly sterilized prior to disposal. This issue of Spore News addresses some of the most common inquiries we receive about this topic.

Q: Do I need to monitor my waste bags with Biological Indicators (BIs)?

A: Since it's important to avoid sending inadequately processed medical or micro-lab waste to landfills or other disposal sites, monitoring waste bags with BIs is strongly recommended. Routine monitoring is critical in detecting problems such as uneven temperature distribution, inadequate air removal or other equipment failures which may otherwise go unnoticed. Regular monitoring of waste bags with BIs will allow you to achieve a high level of sterility assurance.

Q: Do I actually need to place the BI inside the waste bag being sterilized?

A: Yes! In order to monitor whether sterilization of the medical or micro-lab waste was achieved, it is critical to place the BI in the waste bag. (Placing the BI outside of the waste bag will provide information about the empty area of the chamber, but will tell you nothing about the conditions inside of the bag.) Since the lower portion of the bag will be the most challenging area to sterilize, this is where the BI should be placed. You will need to retrieve the ampoule after sterilization, so a simple solution is to tie a wire (or string) around the groove in the neck of the ampoule, leaving the other end of the wire outside of the bag. After sterilization, the ampoule may be easily retrieved.

Q: Is it really important to monitor my waste bags with glass ampoules or will 'crushable' self-contained BIs or spore strips work as well?

A: When sterilizing waste, the contents of the bag are often liquid (or the contents are melting, in which case they become liquid). For this reason, a "sealed" BI such as a glass ampoule must be used. When crushable self-contained BIs (SCBIs) are used to monitor steam sterilization, biological kill is achieved when steam enters the device through holes in the top of the cap. Similarly, when spore strips are used, steam penetrates

through small pores in the glassine envelope. If either a crushable SCBI or spore strip were used in a waste bag, liquid contents could easily enter or adversely affect the BI, rendering the test invalid. Specifically, sporicidal chemicals in the bag can lead to false-negatives, and melted items that "coat" and protect either device from the steam can result in false-positives. Sealed glass ampoules are unique in that biological kill is achieved through heat-transfer through the glass, and contents of the waste bag have no way of entering the BI.

Q: What type of cycle should be selected for sterilizing lab waste?

A: Regardless of the sterilization cycle chosen, it is important to begin the cycle with a pre-vacuum phase. (This type of cycle is also used when sterilizing porous or wrapped goods.) Because air must be removed from the autoclave bag in order to achieve proper steam penetration, any trapped air left in the bag (particularly at the bottom of the bag) will protect the contents from the steam, thus increasing the possibility of a cycle failure. In addition to utilizing a pre-vacuum cycle, it is also important to leave the top of the waste bag open so that air may be removed.

Q: What temperature and time should I use for my waste cycles?

A: If a pre-vacuum cycle is utilized to remove air from the waste bag, a 121°C, 45 minute cycle may be adequate to achieve sterilization. (With larger or more dense loads, a longer cycle may be required.) BI lethality (and more importantly, sterilization of the load) will ultimately depend upon the combination of time and temperature of the cycle. For example, a cycle with a temperature of 132 or 134°C could potentially be shortened (e.g. to 10 or 15 minutes), assuming appropriate air-removal. Demonstrating biological kill of a Log 6 BI in the area of the waste bag which presents the most difficult challenge to sterilization (i.e. near the bottom, but not "at" the bottom of the bag) will provide a high level of confidence that sterilization was achieved.

Russ Nyberg has worked at the Omaha Biological Indicator manufacturing facility for Mesa Labs for the past 19 years. He has held the positions as Director of Manufacturing and Production and currently works in the area of Technical Support. Russ is a committee member and active participant with the Association for the Advancement of Medical Instrumentation (AAMI) in

Russ is a committee member and active participant with the Association for the Advancement of Medical Instrumentation (AAMI) in the Industrial Steam, Resistometer and Process Challenge Device working groups.

Russ holds a B.S. in Biology from Wayne State University, a B.S.Ed from the University of Nebraska and an MAM from Bellevue University.

Annette Bojanski, M.D. is a Technical Sales Specialist at Mesa Labs' Omaha Manufacturing Facility and has been with the company since April of 2007. She is a member of the Association for the Advancement of Medical Instrumentation (AAMI) and the Parenteral Drug Association (PDA).

Annette holds an M.D. from the University of Nebraska Medical Center.