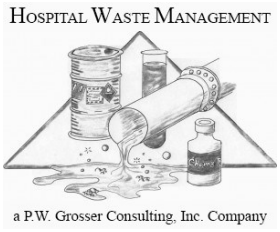
Volume 19, Number 1

HOSPITAL WASTE MANAGEMENT



Spring 2017

Special points of interest:

- **Which Biological Safety Cabinet Should You Install in Your Pharmacy?**
- **King County Prohibits Sewering of Unwanted Controlled Substances**

Inside this issue:

Hospital Waste

Which Biological Safety Cabinet Do You Install to Satisfy DOH, USP 800 and L&I's Hazardous Drug Rule?

Now that OSHA, Washington Labor & Industries and the U.S. Pharmacopoeia have largely finalized their guidelines for handling hazardous drugs, pharmacies are designing new facilities to comply (pharmaceutical waste is a different matter; U.S. EPA and Ecology won't finalize their pharmaceutical waste regulations until mid– to late 2018). The big thorn in everyone's side is what kind of biological safety cabinets (BSC) conform to compounding hazardous drug requirements in the pharmacy?

Biological safety cabinets (BSCs) are designed to protect workers compounding hazardous drugs by capturing dusts and aerosolized droplets on filters or exhausting them to the air outside the facility. They come in various flavors with very different price tags, for the BSC as well as the exhaust infrastructure required in the facility.

There are three BSCs commonly considered by those designing, building and inspecting pharmacy equipment:

- Class II, Type A2—This style of BSC captures dusts and droplets on a HEPA filter and exhausts 70% of the purified air back into the hood.
- Class II, Type B1—This style of BSC uses a filter and exhausts 50% of the purified air back into the hood.
- Class II, Type B2—This style of BSC uses a filter but exhausts 0% of the purified air back into the hood.

In Washington the Departments of Health and Labor & Industries appear to allow the Class II, Type A2 BSC if the pharmacy can show that it adequately protects workers. Group Health (now Kaiser Permanente) is researching whether a Class II, Type A2 will adequately protect pharmacy workers when working with volatile hazardous drugs. This research with surrogate compounds is expected to be published in late April 2017.

Liquid hazardous drugs can evaporate or solids can decompose in a hood, forming a gas or vapor phase that may or may not be captured on a filter. If exhausted back into the hood, these materials could expose a pharmacy technician to volatilized hazardous drug.

Only a few of the hazardous drugs in the NIOSH 2014 lists are liquid or decompose below 72° F. according to The Merck Index[1] and package inserts:

- Carmustine: m.p. = 31° F
- Chlorambucil: m.p. = 65° F
- Cyclophosphamide: m.p. = 43° F
- Dinoprostone: m.p. = 67° F
- Divalproex: m.p. not known, liquid

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Your Facility's Hazardous Drug Control Plan

Washington Labor & Industries wrote our state's Hazardous Drug Rule in 2012, which is now WAC 296-62-500, Part R. Every facility that manages hazardous drugs should have a written plan (effective January 1, 2015) to mitigate exposure to employees, including pharmacy, operating room, caregiver, receiving, material management, and environmental services staff.

One provision of that law that is repeatedly found missing from facility Hazardous Drug Control Plans is a description of the way a hazardous drug enters, flows, and leaves the facility to determine where exposure occurs.

Hospital policies rarely contain drawings, photos or verbal descriptions of work areas, but those are exactly the kind of documentation that is required in your facility Hazardous Drug Control Plan.

Plan authors can insert a physical description of each work environment where hazardous drugs are managed as a written description, maps, video, pictures or any combination of those elements. Areas that should be so described should include the:

- pharmacy,
- compounding room,
- pharmaceutical receiving area,
- infusion areas,
- obstetrics and delivery rooms,
- operating rooms, and waste collection areas.

Hazardous Drug Control Plans must include a physical description of work areas using drawings, photos, maps or detailed language where exposure to hazardous drugs may occur. The description must describe the flow of hazardous drugs into, through and out of each work area.

It has been two years since these plans have been required, so it's unlikely that there is any grace period left in the law. Check your own Hazardous Drug Control Plan for the other required elements:

1. A list of hazardous drugs used at your facility;
2. Job hazard assessments with associated risk levels; and
3. Training for workers.

Struggling with Your Facility's Tier II Report?

Each year many healthcare facility directors receive a letter from their medical gas vendor warning them that they are required to complete a Tier II report detailing their med gas storage and file it by March 1st. For most businesses, cryogenic and compressed gases must be reported on an annual Tier Two report, but not hospitals.

Hospitals and laboratories do not have to report their cryogenic and compressed gas storage as long as those materials are under the supervision of an onsite engineer.

However, hospitals are required to report the diesel storage that they have if it exceeds 10,000 lbs, which is about 1,412 gallons of diesel #2. The information about hazardous material storage must be annually submitted to Washington Ecology, your local fire marshal, and your Local Emergency Planning Committee (LEPC).

Tier II reports are part of Section 312 of the Emergency Planning & Community Right-to-Know Act (EPCRA), also known as SARA Title III.

More information is available at: http://www.ecy.wa.gov/epcra/

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- Ifosfamide: m.p. = 40° F
- Ixabepilone: m.p. not known, liquid
- Misoprostol: m.p. not known; oil
- Thiotepa: m.p. = 51.5° F

If your pharmacy prepares or compounds any of the drugs on this list, you likely should have available a Class II, Type B2 BSC for compounding (you could have other BSCs with a lower safety rating). Other hazardous drugs that are not liquid at 72° F (normally ambient temperature) should be safe to prepare in a Class II, Type A2 BSC with a HEPA filter as will not evaporate at this temperature.

Department of Health and Board of Pharmacy technical reviewers are generally coming down on the side of caution and advising Class II, Type B2 BSCs when there's even a hint of the possible use of volatile hazardous drugs. If you plan to use a BSC other than a Class II, Type B2, be prepared to defend your choice and it's efficacy in protecting your pharmacy technicians.

The Group Health research results are being eagerly awaited by a number of pharmacy directors who are delaying remodel construction in the hope that less expensive hood and ventilation options may be valid.

[1] 14th edition

King County Industrial Wastewater Prohibits Controlled Substance Discharge to Sewer

King County's Industrial Waste Program has long issued Minor Discharge Authorizations to its hospitals to allow these facilities to operate and "discharge limited amounts of industrial wastewater into King County's sewer system in accordance with the effluent limitations and other requirements and conditions set forth in the document and the regulations outlined in King County Code 28.84.060." Some of these authorizations are now up for 5-year renewal.

Under these Minor Discharge Authorizations most healthcare waste managers have assumed that their caregivers could legally discharge unused partial doses of controlled substances to the sewer in accordance with U.S. Drug Enforcement Agency (DEA) guidelines.

The Minor Discharge Authorizations actually stated, under the category of "various pharmaceuticals (partially used, expired, or unused drugs), that pharmaceuticals were "Not acceptable to the sewer."

In the process of constantly reviewing Best Management Practices, King County's Industrial Waste Program has now interpreted its policy as **prohibiting any unused controlled substance discharge to the sewer**.

In practice, this means that caregivers may no longer witness and sewer partial doses of controlled substances to the sink or toilet in King County.

New 5-year Minor Discharge Authorizations to King County hospitals will contain language that emphasizes this ban on sewering unwanted partial doses of controlled substances.

This policy change is consistent with recent changes in both Washington Ecology's *Interim Pharmaceutical Waste Policy* and the U.S. EPA's proposed Part P rule *Hazardous Waste Pharmaceuticals* (due to be finalized in early 2018). Neither of these latter allow the sewering of any unwanted pharmaceutical.

Some other Washington local wastewater treatment districts have prohibited sewering any controlled substance waste for some time, notably Spokane.

Most Washington hospitals are now exploring sequestration systems to capture partial doses to allow for final incineration.

HOSPITAL WASTE MANAGEMENT

a P.W. Grosser Consulting, Inc. Company

17629 NE 138th Street
Redmond,
Washington 98052-1226

Phone: 425-883-0405
Fax: 425-895-0067
E-mail: ajones@pwgrosser.com

www.hospitalwastemgmt.com

Hospital Waste is published quarterly for hospital, clinical and medical laboratory waste and hazardous material managers to assist them in managing these materials.

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OPA Use Declining; Peroxyacetic Acid Use Increasing as Sterilant

High-level, cold sterilants for use with instruments that cannot be heat-sterilized have undergone several evolutions of late.

Gluteraldehyde gave way to *o*-phthalaldehyde (OPA) years ago. The use of OPA has, in turn, given way to peroxyacetic acid (aka peracetic acid) occasionally combined with hydrogen peroxide.

Gluteraldehyde was never liked by caregivers because of the odor and by employers because of the need to monitor exposure levels to staff.

Spent OPA cannot be discharged to the sewer without treatment with either glycine or a commercial product. Such onsite waste treatment must be logged and reported annually on the facility's dangerous waste annual report.

Peroxyacetic acid is largely neutralized during use to a pH that allows it to be discharged to the sewer without pretreatment. If hydrogen peroxide is also present in the sterilant, it is converted to gaseous oxygen and water during use.

These latest peroxyacetic acid sterilants are still quite hazardous to technicians, but the waste is no longer such an issue. Healthcare continues to use fewer and fewer hazardous materials in its quest to be more environmentally friendly.