Revisions on Regulated Medical and Chemotherapeutic Waste

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Management of medical waste captures public attention only intermittently. Media headlines abound when syringes or other medical wastes wash up on beaches, or when infectious diseases such as Ebola necessitate use of highly protective procedures to handle patient waste. In contrast, the daily generation, transportation, processing and disposal of medical waste raises scant public concern, perhaps due to the success to date of regulatory programs and industry efforts to avoid adverse public health impacts.

Evaluating and minimizing the risks posed by different types of medical wastes to human health and the environment are fundamental elements of efficient and effective waste management programs. Infectious wastes are generated in the diagnosis, treatment, immunization or autopsy of humans or animals and have the potential to cause disease. Chemotherapeutic wastes result from use of agents to kill malignant cells and may have toxic effects. In Pennsylvania, the Solid Waste Management Act, the Infectious and Chemotherapeutic Waste Disposal Law and their implementing regulations provide a comprehensive program for managing infectious and chemotherapeutic waste (ICW). On Nov. 8, the Pennsylvania Environmental Quality Board (EQB) published in the Pennsylvania Bulletin final-form amendments to Pennsylvania's ICW regulations. Using experience gained in implementing its ICW regulatory program, lessons learned from federal programs and capabilities enhanced by technology, the updated regulations more effectively address the risks that ICW pose to the public while recognizing the important economic role that health care businesses play.

The revisions to the ICW regulations affect numerous businesses in Pennsylvania. The Department of Environmental Protection (DEP) estimated that there are over 16,000 hospitals, medical offices, veterinary practices and other health facilities and laboratories in the state that generate ICW. When facilities processing this waste by disinfection, incineration or other means—facilities such as landfills accepting the wastes or incinerator ash for disposal—and transporters of the waste are also considered, the significant potential impact of these regulations is apparent.

Key outcomes of the revisions include greater consistency with federal regulations, enhanced efficiency without compromising safety, and requirements tailored to the risk posed by a waste stream or activity. This article discusses examples of these outcomes.

The revisions to conform Pennsylvania and federal rules are evident in the new title of the revised regulations, "Regulated Medical and Chemotherapeutic Waste." The term historically used in Pennsylvania, "infectious waste," has been replaced with "regulated medical waste." Even though regulated medical waste and infectious waste are synonymous, labels on containers of infectious waste and signage on vehicles transporting infectious waste must utilize the new name. After a two-year transition

period, the words "infectious waste" now seen on vehicles and containers will be a historical relic. Either or both terms may be used during the transition.

Following the lead of federal regulations may also enhance efficiency. The transporter obligations include verifying that the generator has placed the proper markings on the containers to the extent that the containers in the vehicle can be visibly inspected. To assist the generator, consistent with U.S. Department of Transportation rules, the transporter may allow labeling of the vehicle in lieu of labeling each container when the containers originate from a single generator. The adoption of federal terminology and practices eliminates the need for two labels on each container and two signs on each truck, and makes the management of ICW more efficient.

The revised regulations also use federal regulations as a reference, even when federal requirements are not directly applicable. The previous regulations exempted empty containers from the definition of ICW, but did not specify when a container is "empty." The revised regulations define empty containers by referencing the federal criteria used to classify a container as empty for purposes of the hazardous waste regulations.

The revised regulations also enhance efficient management of ICW by recognizing technological advances. Previously, Pennsylvania required that a paper manifest accompany the ICW shipment and be signed by the processing or disposal facility receiving the waste. These documents assist the DEP in ascertaining whether the wastes were sent to an authorized facility.

The revised regulations no longer use the term "manifest." Instead, they broaden the permissible waste tracking documents to include a "log or shipping paper" that records, among other things, the name of the generator and the transporter, the code for the type of waste and the designated facility receiving the waste. The facility accepting the waste may now place an electronic or stamped signature on the log or shipping paper to acknowledge acceptance of the waste in lieu of a handwritten signature. As industry and the DEP move toward using an electronic tracking system, the tracking process should become more efficient.

The revised regulations also enhance the efficiency of ICW storage and transportation. Regulated medical and chemotherapeutic wastes must still be placed into separate containers and not commingled with other wastes. The revised regulations, however, now clearly allow separately containerized ICW to be stored in the same location as municipal waste, including a cart.

Likewise, containerized ICW can be transported in the same vehicle as containerized municipal waste. The ICW containers must be leak-proof on the sides and bottom and maintained in an upright position. They also must be of sufficient strength, a performance standard that dispensed with specifying numeric requirements.

Permissible storage times have been revised to allow more efficient use and disposal of containers. Previously, the maximum 30-day storage period for a container holding regulated medical or chemotherapeutic waste commenced on the date that waste was first placed into the container. This often resulted in the disposal of containers that were

only partially filled. Under the revised regulations, containers may be stored until filled with medical or chemotherapeutic waste or until sealed, whichever occurs first. This will result in fewer shipments of partially filled containers and therefore lower costs and reduce energy use.

The risk-based approach of the revised regulations underlies numerous provisions, including those involving the handling and disposal of sharps, i.e., equipment such as syringes, glassware and plasticware. Sharps that have been exposed to an infectious agent or used in animal or human patient care are termed "used sharps" and fall within the definition of "infectious waste." Under the previous regulations, "sharps" and "used sharps" were separately defined, raising the inference that even a clean sharp must also be handled as an ICW when disposed. Although a clean sharp can create a puncture wound, it cannot cause infection or disease. Because a waste is infectious only if it is capable of causing disease, the revised regulations incorporate the definition of "sharps" in the term "used sharps," thereby allowing clean sharps to be managed like other municipal waste. "Used sharps" continue to be a subset of infectious waste.

The risk-based approach also supported revisions to requirements for autoclaves. An autoclave uses high-pressure steam to heat a load of waste to a temperature sufficient to disinfect the waste. Validation is a procedure to verify that the autoclave process is in fact killing the infectious organisms. The previous regulations required the operator of the autoclave to validate the autoclave at least once a year even if the manufacturer did not so specify. The revised regulations focus on actual risks by requiring validation as specified by the manufacturer and when autoclaves are most likely to perform inadequately: when a new autoclave is installed or when an autoclave is modified or repaired or has malfunctioned.

Perhaps the most poignant example of achieving all three outcomes (conformity to federal requirements, efficiency and risk-based requirements) in the revised regulations is the exemptions granted for those wastes produced by vaccine manufacturers and other biologics companies that do not pose an appreciable risk of disease. The Centers for Disease Control and Prevention (CDC) publication, "Biosafety in Microbiological and Biomedical Laboratories," categorizes infectious agents into biosafety levels (BSL) 1 through 4 based on the degree of risk that the agents pose. BSL-1 is applied to agents that are not known to cause disease in normal, healthy humans. The National Institutes of Health published similar guidelines. In its regulations implementing the Medical Waste Tracking Act (now expired), the U.S. Environmental Protection Agency concluded that based on their risk of causing disease, only wastes in classes 2 through 4 are properly termed infectious and warrant regulation.

Use of these classifications would not provide much benefit to most hospitals and other medical providers. These generators of ICW ordinarily do not characterize the biosafety level of each of their myriad waste streams, nor could they routinely do so. The infections or other medical conditions of even a single patient are frequently unknown when the waste is created. The commingling of waste from numerous patients with varied medical conditions further complicates classifying the risk posed by the combined waste stream. Under the revised regulations, these wastes must still be managed based on the potential for a range of infectious agents to be present.

In contrast, during the research and development and manufacturing stages, biologics manufacturers and their expert scientists and consultants carefully characterize the vaccine viruses and other agents that they use. The Federal Food, Drug and Cosmetic Act classifies vaccines as drugs and its implementing regulations impose requirements to ensure the purity and safety of the products. Comprehensive testing and qualification of the biological materials and implementation of good manufacturing practices are designed to exclude unwanted infectious agents from the vaccine. Advances in technology have allowed some vaccine viruses and other agents to be attenuated (weakened) or inactivated to reduce their hazard while maintaining their efficacy in preventing disease. Many of these agents are classified as BSL-1.

The revised regulations recognize the important difference between the well-characterized wastes from biologics facilities and the commingled wastes from medical providers. They exempt from the definition of infectious waste those wastes, mixtures of wastes and cell lines from biologics facilities containing only BSL-1 agents. Similarly, plasticware generated by biologics facilities that have not been in contact with BSL-2 through 4 agents are excluded from the category of "used sharps." The regulations further allow biologics companies that operate in accordance with specified requirements to perform autoclave validation in a manner designed by an appropriately certified expert to achieve the required disinfection for the well-characterized infectious agent in the waste.

The revisions to the Regulated Medical and Chemotherapeutic Waste Regulations are a major step forward. They harmonize Pennsylvania and federal requirements, take advantage of technological advances, promote efficiency and tailor the regulations to the risk posed by the waste or activity being regulated. They carefully accomplish these goals while continuing to protect public health. If these revisions are representative of the approach that the DEP will take when modifying other environmental regulations, the future bodes well.

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