First Quarter 2009 Issue 16

TSIG NEWS

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Inside this issue:

Windy City Welcome!

TSIG is pleased to welcome healthcare facilities in the Chicago Metropolitan area to attend a free one-day seminar on May 8, 2009 at the Rehabilitation Institute of Chicago.

This education program will provide attendees a unique perspective on mastering the 2009 Triathlon- by providing winning strategies to meet the new Environment of Care, Emergency Management and Life Safety Standards, as well as understand the impact of the new Joint Commission scoring process. Ode Kiel & George Rivas will co-present this dynamic program and space is limited so contact us soon at info@tsigconsulting.com for early registration.

New Option for Hospital Accreditation

By Ode Keil

The Joint Commission no longer has the almost exclusive position as the independent hospital accrediting body with deemed status for Medicare reimbursement. While it is true that the Joint Commission has shared deemed status for Medicare reimbursement with the American Osteopathic Association (AOA) since the inception of the Medicare program the practical reality is that the AOA has had little appeal to hospitals that were not based on the osteopathic model of medical care.

NDV Healthcare is a division of Det Norske Veritas that was granted deemed status by CMS through September 26, 2012. The parent company was founded in 1864 as an inspector of ships. It has since expanded into other markets as an inspection and quality systems evaluator. The new company is expected to base its accreditation on the Medicare Conditions of Participation and the ISO 9001 quality management program assessment process.

The new program is called the National Integrated Accreditation for Healthcare Organizations. The program is headquartered in Houston Texas and has operational offices in Cincinnati Ohio. Through the end of 2008 the program has accredited a few dozen hospitals. While this may not seem significant it represents the first time in 30 years that hospitals have had a choice of who to choose for accreditation. Perhaps more significantly it gives CMS new leverage to push the Joint Commission to change the way it does business to more closely align accreditation processes and standards with the Medicare Conditions of Participation. This point was driven home by CMS when they published the notice in the October 24 *Federal Register* that the Joint Commission program for the accreditation of critical access hospitals does not meet the requirements of the Medicare Conditions of Participation.

The new program appears to be closely based on the Conditions of Participation and the principles of the ISO 9001 process. The ISO process emphasizes several key aspects of an organization. The first is documenting what the organization does. This serves as the foundation for designing processes to accomplish the goals of the organization. This is similar to the requirements for process design found in the Joint Commission leadership and other standards. In the EOC standards it closely aligns with the requirement for a proactive risk assessment to identify what risks the services of an organization pose to patients, staff, and visitors and the use of the proactive risk assessment to develop procedures and controls to manage the risks. The ISO process also emphasizes strong documentation of the processes. The documentation is the foundation of an audit of the processes to determine if the work performed is effective as defined by the process documentation.

While much of this sounds familiar to those accredited by the Joint Commission, supporters of the DNV program claim several distinct differences exist. Chief among the differences is the fact that hospitals are given the freedom to choose what they want to focus on and to develop action plans to move forward. DNV then monitors the progress the hospital is making and makes recommendations for improving the process. Hospitals that have undergone the DNV and Joint Commission processes also claim the DNV process is more collegial. The general feeling is that the hospital is not being forced to build a quality and patient safety program that conforms to a specific model such as the one built into the Joint Commission standards.

By contrast the DNV process is described on critiquing the programs built by the organization. Another difference is that the DNV program includes an annual audit as opposed to the nominal three year cycle of the Joint Commission. Fees for the two programs over three years are described as comparable.

The Joint Commission is being a good sport about the situation. In a widely distributed e-mail the Joint Commission stated that the combination of its 50 years of experience, standards, National Patient Safety Goals and other factors set a very high bar for quality and safety. While the tone of the e-mail appears to be neutral, it is clear from the activity the Joint Commission is trying to bring its standards closer to the Medicare Conditions of Participation it is not taking the threat of a potentially strong competitor lightly.

Understanding Hazmat Responsibilities and Requirements

Part 2

HAZMAT INCIDENT MANAGEMENT

Chain of command

The HAZMAT disaster plan for a community should clearly define who is in charge of a situation. This person ultimately is responsible for protecting public health and the environment and ideally be a specially trained individual representing either the HAZMAT team or the LEPC. The ERP should clearly delineate the authority of this person, even on private property or private facilities.

The ERP must address many aspects other than medical care. The plan should stipulate the reasons for evacuation as well as local evacuation centers. The incident commander must consider public and rescuer hazards from toxic and corrosive materials as well as those from explosive or flammable materials. Finally, the plan must stipulate at what point EMS personnel, not trained to attend to HAZMAT issues, will interact in patient care.

The community disaster response plan delineates the chain of command for a situation and specifies how the EMS system will interact with the HAZMAT team. Defining the point at which the EMS system gets involved with injured persons is not an easy task. Ideally, specially trained HAZMAT workers decontaminate all exposed individuals prior to turning them over to the EMS system. However, in any individual situation, the severity of a patient's injuries and degree and type of contamination must be weighed against the medical training of the HAZMAT worker and the EMS system.

The ideal situation is that of Los Angeles County, where the HAZMAT team is made up of specially trained members of the fire department who also are cross-trained as paramedics or emergency medical technicians (EMTs). However, smaller communities commonly do not have this luxury. Especially in situations in which the HAZMAT team is not trained in prehospital care, involving medical control physicians and poison control centers in patient care decisions is essential.

Goals in managing a HAZMAT incident

The goals of managing a HAZMAT incident include the following:

- Recognition of the situation and notification of emergency services
- Establishment of a command center
- Protection of site and emergency workers from any further exposure
- Identification of the hazardous materials involved
- Assessing the hazard risk and the degree of personal equipment required
- Rescuing any victims of hazardous materials exposure that are on-site
- Crowd control and keeping ambulatory exposure victims on-site until they are decontaminated
- Notifying local healthcare facilities of the incident and the number and type of victims
- Decontamination and initial medical care of victims
- Containment of the hazardous material, including runoff from decontamination activities

Evaluation of further public exposure and evacuation where necessary

Obviously, many of these functions are performed concurrently. Recognition of the danger may seem a simple matter, but this usually depends on local workers or first responders. Most industrial site workers should be familiar with the site's ERP, including contact information in case of emergency and what to report. Potentially disastrous situations occur with motor vehicle or agricultural accidents in which the first responders are not aware of hazardous material dangers. In one series of HAZMAT incidents, 14% of exposed individuals were first responders. This emphasizes the importance of emergency medical personnel being trained, at a minimum, to the level of first responder awareness.

Site command center

One of the earliest priorities is the establishment of a site command center. Ideally, locate the command center near the incident but far enough away to avoid any exposure. The command center should be located upwind and uphill to avoid contact and should have a wind monitor and alarm system to warn of any shifting wind currents that may carry hazardous materials toward the command center. The command center should have a rapidly deployable communications system. This is critical to maintain contact with on-site workers and off-site emergency management and medical personnel to access information on the hazardous substances involved and necessary containment and safety procedures.

The site should be divided and managed within 3 zones

- The contaminated area is known as the hot zone. Only individuals with appropriate PPE and specialized training are allowed into this zone.
- The intermediate zone, also known as the decontamination zone, is where patient decontamination should take place.

A degree of contamination still is found in this zone; thus, some PPE is required, although it is usually of a lesser degree than that required for the hot zone.

- The command zone is located outside the decontamination zone. All exposed individuals and equipment from the hot zone and decontamination zone should be decontaminated before entering the command zone. Access to all zones must be controlled. Keeping the media and onlookers well away from the site is critical.

After decontamination, victims who require medical care can be picked up in the command zone. Only trained individuals wearing necessary PPE should be allowed into the decontamination zone. This produces a dilemma when persons exposed to hazardous materials require immediate medical attention. If this is the case, the ideal situation is for some EMS personnel to have the appropriate level of training to work in PPE. If this is not possible, the medical control physician and the site commander must make decisions on an individual basis.

Transportation

Placing a contaminated patient in an ambulance is strongly discouraged. This is a closed environment and presents increased risk to those in the ambulance. This action also results in the contamination of the ambulance and its equipment. No further use of the ambulance is allowed until it can be decontaminated appropriately. Ambulances usually are resources that most communities cannot spare. Transportation prior to decontamination increases the amount of time the patient is in contact with the hazardous material.

Some have recommended that patients be transported in the back of open trucks. These patients are not medically monitored or treated while being transported in these cases. Consider transportation in the back of an open truck only in those situations where no decontamination options exist at the scene and the hospital is prepared for decontamination.

Hazard identification

Identification of the hazardous materials involved is critical to all aspects of the rescue operation. As part of the SARA legislation, industrial sites are required to report all hazardous materials at their facility to the local emergency planning agency. In most instances, this information is maintained by the fire department or emergency planning agency. Industries also are required to post this information in a location external to the site, usually in an external electrical box or fire safety location. This assumes that the information contained in the external location or by the fire department is current. Problems may arise when new chemicals are added to an inventory and the lists are not updated.

The DOT requires all vehicles carrying chemicals to display placards identifying them. Generally, these are diamond-shaped signs that have specific colors and numbers that define the class of hazardous material that is present. The DOT classes and defining colors of hazardous materials include the following:

- Explosives (solid orange color)
- Nonflammable gases (solid green color)
- Flammable liquids (solid red color)
- Flammable solids (white and red stripes)
- Oxidizers and peroxides (solid yellow color)
- Poisons and biohazards (solid white color)
- Radioactive materials (half white, half yellow with black radiation symbol)
- Corrosives (half white, half black)

Other (usually white)

Each placard usually contains a descriptive color, symbol, and number. The triple redundancy is so that, in case of an explosion, any remaining portion of it can be used to identify the type of material present. The DOT identification system only identifies the type of hazard present and does not identify specific materials.

Many placards also contain a 4-digit number, known as the United Nations (UN) identification number. These numbers identify individual chemicals or groups of chemicals. Because several hundred thousand chemicals are known, obviously, only a relatively few can be identified by a 4-digit classification system. For this reason, many chemicals with similar characteristics are given the same UN number.

One-Time Extension Based on Unforeseen Conditions

Question—When the Joint Commission grants an organization an extension for one or more PFI items, does the organization receive a new six-month window beyond the newly approved completion date?

Answer— The universal answer is "no". Organizations are not given an automatic additional six month extended completion date. When requesting a one-time extension it is the expectation that the revised completion date has been thoroughly considered, major impediments are cleared, and the new date is accurate.

The Joint Commission will review, on a case-by-case basis, extension dates that have not been achieved. Under extraordinary conditions, a further extension may be granted. This will be the rare exception to their policy of a one-time extension based on unforeseen conditions.

New York Association of Homes and Services for the Aged (NYAHSA)

TSIG is proud to announce that we have become associate member and a Service Provider to the **New York Association of Homes and Services for the Aged (NYAHSA),** which has over 500 members, all across New York State. NYHASA Services, Inc, a wholly owned subsidiary of NYAHSA provides members of the association with a select list of service providers. As such, TSIG is uniquely positioned to supply services that are offered by no other service providers as follows:

1. Condition assessments of mechanical and electrical equipment in the facility with remaining equipment service life and deficiencies requiring repair along with associated costs. This will assist in the preparation of Capital Reports and forecasting renewal budgets.
2. Preparation of accurate drawings in CAD. This is important for showing barrier plans in compliance with accreditation agencies requirements as well as creating square foot area reports by type of space and departments. Computer Assisted Facility Management (CAFM) software applications in various products is also available.
3. For those members who wish to be accredited by The Joint Commission, TSIG provides extensive accreditation services including SOC and EC consulting.
4. Emergency Preparedness Consulting.
5. Damper survey and remedial work.
6. Mock surveys to meet accreditation agency requirements-DOH,CMS ,TJC,CARF.
7. Penetration survey and remedial work.
8. Temporary staff for Facility Directors.

We look forward to a mutually beneficial relationship with this wonderful organization.

2009 Joint Commission Changes

The Joint Commission has made some significant changes to the accreditation process, effective January 1, 2009. And although significant concern was raised by the emergence of the independent Emergency Management and Life Safety Chapters, it is important to recognize that the individual Elements of Performance have undergone very little change. In fact, most healthcare facilities are already meeting the spirit of these revised requirements. Many of these requirements simply add additional specificity to existing Joint Commission standards in order to remain consistent with CMS requirements and others have led to entirely new Joint Commission requirements. Compliance with any requirements that are completely new will be reviewed by surveyors beginning January 1, 2009, but will not be scored until July 2009, consistent with The Joint Commission's policy to provide organizations with a six month advanced notice of any changes to the requirements.

The most significant and interesting developments with these changes can be found under LS.01.01.01 EP 4 that states:

> *The hospital maintains documentation of any inspections and approvals made by state or local fire control agencies*.

This new requirement not only requires hospitals to provide the documentation of other regulatory agency survey findings, but it is interesting to note whether Joint Commission surveyors will be using these records to verify if organizations have documented, corrective actions based on other AHJ findings whether they be state or local authorities.

Of greater concern, and immediate impact is the fact that The Joint Commission has revised its scoring and decision processes which now focus on how critical an issue is to patient care or safety, as identified by noncompliant standards. The more critical the issue is, the shorter the time frame that an organization has to address it. In order to understand the criticality of each Element of Performance, one must first recognize the impact of the icons printed next to each Element of Performance as per the legend below:

Icon	Explanation
Ⓓ	Documentation is required
2	Situational Decision Rules apply
3	Direct Impact Requirements apply
A	Scoring category A EPs. Usually related to structural requirements (policies or plans) that either do or do not exist and are scored either 0 or 2. May address an issue that must be fully compliant (for example, National Patient Safety Goals).
C	Scoring category C EPs. Scored based on number of times an organization does not meet the requirements of a particular EP: Scored 2 (satisfactory compliance) if there are one or no occurrences of noncompliance Scored 1 (partial compliance) if there are two occurrences of noncompliance Scored 0 (insufficient compliance) if there are three or more occurrences of noncompliance
Ⓜ	Measure of Success is needed

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Maintaining your Fire-Rated Doors

Fire-rated doors are integral components of any passive fire-protection design in the built environment. While occupants and visitors use some of these doors daily, they rarely use other fire doors, which remain held open or closed. Without proper design specifications and comprehensive inspection and maintenance procedures, fire doors that fall into this latter category are significantly less likely to effectively protect the opening.

To protect against the spread of fire and smoke within your buildings, it is highly recommended that Facility Managers seriously consider implementing a preventive maintenance program for fire doors in accordance with locally adopted codes and national standards.

Background

While several tragic fires have led to significant revisions to the model codes and standards related to fire doors, building owners and managers continue to neglect inspection and maintenance procedures.

To understand the scope of fire doors, it is important to know these definitions by the National Fire Protection Association (NFPA) and the International Code Council. A fire door is the door component of a fire door assembly. This assembly is any combination of a fire door, frame, hardware and other accessories that together provide a specific degree of fire protection to the opening.

Fire doors fall into categories that include: swinging; horizontal sliding; sliding special purpose; vertically sliding; rolling steel; fire shutters; service counter; hoistway doors for elevators and dumbwaiters; chutes; and access. NFPA 101, the Life Safety Code, and the model building codes and fire codes specify the minimum fire-protection rating for fire doors as ranging from 20 minutes to three hours or more.

The NFPA claims that failure to close is the most common failure mode of fire doors in actual fires. Contributing factors include: lack of maintenance; physical damage to the closure, door, guides, or tracks; and doorway blockages. Some common faults observed on swinging fire doors include inoperative latches and improperly adjusted closing devices.

Organizations cannot ensure reliable fire-door performance unless doorways remain clean and Maintenance mechanics maintain doors in operating condition. NFPA 1, NFPA 101, and the International Fire Code all state that organizations must maintain fire doors used to protect openings in walls, floors, and ceilings to prevent or retard the spread of fire and smoke within, into,, or out of buildings according to NFPA 80, Standard for Fire Doors and Other Opening Protective.

NFPA 80 mandates facilities use only labeled fire doors, and a label must be affixed permanently to the door. Doors, shutters and windows must be operable at all times and kept closed and latched or arranged for automatic closing.

When replacing fire doors, shutters, windows or their frames, the glazing materials, hardware, and closing-mechanism replacements must meet the requirements for fire protection and be installed as required by standards for new installations. Also, technicians without delay must make repairs and correct defects that could interfere with operation.

In cases of field modifications to a fire-door assembly, technicians should contact the laboratory whose label is on the assembly and describe the modifications. If the laboratory finds the modifications will not compromise the integrity and assembly's fire-resistance capabilities, it will authorize the modifications without a field visit.

Inspection & Testing

To minimize failures and improve reliability, NFPA 80 states, "Fire door assemblies shall be inspected and tested not less than annually, and a written record of the inspection shall be signed and kept for inspection by the Authority Having Jurisdiction (AHJ)."

Facility managers may choose to schedule inspections, testing, and maintenance for fire-door assemblies under a written performance-based program, and this is also encouraged by The Joint Commission as part of a building maintenance type program designed to perform preventive maintenance on the components of your life safety program. However it is important to ensure that the goals established under such a program should ensure the assembly will perform as intended when exposed to fire conditions.

Facility managers need to document the technical justification for inspection, testing, and maintenance intervals. The performance-based option should include historical data acceptable to the AHJ. Individuals with knowledge and understanding of the operating components of the type of door being tested should perform functional testing of fire-door and window assemblies. Before testing, the inspector should perform a visual inspection to identify damaged or missing parts that could create a hazard during testing or affect operation or resetting.

Organizations should follow NFPA 80 guidelines for swinging doors with building hardware or fire-door hardware, and visual inspections of fire doors should cover both sides to assess the overall condition of the assembly. As a minimum, inspectors should verify these items:

- No open holes or breaks exist in surfaces of the door or frame.
- Glazing, vision light frames, and glazing beads are intact and securely fastened, if so equipped.
- The door, frame, hinges, hardware, and non-combustible threshold are secured, aligned, and working, with no visible damage.
- No parts are missing or broken.
- Door clearances at the door edge to the frame on the pull side of the door do not exceed 1/8-inch or 3/4-inch undercut.
- Any factory or field installed kick plates do not exceed 16” from the bottom of the door (48” if deemed a hazard room door).
- The self-closing device works; that is, the active door completely closes when operated from the full open position.
- If a coordinator is in place, the inactive leaf closes before the active leaf.
- Latching hardware operates and secures the door when it is in the closed position.
- The door or frame has no auxiliary hardware items that interfere or prohibit operation.
- The door assembly has no field modifications that void the label.
- Inspections verify the integrity of gasketing and edge seals, where required.

Preventing door blockage is critical to minimizing the spread of fire and smoke. Door openings and the surrounding areas must be clear of anything that could obstruct or interfere with the door’s free operation. Where necessary, technicians should build a barrier to prevent the piling of material against sliding doors. Blocking or wedging doors in the open position must be prohibited.

Summary

Proper maintenance of closing mechanisms is equally important in protecting occupants and visitors. NFPA 80 mandates the following:

- Self-closing devices must be in working condition.
- At frequent intervals, operate swinging doors normally held in the open position and equipped with automatic-closing devices to ensure operation.
- Annually inspect and test all horizontal or vertical sliding and rolling fire doors for operation and full closure.
- Reset the release mechanism according to the manufacturer’s instructions.
- Maintain and make available to the AHJ a written record.
- When conducting the annual test for operation and full closure on rolling steel fire doors, perform two drop tests. The first test checks for operation and full closure, and the second test verifies the automatic-closing device has been reset.
- Do not paint fusible links or other heat-actuated devices and release devices.
- Prevent paint from accumulating on movable parts.

The model codes and NFPA 80 offer ample measures for the inspection and maintenance of fire doors, closing devices, latches, and hardware. Many buildings, including high-rises, health care facilities, office buildings, and warehouses are likely to have fire doors. Should a fire occur, the health, safety and welfare of building occupants and emergency responders depend on a proactive, comprehensive fire-door preventive maintenance program.

2009 Joint Commission Changes

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Icons

These new Icons will be used to identify the scoring category, measure of success designation, whether documentation is needed, and the criticality of select Elements of Performance. It is essential that these icons are closely monitored when developing compliant measures. If a "D" is in front of an Element of Performance, then it is expected that documentation be available for review come time of survey. Equally important is recognizing the relevance of no icons. For example, those Elements of Performance that do not have a "2" or "3" icon are considered Indirect Impact requirements (Level 4). Although no Element of Performance is marked as an 'Immediate Threat to Life' requirement, any Immediate Threat to Life situation will typically be issued during survey as a result of noncompliance with a combination of Element of Performance at any or all of the Situational Decision Rules, Direct Impact and Indirect Impact levels.

Scoring

The standards fall into one of the following four levels of criticality:

- Indirect Impact requirements (Tier 4): Typically applied to planning and evaluation of care processes, the risk to patient safety increases if these requirements are not resolved over time.
- Direct Impact requirements (Tier 3): Based on the implementation of care processes that are likely to create an immediate risk to patient safety or quality of care if these requirements are not adhered to.
- Situational Decision Rules (Tier 2): Based on specific situations at the time of an on-site review, some issues will generate a recommendation to the Board of Commissioners for Conditional or Preliminary Denial of Certification.
- An Immediate Threat to Health and Safety (Tier 1): Identified during an on-site review will continue to drive an expedited decision of Preliminary Denial of Certification.

Decisions

- Decisions of Conditional Certification and Preliminary Denial of Certification will be driven by those standards that have the most Direct Impact on patient care or safety.
- There is no longer a supplemental section in the Certification Report. All findings of less than full compliance require resolution via submission of Evidence of Standards Compliance.
- The use of "thresholds" to determine Conditional Certification and Preliminary Denial of Certification will no longer occur. Instead, they will be used as "screens" for identifying organizations whose survey findings require more extensive review by Joint Commission Central Office staff.
- The screens are based on the number of Direct Impact standards that are noncompliant. Reviews that generate five or more requirements for improvement will be screened.

In our next issue, we will weight the potential consequences of this new scoring process. Stay tuned, this is going to get interesting!

TSIG'S LIFE SAFETY CODE TIP

As part of our ongoing effort to keep our readers up to date on the current focus of Life Safety surveyors during the survey process, we are providing a useful tip in each issue for organizations in hopes to minimize similar code violations during your next survey.

NFPA 101 7.2.2.5.4 requires that stair identification signage be posted within stairs serving five or more stories, yet many organizations are unaware that their own facility may not have the appropriate text content, approved location or the signage even posted.

To assure your facility is compliant with this code, be advised that, these signs must be provided within the stair enclosure at each floor landing. The signage must also indicate the story, the terminus of the top and bottom of the stair enclosure, and the identification of the stair enclosure. The signage also must state the story of, and the direction to, exit discharge. Posting of said signage must be inside the enclosure located approximately 5 ft above the floor landing in a position that is readily visible when the door is in the open or closed position.

The intent of this provision is to provide vital egress information to the occupants of a building and responding firefighters. To reduce information overload to occupants during emergency egress, the code allows for a sign indicating the floor level of and the direction to the exit discharge be permitted to be placed as a separate sign with another sign indicating the floor level, the terminus of the top and bottom of the stair enclosure, and the identification of the stair.

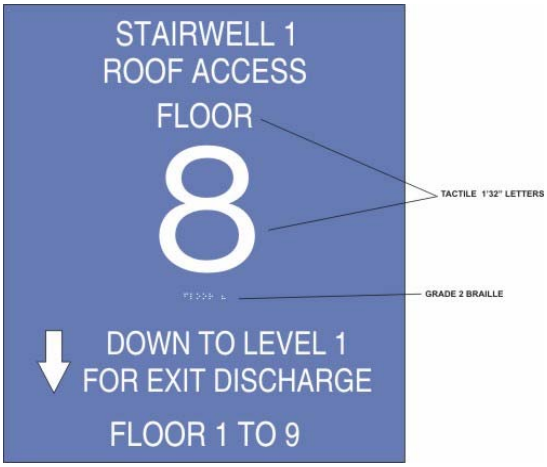

Figure 1.
Note: the size of tactile lettering and Grade 2 Braille are not requirements

Funny Facts from the 1500's

The next time you are washing your hands and complain because the water temperature isn't just how you like it, think about how things used to be. Here are some facts about the 1500s:

Most people got married in June because they took their yearly bath in May, and still smelled pretty good by June. However, they were starting to smell, so brides carried a bouquet of flowers to hide the body odor. Hence the custom today of carrying a bouquet when getting married.

Baths consisted of a big tub filled with hot water. The man of the house had the privilege of the nice clean water, then all the other sons and men, then the women and finally the children. Last of all the babies. By then the water was so dirty you could actually lose someone in it. Hence the saying, Don't throw the baby out with the Bath water..

Lead cups were used to drink ale or whiskey. The combination would sometimes knock the imbibers out for a couple of days. Someone walking along the road would take them for dead and prepare them for burial. They were laid out on the kitchen table for a couple of days and the family would gather around and eat and drink and wait and see if they would wake up. Hence the custom of holding a wake.

England is old and small and the local folks started running out of places to bury people. So they would dig up coffins and would take the bones to a bone-house, and reuse the grave. When reopening these coffins, 1 out of 25 coffins were found to have scratch marks on the inside and they realized they had been burying people alive. So they would tie a string on the wrist of the corpse, lead it through the coffin and up through the ground and tie it to a bell. Someone would have to sit out in the graveyard all night (the graveyard shift.) to listen for the bell; thus, someone could be saved by the bell or was considered a dead ringer.

Pharmaceutical Wastes

The EPA is proposing to add hazardous pharmaceutical wastes to the Universal Waste Rule in order to provide a system for disposing hazardous pharmaceutical wastes that is protective of public health and the environment. The proposed addition will make it easier for generators to collect and properly dispose of these items as hazardous wastes, resulting in a simpler and more streamlined waste management system.

The rule encourages generators to dispose of non-hazardous pharmaceutical waste as universal waste, thereby removing this unregulated waste from wastewater treatment plants and municipal solid waste landfills. The addition of hazardous pharmaceutical waste to the Universal Waste Rule will facilitate the collection of personal medications from the public at various facilities so that they can be more properly managed.

Currently the federal Universal Waste Rule includes batteries, pesticides, mercury-containing equipment, and lamps. Universal wastes are typically generated in a wide variety of settings including industrial settings and households, by many sectors of society, and may be present in significant volumes in non-hazardous waste management systems.

Frequent Questions

How is "pharmaceutical" and "pharmaceutical universal waste" defined under the proposed rule?
For the purposes of this proposed rule, pharmaceutical means any chemical product, vaccine or allergenic, not containing a radioactive component, that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or injury in man or other animals; or any chemical product, vaccine or allergenic, not containing a radioactive component, that is intended to affect the structure or function of the body in man or other animals. This definition includes products such as transdermal patches, and oral delivery devices such as gums or lozenges.

Also, in this proposed rule, a pharmaceutical universal waste is defined as a pharmaceutical that is a hazardous waste as defined in § 261.3, and containers (e.g., bottles, vials, IV bags, tubes of ointment/ gels/creams, ampules, etc.) which have held any hazardous pharmaceutical waste and which would be classified as hazardous waste under § 261.7.

What pharmaceutical drugs are considered hazardous waste?
There are approximately 31 commercial chemical products listed on RCRA's P- and U-lists that have pharmaceutical uses. As the P- and U-lists are based on chemical designations, this number does not completely represent the total number of brand name pharmaceuticals that may actually be listed hazardous wastes. For example, the following chemotherapy drugs, CTX, Cytotoxan, Neosar and Procytox, are U058 (cyclophosamide).

In addition, waste pharmaceuticals may also be hazardous because they exhibit one or more of the four characteristics of hazardous waste: ignitability, corrosivity, reactivity and toxicity. Characteristic pharmaceutical wastes include those that exhibit the ignitability characteristic, such as solutions containing more than 24% alcohol. An example of a pharmaceutical that may exhibit the reactivity characteristic is nitroglycerine. Pharmaceuticals exhibiting the corrosivity characteristic are generally limited to compounding chemicals, including strong acids, such as glacial acetic acid, and strong bases, such as sodium hydroxide.

What facilities generate hazardous pharmaceutical wastes and are they included in this proposal?
This proposed rule applies to hazardous pharmaceutical wastes generated by the following types of facilities: pharmacies, hospitals, physicians' offices, dentists' offices, other health care practitioners, outpatient care centers, ambulatory health care services, residential care facilities, veterinary clinics and reverse distributors. This rule does not apply to pharmaceutical manufacturing or production facilities.

Why is management of pharmaceutical waste difficult under the RCRA subtitle C hazardous waste regulations?

Hazardous waste generation and management practices at health care facilities and other generators of hazardous pharmaceutical wastes differ from practices of industrial hazardous waste generators in several ways that make the application of RCRA Subtitle C hazardous waste regulations difficult. Pharmaceutical waste is typically generated at a large number of points in relatively small quantities across a facility, such as at nursing stations, pharmacies, and patient, emergency and operating rooms. Furthermore, generators of hazardous pharmaceutical wastes tend to generate hundreds of different types of pharmaceutical waste while, in contrast, many industrial generators tend to generate only a few predictable waste streams in large quantities at relatively few generation points. Some of the difficulties that generators of hazardous pharmaceutical wastes have expressed concerning the current hazardous waste generator regulations relate to making the waste determination, generator status upgrade due to generation of acutely hazardous waste, hazardous waste listings, and accumulation time limits.

Why can pharmaceutical waste be considered a universal waste?

EPA believes that hazardous pharmaceutical wastes meet the factors considered when determining whether a waste is appropriate for inclusion in the Universal Waste Rule. Specifically, most hazardous pharmaceutical wastes present a relatively low risk during accumulation and transport due to their form and packaging, which is typically in small, individually packaged dosages, such as pills or capsules. Hazardous pharmaceutical wastes are frequently generated in a wide variety of settings, including hospitals, pharmacies, long-term care facilities, veterinary offices and by reverse distributors, as well as in households. They also are generated by several different types of personnel at these facilities, including pharmacists, doctors, nurses, and patients.

What are the major requirements under the proposed universal waste rule?

The proposed Pharmaceutical Universal Waste Rule is designed to streamline and reduce the complexity of the RCRA hazardous waste collection requirements. EPA expects management of hazardous pharmaceutical wastes to improve, while decreasing the regulatory burden for many hazardous pharmaceutical waste generators, large and small. Specifically, the universal waste program includes modified requirements for storage, labeling, shipment off site, employee training, responses to releases, and notification. For example, the streamlined standards include modified requirements for storage up to a year.

How do these differ from the current generator regulations?

Under current RCRA requirements any facility that generates RCRA hazardous pharmaceutical waste is subject to the RCRA generator regulations that are applicable to its generator status, which could be a large quantity generator, a small quantity generator or a conditionally-exempt small quantity generator, depending on the total amount of hazardous waste generated at the site in a calendar month. Under the universal waste program, generators of hazardous pharmaceutical wastes will have the option of managing these wastes as "universal wastes." If a facility opts to manage its hazardous pharmaceutical waste under the universal waste option, then that facility will become a "handler" of pharmaceutical universal waste, rather than a "generator" of hazardous pharmaceutical waste. Compared to a generator of hazardous pharmaceutical waste, a handler of pharmaceutical universal waste will have the following benefits: 1) an increased accumulation threshold; 2) an increased on-site accumulation limit; 3) an increased storage time limit; 4) no manifest requirement; and 5) basic training requirements.

Should pharmaceutical waste be disposed of down the drain or via sewer systems?

In many instances, at health care facilities and pharmacies, pharmaceuticals are sent to a regulated medical waste incinerator. Additionally, many pharmaceutical wastes are disposed of down the drain. EPA generally considers sewer disposal inadvisable for pharmaceuticals and discourages this practice, unless specifically required by the label on the particular pharmaceutical. In hospitals and other health care facilities, the practice of disposing of pharmaceuticals to sewers has taken place. This has occurred despite the potential adverse effects of introducing waste pharmaceuticals into the environment, and the inability of wastewater treatment plants to treat some pharmaceuticals effectively.

Recent studies have documented the presence of various pharmaceutical chemicals and metabolic by-products in surface waters and groundwater in the United States, and the issue of pharmaceutical use and management has become increasingly important. EPA is conducting research on the presence of pharmaceutical compounds in waterbodies and any ecological effects the compounds may be causing, as well as research directed towards improving water treatment capabilities. For these and other reasons, pharmaceutical waste management has become an increasingly critical issue in environmental management for health care facilities. Information on EPA's research in pharmaceuticals and personal care products in the environment can be found at: http://www.epa.gov/ppcp/work2.html

What is the economic impact of this rulemaking?

This proposed rule does not have any significant economic impacts on the regulated community. In addition, this action does not adversely affect small businesses. EPA estimates that the cost savings of the proposed rule will range from $33.9 million to $35.2 million per year for hospitals and reverse distributors combined. These cost savings largely reflect reduced disposal costs.

When will this rulemaking go into effect?

As established by the Administrative Procedure Act, this rulemaking must undergo the notice and comment process. Once public comments are received, comments will be reviewed and the proposed rulemaking will be re-evaluated to determine if changes are warranted. This process takes several months to over a year depending on the nature of these comments. We expect that this rulemaking will be finalized in 2010. However, because this rule is less stringent than current RCRA generator regulations, authorized states are not required to modify their programs to adopt this regulation. Therefore, the regulated community cannot choose to manage their pharmaceutical wastes as universal wastes until the rule is adopted in their particular states.

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Dear Sir:

I am writing to express our appreciation for your consultant, George Rivas. His knowledge of TJC standards, Life Safety codes and highly effective consulting has been evident through the years. Members of our Medical Center's Environment of Care Safety Council first heard George speak at an EC Conference in 2002. As a result of his excellent presentation, we invited George to conduct a Mock EC Survey at our facility in preparation for our Joint Commission survey.

Since that time, Mr. Rivas has provided us with thorough survey preparation and, as a result, we have had very successful surveys with few RFI's. Thanks to George Rivas for his continued guidance and support in Environment of Care, Emergency Management and Life Safety.