Resources for Evaluating Medical Waste Treatment Technologies

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PURPOSE. To provide guidance and references for a public health evaluation of the effectiveness of medical and pharmaceutical waste treatment technologies. Mention of a commercial waste treatment product or vendor is for illustration only and does not constitute an endorsement by the government.

REFERENCES. See Appendix A for a list of reference information.

POINTS OF MAJOR INTEREST AND FACTS.

Current Waste Regulations

Regulated medical waste (RMW) is defined by the Army Medical Command (MEDCOM) Regulation 40-35 and its management, disposal, and transport is regulated by states, U.S. Department of Transportation (DOT) hazardous substance transport regulations (49 CFR 100-185), DOD regulation (DLA 1997) and local garrison and medical treatment facility (MTF) regulations. Local wastewater treatment plants may also regulate or prohibit down-the-drain disposal of medical waste including blood or saline.

Hazardous pharmaceutical waste is defined and regulated by the Federal Resource Conservation and Recovery Act (RCRA), more stringent state hazardous waste regulations, DOT hazardous substance transport regulations, DOD and Army regulations (DLA 1997 and AR 200-1), and local garrison and MTF regulations. Local wastewater treatment plants may also regulate or prohibit down-the-drain disposal of pharmaceuticals.

Pharmaceutical controlled substances are defined and regulated by the U.S. Drug Enforcement Agency (DEA), state, and local garrison and medical treatment facility (MTF) regulations. Waste pharmaceuticals that are not RMW (chemotherapy), hazardous waste

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or controlled substances are usually not regulated. The U.S. Environmental Protection Agency (EPA) published draft guidelines for the safe disposal of waste pharmaceuticals including those that are non-regulated (USEPA 2010).

Applicable DOD, Army, garrison, or MTF waste management, return vendor, or single-use device (SUD) reprocessing contracts may set additional standards for waste management.

Army MTFs and garrisons cannot collect and dispose of RMW or waste pharmaceuticals generated from patient homes. MTFs and garrisons may cooperate with local pharmaceutical take-back events as long as state or local governments manage and fund the transportation and disposal of any waste collected during waste turn-ins.

Overseas garrisons are subject to host nation final governing standards which may include compliance with host nation regulations.

Reasons for Change

Most Army facilities use waste management contracts to transport and dispose of RMW, hazardous, pharmaceutical and solid wastes at offsite disposal facilities. Army MTFs do not treat or dispose of RMW or hazardous or controlled substance pharmaceutical waste onsite. Most Army garrisons do not treat or dispose of solid waste onsite, although some have waste-to-energy plants, legacy solid waste landfills, or composting either onsite or on leased property. Some wastes are diverted from disposal through pharmaceutical return vendor contracts, SUD reprocessing contracts, or offsite recycling or composting contracts.

No new regulations or public health concerns require any change to existing garrison and MTF waste management. The drivers for change are listed below.

- Army Net Zero Energy Conservation and Solid Waste goals (Army Energy Program 2012). To reduce solid waste disposal costs, to generate energy onsite, and to increase garrison energy security, many garrisons are considering acquiring Waste-to-Energy technology (IMCOM 2010).

- Onsite RMW disposal technology in case of natural disaster, extreme weather, or other events that prevent offsite RMW disposal under current contracts.

- Public and non-governmental organizations' (NGO) concern with pharmaceutical residuals in waste water and drinking water.

- Management of wastes from contingency operations or deployed forces. Army is evaluating commercial off-the-shelf (COTS) technology for improving waste management, alternative sources of energy generation, and fuel conservation at overseas deployed forces bases (NDCEE 2012).

Commercial Off-The-Shelf Technology Descriptions

Available COTS technology for medical and pharmaceutical waste management onsite includes Waste-to-Energy (WTE) technologies, small incinerators, RMW shredding with sterilizing, and equipment or methods for small-scale pharmaceutical treatment or disposal.

WTE technologies use thermal energy from burning waste and usually an augmenting fuel supply to incinerate hazardous, solid, and medical waste and generate usable electricity or steam. Typical technologies used are incineration, plasma-assisted incineration, or plasma arc torches. WTE technologies are regulated for air emissions and residual waste management, typically require trained operators or contract support and are overseen by the garrison environmental office (as well as applicable contracting officers). These devices are most often proposed for waste reduction and energy generation at U.S.-based garrisons or for deployment and contingency operation use. Successful destruction of infectious pathogens in RMW depends on temperature, residence time, and mixing (U.S. Congress 1990). The required temperature ranges for destroying pathogens in gases are 1600-2200 degrees F (U.S. Congress 1990, WHO, 1999). Examples are given below. Capabilities are from marketing literature and are provided for illustrative purposes only.

- Micro Auto Gasification System (MAGS^{TM}). Feed rate 1 ton/day, not designed for hazardous wastes, generates syn-gas (carbon dioxide and hydrogen) that it uses as fuel, carbon "bio-char" that can be landfilled or used as a soil additive, and metal and glass waste.

- Pyrogenesis air plasma torch. Feed rate 1-100 tons/day depending on model, some models designed for hazardous wastes, generates syn-gas and 50 to 500 kilowatts electricity and metal and glass waste.

Small incinerators have been purchased by city and county law enforcement to destroy contraband drugs and narcotics. These incinerators are portable, use fuel to destroy waste, can claim exemptions from air emissions regulations (but not waste management regulations) only when used to destroy contraband, and are simple enough to be operated by trained facility staff. Although local law enforcement agencies have used these devices to destroy waste pharmaceuticals from pharmaceutical turn-in programs, this practice is now forbidden under recent EPA interpretive guidance (USEPA Region 6 2011). The Army has evaluated such devices only for use during contingency operations or deployment (NDCEE 2012). Examples are given below. Capabilities are from marketing literature and are provided for illustrative purposes only.

- Elastec Drug Terminator™ and Mediburn™. The Drug Terminator™ attaches to a 55-gallon metal drum, burns charcoal or wood with electric blower assist, destroys drug contraband or prescription pharmaceuticals, generates ash and heat-sterilized residual. The larger diesel-fueled Mediburn™ models can handle 8 – 10 cubic feet batches of waste with burn rates of 40-66 pounds/hour and burn at up to 1800 degrees F.

- SuperNova Eliminator™ incinerators. Diesel-fueled small-scale incinerators can handle 250 – 3000 pounds of waste per day with burn rates of 100 – 300 pounds/hour and burn at up to 1600 degrees F. These are designed for use by farmers or veterinarians destroying animal carcasses and for law enforcement destroying contraband.

Devices for RMW shredding with sterilizing are not currently used by Army MTFs. These devices render RMW unrecognizable and remove any chance of infection by killing bacteria and viruses using steam, dry heat, chemicals, or microwave radiation. The disinfected waste is disposed of as a non-regulated solid waste. State and local solid waste and RMW regulations apply to facilities using these devices. Garrison or MTF staff could operate the devices and environmental and preventative medicine staff would oversee their use. Onsite RMW treatment may be considered as a contingency option to existing RMW contracts. Examples are given below. Capabilities are from marketing literature and are provided for illustrative purposes only.

- BMM Weston Ecodas™ shredder sterilizer. Shreds and applies steam heat and pressure to disinfect medical waste. Batch capacities range from 40 – 525 gallons/cycle.

- SteriMed medical waste processors. Shred RMW, disinfect with chemical disinfectant SterCid, and dewater. Batch capacities are up to 18 gallons RMW or 4 gallons sharps.

- Med Legal/Sanitec Microwave Disinfection System™. Shreds and grinds wastes and thermally treats it using microwaves. Capacity is up to 1800 pounds/hour RMW.

Pharmaceutical treatment or disposal methods range from onsite stabilization to mail-back to third-party vendors (that is, parties other than the manufacturer or the MTF) and are not typically used by Army MTFs. These methods are regulated under hazardous waste, RMW, controlled substances, and transportation regulations, depending on the waste, how it's transported and disposed, and whether the waste comes from the MTF or from the patient's household. The treatment or disposal method may be used by either MTF staff or patients. Preventive medicine and garrison environmental staff would oversee MTF use and could advise but would not oversee patient use. These methods are typically marketed to MTFs or patients for the management of non-hazardous, non-controlled substance pharmaceuticals only. Examples are given below. Capabilities are from marketing literature and are provided for illustrative purposes only.

- Drug Buster Instant Disposal System™ is a liquid that dissolves medications (including controlled substances) so they are unrecoverable and can be disposed of as non-regulated solid waste.

- Cactus Smart Sink™. This device contains chemicals in cartridges that make solid or liquid medications unrecoverable and safe for solid waste disposal.

- MedClean Management Solutions pharmaceutical mail-back program. Prepaid containers are provided, filled with waste pharmaceuticals and mailed to the company for disposal. Hazardous pharmaceutical waste, controlled substances, RMW, or other hazardous waste are not accepted.

Evaluating Treatment Effectiveness

For a given waste treatment or disposal technology, the treatment effectiveness is a measure of the technology's elimination or reduction of a waste's hazards to levels below regulatory requirements. Applicable federal, state, local, and Army

regulations identify the hazards, the treatment level, and how the facility or manufacturer must demonstrate treatment effectiveness. Facilities may need to demonstrate site technology treatment effectiveness as part of a state or local waste treatment permit application. The guidelines below only apply to waste generated by an MTF, not to RMW or pharmaceutical waste generated by patients in their homes.

The hazard of RMW is the risk of infection from bacteria or viruses. RMW treatment is effective if it inactivates or kills a significant number of the microorganisms that can cause infection. Because RMW is regulated at the state level, treatment standards are set by state regulation and typically require a significant reduction in test microorganisms. A representative treatment standard, from Colorado state regulations (Colorado DPHE 2012), is below.

> "….a 6 Log10 reduction (i.e., a 99.9999% reduction) in the concentration of the biological indicator Mycobacterium phlei or Mycobacterium bovis AND a 4 Log10 reduction (i.e., a 99.99% reduction) in the level of biological indicator Bacillus stearothermophilus, Bacillus subtilis or Bacillus atrophaeus endospores."

The EPA report *Guidance for Evaluating Medical Waste Treatment Technologies January 1993* (USEPA 1993) describes in general inactivation levels, test organism selection, and test load preparation, exposure, and evaluation. The report discusses incineration, steam autoclaving, chemical and mechanical/chemical, and non-ionizing radiation treatments. A similar 1990 report from the U.S. Congress Office of Technology Assessment (U.S. Congress 1990) also evaluates medical waste treatment technologies.

Pharmaceutical waste is hazardous if it is ignitable, corrosive, toxic, or reactive. Hazardous waste treatment is effective if it removes the applicable hazards below regulatory standards or otherwise meets federal and state regulatory treatment standards. Off-site treatment by a contractor and almost all on-site treatment by a garrison requires a permit and incurs significant regulatory oversight.

Controlled substances must be destroyed by a DEA registrant (for example, a hospital, law enforcement, or waste management company) such that they are unrecoverable and beyond reclamation.

Non-hazardous and non-controlled substance pharmaceuticals <u>should</u> be destroyed such that they are unrecoverable and beyond reclamation. In addition,

the active ingredients should not be released into soil, water, or air (USEPA 2010). Unlike other wastes discussed in this section, these wastes are not yet regulated (although state and local exceptions may exist) and facilities need not demonstrate treatment effectiveness.

Facilities should evaluate the impact on treatment effectiveness of technology configuration, operation, and maintenance.

Evaluating Regulatory Compliance

U.S.-based MTFs should consult with the garrison environmental office, the MTF pharmacy, and the preventive medicine ESEO to ensure that new waste treatment or disposal technology complies with applicable regulations. Overseas facilities must ensure new technologies comply with the host nation Final Governing Standards, the Overseas Environmental Baseline Guidance Document, and applicable operating orders.

Other Considerations

Equipment and system installation, calibration, operator training, operation, maintenance, repair, and interface with other garrison or MTF equipment and systems will affect treatment effectiveness, regulatory compliance, and protection of public health and the environment. Ensure that these are addressed during the evaluation.

Army facilities may consider the technologies discussed here for contingency waste management if external waste management facilities or regional transportation are disrupted by weather, natural disaster, or economic factors. When evaluating technology for contingency use, consider how the equipment needs for fuel, electricity, clean water, trained operators, and specialized maintenance will be met during the contingency.

Summary

The Army's current contract waste management approach transfers the responsibility of demonstrating and maintaining treatment effectiveness and regulatory compliance to external waste management contractors. Onsite waste management may reduce costs and provide continuity of operations during weather or natural disasters, but it requires the government to demonstrate and maintain treatment effectiveness and regulatory compliance. Most

manufacturers will be able to provide documents necessary to meet the applicable federal, state, local, or host nation regulatory requirements. Otherwise, the garrison or MTF must purchase the necessary sampling and regulatory applications.

Include the following in the evaluation of and return on investment calculations for alternative waste management technology:

- Understand existing waste management processes, including the waste hazardous and regulatory status, waste generation volumes or weights, labor, collection, packaging, storage, transportation, and final disposal.

- Review applicable federal, state, local, Army, and DOD regulations.

- Coordinate with garrison environmental, preventive medicine, existing waste management contract managers, garrison operations and management staff, and facility managers.

- Determine how the new equipment will be operated and maintained during normal operation and during any contingencies.

- Document treatment effectiveness with manufacturer literature or through sampling.

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Appendix A

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