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TSIG NEWS

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Not Everything Stays in Vegas!

We at TSIG Consulting would like to think that this year's record attendance at the EC Summit in Las Vegas was due in part to our very own George A. Rivas serving as Proctor, Presenter & Tour Guide. In fact, George again received the highest favorable scoring among all the attendees. And we're sure that many of them took a little EC knowledge back home with them for future's use. For those of you who missed this superb educational seminar, here's what just a few attendees had to say:

Thank you so much!! The conference was incredible and we all talked about the fact that you by far exceeded our expectation.
Your credibility and knowledge was great!!
George, The EC Summit was great and I want to thank you for the great tools that we can implement now that we are home.
I enjoyed all of your presentations at the EC Summit last week in Las Vegas. Great job at the EC Summit!
Thanks for the great presentations at the EC Summit.

New Hazardous & Utility Systems Requirements

By Ode Keil

The 2009 Environment of Care (EC) standards introduce new hazardous material and HVAC system management challenges for hospital facility managers. The Hazardous Materials and Waste standards introduce the plumes created when cautery or lasers are used during surgical procedures as hazardous vapors. There is little specific information available about the hazards related to exposure to the plumes and there is little or no guidance on what level of exposure is acceptable. The concern expressed by several investigators is that live biological cells or cell contents that are known to be infectious could be inhaled through surgical masks of OR staff working with lasers. Research on the subject is not conclusive. There is clear evidence that particles able to pass through typical surgical masks are generated. There was not consistent identification of particles that are potentially infectious.

Safety recommendations from OSHA and the Canadian Centre for Occupational Health and Safety are to use a smoke evacuator with a HEPA or ultra low penetration air (ULPA) filter to trap the particles. The challenge both acknowledge is that the smoke evacuators are not within 1 or 2 centimeters of the surgical site they quickly become ineffective. In addition some experts recommend use of organic vapor and dust filtering half face respirators as both general room ventilation and point evacuation systems are not reliably effective in removing the plume.

The only recognized national standard is ANSI standard - *Z136.3-2005*, Safe Use of Lasers in Health Care Facilities, (2005) that addresses laser safety in hospitals. There are many other publications addressing laser safety. Very few address the plume. Most are focused on the hazards of direct exposure of eyes and skin and the hazards lasers pose to patients during surgical procedures. The lack of definitive information leaves hospitals in the awkward position of having to make decisions about management of the plume. It is important to note that the revises HAZMAT standards also classify lasers as a hazardous energy source and require the development of a safety program related to exposure.

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Understanding HAZMAT Responsibilities & Requirements
Part 1 of a 3 Part Series

One of the most challenging aspects of providing emergency medical care is attending to patients who have been contaminated with hazardous materials. HAZMAT is a term used to describe incidents involving hazardous materials or specialized teams who deal with these incidents. Hazardous materials are defined as substances that have the potential to harm a person or the environment upon contact. These can be gases, liquids, or solids and include radioactive and chemical materials. Biological organisms, such as viruses and bacteria, are not included as hazardous materials in this article.

Most hospitals in the United States lack plans or facilities for attending to patients exposed to hazardous materials, even though this can be a common problem in some areas. Recent terrorist activities in the United States, Japan, Europe, and Asia highlight the need for hospital preparedness. Federal statutes require hospitals to participate in the planning and care of persons exposed to hazardous materials and to train and provide protection for employees who may be exposed while providing medical care.

The potential for exposure to hazardous materials in the United States is significant. More than 60,000 chemicals are produced annually in the United States, of which the US Department of Transportation (DOT) considers approximately 2000 hazardous. More than 4 billion tons of chemicals are transported yearly by surface, air, or water routes. These shipments are initiated from more than 100,000 different locations, with more than 1 million people directly involved in the transportation process. More than 500,000 shipments of hazardous materials are made every day, totaling approximately 1.5 billion tons per year.

The incidence of hazardous materials exposures cannot be ascertained accurately because a national reporting system does not exist. In an attempt to better define the magnitude of this problem, the Agency for Toxic Substances Disease Registry developed the Hazardous Substances Emergency Events Surveillance (HSEES) system in 1990. Fifteen state health departments participate in the reporting system. In these states, the system has shown the following findings:

- About 9000 releases of hazardous substances occur annually, with 75% occurring at chemical facilities and 25% occurring during transportation.
- Most transportation-related incidents occurred during ground transport (85%) and 26% occurred in residential areas.
- Human error and equipment failure account for most releases.
- The most common substances involved were inorganic substances (24%) followed by volatile organic compounds (20%).
- More than 2000 people are victims of hazardous materials releases in these states each year. Approximately 50% of these are transported to hospitals. Respiratory and eye irritation are the most common types of injury. Over a 4-year period, 132 hazardous material–related deaths occurred.
- More than 7500 people required decontamination during HAZMAT events over a 4-year period in these states. Of these, 2643 were decontaminated at medical facilities.

Several important points can be drawn from the above statistics. Most importantly, this is not a rare problem. Cities, pre-hospital-care providers, and hospitals need to have plans for dealing with these incidents and caring for victims of hazardous material exposures. Because most incidents occur at fixed sites, knowing the industries that operate in the catchment area of a hospital and the chemicals used or stored at those sites is imperative. Trauma centers need to have a plan to care for trauma patients who are contaminated because 25% of the incidents occurred during transportation and 9% of victims of hazardous materials exposure also had traumatic injuries.

HOSPITAL AND COMMUNITY PLANNING FOR HAZMAT INCIDENTS

Most hospitals are unaware of the requirement by several different federal agencies, as well as the Joint Commission to participate in community planning for HAZMAT incidents. The most important federal statute that hospitals must be familiar with is SARA Title III, a portion of the Superfund Amendments and Reauthorization Act, otherwise known as the Emergency Planning and Community Right to Know Law.

SARA Title III states that facilities manufacturing or storing hazardous chemicals must report inventories and every hazardous material release to public officials and emergency health agencies. This act also requires the establishment of state emergency response commissions (SERC) and local emergency planning committees (LEPC). The LEPC includes local officials, police, fire, and public health authorities in addition to representatives of local hospitals, media, and the community.

Emergency response plans

The primary responsibility of the LEPC is to develop emergency response plans (ERPs) to do the following:

- Identify local facilities using hazardous substances
- Designate community and industrial coordinators
- Establish mechanisms of emergency notification
- Establish procedures for determining the occurrence of a release and an estimation of the affected population
- Identify community emergency equipment facilities
- Establish evacuation plans

Establish and schedule training programs for emergency personnel

Hospitals are required to be an integral part of the ERP. Additionally, emergency medical services (EMS) units and coordinators have critical roles in the planning and execution of an emergency response. The plan for each community varies depending on the types of industries involved, chemicals used, and resources available. For example, many fire departments in metropolitan areas have developed specialized HAZMAT teams to respond to these situations. These teams are responsible for containing releases and for decontaminating persons exposed to hazardous materials. After decontamination, these patients can be transported safely and treated in the hospital with minimal precautions.

Conversely, in communities where a HAZMAT team is not available, the ERP must consider how persons exposed to hazardous materials will be decontaminated and transported. Hospitals must be capable of caring for severely contaminated patients under the ERP guidelines. Because most hospitals are poorly prepared to attend to a severely contaminated patient, early involvement of hospital representatives in the planning process is critical. Similarly, EMS coordinators must train emergency medical personnel to attend to contaminated patients and to establish contingency plans for their transport and care.

Joint Commission Requirments

Several Joint Commission requirements relating to hazardous materials affect hospitals. Previous requirements concerning specific protocols for dealing with radiation exposures have been dropped and more general requirements governing dealing with any hazardous materials and participation in community emergency response planning were added. Some of the more specific Joint Commission standards (2008) are as follows:

- EC 1.10.5 - The hospital uses the risks identified to select and implement procedures and controls to achieve the lowest potential for adverse impact on the safety and health of patients, staff, and other people coming to the hospital's facilities.
- EC 3.10.9 - The hospital identifies and implements emergency procedures that include the specific precautions, procedures, and protective equipment used during hazardous materials and waste spills or exposures.
- EC 4.1.2 - The hospital establishes the following with the community:
    - Priorities among the potential emergencies identified in the hazard vulnerability analysis
    - The hospital's role in relation to a community-wide emergency management program
    - An "all-hazards" command structure within the hospital that links with the community's command structure
- EC 4.2.4 - The hospital participates in at least one community-wide practice drill a year (where applicable) relevant to the priority emergencies identified in its hazard vulnerability analysis. The drill assesses the communication, coordination, and effectiveness of the hospital's and community's command structures.

Understanding HAZMAT Responsibilities & Requirements (Con't)

Occupational Safety and Health Administration regulations

The Occupational Safety and Health Administration (OSHA) has issued several regulations that pertain to any hospital employee who may come into contact with hazardous materials, including those on patients seeking medical care. Regulation 29 CFR 1910.120 (q) standard describes respiratory protection for all employees potentially exposed to hazardous chemical vapors as well as the minimal degree of training for any employee involved in decontamination. Other standards (ie, 29 CFR 1910.132 [d], 1988) delineates that employers must assess the workplace for potential hazards and have employees use personal protective equipment (PPE) appropriate for that hazard.

Under OSHA standards, an emergency response team is defined as an individual or group who responds to a release of a hazardous material, no matter where it occurs. This regulation initially was intended for hazardous waste operators and emergency response personnel at hazardous waste facilities; however, in the case of a patient who has been contaminated, hospital and EMS personnel also may be included.

The current regulations state that all ED personnel must be trained at a minimum of first responder awareness level (level 1), and any personnel involved in patient decontamination must be trained to first responder operation level (level 2). OSHA has not fully determined how these standards will apply to hospitals and healthcare facilities that are off-site. Planning the roles of HAZMAT and EMS workers requires familiarity with the definitions and training requirements (described below) of individuals who may respond to a HAZMAT incident as defined by the Hazardous Waste Operations and Emergency Response (HAZWOPER) standards. If emergency medical transport personnel are expected to transport contaminated individuals or to provide medical care in the field prior to decontamination, they at least should have the appropriate level of training. Five levels of HAZMAT responder training are defined in CFR 1910.120 (q).

Environmental Protection Agency

Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), EMS scene responders are protected under a "Good Samaritan" clause. However, healthcare facilities must contain any runoff from decontamination activities.

Hospital and community planning

Hospitals must have adequate plans for addressing HAZMAT incidents and incorporate these into community plans. Some of the aspects that need to be included in the plans include the following:

- Triage
- Personal protective equipment (PPE)
- Decontamination procedures
- Crowd control
- Dealing with victims who arrive by private vehicle
- Medical care after decontamination

Public relations and press releases

The responsibility of hospitals cannot stop at the planning stage. Employees must be trained to use the PPE and how to perform decontamination. Incidents of hospital workers becoming ill as a result of chemical exposure when caring for a contaminated patient have been reported. If this occurs, the legal position of the hospital is tenuous.

Providing universal guidelines for all communities is difficult. In formulating hospital and community response plans, the most critical aspects to consider are location of and responsibility for decontamination. Ideally, decontamination takes place in the field and is performed by specially trained HAZMAT teams. In this case, subsequent prehospital and hospital care can be performed with little change in the usual routine and with minimal risk to healthcare providers. In situations where several hospitals are located in a given area, it is not financially feasible for all hospitals to have good decontamination facilities. One hospital should be chosen as the receiving facility. The choice of hospital should be based on the availability of decontamination facilities, intensive care facilities, training of ED personnel, and staff trained in medical toxicology.

Regardless of whether a hospital is a receiving facility or if it is in an area where a trained HAZMAT team is located, situations always occur when contaminated patients present to other prehospital or hospital systems. In any mass casualty situation, it is likely that victims will leave the scene and travel by private vehicle to the healthcare facility of their choice. For a hospital that was not a designated decontamination facility to send these patients to another facility would constitute an Emergency Medical Treatment and Active Labor Act (EMTALA) violation. Consequently, all hospitals should have a plan and appropriate employee training for attending to the contaminated patient. See our next issue for Part 2

New Hazardous & Utility Systems Requirements (con't from cover)

The ANSI standard and the related resources provide a great deal of information about everything from construction to protective eyewear. These documents can be applied to developing a solid laser safety program to all hazards except management of the plume.

The utility systems management standard addressing management of airborne matter is expanded to cover airborne contaminants. The list of examples built into the standards includes biological agents, gases, fumes, and dust. This is a more comprehensive list than covered by previous generations of the EC standards. While not using the term this list and the use of airborne contaminants suggests that the Joint Commission is pressing hospitals to manage indoor air quality. The standard goes on to state that ventilation systems must provide appropriate pressure differentials, ventilation rates, and filter efficiencies. This seems to be a clear tie to the AIA guidelines citation of ASHRAE design standards for hospital ventilation systems. The AIA guidelines are cited as a source of information for design in a different section of the EC standards. The enhanced scope of the language may require an expansion of existing test and balance programs, filter efficiency monitoring programs, and documentation of compliance with design standards for licensure.

The enhancement of the HVAC component of the utility system standards should come as no surprise. The Joint Commission is clearly on record as being interested in reducing the potential for hospital acquired infections. Proper management of airborne materials can assist in meeting that goal. In addition, the EC standards have, since the beginning, focused on worker safety. Identifying airborne contaminants that are potential source of health concerns as part of the proactive risk assessment and putting ventilation system maintenance and performance management programs in place to address them are simply part of meeting the intent of the safety program.

a. Nezhat C, Winer W, Nezhat F et. al.: Smoke from Laser Surgery: Is there a hazard? "Lasers in Surgery and Medicine" 7: 376-382, 1987.
b. Fisher RW: Laser smoke in the operating room, "Biomedical Technology Today" 191-194, 1987.
c. Garden JM, O'Banion KM, Shelnitz LS et. al.: Papillomavirus in the vapor of carbon dioxide laser - treated verrucae, "Journal of American Medical Association," 259: 1199-1202, 1988.

The 2009 Joint Commission Medical Equipment Standards

The Joint Commission History

The Joint Commission (TJC) is an independent, not-for-profit organization. When congress passed the Social Security Amendments of 1965 (Public Law 89-97), there was a provision in the law that permitted hospitals accredited by the TJC to be "deemed" in compliance with the Medicare Conditions of Participation for hospitals. This provides hospitals with an alternate path that many consider preferable to a survey done by the individual state survey agencies on behalf of the Centers of Medicaid and Medicare Services (CMS) to qualify for Medicare and Medicaid reimbursement. The Conditions of Participation for hospitals are contained in 42 CFR 482.

TJC Medical Equipment Standards

The two new 2009 TJC medical equipment standards are EC 02.04.01 and EC 02.04.03, and continue to remain in the "Management of the Environment of Care (EC)" chapter. In addition, as part of the standards initiative re-organization, references to other standards are present within these two chapters, and requirements that affect medical equipment management from those chapters are equally important to your program.

EC 01.01.01

7) Medical Equipment Management Plan

This EP requires the hospital to have a written plan that describes the processes for managing the effective, safe, and reliable operation of medical equipment. The plan should provide an overview of how the equipment is managed at the hospital, not simply a recitation of the medical equipment standards. It should also be a link between the TJC medical equipment-related standards and the function of managing medical equipment at the hospital. Applicable hospital policies, procedures, and standards should be referenced in the management plan. (see also EC.04.01.01 EP 15)

(Con't on page 8)

Recent Survey Experiences

The following are the notes from a 1100 bed NYC hospital recently surveyed during the month of October.

Survey #1

The Survey team consisted of 7 Surveyors plus the addition of the LSS for the last 2 days of Survey.

Here is the way the surveyors split their responsibility in our hospital - one surveyor for 1 day just did tracers in Psychiatry, one surveyor did tracers in Clinics and Ambulatory Care for 2 days, two surveyors spent 3 days at Main hospital and Off-site facilities and 3 surveyors spent 5 days at main facility. On the 4th Day one of the surveyors became the LSS for the Off-Site Facility. One surveyor was strictly a LS. So in total we ended with two LSS.

We were told right at the start that if documentation is asked for, we have until end of day to produce it, unless other arrangements were made with surveyor. This was strictly adhered to as evidenced by the Supplemental Recommendation immediately issued for not showing evidence of inspection for the Fire Department Connections in a timely manner.

The following is a summary of what happened with the Life Safety Surveyor:
On Thursday when the Life Safety Surveyor showed up and he was introduced and then got right to work. He met with Directors of Safety and Engineering and VP of Facilities.

We were handed a very comprehensive list, each categorized by standard and by EP with the required documents that he was interested in and which he wanted to see in order of :weekly, monthly, semi-annually, annually, and beyond.

Documents were produced for all alarm testing devices. He wanted to know how we knew if it passed or failed as the documentation did not have a column that showed this. We explained that we receive a print-out that shows when the device was tested with the date, whereupon he tried several times to find one that was not tested. In the end he still suggested a column with a pass / fail to make it easier for a surveyor to see the results. He also looked for the annuals for audible and visual test, and again looked for a pass/fail. He wanted to know how we know that all devices are working, and how we soon replaced them if failed.

The surveyor paid particular attention to water-based testing and generator testing documentation. He wanted us to explain how the central station testing was done and to show documentation of all the components i.e.: phone lines, battery, etc. (we had ADT fax the tech reports to us).

The surveyor wanted to see the annual documentation for the main drain tests, inclusive of the original static pressure and residual pressure as compared to the previous year's findings including time taken for the system to restore pressure.

When examining records for the testing of our generators, he wanted to see the connected load time on the documentation. It was not present and we explained it would be added, for which we received a Supplemental Recommendation.

For the medical gas and vacuum systems he wanted to see the entire tests from 2007 and 2008.he then checked for failures and looked for documentation of repairs. We showed documentation for items being repaired but not as individual repairs, i.e.:" Rooms 10-19 had repairs required" and we had documentation stating "all repairs were completed". This was unacceptable; instead he asked for "repaired leak in Rm#16", "Repaired loose wall mount in Room #10" etc…

He also wanted to see inventories for fire extinguishers, fire hoses and spares. His recommendation was to bar code every thing to ease tracking of supplies.

The surveyor wanted to see documentation of the testing of the kitchen systems. We explained that they are tagged and in fact the tag was on the system. He made a comment that usually the company sends a certificate of compliance and we should make sure we get it.

He questioned how we did the tests for the roll down doors, fan shutdowns, and emergency lighting. We explained that on roll down doors we have a sticker with annual inspection date on key side.

Going over emergency lighting documentation the surveyor found two emergency lights that were not tested for two months. Both were in the operating suite and this resulted in another supplemental recommendation.

Survey #1 (continued)

The surveyor asked us to pick a project and show him ILSM documentation. We produced two projects, both of which fall under DOH surveys, and for which we had documentation for the training of the contractors and training the staff on the units on each side. We showed pictures of signage placed on doors and in the elevator lobbies. We also showed sign in sheets stating that there were meetings with supervisors of Environmental and Food Service as well as Nursing. This was not good enough as he wanted to see how we documented training for Hospital wide as per;

EC5.5 EP2 Conducting hospital wide safety education programs, to promote awareness of fire-safety building deficiencies, construction hazards, and ILSM. This resulted in another supplemental recommendation.

At the end of the first day of survey, while being escorted out of the hospital, the surveyor walked passed a door to a vacant X-Ray/CT-Scan reading room that was propped open with a crushed cardboard box. Although nothing was said to us, it made it to the Supplemental findings report as well.

Lessons learned: do all the necessary testing and prepare all required documentation and above all, have them available.

- Chemo storage
- MSDS maintenance
- Administrator review of EC Documents

All 7 management plans and annual evaluations provided prior to session and were read.

The first 1½ hours devoted to 6 of the plans: Safety, Security, Hazardous Materials, Fire Prevention, Utilities and Patient Care Equipment.

Safety:	Environmental rounds, data collection/aggregation and trends
	Proactive risk assessment
Security:	Infant/child security
	Proactive risk assessment
	Suicide risk patients in med/surg areas
Haz Mat:	Organization of waste management
	Training for signing manifests
	Pharmaceutical waste process
Fire Prevention:	Lessons learned from drills
	Critiques with staff positives as well as negatives
Utilities:	Goals
	Patient Care Equipment: failures causing harm
	How does unusable equipment get to Bio Med/how fast after a problem identified
Emerg Mgmt	Provided the HVA with the other documents
	Discussion of drill or real event this year/review of action plan
	Asked who was first to get hands on this situation, then followed through process for calling Code Orange and getting patients into the system
	Asked everyone present their role in a disaster
	We talked about community involvement, Bio terrorism and pan flu planning, grant dollars and how spent
	Never asked about the 96 hour rule or planning for it (we did provide some information on what we are looking into with fiscal, payroll, billing, supplies and food)

The last 1½ hours was an evaluation held in the Emergency Command Center at which time a disaster scenario was presented followed by detailed Q & A session with key Emergency Management personnel.

Received one EC RFI in LSC (EC 5.20): basically the surveyor said anyone should just plan on getting this as they will look until they find enough deficiencies; and that is what he did.

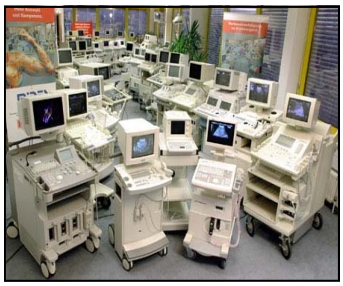
The plan should be tailored to the type of organization (hospital, ambulatory, long-term care, etc, or multiple settings like hospital and ambulatory), the patient services provided (dialysis, nuclear medicine, surgery, etc), and the medical technology used (lasers, dialysis units, MRIs, etc). It should briefly describe how each EP that is relevant to the medical equipment and how the requirements in other TJC standards that have a link to the medical equipment program—such as IC.02.02.01, LD.04.04.01, and EC.03.01.01—are carried out. The management plan is the "linchpin" in complying with the medical equipment management standards, and is one of the key documents reviewed by the TJC surveyors.

EC.02.04.01

1) Selection and Acquisition of Medical Equipment

This EP requires the hospital to describe its process for selecting new equipment. This should include a needs assessment, selection criteria, comparative evaluations, and a life-cycle cost analysis. The acquisition process would include evaluating the medical equipment for clinical effectiveness, patient safety, and human factors before final selection. It should also include initially evaluating the condition and function of the equipment after delivery and evaluating the training of the users, before it is used on the patients. The hospital must solicit input from individuals who operate and maintain the equipment during the selection process

2) Inclusion of Risk Criteria and Inventory



This EP gives the hospital a choice to either include all of the equipment in the program, or to select certain types of equipment to be included in the program based on equipment function; physical risks with use; and incident history, which are called inclusion or risk criteria. There are various versions of the equation used to combine these numerical criteria based on the original Fennigkoh and Smith model. There can be considerable variation between the risk rankings resulting from the different versions of risk-based calculators. The factors used in the various risk-based approaches, their weighting, the value above which one decides to include the device in the management program, and what preventive maintenance (PM) interval to use have been described as somewhat arbitrary. The risk-based sub-inventory allows the hospital to exclude PM completion rate reporting, for the so-called low-risk items. However, the all-inclusive inventory approach is less confusing and allows you to control equipment-management functions for all of the devices in your maintenance program. (see also EC.02.04.01, EPs 1 and 3)

This EP requires the hospital to establish a current, precise, and unique inventory of all medical equipment managed under the medical equipment program, regardless of ownership. The inventory should consider for inclusion all medical equipment in use at the hospital including hospital-owned and non-hospital-owned equipment (leased, rented, physician-owned, patient-owned, etc). Any medical equipment managed by other vendors should also be considered for inclusion in the medical equipment inventory. The medical equipment inventory should not be restricted to devices included in the medical equipment maintenance program. An accurate and complete inventory is critical for various medical equipment management functions, including tracking of manufacturers' recalls, documenting the cost of maintenance, replacement planning, scheduling maintenance work, and tracking model-specific and device-specific issues. It is desirable to keep the medical equipment inventory highly accurate, and random samples should be taken periodically to assess the inventory's accuracy. One method could be to document monthly the number of items that could not be located that are on a monthly preventive maintenance (PM) schedule. The number of "unable-to-locate" items should be low if the inventory listing does not include any items that are not in fact present at the facility. Conversely, items missing from the inventory make themselves apparent because they do not carry either a PM sticker or an equipment control number. Another approach would be to print annually departmental inventories and verify that all items listed are in the hospital by walking through the entire hospital. This would also identify any items in the hospital that are not on the inventory.

3) Maintenance Strategies

This EP requires the appropriate selection of maintenance strategies for all of the equipment in your medical equipment management plan inventory. The strategies listed in the TJC standards include predictive maintenance (using the concepts of reliability-centered maintenance), interval-based inspections, corrective maintenance (that is, repair or replace if defective), and metered maintenance (hours of run time or number of images processed, for example). (see also EC.02.04.03, EPs 2 and 3)

4) Maintenance Intervals

This EP requires the hospital to define appropriate maintenance intervals for their equipment based on manufacturers' recommendations, risk levels, and the organizational experience. In 2001, TJC removed the annual performance and safety testing requirement for medical equipment. This change signaled recognition that the safety and reliability of medical equipment has improved significantly in recent times. (see also EC.02.04.03, EPs 2 and 3)

5) Incident Reporting and Monitoring

Safe Medical Devices Act (SMDA) of 1990 This EP requires a description of the hospital program for monitoring and reporting incidents as required by the SMDA. The SMDA requires user hospitals and other health care facilities to report device-related deaths to the US Food and Drug Administration (FDA) and the device manufacturer, report device-related serious injuries to the manufacturer or to the FDA (if the manufacturer is not known), and to provide a summary of all reports submitted during the year to the FDA on an annual basis.

6) Failure Procedures

This EP requires the hospital to develop emergency procedures that identify the roles and responsibilities of users and maintainers, with respect to equipment disruption or failure; procedures on when and how to perform emergency clinical interventions when the medical equipment fails; and provisions for backup equipment and how to obtain repair services. The users and maintainers should evaluate the medical services provided by the hospital to determine which types of equipment are critical for patient care and to prepare a list of the critical equipment. After this, the hospital should develop procedures for managing the clinical consequences of critical equipment failure and for obtaining repair services during regular and after-hours, or replacement/loaner equipment from storage or outside suppliers.

E.C.02.04.03

1) Performance and Safety Testing

This EP requires the hospital to test all medical equipment for safety and performance before it is initially used in the hospital. This testing should also include non-hospital equipment that is leased, rented, etc.

2) and 3) Maintenance on Life Support and Non-Life Support Equipment

Not too long ago, The Joint Commission considered 95% maintenance completion to be a "pass" for a medical equipment program. In 2004, it discontinued the 95% requirement and added specific "life support" language to the standard EC.6.20. The intent of these changes was to ensure that critical equipment receives priority attention. It requires the organization to separately track and report the maintenance completion of medical equipment in two categories: life support and non-life support. The Joint Commission defines life support equipment as "those devices intended to sustain life and whose failure to perform its primary function, when used according to manufacturer's instructions and clinical protocol, is expected to result in imminent death in the absence of immediate intervention. Examples include ventilators, anesthesia machines, and heart-lung bypass machines)." Anesthesia ventilators, external pacemakers, intra-aortic balloon pumps, and ventricular assist devices could all be included in the life support category. The hospital should develop a list of life support items based on the above definition and organizational experience. (see also EC.02.04.01, EPs 2, 3, 4 and PC.02.01.11, EP2)

The 2009 Joint Commission standards do not contain an explicit PM completion requirement. However, based on the scoring guidelines, it would be appropriate to set a goal for an on-time maintenance completion rate for life support equipment at 100%, and the goal for the non-life support equipment at better than 90%. The maintenance completion for life support equipment is scored more stringently than the completion rate for non-life support equipment. It is possible that if maintenance of a single life support device is missed, the survey team could generate an adverse, noncompliance "finding." However, it has been reported that it is more likely that the surveyors will focus on investigating the gaps in the process that led to the missed PM.

4) Performance Testing of All Sterilizers

This EP requires the hospital to document performance testing of all sterilizers. Sterilizers may be found in surgery, central service, and other departments. Usually, the departments that have sterilizers are responsible for verifying proper sterilization performance and for keeping a record of the testing. Each department's data must be aggregated and reported. (see also IC.02.02.01, EP2)

5) Dialysis

This EP requires the hospital to do chemical and biological testing of the water used in hemodialysis and to perform other required tests based upon regulations, manufacturers' recommendations, and hospital experience. If dialysis service is provided on a contract basis, the hospital must ensure that all the proper tests are done and records are maintained.

Summary

Although the standards promulgated by The Joint Commission (TJC) are one of the primary drivers of clinical engineering programs, there are several other organizations, including federal and state agencies, that set standards and regulations regarding the use of medical equipment in hospitals. It should be noted that a comprehensive medical equipment program should take into consideration each of the various regulatory agency requirements as well as determine those processes that best fit the organization while also assuring the integration of best demonstrated practices.

Infant Security for Thought

Imagine if one day your hospital becomes victim to the following… A kidnapper accesses the main lobby facility displaying a false identification card and abducts an infant successfully? How would your organization deal with its image? How would this affect your organization's reputation? Infant abductions remain a security nightmare that no organization can afford to suffer and despite the less frequent reports of said events, it remains a serious concern.

In fact recent reports illustrate that more complex & diverse means of abducting infants are being attempted, even outside of the hospital. For example, a 20 year old woman from Missouri pled guilty just last month to attempted kidnapping of a pregnant teenager she met online in a plot to steal her unborn child. In court, the perpetrator admitted to meeting the mother on the social networking website: '"MySpace" where a foiled plot was admitted to.

However the threat and risk of this horrifying reality occurring at any hospital still exists and remains a serious concern in the United States. According to the National Center for Missing and Exploited Children a total of 253 infants were abducted from hospitals. The statistical breakdown of newborns removed includes 62 Hispanics, 105 black, 77 white, 3 Asian, 2 American Indian and 4 biracial (www.missingkids.com).

The profile abductor usually is;

Female (predominately Black, White, Hispanic)
Age range 12-50
Possesses the following traits; compulsiveness, manipulation, lying and deception
Often indicates she lost an infant (through miscarriage, etc)
Cannot have one for medical reasons
Often married or cohabitating where the her companion has a desire for a child
Usually lives in the vicinity where the adduction occurs and visits nursery and maternity units at several hospitals prior to carrying out the abduction
Questions hospital staff detailed questions about procedures and maternity floor layout
Frequently uses fire exit stairwells and impersonates a nurse or other hospital person
Usually plans the crime but does not necessarily target a specific infant
Becomes familiar with hospital staff, work routines as well as the victims parents
Demonstrates capabilities to provide good care to the baby once the abduction occurs.

Infant abductions are considered sentinel events and must be reported to the Joint Commission. It is equally important to note that an infant discharged to the wrong family is also considered a sentinel event.

The hospital's obligation to provide a secure environment for infants initiates with the Security Program. Physical security, infant security systems (technology), policies, procedures and staff training are the ingredients for such a vital program. It involves the collaboration of both clinical and non-clinical personnel. Both nursing staff and security personnel have to be trained both on the actual operation of infant security technology systems and related policies and procedures. What will the role of law enforcement be? Drills should be conducted in tandem with law enforcement.

The national Center for Missing and Exploited Children has published a healthcare assessment tool named NCO5 (www.missingkids.com/en_us/publications/NC05assessment.pdf). It is suggested that healthcare organizations utilize this guide and assess their facility and protocols.

Another existing challenge is assuring Life Safety compliance, while also affording facility security & protection. Question…"What if the hospital is faced with a fire alarm as well as an infant security alarm at the same time? Do you secure doors?" This can actually prove a tactic to divert the attention of an abductor in a real life situation. Joint Commission surveyors examine locking devices very closely during their building inspections and many hospitals have been found in violation of NFPA 101 Life Safety Code, as a result of locking means of egress for security purposes. Jurisdictions are beginning to talk about these realities while understating a need to stay compliant with fire regulations. In fact, at a recent National Fire Protection Association (NFPA) conference, the speaker discussed the dilemma of assuring code compliance while affording adequate security, stating that NFPA has been working hard to identify how to best match the Life Safety Code requirements with hospital security needs. In our next issue, we will provide details on how you can ensure that your current security systems meet the requirements of the NFPA Life Safety Code.

A New Team on The Block

A new team of accreditation **surveyors** that is! On September 26, 2008 the Centers for Medicare and Medicaid (CMS) provided deemed status to a new accreditation process for the first time in more than 30 years creating another option for healthcare entities choosing to be accredited. There are now 3 accreditation organizations now (outside the scope of direct CMS accreditation) available for healthcare organizations to choose from. The Joint Commission (TJC), the American Osteopathic Association (AOA) and now DNV Healthcare's National Integrated Accreditation for Healthcare Organizations program (NIAHO). Providing organizations with 3 options for accreditation should be good for the hospitals, and ultimately the patients served.

The NIAHO accreditation process integrates the nationally recognized IS

O 9001 Quality Management System with the Medicare Conditions of Participation, making it the first and only hospital accreditation program that requires continual quality improvement. Incorporating ISO 9001 in to the accreditation process creates a culture of self policing your operations like never before.

Survey teams consist of clinicians, generalists, and life safety specialists. All NIAHO surveyors have been cross-trained as ISO 9001 Lead Auditors. Surveyors visit accredited hospitals annually to ensure progress.

The NIAHO piece of the equation simplifies the process of adhering to the CMS Conditions of Participation (COP). The standards are straight forward and allegedly designed not be loaded with 'fluff'- allowing the organization to focus on meeting the specific COP standards, while minimizing the opportunity for "Gray Areas" from surveyors.

For several years, select member of the TSIG staff have served as a part (surveyor) of the "proving" portion of DNV Healthcare's process to become "deemed" and have seen the accreditation program in action. Feel free to contact TSIG Consulting, Inc. for any questions you may have. If you'd like preparation assistance, etc. we'd be glad to assist.

Return On Investment -ROI

In these very difficult financial times, hospitals have a responsibility to protect any expenditure by clearly defining that any money spent is not only well spent, but fully justifiable. It is hard to prove that an expenditure has a financial return, but in the case of assuring current & accurate Life Safety drawings for your buildings, there is no question that the costs associated with said product can prove a significant and rewarding return.

Often times healthcare organizations do not maintain accurate updated drawings, which has led this to be one of the most frequently identified Recommendations for Improvement during Joint Commission, CMS and DOH surveys. This is due in large part as a result of continuous renovations and changes in floor plans, coupled with the fact that few organizations have a draftsperson on their staff that can actually devote his/her time to this effort. Furthermore, many of those fortunate to have someone assigned to this task, may not be as familiar with Life Safety Code requirements per NFPA 101, and therefore can either underestimate and/or overcompensate code compliant measures.

Here's an example of what could be at stake. Consider that every foot of smoke or fire barriers carries with it the possibility of penetrations, door issues and potential damper problems. It can cost $50 to seal a penetration, $50-$150 to fix a damper and $75- $1000 to repair / replace a door. Thus, it is reasonable to accurately define only those required barriers per the code so as to minimize the associated costs without compromising life safety. The savings for maintenance of said barriers will follow from one year to the next. Determination of correct occupancies, designation of compliant suites, and simply verifying the accuracy of the floor plans should not be left to the judgment of an inexperienced person. This is why we highly recommend that you consider engaging TSIG to assist your efforts for an immediate pay back- which we believe has a Return of Investment- usually in less then one year, based on our experience. You can't find a better return on your investment as this, and it's as simple as just contacting us to have one of our Life Safety experts assist you in this effort..

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