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Hazardous Materials Management Considerations in Healthcare

Mae Ping Grogg, MS, CSP
BJC HealthCare
St. Louis, MO 63110

Paul Halliburton, MS, CHMM
Barnes-Jewish Hospital
St. Louis, MO 63110

Introduction

BJC HealthCare is one of the largest nonprofit health-care organizations in the United States, delivering services to residents primarily in the greater St. Louis, southern Illinois and mid-Missouri regions. With net revenue of $2.6 billion, BJC HealthCare serves urban, suburban and rural communities and includes fourteen (14) hospitals and multiple community health locations. Services include inpatient and outpatient care, primary care, community health and wellness, workplace health, home health, community mental health, rehabilitation, long-term care and hospice.

As one of the largest nonprofit health-care delivery organizations in the country, BJC HealthCare is committed to improving the health and well-being of the people and communities served through leadership, education, innovation and excellence in medicine.

BJC HealthCare maintains an Environmental Safety and Health (EH&S) system committee comprised of representative Safety Managers from each location. The committee reviews performance metrics, current regulations, industry standards, and best practices, and also develops policies, programs and materials as part of the overall mission. One recent EH&S committee goal has been to focus on the management of Hazardous Materials and Waste.

This session will address compliance requirements surrounding a healthcare network in the area of hazardous materials and waste management, as it relates to both OSHA and EPA standards. The presentation will emphasize the key issues found at our locations, outline our solution processes, as well as provide tools to assist hospitals with their overall hazardous materials management process.

When the National Institute for Occupational Safety and Health (NIOSH) published their guidelines for “Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Healthcare Settings” in 2004, BJC HealthCare conducted a risk assessment to help assess potential issues and identify any gaps in performance. This initial risk assessment determined

that there were some inconsistencies among the hospitals pertaining to the management of hazardous materials and waste.

Initially in 2005, the focus was to determine possible solutions within the pharmacies to assist them in managing their hazardous drug inventory, as well as to ensure compliance with the regulations. A “task group” of key content experts within the system was formed to review the current processes and make improvements in this area. Then, in 2006, the BJC System EH&S Committee agreed to add as a general goal for all hospital locations, the improvement of hazardous materials and waste management. This continues to be a goal for our locations into 2007.

Initial Findings

Initial findings exposed potential hazardous materials management concerns within the pharmacy setting. These findings also revealed that although referencing the NIOSH guidelines may assist with worker protection when dealing with hazardous drugs, further steps still need to be taken to ensure hospitals and pharmacies maintain compliance with specific Occupational Safety and Health Administration (OSHA) standards and the Environmental Protection Agency (EPA) Resource Conservation and Recovery Act (RCRA) requirements.

These findings are consistent with some of the most cited standards by OSHA and EPA in healthcare. A summary of the key items noted are categorized as follows:

Personal protective equipment (29 CFR 1910.132)

- Glove usage when handling hazardous drugs.

Respiratory protection (29 CFR 1910.134)

- Fit-testing for staff who respond to incidental chemotherapy spills.

Hazard communication (29 CFR 1910.1200)

- Chemical inventory maintenance.
- Consistent labeling of storage bins. Ensure labels do not indicate as "biohazard".
- Material safety data sheet maintenance.

RCRA (40 CFR 260-265)

- RCRA initial waste determination.
- RCRA inventory list.
- Container types and labels.
- Proper classification and disposal considerations.
- Manifests maintenance.

Personal Protective Equipment and Respiratory Protection

To address this issue, a personal protective equipment (PPE) assessment, specific to the pharmacy needs, was developed and distributed to the hospitals. This was completed as part of a policy update to assist with addressing the recommended minimum protection levels for the various job tasks when handling hazardous drugs. Ongoing, assessments will continue to be developed, evaluated, and updated for various hazardous materials. This PPE assessment was also developed with the intent to comply with the 29 CFR 1910.132(d) requirements.

Key staff members that needed to be fit-tested were incorporated into the hospitals' existing respiratory protection programs, to ensure compliance with the 29 CFR 1910.134(f) requirements.

Hazard Communication

OSHA requires that a list, or chemical inventory, and material safety data sheets (MSDS) be maintained for hazardous chemicals, as part of the Hazard Communication 29 CFR 1910.1200 requirements. This can be challenging at times for hospital locations, in particular pharmacies, depending on the volume and variety of hazardous drugs maintained at a particular location.

Some hospital locations have opted to use a computerized MSDS management tool to manage their chemical inventories and MSDS for all their departments. These tools can be advantageous as long as each hospital designates a department, or person, to oversee the process. These tools may also assist with RCRA requirements.

There also seemed to be some confusion as to which chemicals were subject to the different hazardous materials regulatory requirements. Therefore, since every hospital must maintain a chemical inventory listing, the locations were asked to review this list as part of a process to determine which materials were also considered hazardous drugs. They were also asked to determine which materials would be subject to the RCRA requirements. Based on this review, the hospitals were requested to develop a separate RCRA inventory that will then provide the basis for the RCRA waste determination.

Key individuals who maintained responsibilities for the hazardous materials management process within the hospitals also attended internal training sessions to become better educated about the potential issues found, as well as to gain a better understanding of the both the OSHA and RCRA requirements. These training sessions also concentrated on the RCRA hazardous materials and waste management process.

Hazardous Waste Management

Hazardous waste can be defined as a single waste or combination of waste that because of its quantity, concentration, physical, chemical, or infectious characteristics when improperly disposed leave a deleterious impact to humans or the environment. The federal and state regulations are designed to ensure that hazardous waste is properly identified, stored, transported and treated properly to prevent any adverse affects to humans or the environment.

Some common violations among hospitals include:

- Failure to determine facility's (hospital) generator status.
- Failure to make waste determinations.
- Improper storage & labeling of waste materials.

Within a hospital setting hazardous waste may be generated by several departments, including:

- Pharmacy
- Laboratories
- Patient care areas
- Facilities maintenance
- Clinical engineering

It is the responsibility of the generator (hospital) to determine if the waste products generated are consider hazardous or non-hazardous according to the RCRA solid waste guidelines (40 CFR Part 260 Appendix I).

Generator Status

Hospitals are required to classify their hazardous waste generator status. A hospital's generator status is based on the amount of hazardous waste that is generated or stored in a one (1) month period. Hazardous waste generators fall into three different categories.

- Conditionally Exempt Generators (CEG) -Generate or store less than 220 lbs. of hazardous waste per month.
- Small Quantity Generators (SQG) – Generate or store between 220 lbs. to 2,199 lbs. of hazardous waste per month.
- Large Quantity Generators (LQG) Generate or store more than 2,200 lbs. of hazardous waste per month.

Once a hospital has determined their generator status the hospital may have to obtain an EPA ID number. EPA requires all small and large quantity facilities to have an EPA ID number. Some state regulations require that a conditionally exempt generator also obtain an EPA ID number.

Hazardous Waste Determination Process

The generator of waste material is obligated to determine if the waste is hazardous or not. This is done either by conducting an analysis on the waste material or through generator knowledge of the process generating the waste.

EPA states in its regulations that a waste is considered a hazardous waste if the following applies:

- Listed as a hazardous waste in Federal or state regulations;
  (Listed waste includes F, K, P, and U lists.)
- Has not been excluded by federal or state law; and

- If waste has characteristics of :
  - Flammable
  - Corrosive
  - Toxic
  - Reactive

The first step in the waste determination process is identifying if the waste generated meet the definition of a RCRA solid waste. RCRA defines solid waste as any liquid, gas, or solid materials that has been spent, expired or no longer serves the intended purpose and must be discarded.

The RCRA regulations and the lists of possible waste materials (F, K, P, & U) have not changed greatly since 1976; however, this does not relieve the generator of their responsibility to properly perform a waste determination. Again, most materials used within a hospital can be evaluated for potential hazardous characteristics by reviewing the chemical inventory lists and associated material safety data sheets (MSDS).

A common example of a waste determination could begin with methanol listed on the laboratory's chemical inventory list. Generator knowledge of this chemical is that methanol is a flammable liquid. The MSDS also confirms this in section 2 (composition), section 3 (hazard information) and also in section 13 (disposal information). Beware that just because the methanol initially meets the definition of a flammable liquid (flashpoint equal to or less than 140°F) it depends on the characteristic of the methanol waste generated at the end of the process. An alcohol waste containing no other RCRA waste is exempt if the volume of alcohol is 24% or less so, further investigation remains. The continued investigation would be to scrutinize every process within the laboratory that utilizes methanol and evaluate each process separately if it is determined that the end product of each process contains alcohol in volumes of 24% or greater, or commingled with another possible regulated waste (i.e. metals, other solvents, toxics). By generator knowledge this could be declared a RCRA waste without analytical testing. However, if the generating process in question contains less than 24% methanol by volume and there is no presence of any other possible RCRA material, than this waste stream could possibly be handled as a non-RCRA waste.

Other materials from a laboratory setting that could be evaluated in this manner are acids, bases, and other flammable liquids such as xylene and toluene. Remember, depending on the generating process for acetone, xylene, and toluene it could meet the definition of an F-listed waste. Also the 24% alcohol by volume exemption only applies to alcohol compounds not acetone, xylene, toluene or any other solvents.

Generator knowledge of a process can reduce redundancy of testing and also alleviate expensive analytical testing. When generator knowledge does not conclusively determine that a waste material meets the definition of a RCRA hazardous solid waste, then the only alternative for the generator is to perform analytical testing in accordance with the EPA regulations to ensure proper management and waste disposal.

Waste determinations must also be performed in the areas of pharmaceutical compounding and drug administration. The discovery of a variety of pharmaceuticals in surface,

ground, and drinking waters around the country is raising concerns about the potentially adverse environmental consequences of these contaminants.

Pharmaceuticals that are utilized frequently through out healthcare and also appear on the EPA RCRA list include but are not limited to the following:

- Nicotine
- Nitroglycerin
- Warfarin
- Epinephrine
- Nine Chemotherapeutic agents

As stated earlier, the EPA's RCRA list was created in 1976 and has not changed significantly since then. The pharmaceutical industry is producing new drugs at a rate much quicker than the EPA can evaluate them for hazardous characteristics, but this by no means alleviates the generator from making a waste determination and ensuring proper disposal. Trial drugs are typically accompanied by an MSDS which list the active ingredients as a trade secret; again this does not exempt the generator from making a waste determination and disposing of the drugs properly.

The characteristics for hazardous drugs established by NIOSH are:

- Genotoxicity
- Carcinogenicity
- Mutagenicity
- Teratogenicity
- Antineoplastic agents

The best disposal practices for drugs, new or old, that meet the NIOSH definition of a hazardous drug are to dispose of these drugs by RCRA standards. Reverse distribution for expired and unused pharmaceuticals regardless if they meet the RCRA or NIOSH definition for a hazardous drug is an excellent and beneficial way to dispose of those types of materials.

Collection Process

Once the waste determination process has taken place and areas of waste generation identified, next a collection process including container types, storage locations, labeling and inspection of storage areas needs to be developed by the facility.

Waste Determination reveals that RCRA waste is typically generated in the following areas of a hospital:

- Pharmacy
- Nursing/Patient Care
- Clinical/Research laboratories
- Clinical Engineering
- Radiology
- Maintenance shops

Satellite Accumulation Storage Areas

The collection process will consist of selecting a container for each satellite accumulation storage area. A satellite accumulation storage area is an area with a container for collection of waste material located near or at the point of the waste generating process. The size of the container for the satellite accumulation storage area will depend on the type of waste generated in the area and the frequency of generation. Satellite Accumulation Storage Areas should be managed in accordance with 40 CFR 260.34(c) which state that these areas will adhere to the following:

- Utilize containers of good integrity.
- Container is labeled.
- Container is dated when accumulation began.
- Waste material is compatible with container.
- The container is always kept closed except when waste is being added.
- Container once filled must be removed from the satellite accumulation storage area within three (3) days.
- Weekly inspection of satellite accumulation storage areas must be performed.

Satellite accumulation storage areas for Patient Care divisions are usually located in the soil utility room. Satellite accumulation storage areas for waste generating departments other than Patient Care areas within the hospital are typically at the point of waste generation. For example, in a laboratory there may be a collection container at the end of a workbench adjacent to the testing or procedure that produces a RCRA waste. By having the container at the point of generation you reduce the risk of improper disposal and minimize spills from occurring.

One Hospital's Solution

Barnes-Jewish Hospital is a licensed 1,277 bed facility. Barnes-Jewish Hospital being a major healthcare facility has to comply with many EPA regulations such as air permit requirements (Title V Part 70), water discharge permit requirements (NPDES), the Spill Prevention Countermeasure Control Plan (SPCC), underground storage tank provisions, in addition to RCRA and other EPA regulations that affect the hospital due to the size of the campus.

In an effort to manage overall environmental compliance, Barnes-Jewish Hospital created and implemented a comprehensive environmental auditing program for all areas of environmental compliance (Air, Water, SPCC, RCRA, UST). The segment of the Environmental Audit Program that pertains to RCRA shares the responsibilities of regulatory compliance between the department generating the waste material and the Environmental Health &Safety (EH&S) Department.

The generating department is responsible for the following:

- Contacting the EH&S Department prior to a process change or the introduction of a new chemical, so that a waste determination can possibly be reached prior to generating a waste material.
- Labeling and dating satellite accumulation storage container.

- If a temporary satellite accumulation storage area is located in a department generating waste, that department is responsible for performing a weekly inspection of the satellite area to ensure compliance with RCRA requirements for satellite storage areas. Inspection results are electronically sent or faxed weekly to the EH&S Department.
- Contacting the EH&S Department when containers of waste are filled for prompt removal in accordance with RCRA satellite storage regulations.

The EH&S department is responsible for the following:

- Final waste determination.
- Selection of containers for waste collection.
- Providing appropriate labels.
- Overall regulatory compliance (perform quarterly inspections).
- Providing RCRA guidance & training to staff.
- Acting as a liaison between hospital and regulatory agencies.
- Recording and retaining documents.

When first implemented, this environmental audit program identified other areas for improvement within the environmental management scope including training needs to comply with Department of Transportation requirements, shipping documents preparation, and hazardous materials awareness.

In 2006 the Environmental Management System helped Barnes-Jewish Hospital to identify and correct several issues that could have otherwise led to potential EPA ramifications. Since implementation of the environmental audit program and adherence to the program components, Barnes-Jewish Hospital has reduced its potential environmental liability and enhanced overall compliance with both EPA and OSHA regulations.

Overall Improvements and Next Steps

BJC HealthCare, through its overall safety committee structure, has committed to focus attention toward improving its existing hazardous materials management program. At the corporate level, this initiative has been coordinated through the BJC Risk Management Department. This department's goal was to provide overall support services and improvements to assist all the 14 hospitals towards ensuring better overall management as well as compliance with related OSHA and EPA regulations.

Program enhancements included:

- Discussions with the healthcare system's pharmacy group to educate and understand the hazardous drug management processes at our facilities.
- Policy reviews and updates to better ensure consistency and standardization of the hospitals processes and practices.
- Contract negotiations with a local hazardous waste vendor to standardize the management and disposal process.
- Contract negotiations with a computerized MSDS system vendor to improve management of chemical information.

- Educational and training sessions that focused on RCRA requirements with each hospital's designated safety and hazardous materials management contacts.
- Attendance at professional development seminars and conferences for key individuals to become more knowledgeable about current issues, trends, and requirements.

BJC HealthCare will continue to work with its hospitals toward improving the overall hazardous materials management and compliance program. Next steps for 2007 include additional internal training sessions on key areas such as manifests, continued vendor contract negotiations, and ongoing review of association, industry, and regulatory materials. Hopefully, these efforts will continue to enhance the overall hazardous materials management process and compliance efforts.

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