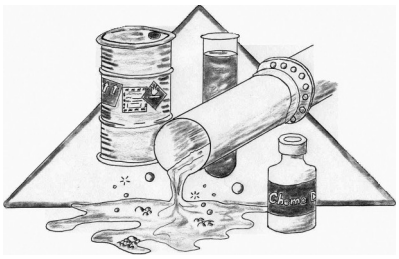

"Helping Hospitals Manage Waste"

Hospital Waste

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DEA Proposes Rule for Expanded Options to Collect CSs from Users for Secure Destruction

The U.S. Drug Enforcement Administration (DEA) has released proposed regulations to implement the Secure and Responsible Drug Disposal Act of 2010 by expanding options to collect controlled substances from ultimate users for secure destruction. The comment deadline for the new rule ended February 19, 2013.

Pharmaceutical waste has been recognized as generally toxic, not destroyed in wastewater treatment processes, and a factor in disturbing ecology balance from the proportions of gender (more female amphibians and fish) to mutations. Healthcare facilities in Washington have been generally managing their pharmaceutical waste more responsibly (by incineration) the past several years, but in communities there have been few, if any, options available for citizens to responsibly dispose of unwanted pharmaceuticals.

There have been several attempts to offer unwanted pharmaceutical collection programs to communities. These programs are designed to prevent pharmaceutical waste from going to landfills or being flushed down the sewer.

One primary difficulty these take-back and collection programs have faced is that controlled substance (CS) waste can only be accepted by a law enforcement agency or a licensed reversed distributor. It is difficult and time-consuming to segregate Schedule II through V controlled substance waste from all other patient pharmaceutical waste [Schedule I controlled substances are illegal], yet patients regularly co-mingle CS and other unwanted pharmaceuticals in take-back receptacles.

Options proposed in the new rule include:

1. **Take-back events**—conducted by law enforcement agencies only
2. **Mail-back programs**—operated by authorized manufacturers, distributors, reverse distributors, retail pharmacies or law enforcement agencies.
3. **Collection receptacle locations** (i.e., permanent drop-off boxes) - operated by authorized manufacturers, distributors, reverse distributors, retail pharmacies or law enforcement agencies. These may be operated at long-term care facilities (LTCFs), but only when maintained by a retail pharmacy.

A crucial element of the proposed rule is that controlled substances and non-controlled medicines can be co-mingled, including loose pills. Existing best practices for patient confidentiality can be used and collected medicine cannot be inventoried, further protecting patient information. All medicine shall be handled at a security level appropriate to Schedule II controlled substances. All collection methods are voluntary, but there is no funding mechanism provided in the rule.

An existing registrant will be able to amend their registration with the DEA to become a collector. Non-registrants such

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Our firm…

Hospital Waste Management is committed to assisting healthcare facilities in complying with hazardous material management and waste disposal regulations and better managing their wastes. Our clients are hospitals, clinics, and medical labs.

Our services include conducting dangerous, solid, radioactive, and regulated medical waste audits; risk assessment; hazmat audits; developing waste management plans for Joint Commission compliance; hazmat emergency response training; and annual dangerous waste and Pollution Prevention reporting.

Our e-mail address is: AlanBJones@frontier.com. For past Hospital Waste issues, check our website at http://www.hospitalwastemgmt.com/.

Hospital Waste

"Helping Hospitals Manage Waste"

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Hospital Waste is published quarterly for hospital, clinical, and medical laboratory waste managers.

Hospital Waste Management is committed to serving the Healthcare Industry by assisting hospitals in managing their waste. **Hospital Waste** aims to disseminate information about waste regulations and waste management initiatives and to provide helpful hints and general waste information to healthcare waste managers.

If this newsletter has reached you in error, please notify the Editor by phone, fax, or e-mail. If you wish to be placed on our quarterly mailing list, please contact the Editor. For past issues and an index of articles, check our website at **http://www.hospitalwastemgmt.com**.

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Our Editorial Policy

While every effort was made during the development of this newsletter to insure accuracy, we make no warranties or certifications. We encourage you to contact the references listed in the articles or Alan B. Jones for further information about any topic mentioned in this newsletter.

Not All Anesthesia Gas Dryers Designate As Special Waste

A new product is being tested at several Washington hospitals that is designed to be a less corrosive alternative to SodaSorb™, an industry standard. These products are used in surgery by anesthesiologists to scrub carbon dioxide (CO_2) gas and moisture from the breath of patients so that anesthesia gas can be recirculated. To neutralize carbon dioxide these products are manufactured to be highly alkaline.

SodaSorb™ contains calcium, sodium and potassium hydroxides, the combination of which causes the spent material to have a pH greater than 12.5 and designate as Special Waste, a solid, corrosive dangerous waste.

Drägersorb™ is an increasingly common and less corrosive alternative to SodaSorb™. Drägersorb™, when spent, has a pH of about 12.0 and does not designate as a dangerous waste. When spent, Drägersorb™ can be deposited in the trash [do not deposit spent Drägersorb™ in a biohazardous waste container. Spent Drägersorb™ is not biohazardous and managing it as such is simply a waste of money.]

The new product, Litholyme™ (Allied Healthcare Products, St. Louis, MO), also has a measured pH of less than 12.5, which means that it does not designate as a solid corrosive waste (D002) and need not be managed as a Washington Special Waste (WSC) when spent. Litholyme contains calcium hydroxide, but no sodium or potassium hydroxide.

Litholyme™'s pH as a fresh product is 12.0—12.25. According to Washington's Dangerous Waste Regulations, if the pH is less than 12.5 the material can be disposed of as solid waste.

The major question is whether Litholyme™ functions as well as SodaSorb™ and Drägersorb™ in removing CO_2 from patient breath and whether it will be acceptable to anesthesiologists. These products function by neutralizing carbonic acid, formed by dissolved CO_2 in breath moisture. The less alkali in the form of a hydroxide that the product contains, the less efficient it is in neutralizing carbonic acid in patient breath.

If your surgery department is using SodaSorb™, the spent waste should be collected separately in barrels and managed as Special Waste.[1] If your surgery department is using either Drägersorb™ or the new Litholyme™, these wastes can be disposed of in the trash.

If your facility uses BaraLyme™, which contains the metal barium, the waste designates as a D005 Listed Waste and must be disposed of as a RCRA waste by your hazardous waste vendor. It should be collected in barrels and segregated from other waste.

Special Waste volumes should be reported on a facility's Dangerous Waste Annual Report, although this waste does not count towards the facility's total dangerous waste volume or generator status. If your facility is a Small Quantity Generator, check the TurboWaste Site Identification Form box [10.-13] for "Generator of Special Waste." If your facility is a Regulated Generator (Medium or Large Quantity Generator), complete a Generation & Management Form for the Special Waste stream.

[1] Special Waste: WAC 173-303-073

Formalin Alternatives: Joint Commission Pushes Hospitals to Reduce Formalin Use

Joint Commission reviewers have begun suggesting to hospitals that they reduce the amount of formalin being used. There are a few formalin alternatives available in the commercial marketplace, but their use has been historically resisted by pathologists as unsuitable.

Formalin is a solution used to preserve tissue in the morgue, surgery, pathology, gross anatomy, dermatology, and a variety of other departments. Comprised of a buffered saline solution of formaldehyde gas, it is a known human carcinogen and considered toxic by the Washington Department of Labor & Industries (L&I). Its use is governed in Washington by L&I's formaldehyde regulations, WAC 296-856.

Two commercially-available tissue preservatives are (1) Carosafe, sold by Caroline Biological Supply Company (http://www.carolina.com) and (2) Formalternate, sold by Flinn Scientific (http://www.flinnsci.com). Both products are propylene glycol-based. Both are suggested for storing preserved specimens, but not for tissue fixation.

(DEA Rule, continued from page 1)

as government entities, hazardous waste collection facilities, community centers, etc. cannot serve as collection locations. Hospitals cannot be authorized collectors, but a retail pharmacy that is co-located within a hospital may participate.

Collectors shall either destroy the collected drugs onsite or transfer the drugs to either a distributor or reverse distributor for final disposal.

Long-term care facilities will not be permitted to dispose of a controlled substance on behalf of a patient without a collection receptacle. Each collection receptacle must be included in a retail pharmacy registrant's registration. Otherwise, only the patient or patient's legal guardian or executor can dispose of unwanted controlled substances.

Destruction means that collected CSs must be rendered "non-retrievable" to permanently alter the physical or chemical state of the CS. Although destruction methods are not specified in the rule, flushing and mixing CSs with coffee grounds or kitty litter does not meet the non-retrievable standard. Examples of current technology that may achieve the non-retrievable standard include incineration and chemical digestion.

The link to the complete rule in the Federal Register is https://www.federalregister.gov/articles/2012/12/21/2012-30699/disposal-of-controlled-substances.

Medical Surveillance Guidelines Released by NIOSH Will Not be Incorporated into the Hazardous Drug Rule For Now

When the Hazardous Drug Rule was first drafted by Washington's Labor & Industries (L&I) medical surveillance of staff exposed to hazardous drugs was a core element. It quickly became a contentious issue for many reasons including cost, what kind of surveillance is appropriate, and questionable value. L&I elected to defer implementation of employee medical surveillance in the Hazardous Drug Rule. One of the reasons for deferment was to await updated medical surveillance guidelines from the National Institute of Occupational Safety & Health (NIOSH).

In November 2012 NIOSH released an updated *Medical Surveillance for Healthcare Workers Exposed to Hazardous Drugs* guideline [http://www.cdc.gov/niosh/docs/wp-solutions/2013-103/]. This guideline was first published in 2007.

After a review of the updated NIOSH guideline L&I has elected to defer indefinitely any personnel medical surveillance requirement for the Hazardous Drug Rule. L&I staff recognize that implementing the existing elements of the Hazardous Drug Rule is a major step and should be implemented, reviewed, amended and adjusted before embarking upon a new and additional effort.

The 2012 NIOSH medical surveillance guideline calls upon employers to establish baseline exposure data, but not to collect this data annually unless an employee has experienced a significant exposure event. Baseline data involves collecting and interpreting data to detect changes in the health of working populations exposed to hazardous drugs.

NIOSH recommends that employers establish an employee medical surveillance program as part of a comprehensive prevention program that also minimizes worker exposure through engineering controls, good work practices, and personal protective equipment (PPE) and provides education about working with hazardous drugs.

The 2012 Washington Hazardous Drug Rule requires retail pharmacies, hospitals, veterinary clinics, and other medical facilities with patient contact to implement a written Hazardous Drug Control Plan by January 1, 2014. A Hazardous Drug Advisory Committee of stakeholders is preparing a tool for medical facilities to use in compiling a compliant plan. In the interim, facilities are preparing Job Hazard Assessments for workers who are exposed to hazardous drugs, required elements of each facility plan.

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TO:

"Helping Hospitals Manage Waste"

Arthroscopic Epinephrine Irrigation Solution Captured by Neptune is Merely Liquid Waste

Stryker Neptune Waste Management Systems™ are installed in operating rooms across Washington as a safer alternative to suction canisters. They protect staff from splash exposure with a closed system that allows liquid surgical waste to be discharged to the sewer after procedures. Only a few wastewater treatment districts have banned their use in local hospitals, generally because of the additional solid organic load they place upon the wastewater treatment system.

Occasionally during arthroscopic shoulder or knee surgery epinephrine-saline irrigation solutions are used to limit bleeding. During the procedure this irrigation solution is further diluted by patient fluid, which is then collected by the Neptune Rover. Epinephrine, a pharmaceutical, can designate as a P042 Extremely Hazardous Waste or as a WT02 Washington toxic waste, depending upon how it is used and disposed.

When the epinephrine-saline solution is flushed over the surgical site and then collected, it has been used for its intended purpose, is not a discarded product and the P042 designation does not apply. Then it becomes a matter of designating the solution as a liquid waste.

Typically epinephrine is added as 1cc/liter of saline, which is 0.1% or 1,000 ppm, to function as an irrigation solution to reduce bleeding. This concentration is the threshold for designation as a WT02 toxic waste. When the irrigation solution is flushed into the surgical site and further diluted with patient fluid, the concentration of the liquid waste captured by the Neptune Rover should fall below 0.1% and would not designate as WT02.

Because epinephrine-saline irrigation waste does not designate as either a P042 or WT02 dangerous waste, it can be discharged to the sanitary sewer if allowed by the local wastewater treatment district. If your facility uses Stryker Neptune units in its operating rooms, you should contact your local wastewater treatment district and inquire about authority to discharge directly to the sewer. The additional organic load imposed by discharging liquid surgical waste to the sewer can be substantial.