

Baxa Corporation

Safe Handling of Hazardous Drugs

Technical Paper

Discussions from a scientific advisory board on the impact of USP <797> and the NIOSH Alert for guiding the safe handling of hazardous drugs in healthcare settings



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Introduction

2004 was a year of big change for United States pharmacy IV admixture services. That year, two documents were released with major regulatory implications for pharmacy practice:

1. USP Chapter <797>. The U.S. Pharmacopoeia (USP) issued USP General Chapter 797, "pharmaceutical compounding – sterile preparations" in January, 2004. The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) has adopted these standards for their own use as of July 1, 2004, and now includes adherence to the requirements as part of their accreditation audits. The full USP 797 implementation process is a staged series of escalating compliance issues. The entire chapter becomes enforceable in January 2008. In the meantime, numerous individual State Pharmacy Boards are including these standards in their inspections.
2. NIOSH Alert. On March 25, 2004, the National Institute for Occupational Safety and Health (NIOSH) issued a long-awaited study, "Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Health Care Settings." NIOSH is an arm of the better-known OSHA (Occupational Safety and Health Administration) that will likely consider the Alert in its future regulatory influence on worker safety issues.

Experts in the field and other interested professionals assembled in San Antonio, Texas in the fall of 2004 for a scientific advisory board on the advancement of safe practice and the impact of the new regulatory requirements. This paper is a summary of viewpoints shared on the issue of hazardous drug handling from those in attendance. The scientific advisory board was co-sponsored by Carmel Pharma and Baxa Corporation. Attendees included employees from both sponsors, industry thought leaders, participants from the NIOSH Hazardous Drug Safety Working Group, and healthcare practitioners.

The Importance of the NIOSH Alert

Tom Connor, PhD from the Division of Applied Research and Technology at NIOSH, and a member of the NIOSH Drug Safety Working Group, says there is certainly sufficient scientific evidence to support the Alert. He wants to get more people involved with safe handling issues.

"We tried to make [the Alert] evidence-based. And, we have an extensive bibliography and cite many studies. So I think we have the support that we need to address some of the issues in the Alert," Connor explains. "It's really difficult to get the information out there. We have nurses. We have pharmacists. We have people in home health care. And we've tried to include these people in our working group so that we can get the message out to them. I think the biggest thing is getting the message out to the people who need to have it."

Further, Melissa McDiarmid, MD, MPH of the University of Maryland and a fellow member of the NIOSH Drug Safety Working Group noted, "The NIOSH Alert is an opportunity for everyone to refresh on what, theoretically, they should have already

known and already put in place. But, we know from studies – as well as from a lot of walk arounds, walk through rounds, and epidemiology – that people were not honoring the OSHA guidelines. And, as the toxicity of anti-cancer drugs and the anti-viral agents gets ever greater, and we talk about different kinds of therapy, there's only going to be a need for increased vigilance."

Roger Anderson, D PH, RPh, Senior Vice President and Chief Pharmacist of Medco Health Solutions and former Director of Pharmacy for the MD Anderson Cancer Center was an early supporter of closed-system solutions for safe handling of hazardous drugs. Also a member of the NIOSH Drug Safety Working Group, Roger observed, "Pharmacists are now on record as having to do something about environmental contamination. The Alert finalizes what we have been working on for over twenty-five years, and now have well documented, that pharmacists and other healthcare workers must do something to change current practice."

The Implications of USP <797>

According to Professor Graham Sewell, professor "UPS 797 and the NIOSH Alert are milestones for US pharmacy practice. Clearly they need to be brought together and can't be taken individually. One document obviously protects the product, and the other is designed to protect the operator." "Sewell continues, "In actual practice, you can't separate those two issues. So they need to draw together and develop a common approach, in my view,"

According to Roger Anderson, Chapter 797 addresses sterility issues and the potential for cross-contamination – both bacterial and other drugs – and offers applications for the PhaSeal® products, given that the device maintains a closed system that offers protection against touch contamination in addition to preventing environmental contamination.

"The guidelines in USP 797," continues Anderson, "as they relate to isolators, are a little bit more clear cut as far as the potential microbiological contamination of products. But, the application to the cytotoxic drug exposure to personnel and to the environment, to me, is extremely limited by the use of isolators. I have never believed that the use of isolators has much to do at all with environmental contamination. The exposure still occurs." "The environmental aerosolization of drug products still occurs within the isolator environment...Other products that will come out of the isolator, to me, will carry the contamination. And I have never seen a system to definitely clean the products that come out that will then be dispensed to the wards. So to me, they carry out the contamination," Anderson explains.

"I think the most important thing is that these two alerts – NIOSH and USP797 – have different points of view," asserts Johan Vandembroucke, PhD of the University of Ghent in Belgium. "...somehow, we have to combine these two together. The protection of the employee and the protection of the product. And, I think they have an equal importance if you look at the safety of the patient, too. If you look at isolators, if you look at the PhaSeal system, if you look at biological safety cabinets and clean rooms, I think the most important thing is to fit it well into the [heuristic] order of protection," Vandembroucke explains.

Applications for PhaSeal

The PhaSeal System is the first, documented closed system designed to prevent environmental contamination when reconstituting, withdrawing, transporting and administering hazardous drugs. Participants discussed their experiences with the products and their application for addressing the guidelines in the NIOSH Alert and USP 797.

"Our experience with PhaSeal has been outstanding," said Jim Jorgenson, MS, RPh System Director of Pharmacy at the University of Utah Hospital and Clinics. "You know we piggy-backed on the early work that was done at MD Anderson by Roger Anderson, and brought the product in and actually studied it at our facility. We looked at the impact that it had on actually reducing both surface and personal contamination. From our results, there was a huge groundswell to implement it throughout the organization very quickly. It's being used everywhere that we prepare and administer chemotherapy right now."

Regarding PhaSeal, Anderson noted, "The potential use [of PhaSeal] within an isolator, means that we capture the aerosolized product contamination before it even gets into the environment within the isolator. So it stops it there. And, to me, that's the big plus for the PhaSeal device. The isolator alone, for cytotoxic drugs, to me, has almost no application [in meeting NIOSH recommendations]."

Thoughts On Barrier Isolators

"Barrier isolators are very good at containing cytotoxic contamination," noted Sewell during the discussion. He continued, "We have to remember that in that process, they themselves become heavily contaminated on the inside, unless you take steps to prevent or reduce the amount of contamination that's produced during cytotoxic reconstitution. Clearly, devices such as PhaSeal should help enormously in that aspect. And should reduce the amount of internal contamination in an isolator. And that's important because we want to make sure that we reduce the amount of contamination that's transmitted from the isolator onto products; syringes, bags, etc, that actually go to the patient. I think the whole chain of contamination needs to be addressed, and clearly PhaSeal is an approach that should help that." "Further," Sewell cautioned, "as US pharmacists look at USP 797 compliance, an isolator does not replace the need for a cleanroom. And I think we need to be really clear about that."

Regarding isolators, Jorgensen explains, "We considered isolators, but you know we looked at isolators [as being] more interchangeable with biological safety cabinets. We really didn't look at isolators as a replacement for PhaSeal. We think that PhaSeal needs to be complementary with either of those two technologies -- barrier isolators or biological safety cabinets. So, for our purposes, the biological safety cabinets still made more sense to us."

Jorgensen continued the discussion noting that in the United States there are still a lot of misconceptions about what isolators do and don't do, and, where they should be

positioned and how they should be used. "I think [isolators] are much more well-established in Europe. They've had a lot more experience than we have using isolators. I think the biggest take away is that an isolator is not a replacement for PhaSeal. It's something that should be, if you're going to use it, it should be used in tandem with PhaSeal," he concluded.

Thoughts From NIOSH Conference Attendees

Following the scientific advisory board, NIOSH kicked off its educational conference on safe handling of hazardous drugs. Participants were interviewed regarding their reasons for participating in the workshop, and their understanding of the requirements for compliance with USP 797 and the NIOSH Alert.

"I came to the NIOSH Hazardous Drugs conference because I'm an industrial hygienist," stated Erica Stewart, BS of Kaiser Permanente. "I'm very concerned about being able to protect workers from hazards associated with potent and hazardous drug use. So that's the number one reason. And secondarily, we're also interested in what's on the forefront for medical surveillance in regards to hazardous drugs," she continued.

"At Kaiser Permanente we've been working with our pharmacy group to establish what USP 797 means to Kaiser Permanent operations, especially in regards to the way we're built. We're very concerned about being able to meet those standards even if they aren't adopted by the boards of pharmacies in all states. It will still be a de facto standard that the Joint Commission will certainly be looking at when they come in to gauge compliance."

Mary Gullatte, RN, of Winship Cancer Institute actually downloaded the preliminary NIOSH guidelines back in March. "When I read them and started talking to our team in terms of looking at our current policies and procedures and what may be needed from the new guidelines that have come out." Gullatte added, "I thought that we really needed to implement some of these programs because one of the things that we make a point of doing is making sure that patients are safe in terms of compliance with patient safety guidelines from the Institutes of Medicine. But at the same time, we have a responsibility for our staff. To make sure they're safe in terms of these hazardous drugs that they are using day to day in terms of treating patient with chemotherapeutic agents."

About Baxa Corporation

Baxa Corporation offers the only closed system for safe handling of antineoplastic and other hazardous drugs. This system, PhaSeal, uses dry connections and a built-in expansion chamber to prevent drug aerosol leakage and subsequent transfer into the work environment. As a closed system, it contains hazardous drugs throughout the entire process of drug transfer, preparation, transport, administration and disposal – eliminating the risks of environmental and occupational exposure.

A leading provider of devices and systems for the preparation, handling, packaging, and administration of liquid medications, Baxa Corporation manufactures and markets a wide range of healthcare products for use in hospitals, critical care units and alternate-

site pharmacies. Headquartered in Englewood, Colorado, Baxa has subsidiaries and sales offices in Canada, the United Kingdom; Denmark, and Germany; and distribution partners worldwide. Further information is available at <http://www.baxa.com>.

About the PhaSeal System

The PhaSeal System is currently in use for handling hazardous drugs in more than 200 leading cancer hospitals and treatment centers in the US. The system is also used in progressive hospitals throughout Europe.

PhaSeal is manufactured in Sweden by Carmel Pharma ab of Göteborg, Sweden. Introduced in Europe in 1994, the PhaSeal System is now used in most Swedish hospitals, with its benefits documented by a significant body of scientific research on the health risks associated with the preparation and administration of cytotoxic drugs. The PhaSeal System is protected by a comprehensive patent portfolio in the U.S., European Union and Japan. For more information on Carmel Pharma, please visit <http://www.carmelpharma.se>.

Additional Resources

The full text of the NIOSH Alert can be found at <http://www.cdc.gov/niosh/docs/2004-165/>.

The full text of USP 797 can be found at (<http://www.usp.org>). Complementary materials on USP 797 are available on the Baxa Corporation Web site (baxa.com/OnlineHelp/Default.asp?ID=4&Item=11), and at the ASHP Web site (ashp.org/SterileCpd/).