Infectious Liquid Regulated Medical Waste Management: The Impact on Infection Control, Employee Health and Environmental Pollution

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Fluid medical waste streams collected by hospitals, ambulatory surgery centers and other medical treatment facilities (MTFs), containing blood, body fluids or other potentially infectious materials (OPIM), are classified as an infectious liquid regulated medical waste (RMW) in the United States by federal, state and local government agencies. At the same time, with exceptions enacted by some state and local agencies, these infectious liquid RMWs are discharged untreated to municipal sanitary sewer systems in all 50 States.

The paradox is the result of three critical factors: 1.) lack of a commercially available on-site treatment system to base unified regulatory standards; 2.) reliance on publicly owned treatment works (POTWs) to be able to treat liquid RMW; and, 3.) absence of a single, unifying set of federal, state and local regulations governing liquid RMW disposal practices. A closer look at liquid RMW in terms of regulatory landscape, treatment alternatives and the POTW burden underscores the challenges surrounding infection control, employee health and environmental pollution faced by hospitals and other MTFs in the "cradle-to-grave" management of liquid RMW and explains why liquid RMW is being discharged untreated to sanitary sewer systems.

1.0 Navigating Disparate Regulatory Standards

1.1 Federal Regulatory Agencies

Individual agency federal regulations that address infectious liquid RMW are concerned with workplace handling and transportation of liquid and solid RMW and disposal of solid RMW. Liquid RMW is recognized as a hazard to employees in the workplace and to the public during off-site transport for disposal; yet there are no federal regulations governing the disposal of infectious liquid RMW or federal prohibitions to the discharge of infectious liquid RMW to sanitary sewer systems. The majority of regulations governing the definition and disposal of liquid and solid RMW are enacted at the state and local level, with regulatory oversight in many states shared by multiple agencies. The following federal agencies are responsible for regulations pertaining to infectious liquid RMW.

OHSA

The U.S. Department of Labor, Occupational Safety and Health Administration (OSHA), *"Occupational Safety and Health Act of 1970"* classifies liquid medical wastes as *"biohazardous"* or *"infectious medical"* RMW for their potential to spread infections and diseases. Employees responsible for their collection and handling for disposal are protected under exposure control plans that meet the requirements of OSHA's Bloodborne pathogens standard.[1]

EPA

The U.S. Environmental Protection Agency (EPA) has played a historical leadership role in focusing attention on and developing regulations for infectious medical waste management through their *"EPA Guide for Infectious Waste Management"*[2] published in 1986 and the "*Medical Waste Tracking Act of 1988"* [3](MWTA).

The *"EPA Guide for Infectious Waste Management"* focused primarily on solid infectious medical waste and is dated in terms of today's understanding of infectious medical waste and available treatment technologies. However the Guide made three noteworthy observations that were precedent to today's growing concern over the discharge of untreated liquid RMW to the sanitary sewer: 1.) *"On-site treatment of infectious waste provides the advantage of a single facility or generator maintaining control of the waste"*[4]; 2.) *"… treated liquid infectious waste or ground up solids may be discharged directly to the sanitary sewer"*[5]; and, 3.) *"… blood and blood products also may be discharged directly to the sanitary sewer for treatment in the municipal sewerage treatment system provided that secondary treatment is available."*[6] The emphasis in their guidelines is "on-site" and "treated" for direct discharge to sanitary sewers.

The "*Medical Waste Tracking Act of 1988"* (MWTA) enabled the EPA to create a two year medical waste management and tracking system demonstration program which produced studies and standards related to the creation, transportation and destruction of solid RMW. The program drew national attention to the hazardous potential of solid RMW and has served as a model for states and other federal agencies in developing their respective medical waste management programs.

Today, the EPA maintains regulatory oversight of medical waste management through the *"Resource Conservation and Recovery Act"* (RCRA) which regulates hospital "cradle-to-grave" management of solid RMW[7], the *"Clean Air Act"*

[1] Bloodborne pathogens, 29 C.F.R. §1910.1030 (2015)
[2] U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response, "EPA Guide for Infectious Waste Management", National Technical Information Service, U.S. Department of Commerce, May 1986.
[3] Demonstration Medical Waste Tracking Program, 42 U.S.C. 82 §6992
[4] U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response, "EPA Guide for Infectious Waste Management", National Technical Information Service, U.S. Department of Commerce, May 1986. pp. 33
[5] Ibid pp. 64
[6] Ibid pp. 66
[7] Protection of the Environment, 40 C.F.R. §240 - §282 (2015)

(CCA) which regulates air pollution emissions from hospital, medical and other infectious waste incinerators[8] and the *"Federal Insecticide, Fungicide and Rodenticide Act"* (FIFRA) which requires registration of all antimicrobial agents and claims for the treatment of RMW.[9]

DOT

The U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration (PHMSA), *"Hazardous Materials Regulations"* (HMR) classify liquid medical wastes as a "Division 6.2 material" defined as an *"infectious substance"* RMW known or reasonable expected to cause illness or disease in humans. HMR establishes "Regulated Medical Waste Packaging" regulations to ensure safe transportation and public safety when RMW is being transported by highway, rail, water or air and places responsibility for compliant packaging on the hospital as the shipper.[10]

Commercial acceptance of liquid medical waste solidifiers used by hospitals and other medical treatment facilities, for the gelation of liquid medical wastes collected in disposable suction canisters, requires a further explanation of how "solidification" of liquid RMW by hospitals relates to the "Regulated Medical Waste Packaging" in the HMR.[11] The relationship exists because HMR makes key distinctions between packaging requirements for liquid and solid RMW and provides the definitions hospitals should use in determining whether they are packaging a liquid or solid RMW for off-site transport.

Key distinctions in the packaging requirements are: 1.) Liquid RMW require *"a watertight primary receptacle"*, *"a watertight secondary packaging"*, *"an outer packaging"* and *"an absorbent material between the secondary and outer packagings"* capable of absorbing the total volume of liquid waste; and, 2.) Solid RMW may use a *"plastic film bag"* as an inner packaging when placed in a wheeled cart or bulk outer packaging. The regulatory criteria that determine whether the RMW is a liquid or solid is based on the material's phase at a specified ambient temperature set forth in the regulation.[12]

The critical issue raised for hospitals using liquid medical waste solidifiers is whether the "solidified" RMW has to meet the regulatory packaging requirements set forth for a liquid or solid RMW. In the case of packaging a RMW containing absorbed liquid, such as liquid medical waste that has been treated with a liquid medical waste solidifier the regulations state the *"absorbed liquid may be packaged as a solid in a plastic film bag if the bag contains sufficient absorbent material to absorb and retain all liquid during transportation"*.[13] In addition, while "solidification" may phase change a "free flowing liquid" into a "solid" for handling within the hospital, if the "solidified" RMW may be exposed to temperatures or other environmental exposures that would cause the "solid" material to become a liquid during transportation the hospital is required to package the "solidified" RMW to meet regulations governing the packaging of liquid RMW.[14] Furthermore, recognizing that "solidified" liquid RMW may phase change back to a "free flowing liquid" raises the issue of "solidified" liquid RMW that remains a "solid" during the time of transportation and phase changes to a "free flowing liquid" after disposition in a landfill that is restricted to accepting only solid medical waste. In this case regulatory compliance with PHSMA regulations may result in an environmental non-compliance where landfill restrictions limit acceptance to solid medical waste.

In summation PHSMA regulations govern the packaging of RMW by hospitals for off-site transportation and do not regulate the handling ("solidification") of RMW within hospitals or the disposal of "solidified" RMW by hospitals.

[8] Emission Guidelines and Compliance Times for Hospital/Medical/Infectious Waste Incinerators, C.F.R. §60 (C)(e) (2009)
[9] Pesticide Registration and Classification Procedures, 40 C.F.R. §152 (2011)
[10] Shippers-General Requirements for Shipments and Packagings, Regulated Medical Waste, 49 C.F.R. §173.197 (2015)
[11] Shippers-General Requirements for Shipments and Packagings, Category A infectious substances, 49 C.F.R. §173.196 (2015)
[12] General Information, Regulations and Definitions, 49 C.F.R. §171.8 (2015)
[13] Shippers-General Requirements for Shipments and Packagings, Regulated Medical Waste, 49 C.F.R. §173.197 (e)(1) (2015)
[14] General requirements for packagings and packages, 49 C.F.R. §173.24(e)(5) (2015)

1.2 State Regulatory Agencies

While all 50 States adhere to federal medical waste management regulations in defining solid and liquid medical waste as a RMW, States differ in their approach to regulatory agency oversight and their scope of regulations that govern medical waste management by hospitals and other MTFs. In some States it is the Department of Public Health or the Department of Environmental Protection and in other States both agencies may share oversight. With regard to on-site and off-site management and disposal practices for RMW the States follow a generally accepted practice of requiring RMW registration and approval for landfilling and incineration, if permitted in the State. However, regulations governing the discharge of untreated liquid RMW to sanitary sewer systems are typically deferred to local government agencies and their respective POTWs responsible for issuing discharge permits to the hospitals and other MTFs. A select sampling of States and their regulations pertaining to medical waste are detailed below.

Colorado

In the State of Colorado, the Department of Public Health and Environment has jurisdiction over all aspects of medical waste management detailed within the State's solid waste regulations: 6 CCR 1007-2, Part 1, Regulations Pertaining to Solid Waste Sites and Facilities, Section 13 of this regulation covers medical waste *"…applies to all medical waste generators, transporters and treatment, storage and/or disposal facilities, unless otherwise exempted, that generate, store, consolidate, treat, process, transport or dispose…"*

Colorado classifies infectious liquid medical waste as a RMW, and states *"13.9.2 Infectious Waste (B) Once treated to achieve the required standard of biological inactivation, infectious waste is considered to have been rendered noninfectious and may be discharged into a sanitary sewer system…"* Furthermore, 13.9.2 Infectious Waste (C) states *"Discharge to a sanitary sewage treatment system is permitted only if discharged in accordance with the wastewater treatment facility's requirements, as applicable, and may require notification to and approval from the wastewater treatment authority."* [15] To date, this is the only documented instance of a State with regulations concerning the treatment and disposal of infectious liquid RMW to the sanitary sewer system.

New Jersey

In the State of New Jersey, the Department of Environmental Protection and the Department of Health have jurisdiction over the State's Comprehensive Regulated Medical Waste Management Act. This act defines a comprehensive program to manage all aspects of *"…regulated medical waste as defined at N.J.A.C. 7:26-3A.6. that is generated, stored, transported, collected, transferred, treated, destroyed, disposed of or otherwise managed in New Jersey."*[16] While infectious liquid medical waste is recognized as a RMW, there is no prohibition referenced in the regulations to the discharge of liquid RMW to sanitary sewer systems. The State defers the disposal of liquid RMW generated by hospitals and other MTFs to local government agencies and permit approvals to the POTW responsible for coupling the hospital to their sanitary sewer system.

Pennsylvania

In the State of Pennsylvania, the Department of Environmental Protection has jurisdiction over the management of infectious waste, including rules for storage, transport, disposal, licensing and processing, defined in PA Code Chapter 284 Regulated Medical and Chemotherapeutic Waste.[17] While infectious liquid medical waste is recognized as a RMW, there is no prohibition referenced in the regulations to the discharge of liquid RMW to sanitary sewer systems.

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[15] 6 CCR 1007-2, Part 1, Regulations Pertaining to Solid Waste Sites and Facilities, Section 13 Medical Waste. Colorado Department of Public Health and Environment. Available at: https://www.colorado.gov/pacific/sites/default/files/Part%201%20eff%2006-30-15.pdf

[16] Title 7. Environmental Protection, Chapter 26. Solid Waste, Subchapter 3A. Regulated Medical Waste, N.J.A.C. 7:26-3A.1 (2009). Available at: http://www.state.nj.us/dep/dshw/resource/2009%20RULES/26%20CHAPTER%203A.pdf

[17] Chapter 284, Regulated Medical and Chemotherapeutic Waste. Pennsylvania Code. Available at: http://www.pacode.com/secure/data/025/chapter284/025_0284.pdf

The State defers the disposal of liquid RMW generated by hospitals and other MTFs to local government agencies and permit approvals to the POTW responsible for coupling the hospital to their sanitary sewer system.

Tennessee

In the State of Tennessee, there is no regulation or department with jurisdiction over the comprehensive management of medical waste, including generation, storage, transportation, or treatment. Tennessee regulations only regulate the disposal of medical waste under The Tennessee Solid Waste Disposal Act.[18] The Tennessee Department of Environment & Conservation (TDEC) which has jurisdiction over solid waste disposal expands the definition of solid waste to include infectious liquid medical wastes as a RMW.[19] While TDEC recognizes infectious liquid medical wastes as a RMW in stating that *"Human blood and blood products and other body fluids may not be landfilled."*[20]; there is no prohibition referenced in the regulations to the discharge of liquid RMW to sanitary sewer systems. The State defers the disposal of liquid RMW generated by hospitals and other MTFs to local government agencies and permit approvals to the POTW responsible for coupling the hospital to their sanitary sewer system.

1.3 Local Regulatory Agencies

In anticipating that federal and state agencies will drive legislative prohibition, there is a tendency to overlook the emerging role being played by local regulatory agencies to protect their communities. In addressing the discharge of untreated RMW to sanitary sewer systems and landfills, it should be noted that medical waste management regulations unlike other regulations in the healthcare industry are unique in that they do not flow down from a single federal or state agency or regulatory standard.

As a result RMW is governed by three independent federal agencies: OSHA, EPA, and DOT. None of these agencies address the discharge of infectious liquid RMW to sanitary sewers or landfills. The States have begun to address liquid RMW disposal with varying levels of regulation from California's[21] and Colorado's[22] comprehensive requirements for handling, treatment and disposal to Tennessee's[23] minimal regulations concerning only landfill disposal. The majority of states today defer the disposal of infectious liquid RMW to local communities and their POTWs.

While local regulations vary as much as the States from strict[24] to nonexistent; it is becoming increasingly apparent that there is a growing public awareness within communities of the threat to human health and the environment from infectious liquid RMW discharges to sanitary sewer systems and landfills. Cities across the United States are enacting ordinances at the local level prohibiting the discharge of infectious liquid RMW to sanitary sewer systems and landfills. Furthermore city ordinances and municipal codes are starting to acknowledge the limitations of current WWTPs to

[18] Part definitions, Tennessee Solid Waste Disposal Act, Chapter 211 – Solid Waste Disposal §68-211-103(8)(A) (2014). Available at: http://law.justia.com/codes/tennessee/2014/title-68/environmental/chapter-211/part-1/section-68-211-103/

[19] Medical Wastes, Solid Waste Processing and Disposal, Solid Waste Management, Tennessee Department of Environment and Conservation, Rule 0400-11-01-.01(a) to 0400-11-.01(g). Available at: http://share.tn.gov/sos/rules/0400/0400-11/0400-11-01.20150527.pdf

[20] Medical Wastes, Solid Waste Processing and Disposal, Solid Waste Management, Tennessee Department of Environment and Conservation, Rule 0400-11-01-.04(iii).. Available at: http://share.tn.gov/sos/rules/0400/0400-11/0400-11-01.20150527.pdf

[21] Medical Waste Management Act, California Health and Safety Code Sections 117600 – 118360. California Department of Public Health. Available at: https://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/2013/MWMAfinal2015.pdf

[22] "Medical and Pharmaceutical Waste Guidance." Colorado Department of Public Health and Environment. Available at: https://www.colorado.gov/pacific/cdphe/medical-and-pharmaceutical-waste-guidance

[23] Medical Wastes, Solid Waste Processing and Disposal, Solid Waste Management, Tennessee Department of Environment and Conservation, Rule 0400-11-01-.01(a) to 0400-11-.01(g). Available at: http://share.tn.gov/sos/rules/0400/0400-11/0400-11-01.20150527.pdf

[24] Discharge of Wastes Into Public Sewer and Storm Drain Systems, Riverside Municipal Code, Riverside, California, Chapter 14.12.240 Infectious Waste Disposal. (Ord. 7032 §2, 2009; Ord. 6637 §2 (part), 2002; Ord. 6232 §2 (part), 1995). Available at: https://www.riversideca.gov/municode/pdf/14/14-12.pdf

manage hospital discharges of infectious liquid RMW reflecting the inherent environmental liability risk being documented in a growing body of published scientific studies.

Anchorage, Alaska

AMC 26.50.050 and AMC 26.50.060:

"It shall be unlawful for any user to discharge or cause to be discharged any wastewater containing medical wastes from industrial users including but not limited to hospitals, clinics, offices of medical doctors, convalescent homes, medical laboratories or other medical facilities."[25]

Riverside, California

Section 14.12.240 Infectious Waste Disposal:

"A. No user that generates liquid infectious waste other than domestic wastewater shall discharge to the POTW without first obtaining written permission from the Director. Such a user shall submit a written request to the Director that shall include: 1. The source and volume of the infectious waste; 2. The procedures and equipment used for waste disinfection; and 3. Employee training procedures for the legal disposal of infectious waste.

B. If the Director believes that the waste would not be completely disinfected, the Director shall issue a written denial to the user and state the reasons for the denial. This denial shall be issued within thirty days from receipt of the written request.

C. If the Director believes that complete disinfection of the waste can be achieved prior to discharge of the waste to the POTW, then a conditional approval may be granted for the disposal of the waste."[26]

Camden, New Jersey

2.0 Prohibitions and Limitations on Wastewater Discharges:

"No person may discharge, or allow to be discharged, into the treatment works of the Authority or any Participant, any wastewater which causes pass-through or interference, or contributes to a violation of any parameter in the Authority's NJPDES Permit or to a violation of a participant's sewer use ordinance…

Medical Waste - Undisinfected tissue fluid, diseased human or animal organ tissue, undisinfected whole blood, or other contaminated solid waste related to the transmission of disease from human or veterinary hospitals, medical facilities, pharmaceutical/research institutions, mortuaries, morgues, funeral parlors, animal shelters or related licensed facilities."[27]

Chattanooga, Tennessee

Section 31-17 and Section 31-51:

"Code of Ordinances" states *"It shall be unlawful for any person to dispose of pathological waste, surgical operating room waste or delivery room waste by discharging same to the city's sewer system."*[28] The Code further states in "Division 2 Pretreatment Standards" on discharges to the POTW *"No person shall introduce into the publicly owned treatment works any pollutant(s) which cause pass through or interference. Additionally, the following specific prohibitions apply: Medical wastes, unless specifically authorized by the superintendent."*[29]

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[25] Prohibited Acts. Pollutant Limits. Anchorage Municipal Sewer Use Code. AMC 26.50.050 and AMC 26.50.060 Available at: https://www.awwu.biz/publicWebsite/media/documents/FieldService/Discharge/AMC_26-50-26-60.pdf

[26] Infectious Waste Disposal. Discharge of Wastes Into Public Sewer and Storm Drain Systems. Riverside Municipal Code. Section 14.12.240. Available at: http://www.riversideca.gov/municode/pdf/14/14-12.pdf

[27] Prohibitions and Limitations on Wastewater Discharges. Camden, New Jersey. Sewer Use Ordinance. Section 2.1. Available at: http://www.ccmua.org/wp-content/uploads/2010/12/SECTION-2-FINAL-STREAMLING.pdf

[28] Hospital or pathological waste, Code of City Ordinances, Chattanooga, Tennessee, Ord. Section 31-17, No. 9409 §1, 6-5-90. Available at: http://www.chattanooga.gov/city-council-files/CityCode/31%20-%20Sewers,%20Mains%20and%20Drainage.pdf

[29] Prohibitions and limitations on discharge into the Publicly Owned treatment works, Code of City Ordinances, Chattanooga, Tennessee, Ord. Section 31-51(b)(13), No. 9409 §2, 6-5-90, Ord. No.12428 §2, 8-31-10. Available at: http://www.chattanooga.gov/city-council-files/CityCode/31%20-%20Sewers,%20Mains%20and%20Drainage.pdf

2.0 Disposal Practices and Biohazard Exposures

While liquid RMW streams are recognized as an infectious biohazard and regulated in their collection and handling to protect patients and employees; the healthcare industry relies on discharging these RMW streams untreated to sanitary sewer systems, landfills, and incinerators. These three generally accepted disposal practices have emerged within the healthcare industry because: 1.) there are no commercially available treatment systems or products for on-site treatment of infectious liquid medical waste stream volumes collected by hospitals and other MTFs; 2.) there is a misplaced reliance upon POTWs to treat all the biological contaminants in infectious liquid RMW; and 3.) the regulatory landscape for medical waste disposal is disparate and spread across multiple authorities within the federal, state and local agencies responsible for regulation.

In the United States there are over 260,000 MTFs generating liquid infectious RMW. Among these MTFs are 11,000 hospitals and ambulatory surgical centers which performed 51.4 million procedures in 2010, according to the Centers for Disease Control and Prevention.[30] These 51.4 million procedures are estimated to have generated approximately 154.2 million gallons of infectious liquid RMW. This volume does not include infectious liquid RMW streams generated from outpatient procedures or healthcare activities in the emergency department and intensive care units.

Hospitals and other MTFs collect these waste streams in: 1.) large capacity fluid medical waste management systems; 2.) small capacity disposable suction canisters with and without disposable liners; and 3.) a variety of fluid collection bags. The choice of collection device is dependent on the surgical procedure or care activity and the amount of anticipated collected liquid waste. Collected liquid waste volumes include surgical irrigant used during procedures.

After collection these infectious liquid RMW streams are disposed of in one of three methods: 1.) on-site as an untreated discharge to the sanitary sewer system; 2.) off-site as an untreated infectious liquid or “solidified” infectious RMW in canisters or bags sent to landfills; or 3.) off-site as an untreated infectious liquid or “solidified” infectious RMW in canisters or bags sent to incinerators. All three disposal methods represent an escalating threat to healthcare workers, patients, and the community from the spread of infectious diseases and environmental pollution.

On-site discharge to the sanitary sewer system and off-site transport and disposal in landfills both result in additional incidental contact exposures for employees handling the infectious RMW coupled with the loss of control over the environmental fate of infectious RMW streams. Off-site transport and disposal by incineration also increases the potential for additional incidental contact exposures for employees handling the infectious RMW and creates hazardous airborne emission exposures for the community.

2.1 On-Site: Sanitary Sewer System Discharge

On-site discharge to sanitary sewer systems is one of three practiced methods in the healthcare industry for the disposal of infectious liquid RMW streams. After collection in reusable suction canisters, disposal suction canisters or kick buckets, the infectious liquid RMW is discharged to the sanitary sewer system through two common disposal methods: 1.) drain disposal via standpipes or floor drains in biohazard and soiled utility rooms; and, 2.) flush disposal via flush sinks in biohazard and soiled utility rooms or toilet disposal in patient rooms or shared bathrooms.

These two disposal methods not only present hazardous exposures to employees and patients, discharging infectious liquid RMW streams to the sanitary sewer system impact the public health of the community and environment. All forms of on-site untreated disposal to sanitary sewer systems represent a loss of control over the environmental fate of an infectious liquid RMW stream.

While hospital wastewater discharges are being permitted by POTWs, there is a growing recognition that wastewater treatment plants (WWTPs) are not designed to treat infectious liquid RMW. Scientific studies have documented the

[30] “Inpatient Surgery.” Hospital and Ambulatory Care. FastStats. Centers for Disease Control and Prevention. Available at: http://www.cdc.gov/nchs/fastats/inpatient-surgery.htm

release of antibiotic resistant bacteria and viruses in the watersheds downstream of WWTPs receiving hospital wastewater.

Drain Disposal

Drain disposal is most often used with fluid management systems. These systems are recognized as “closed” systems designed to protect the employee and the patient from exposures during collection and disposal of an infectious liquid RMW. However when these “closed” fluid management systems are connected to a standpipe or floor drain, the “closed” system is breached creating potential infection control and employee health hazards. Both standpipes and floor drains vent to the atmosphere in the room where they are located creating a potential for release of infectious liquid RMW bioaerosols. When mobilized these bioaerosols may redeposit on contact surfaces within the room or remain airborne as an inhalation hazard with both events representing a potential exposure of employees to pathogenic microorganisms.[31]

Another common drain disposal exposure hazard is the formation of infectious liquid RMW biofilms on the fluid management systems drain hoses and within the drain piping and P-traps. These biofilm formations result from phase changes in the liquid RMW stream where protein and lipid particles agglomerate onto the wetted contact surfaces of the drain hoses and piping system. Biofilm formations can harbor pathogenic microorganisms and release bioaerosols readily recognized as noxious odors. Moreover, these biofilm formations have been found to clog the P-traps of standpipes and floor drains, resulting in the backflow of infectious liquid RMW creating infection control and employee health hazards.

Flush Sinks

Flush sinks are most often used with disposal suction canisters and collection bags; although it is not uncommon for fluid management systems to be discharged into flush sinks when a floor drain or standpipe is not available. These disposable containers with the collected infectious liquid RMW are carried to the nearest flush sink or toilet which may be located in the patient’s room or nearby bathroom. The canister or bag is opened and poured into the basin of the sink or toilet and flushed into the sanitary sewer system.

Pouring and flushing is a discharge site specific potential infection control issue as well as a hazardous exposure to both employees and patients. The infectious liquid RMW stream can splatter onto surround sink and toilet surfaces and onto the employee.[32] Furthermore, pouring and flushing creates an aerosolization of the infectious liquid RMW and exposes the site, the employees and the patients to pathogenic microorganisms.[33] Also inherent in flush disposal is the potential for a clogged flush sink or toilet to overflow, presenting an additional hazardous exposure to employees and patients.

2.2 Off-Site: Transport and Disposal

Off-site transport of infectious liquid RMW in disposable suction canisters and collection bags to landfills and incinerators is another generally accepted disposal practice in the healthcare industry. The infectious liquid RMW may or may not be “solidified” with liquid medical waste solidifier to reduce DOT packaging requirements and minimize incidental contact exposures during handling within the hospital.

[31] Cole, E. C., and C. E. Cook. 1998. “Characterization of Infectious Aerosols in Health Care Facilities: An Aid to Effective Engineering Controls and Preventive Strategies.” American Journal of Infection Control 26 (4): 453–64.
[32] Verani, Marco, Roberto Bigazzi, and Annalaura Carducci. 2014. “Viral Contamination of Aerosol and Surfaces through Toilet Use in Health Care and Other Settings.” American Journal of Infection Control 42 (7): 758–62.
[33] Barker, J., and M. V. Jones. 2005. “The Potential Spread of Infection Caused by Aerosol Contamination of Surfaces after Flushing a Domestic Toilet.” Journal of Applied Microbiology 99 (2): 339–47

Autoclaving may also be employed prior to off-site transport to treat the infectious liquid or "solidified" RMW. It should be noted that there is a significant variable in claiming the efficacy of autoclaving to treat RMW that has been collected in disposable suction canisters and other collection bags and then placed in biohazard bags. Autoclave claims are dependent on time at temperature. The heat transfer properties and density of the RMW in the biohazard bag may not allow the rated autoclave time and temperature to reach the center of mass within the bulk volume of the packaged RMW.

Whether infectious liquid RMW remains untreated or is treated on-site by adding a solidifier or by autoclave sterilization; off-site transport for disposal in either landfills or incinerators places additional biohazard risks on the employee, the public and the environment. Off-site transport creates additional risks for biohazard exposures from: 1.) employee handling required during processing to landfills or incinerators; 2.) loss of control over the environmental fate of infectious RMW disposed of in landfills; and, 3.) hazardous airborne emissions from incinerators.

Liquid RMW Solidification

The primary application for liquid medical waste solidifiers used by hospitals and other MTFs is to "solidify" their infectious liquid RMW, collected in disposable suction canisters and disposable suction canister liners, for off-site transport to a disposal site. Solidification of the liquid RMW allows the hospital, as the shipper responsible for packaging RMW, to meet less stringent DOT hazardous material packaging regulations for off-site transportation of their collected liquid RMW as a solid RMW. A secondary application for liquid medical waste solidifiers is the reduction of incidental contact exposures to employees from handling infectious liquid RMW in canisters that may spill, leak or "drop and break" during transport within the hospital.

In addition some solidifiers are branded as a solidifier/disinfectant containing EPA registered antimicrobial products for the treatment of liquid medical waste that can be subsequently disposed of as a white bag waste in landfills. Among the more common disinfectants employed as a "sanitizing" or "disinfecting' agent in these solidifiers are chlorine and glutaraldehyde which are on the EPA list of registered antimicrobials for medical waste treatment.[34] (Note: EPA's disclaimer cites that the *"… list does not constitute an endorsement by EPA."*) Furthermore a solidifier that incorporates an EPA registered antimicrobial may not make any claims regarding "sanitization" or "disinfection" unless that solidifier has been *"…properly tested and registered with EPA…".*[35] It also should be noted antimicrobials add additional significant solidifier handling exposure hazards to hospital employees responsible for solidification of disposable suction canisters. For example, glutaraldehyde is recognized as an eye, skin and inhalation irritant known to cause conjunctivitis, asthma, headaches, nausea, nosebleed and allergic dermatitis.[36]

Liquid medical waste solidifiers are based on a group of super-absorbent polymers (SAP) chemistries with sodium polyacrylate among the most common SAP employed to solidify infectious liquid RMW. The term "liquid medical waste solidifier" requires a further study to understand the SAP solidification mechanism that is responsible for the phase change from a liquid to a solid. In the case of sodium polyacrylate based solidifiers the solidification mechanism is osmotic pressure which means the solidifier can both absorb and release liquid RMW. Solidification is not a permanent state of the solidified waste. The solidification mechanism is sodium present in the solidifier exchanging places with water in the surrounding liquid by osmotic pressure until the amount of sodium in the solidifier and in the surrounding liquid are in balance creating a gel-like substance or "solidification" of the collected

[34] List J: EPA's Registered Antimicrobial Products for Medical Waste Treatment, August 17, 2012, Office of Pesticide Programs, U.S. Environmental Protection Agency. Available at: http://www2.epa.gov/sites/production/files/2015-09/documents/list_j_medicalwaste.pdf

[35] "In Precedent-Setting Case, Maker of "Antibacterial" Hospital Products Settles With EPA; EPA Warns Consumers of Unsubstantiated Germ-Killing Claims", U.S. Environmental Protection Agency, Newsroom 11/09/1998. Available at: http://yosemite.epa.gov/opa/admpress.nsf

[36] Glutaraldehyde – Occupational Hazards in Hospitals, Centers for Disease Control and Prevention, National Institute of Occupational Safety and Health, NIOSH Publication No. 2001-115. Available at: http://www.cdc.gov/niosh/docs/2001-115/#2

liquid RMW.[37] Since the absorption mechanism that produces "solidification" is based on osmotic pressure, there are significant bulk volume behaviors that should be taken into account in evaluating a liquid medical waste solidifier based on sodium polyacrylate technology.

The presence of sodium (saline solution) or other mineral salts in the collected liquid RMW reduces the sodium exchange, degrading the absorption capacity of the solidifier. This can account for hospitals experiencing solidified liquid RMW that is not entirely solidified and retains sufficient infectious liquid RMW in the canister to be an employee exposure hazard during handling. Furthermore, subsequent exposure of the solidified liquid RMW to sodium, calcium and other mineral salts in the environment that may be present in landfills can reverse "solidification", returning by the same osmotic pressure the solidified liquid RMW to a free-flowing liquid RMW component of landfill leachate.

Landfilling

Landfilling is a common method for the disposal of infectious RMW. Hospitals and other MTFs typically contract out the transport of their generated wastes to certified medical waste transporters, who deliver medical waste to landfills approved for receipt of medical waste. The regulations governing this disposal practice are highly variable depending upon the state and location of the landfill.

Most states, such as Tennessee, prohibit landfilling any infectious liquid RMW, requiring liquid waste to be solidified prior to disposal. Many states[38] go one step further, prohibiting landfilling of infectious RMW altogether. Instead, the waste must be treated on-site by the medical waste generator or at a state approved medical waste treatment facility, prior to disposal in a permitted landfill.[39] Regardless of regulatory oversight, the landfilling of infectious RMW is all too often performed in a manner that violates state regulations.[40,41]

While many landfills prohibit the disposal of untreated infectious RMW, the landfills that do accept this waste create a public health hazard and contribute to pollution of the surrounding environment. This hazard is most evident in the dispersal of landfill leachate, or polluted water, to the surrounding environment. Depending on the design and age of the landfill, leachate drainage will result in an uncontrolled release of toxic drug residuals and pathogenic microorganisms to watersheds and the surrounding environment. Landfill leachate is created as *"biologic, chemical, and physical processes occur that promote degradation of wastes."*[42] The breakdown of solidified infectious liquid RMW is one of the many wastes that is broken down and transforms from a solid into a liquid. Any pathogenic microorganisms contained in the previously solidified infectious RMW are free to drain through the landfill as a component of the leachate. This represents a loss of control over the environmental fate of the infectious liquid RMW and poses a health hazard to the public and the surrounding environment.[43]

[37] Kiatkamjornwong S, (2007) Superabsorbent Polymers and Superabsorbent Polymer Composites, Science Asia 33 Supplement 1: 39-43. Available at: http://www.scienceasia.org/2007.33(s1)/v33s_039_043.pdf

[38] Managing and Disposing of Medical Waste. Texas Commission on Environmental Quality. Available at: http://www.tceq.state.tx.us/permitting/waste_permits/msw_permits/mw_disposal.html/#dispose

[39] Table 1. Regulatory Overview of Medical Waste in Kentucky. Department of Environmental Protection. Available at: http://waste.ky.gov/RLA/Documents/Table%201%20-%20Regulatory%20Overview%20of%20Medical%20Waste%20in%20Kentucky.pdf

[40] "Three South Bay hospitals caught dumping untreated medical waste." Barbara Feder Ostrov. San Jose Mercury News. Available at: http://www.mercurynews.com/portlet/article/html/fragments/print_article.jsp?articleId=5757954&siteId=568

[41] "More medical waste found at Monroeville landfill." Paul Van Osdol. Pittsburgh's WTAE. Available at: http://www.wtae.com/investigations/more-medical-waste-found-at-monroeville-landfill/23700940

[42] Reinhart, Debra R., and Philip T. McCreanor. 2000. "Medical Waste Management: Where Does the Solid Waste Go?" Lab Medicine 31 (3): 141–45. Available at: http://labmed.ascpjournals.org/content/31/3/141.full.pdf

[43] Vrijheid, M. (2000). Health effects of residence near hazardous waste landfill sites: a review of epidemiologic literature. Environmental Health Perspectives, 108(Suppl 1), 101–112. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1637771/pdf/envhper00310-0106.pdf

Incineration

Incineration is common method for the treatment and disposal of infectious liquid RMW. Similar to landfilling, hospitals and other MTFs typically contract out the transport of their generated wastes to certified medical waste transporters. These transporters deliver the waste to incinerators, often out of state, approved for the destruction of regulated medical waste. However, many hospitals independently operate or contract with a medical waste management company to operate an on-site medical waste incinerator.

There is a historical trend since the mid-1990s to close incinerators or move them out of state to minimally populated areas. As of 2006, it was reported that fewer than 70 hazardous airborne emission generating incinerators remain in operation, from a high of 5,600 in the 1990s.[44] This trend is from society achieving a better understanding of negative effects caused by incineration, including the creation of persistent organic pollutants (POPs) that are hazardous to human health and the environment.[45]

3.0 Infectious Agents and Environmental Pollution

While infectious liquid RMW is recognized as a biohazard and regulated in collection and handling to protect patients and employees, the healthcare industry has relied on discharging these RMW streams untreated to sanitary sewer systems. This disposal practice has matured within the healthcare industry because: 1.) there is a misplaced reliance upon POTWs to treat all the biological contaminants in infectious liquid RMW; and, 2.) there are no commercially available treatment systems or products for on-site treatment of infectious liquid medical waste stream volumes collected by hospitals and other MTFs.

3.1 Public Health Burden on POTWs

The hazards of infectious liquid RMW streams is recognized in the multitude of legislation at the federal, state and local level, with various regulations and agencies responsible for everything from employee and patient safety in the hospital to off-site transport and disposal at landfills and incinerators. However, these hazards have been overlooked when the disposal of infectious liquid RMW is included as part of the overall hospital wastewater discharge to the local WWTP.

Hospital wastewater discharges are composed of many different challenge groups, including pharmaceuticals, antibiotics, X-ray contrast agents, disinfectants and pathogenic microorganisms and are *"…complex mixtures capable of generating major environmental problems, as they are 5 to 15 times more toxic than classical urban effluents,"*[46] Infectious liquid RMW is a substantial portion of the hazards present in hospital wastewater discharges: *"Besides recalcitrant and potent chemicals, hospitals discharge plenty of undesired potentially pathogenic propagules, e.g. antibiotic resistant bacteria, viruses, and maybe even prions, etc."*[47]

Within the scientific community, there is a growing awareness of the detrimental effect that infectious liquid RMW streams have on public health and the environment.[48,49] Multiple peer reviewed articles have documented the

[44] "Environmental health advocate Cohen wins MacArthur 'genius' grant." Adam Rubenfire. (2015). Practice Green Health. Available from: https://practicegreenhealth.org/about/press/news/environmental-health-advocate-cohen-wins-macarthur-genius-grant

[45] Franchini, Michela, Michela Rial, Eva Buiatti, and Fabrizio Bianchi. 2004. "Health Effects of Exposure to Waste Incinerator Emissions: a Review of Epidemiological Studies." Annali dell'Istituto Superiore Di Sanita 40 (1): 101—115. Available from: http://europepmc.org/abstract/med/15269458

[46] Emmanuel, Evens, Marie Gisèle Pierre, and Yves Perrodin. 2009. "Groundwater Contamination by Microbiological and Chemical Substances Released from Hospital Wastewater: Health Risk Assessment for Drinking Water Consumers." Environment International 35 (4): 718–26.

[47] Pauwels, B, and Willy Verstraete. 2006. "The Treatment of Hospital Wastewater: An Appraisal." Journal of Water and Health 04 (4): 405–16.

[48] Emmanuel, E., Y. Perrodin, G. Keck, J.-M. Blanchard, and P. Vermande. 2005. "Ecotoxicological Risk Assessment of Hospital Wastewater: A Proposed Framework for Raw Effluents Discharging into Urban Sewer Network." Journal of Hazardous Materials 117 (1): 1–11.

presence of pathogenic microorganisms, some of which are multi-resistant to antibiotics[50,51], through studies performed on hospital effluents in developed countries around the world: *"physicochemical and microbiological characterization studies performed on hospital effluents in several industrialized countries have highlighted the presence of pathogenic microorganism…"*[46] In their groundbreaking appraisal of the potential for on-site treatment of hospital wastewater, Pauwels and Verstraete concluded through review of the literature that *"hospital wastewaters are a source of bacteria with acquired resistance against antibiotics and this with at least a factor of 2 – 10 higher than domestic sewage."*[47]

WWTPs are burdened by the microbial load posed by hospital wastewater discharges that contribute to the emission and spread of multi-drug resistant bacterial strains[52] and viruses[53] to the environment. Studies document the release of antibiotic resistant bacteria[54] and viruses in the watersheds downstream of wastewater treatment plants (WWTPs) receiving hospital wastewater: *"Although wastewater treatment processes reduce number of bacteria in sewage up 99%, in the presented study it was reported that more than 2.7 x 10^3 CFU/mL E. coli reached the receiving water and contributed to dissemination of resistant bacteria into the environment."*[50] Vancomycin-resistant enterococci (VRE) was found in the final discharge of a wastewater treatment plant *"…suggesting that bacteria from hospital origin may survive the treatment process in the urban treatment plant."*[55] Besides the release of multi-drug resistant bacterial strains to the receiving watersheds of WWTPs, biosolids, a by-product of WWTPs and commonly used for fertilizer, have been found to contain *"organic wastewater contaminants (including AMR [antimicrobial resistant] bacteria and genetic determinants) which are incorporated into the soil similarly allowing for the dissemination of resistance."*[55]

Moreover, today's aging sanitary sewer system infrastructure must handle annual increases in fluid waste volumes as well as storm water runoff, resulting in sanitary sewer system overflows (SSOs) of untreated sewage into the environment. According to the EPA, every year there is an estimated 23,000 – 75,000 SSOs due to *"…blockages, line breaks, sewer defects that allow storm water and groundwater to overload the system, lapses in sewer system operation and maintenance, power failures, inadequate sewer design and vandalism."*[56] Untreated sewage discharge from SSOs and back-ups into residences and businesses results in property damage and creates an additional public health burden upon local communities and watersheds.

In addition to the burden on wastewater treatment processes and the aging of sanitary sewer system infrastructure there is the biohazard risk to the operators of the WWTPs. They confront a daily exposure to the bioaerosolization of multi-drug resistant pathogenic microorganisms during the wastewater collection and treatment process. This transfer

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[49] Orias, Frédéric, and Yves Perrodin. 2013. "Characterisation of the Ecotoxicity of Hospital Effluents: A Review." Science of The Total Environment 454-455 (June): 250–76.
[50] Korzeniewska, Ewa, Anna Korzeniewska, and Monika Harnisz. 2013. "Antibiotic Resistant Escherichia Coli in Hospital and Municipal Sewage and Their Emission to the Environment." Ecotoxicology and Environmental Safety 91 (May): 96–102.
[51] Jakobsen, Lotte, Dorthe Sandvang, Lars H. Hansen, Line Bagger-Skjøt, Henrik Westh, Claus Jørgensen, Dennis S. Hansen, et al. 2008. "Characterisation, Dissemination and Persistence of Gentamicin Resistant Escherichia Coli from a Danish University Hospital to the Waste Water Environment." Environment International 34 (1): 108–15.
[52] Rizzo, L., C. Manaia, C. Merlin, T. Schwartz, C. Dagot, M.C. Ploy, I. Michael, and D. Fatta-Kassinos. 2013. "Urban Wastewater Treatment Plants as Hotspots for Antibiotic Resistant Bacteria and Genes Spread into the Environment: A Review." Science of The Total Environment 447 (March): 345–60.
[53] Prado, Tatiana, Dalton M. Silva, Wilma C. Guilayn, Tatiana L. Rose, Ana Maria C. Gaspar, and Marize P. Miagostovich. 2011. "Quantification and Molecular Characterization of Enteric Viruses Detected in Effluents from Two Hospital Wastewater Treatment Plants." Water Research 45 (3): 1287–97
[54] Brechet, C., J. Plantin, M. Sauget, M. Thouverez, D. Talon, P. Cholley, C. Guyeux, D. Hocquet, and X. Bertrand. 2014. "Wastewater Treatment Plants Release Large Amounts of Extended-Spectrum -Lactamase-Producing Escherichia Coli Into the Environment." Clinical Infectious Diseases 58 (12): 1658–65.
[55] Harris, Suvi, Carol Morris, Dearbhaile Morris, Martin Cormican, and Enda Cummins. 2014. "Antimicrobial Resistant Escherichia Coli in the Municipal Wastewater System: Effect of Hospital Effluent and Environmental Fate." Science of The Total Environment 468–469: 1078–85.
[56] "Sanitary Sewer Overflows and Peak Flows." Water, Pollution Prevention & Control, Permitting (NPDES). U.S. Environmental Protection Agency. Available from: http://water.epa.gov/polwaste/npdes/sso/

of the pathogenic microorganisms to the air occurs during any mechanical or biological processing of the wastewater, such as in grit tanks during pretreatment and bioreactor aeration during wastewater purification. It is common knowledge that bioaerosols present a human health hazard, including a variety of pulmonary symptoms such as allergic responses, hypersensitivity, and inflammation. The risk posed by multi-drug resistant pathogenic microorganisms is further elevated when taking into consideration *"…bioaerosols might be a vehicle for the dissemination of human and animal pathogens from wastewater, the workers of WWTPs and inhabitants of WWTPs' surroundings may be exposed to harmful influence of microorganisms from the air."*[50]

The impact of hospital wastewater and infectious liquid RMW on WWTPs and their receiving environment has caused many to question the potential necessity of treating hospital waste streams prior to discharging to the sanitary sewer systems. Korzeniewska et al. conclude *"…the preliminary disinfection of hospital sewage before its inflow into the sewage system might minimize the spreading of antibiotic-resistant bacteria to the environment.*[50] In a more extreme example, Pauwels and Verstraete pose the following response to WWTPs' struggle to address hospital waste streams, *"There may arise situations where the total exclusion of emission from the hospital is required, for instance in the case of multiple antibiotic-resistant strains (MARS). In this review, we pose the question 'Can public policy continue to allow co-treatment of hospital wastewater with domestic sewage?'"*[47]

3.2 On-site Treatment Systems

The U.S. Department of Defense (DOD) has documented that there are no commercially available products or methodologies for the on-site treatment of infectious liquid medical waste streams. In 2005 a Medical Logistics Integrated Research Team (IRT) led by the Telemedicine and Advanced Technologies Research Center (TATRC), U.S. Army Medical Research and Materiel Command (USAMRMC), Ft. Detrick, Maryland recognized the growing threat to human health and the environment from current liquid medical waste disposal practices. The IRT findings launched a TATRC research effort to find an on-site liquid medical waste treatment system that would protect military personnel from biohazard handling exposures and prevent the spread of infectious diseases through the environment.[57]

Following a two year research effort USAMRMC determined that there were no commercially available products, methodologies or design concepts for an on-site treatment system that would allow hospitals and other MTFs to *"render fluid medical/biological waste harmless to the environment"* and *"…pretreat certain medical/biological wastes before they are discharged into municipal sanitary sewer systems,"* because "*…no such system exists today."*[58] The DOD based their determination on a set of design and life cycle performance specifications that required an on-site fluid medical waste treatment system to be a compact, energy efficient and cost-effective appliance capable of continuous flow, volume scalable disinfection of 100% of an infectious fluid medical waste stream with no hazardous by-product emissions to the environment.

Conclusion

Current medical waste management practices are driven by federal, state and local regulations. However, these regulations and practices fail to adequately address the biohazardous exposures and environmental pollution that threaten the health and safety of patients, employees and the public from the improper management of infectious liquid regulated medical waste. The management of infectious liquid regulated medical waste should be approached from a holistic perspective to protect patients, employees and the environment.

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[57] Medical Logistics Integrated Research Team, Seminar Proceedings, May 16 – 18, 2005, Telemedicine and Advanced Technology Research Center, U.S. Army Medical Research and Materiel Command, U.S. Department of Defense

[58] "Innovative Lightweight Energy and Water Efficient Treatment System for Fluid Medical Waste in an Austere Deployed Environment", U.S. Army SBIR/STTR Topic Number A07 T036, Telemedicine and Advanced Technology Research Center, U.S. Army Medical Research and Materiel Command, U.S. Department of Defense, January 22, 2007.

About Innovasan

Innovasan's purpose is to transform global health by eliminating water pollution. Med-San® technology is the only solution for cost effective, on-site treatment of fluid medical waste, is backed by 20 U.S. and International patents granted with 11 patents pending, and is recognized by the U.S. Army Medical Research and Material Command and the American Institute of Biological Sciences as a disruptive innovation. Innovasan is transforming the disposal of fluid medical waste with a solution designed for people and the planet.