Response to June 28 Meeting

Prepared for CMS

By:

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July 17, 2012
Executive Summary

Thank you for your time to openly discuss the December 2011 S&C on maintenance activities for equipment in healthcare organizations. While a welcomed first step toward updating regulations, the CMS clarification statement created confusion, and concern, among those responsible for supporting medical devices and facilities equipment in the healthcare organizations. This document is the first response to questions that were raised by CMS representatives during the June 28th meeting. Through ongoing direct communication between our organizations, we expect to bring further clarity to the remaining points of concern. Collaboration in this manner should serve to eliminate the current differences between actual standards and what is understood (and therefore accepted as common practice) within the field of Healthcare Technology Management (HTM).

It is important to note that during previous discussions, CMS representatives clarified their expectations on several items. For that reason, we wish to completely retract the earlier statements regarding the estimated financial impact. The impact of those clarifications was not appropriately recognized in the documents that were submitted to CMS in advance of the June 28 meeting. We have attempted to correct that oversight in this document.

AAMI and ASHE, as the representative voices of our member professionals, request that CMS consider the additional information in the analysis that follows. Similar to the clarification that CMS has accepted alternatives to the recommended tools and test equipment if there is evidence of equivalent or improved outcomes, we ask your consideration of the enclosed evidence that current maintenance processes are at least as effective as manufacturer recommendations. These types of evidence-based maintenance programs (EBM) have been widely utilized across the United States for decades, and have become an integral part of quality improvement processes within HTM. Some aspects of this approach have been adopted by most healthcare organizations in the United States, regardless of size, ownership, or mission. While there is variation among the programs currently being used, two basic elements are evident: equipment risk analysis and EBM strategies. AAMI and ASHE are working together to take a strong leadership role, directing significant effort toward developing a more universal and standardized approach. The proposed work will address the development of acceptable methods of variation for inspection intervals and procedures. Additionally, it will offer a standardized approach for assessing equipment risk in the facilities, requiring input from the clinical users and risk management teams.

Beyond this response, we hope to work with CMS to address three specific issues:
1) Further clarifications and updates to the current State Operations Manual Interpretive Guidelines, hopefully including the suggestions provided prior to the June 28 meeting, would address the current concerns of HTM professionals.
2) There was mention of a needed compliance assessment guide, for use by surveyors. Our organizations would be available to work with CMS to complete that, and to help educate HTM professionals regarding future expectations for compliance.
3) Input from CMS would be welcomed and appreciated as the AAMI / ASHE work group moves forward in the development of a recommended practice or standard for Equipment risk analysis and maintenance management.

We look forward to continued dialog with you on these topics. After your review of the enclosed analysis, please identify areas where AAMI and ASHE could assist with further clarifications.
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Analysis

CMS representatives provided the following clarifications during previous discussions:

- **The use of equivalent tools, test devices, and diagnostic software is considered acceptable.** Because there is no requirement for those aspects of the manufacturer recommendations to be followed, as long as equivalent outcomes can be obtained through the use of alternative service items, AAMI and ASHE representatives wish to clarify that the prior estimate of $2 - 6 Billion expense for new capital is no longer applicable.

- **Alternative inspection frequencies are permitted in some instances, however alternative maintenance methods are not permitted.** The overall financial impact of this ruling has not yet been determined due to variable interpretations of which devices are considered “critical.” (See examples of the operating cost impact in the response to Question #1 below.)

From the perspective of the healthcare organizations, the December 2011 statement raises the following specific concerns which have not yet been fully addressed:

- **Manufacturer recommendations are only the starting point for development of an effective and efficient equipment management strategy.**
  - Manufacturer-recommended maintenance activities are developed before the devices have any history of utilization in the clinical care environments. The manufacturers have changed their recommendations in some instances after the devices have been in use for a while. *Exhibit A: Zoll Letter, source of the excerpt below:*

  "There are a host of environments and situations that our equipment may be used within, therefore what we state in our Operating Guide is a recommendation, and ultimately how you conduct your defibrillator checks is your decision based on these factors.

  - Manufacturer procedures are more typically developed for the testing activities during initial assembly, and may not be appropriate for the periodic testing activities.
  - Manufacturers are not subject to any independent oversight or analysis process to validate the effectiveness or necessity of the recommended procedures.

- **Maintenance activities are only one portion of the strategy for managing risks associated with equipment.**
  - As the technology has evolved, so have many of the industry standards, and the maintenance activities have changed accordingly.
  - There is evidence of fewer use-related errors when technicians’ time is spent working directly with the equipment users, instead of using that time for routine equipment checks.
  - The same management strategies can be applied effectively to all equipment, regardless of the perceived risk associated with any specific device or system.
    - There is no need to separate critical and non-critical equipment with regard to maintenance requirements.
    - Risks are managed separately from the maintenance efforts.

The expectation for achieving equivalent outcomes is a significant concept. Using the same logical approach that was applied regarding the specific tools, test equipment, and diagnostic
software, please consider the information that follows. The numbered points that follow were identified during the June 28 meeting as areas where CMS wanted further information or examples.

1. **Identify the tangible impact of the CMS memo on healthcare organizations based on current hospital practices that are now prohibited by the S&C letter. Specific examples would be helpful.**
   - For the labor to perform the procedures recommended by the manufacturers, the labor cost estimates for a few representative organizations, based on their respective inventories, have been compiled.
   - The operating cost impact estimate is difficult to determine, given the current variations in evidence-based maintenance strategies. There is a potentially significant financial impact compared to current operations for many organizations, although it varies based on the extent to which each organization currently utilizes evidence-based maintenance processes.
   - It is important to note that the December 2011 requirements limit the future potential reductions in operating cost for organizations that are just beginning to more aggressively apply different types of service strategies.
     - See Table 1 for examples of impact.
     - Note the correlation similarity between Trinity and Community.
       - Trinity inventory is approximately 10 times the size of Community in number of devices as well as in acquisition value (an industry-accepted comparison metric).
       - The number of life-support devices for Trinity is approximately 10 times greater.

2. **Explain what healthcare organizations do differently with life-support (critical) vs. non-life-support (non-critical) equipment.**
   - Accredited healthcare organizations are required to have contingency plans to address failure of life support equipment, which are separate from any maintenance activities. Such plans may include the purchase of additional devices, the development of manual clinical intervention policies and processes, and redundancy in systems to avoid any known potential for a single point of failure.
   - From an equipment management practice perspective, organizations are tracking the location and availability of life-support devices in correlation with the patient census, and often rent additional devices in advance of any actual need.
   - The maintenance activities of life-support devices are given a higher priority in the evaluation of scheduled work, to complete necessary maintenance on those devices first when possible.
   - The service teams work with the clinical care areas to rotate devices if possible, pulling devices that are due for inspection out of service at a time that is clinically convenient. For example, when the patient tubing is due to be exchanged on a respiratory care device, the device may be swapped with one that has already received the scheduled maintenance for that period.
   - For the facility equipment, life-support systems will be designed and installed with redundancy of operation (for example, multiple paths to provide emergency power to critical circuits), in addition to the use of automated controls and remote notifications regarding system performance or alarms.
### Table 1: Sample Operating Cost Impact to Healthcare Organizations

<table>
<thead>
<tr>
<th>Organization</th>
<th># of Devices</th>
<th>Estimated Increase in Hours for Mfg Procedures vs. Current Evidence Based Procedures</th>
<th>Explanation</th>
<th>Resulting Annual Labor Cost Increase</th>
<th>Calculation Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISS— 1 Acute Care Hospital, 400 beds</td>
<td>9,150</td>
<td>33,363</td>
<td>Estimate based on analysis of the 8 device categories containing the highest number of devices; most device types are currently supported through the use of customized procedures and intervals based on documented service.</td>
<td>$ 816,000</td>
<td>Estimate for 20 additional FTE</td>
</tr>
<tr>
<td>Community Hospitals Indianapolis— 4 Acute Care Hospitals and associated care facilities</td>
<td>13,890</td>
<td>657</td>
<td>465 life-support devices, estimated increase of 657 hours (748 to 1405 hrs) and $32,000 for PM and Inspection according to mfg recommended procedure, and with mfg intervals for life-support devices; Requires almost double the current labor for life-support items if cannot alter frequency; Ruling has lower impact for Community on non-life-support devices, as organization is currently following mfg procedures for almost all devices; These rules do limit the opportunity for further cost reductions that could be realized through more extensive evidence-based maintenance practices, estimated at 15% reduction in current labor hours for routine inspections, or future reduction potential of $36,000.</td>
<td>$ 68,000</td>
<td>Calculated based on current Average Hourly Rate plus benefits</td>
</tr>
<tr>
<td>Trinity Health Network— 10 Acute Care Hospitals and associated care facilities</td>
<td>155,000</td>
<td>12,000</td>
<td>4,070 life-support devices, estimated increase of 25% labor hours for performing all PM and inspection activities according to mfg recommended procedures, and with mfg intervals for life-support items.</td>
<td>$ 670,000</td>
<td>Calculated based on % increase at current operating cost average</td>
</tr>
</tbody>
</table>

### 3. Provide descriptions of methodologies used for changing procedures or frequencies away from those indicated in manufacturer recommendations.

- Healthcare Technology Management professionals have been utilizing systems of data collection and analysis for more than 40 years, many portions of which have been developed in response to
standards and regulations related to quality and patient safety. These data have allowed the profession to identify deficiencies, implement corrections, and measure improvements in safety and system performance as well as cost management.

- There is national guidance for hospitals on equipment and facilities maintenance philosophy, and sample procedures have been available for decades.
  - Exhibit B consists of select pages from the ASHE 2009 book—including introduction, table of contents, and sample procedures. This is the 3rd edition of the book with earlier editions published in the 1980’s and 1990’s.
  - These generic guidelines have been utilized in the past as a basis of hospitals developing their own specific policies and procedures based on their unique care settings and patient needs. Exhibit C provides samples from different types of hospitals, to illustrate that they address similar issues but are customized to each setting.
  - Hospitals create procedures which incorporate the various components of a system, and develop practical maintenance procedures which are focused toward the overall system. The manufacturer procedures for each component cannot address how the individual components are configured to work together once they are combined into a system.
  - Risk assessments on facilities systems are a combination of the application (area served) and type of system/service provided. Samples are provided of a utilities management assessment, including a sample form for assessing different areas, and sample PM criteria based on the assessment.
    - Exhibit B: Excerpts from the 2009 ASHE Maintenance Management Handbook, with sample facilities equipment procedures
    - Exhibit C: Sample Utilities Management Assessment policy, sample Utilities Hazard Assessment Worksheet, sample PM criteria

- Equipment management strategy changes have occurred systematically, based on ongoing data collection and analysis of real service histories of the devices in the care environments. In summary, those activities have shifted away from an expectation of touching every device at a regular interval. The focus has become directed toward providing those service activities that are necessary to improve patient care, including direct user interaction and training to help reduce use-related errors.
  - Exhibit D: ECRI Institute’s Sample Device Inspection Procedure
  - Exhibit E: Equipment Service History—Community Hospitals of Indianapolis
  - Exhibit F: Trinity Health Medical Equipment Management—Post-Implementation results

- Specific protocols for medical equipment are attached, as examples for review by CMS.
  - Exhibit G: Schedule Change Worksheet used by Community Hospitals of Indianapolis (Schedule Change Worksheet used for adjustment of intervals only, no changes from manufacturer procedures); Equipment Schedule Assessment Policy; and Medical Equipment Maintenance Intervals policy (with decision flowchart).
  - Exhibit H: Maintenance Strategy Adherence, Trinity Health

4. Send copies of existing AAMI standards and guidance documents.
- Exhibit I: AAMI 2009 Medical Equipment Management Manual
- Exhibit J: AAMI EQ 56 Recommended Practice
- Exhibit K: Excerpt from NFPA 99—2012 Edition (Section 10.5.3.1.2, note the wording “service manuals, instructions and procedures provided by the manufacturer shall be considered”)

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5. **Provide a description of the algorithms used to determine PM strategies/procedures, as well as commonalities among the algorithms.**

   - One approach to estimating the risk level of a particular type of equipment is to use algorithms, which was first proposed by Larry Fennigkoh in 1989. This approach became widely used after it was included in the *Plant, Technology and Safety Management* series of educational publications from The Joint Commission. For each type of medical device, Fennigkoh suggested that an equipment management (EM) number be calculated, and those devices with an EM greater than 12 would be included in the equipment management program. The EM number was the sum of the numbers assigned to the equipment’s critical function (a value from 2 to 10), physical risk associated with clinical application (a value from 1 to 5), and required maintenance (also a value from 1 to 5).

   - Many individual organizations have adopted something similar to the above Fennigkoh approach, and others have moved on to even more complex models that include assessments of the probability and severity. The following examples are for information only, and are not intended to be recommended for the purpose of national standards.
     - **Exhibit L:** *BI&T* Article, September/October 2008
     - **Exhibit M:** Medical Equipment Risk Assessment—Community Health Network Indianapolis
     - **Exhibit N:** Risk Assessment Model—Steve Grimes

   - In May of 2012, AAMI received a New Work Item Proposal (NWIP) requesting the formal development of a standard for scheduled maintenance and performance testing procedures. It is expected that this work proposal will be expanded to also include risk assessment and maintenance interval determination within this new national standard (**Exhibit O**: New Work Item Proposal and Outline). Proposal has been approved by the AAMI Standards Board.

6. **Provide any examples of documentation of evidence-based maintenance, history, etc.**

   - Refer to Analysis Item 3, Exhibits D and E. Specific attention should be directed at the documented outcomes, showing no increase in equipment-related incidents and no increase in the number of repair requests for devices when inspection intervals have been extended.

   - The survey results that were provided prior to the June 28 meeting demonstrate very positive outcomes resulting from maintenance processes that do not strictly adhere to manufacturer recommendations, for both the facilities equipment and the medical equipment.

7. **What are the fail-safes?**

   - Healthcare technology is required to be designed and produced in accordance with Good Manufacturing Practices (GMP), which were not in existence when this profession was originally created.

   - Medical devices are designed to fail in a manner that does not pose a risk to the patient or staff. Internal diagnostics are triggered when the device is turned on, and critical functions are continually analyzed. The devices will either send a notification to the user or shut the device off, or both, before any patient harm can occur.

   - Solid state (digital) technology within the device circuitry is either ‘on’ or ‘off,’ and there are no discreet (analog) components inside devices that will allow voltage variation or calibration drift.

   - **Specific fail-safe examples from service requests received within the past week at Community Health Network:**
     - Forced Air Warming Unit—giving error codes, please check
     - Blood Glucose Unit—Fatal Error message, will not boot up
     - Anesthesia Unit—Battery Backup Failure message
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- Infant Warmer—When turned on, error message says System Failure, power cord getting hot
  - Examples of device internal analysis focused on patient safety:
    - MRI systems use patient weight and programmed scan protocols to identify safe limits for the Specific Absorption Rate (SAR).
    - CT systems calculate the dose rate prior to running each scan, and notify the user if normal limits are exceeded, requiring the user to over-ride the interlock features to continue with the programmed scans.
    - Balloon pumps issue alarms for any loss of helium or any detected blood in line, indicating a possible system leak long before a user could identify it by any other method.
    - Ventilators continuously monitor flow rates, oxygen-concentration rates, and inspired/expired pressures to alert users to any differences that are indicative of a circuit disconnect or a system failure.
- The hospital facilities systems that provide “critical” services for patient care, such as electricity, water, heat, cooling, ventilation, and medical gas, are each composed of several distinct components, often from different manufacturers.
  - Each of these components is a complete piece of equipment such as a fan or pump or generator, designed to perform a specific function.
  - They are seldom designed for a unique healthcare application; rather they may be used in a variety of configurations to serve similar functions for a vast array of facilities such as higher education, commercial or industrial properties.
    - What makes them unique to healthcare is the engineering standards used to design these systems, and the level of monitoring and quality assurance testing used to validate proper performance.
    - The same individual component, such as a cooling tower, may serve both an industrial application and a healthcare application. How it is configured in the system design, and the quality assurance testing performed at commissioning and through its usable life, is dependent on its application. The one thing that remains the same is the manufacturer recommendations for maintenance and service. But one size truly does not fit all for the following reasons:
      - Manufacturer recommendations are generic for all applications ranging from an industrial application such as a paper mill to a healthcare application such as a diagnostic imaging center. Recommendations are often set for the harshest environment—which may be truly excessive for another environment, leading to increased wear and premature failure.
      - Manufacturer recommendations are for a specific individual component—not for the entire system. However, the individual component’s performance is interdependent on the upstream and downstream components and the automated control systems which provide overall system operational control. Manufacturer recommendations often call for testing and maintenance on parts of a component that are not even in use due to its configuration within the system. An example would be a manual control system for a pump which is never used since control is through a computerized building operations system.
    - Complete system testing and maintenance protocols are developed by the design engineer or commissioning agent at the time of system installation. These guide the operational staff on proper operation, testing, and maintenance of the entire system. Individual component procedures are developed in the context of the
larger system, specifically to address the interdependence of components. Manufacturer recommendations provide the starting point for developing these procedures, but are not routinely accessed once the procedures are established.

- Manufacturers rely on industry codes, standards, and guidance for proper design and operations of systems. Within healthcare there is a vast number of standards which apply to the design, operation, and testing of “critical systems.” Examples of these are:
  - Standard for Healthcare Facilities: NFPA 99, which sets design and performance standards for medical gas and vacuum systems, electrical distribution systems, and ventilation systems
  - Standard for installation of sprinkler systems: NFPA 13
  - Standard for inspection, testing, and maintenance of water-based fire protection systems: NFPA 25
  - National Electric Code: NFPA 70
  - National Fire Alarm Code: NFPA 72
  - Standard for Ventilation and Air Conditioning Systems: NFPA 90A
  - Standard for Emergency and Standby Power: NFPA 110
  - Ventilation of Healthcare Facilities: ASHRAE 170
  - FGI Guidelines for Design and Construction of Hospitals and Healthcare Facilities

- Per these design standards, each of these “critical systems” is designed for N+1 redundancy, meaning that, for acute care facilities, there is at least one more device included in the system than is needed to meet the minimum design criteria. For example, an additional vacuum pump or clinical air compressor, an additional boiler or chiller or cooling tower, additional emergency power capacity, etc.
- Because of this N+1 redundancy, “critical” systems do not contain “critical” components whose sudden failure will compromise patient care.

8. **Provide a revised financial implication statement.**
   - We wish to retract the estimates that were previously provided. Please refer to the second paragraph of the Executive Summary above, and Item 1 and Table 1 of the Analysis section above.

**Conclusion**

The use of ongoing evidence-based maintenance and risk analysis, when performed by qualified Healthcare Technology Management professionals with input from the clinical care areas, the risk management / quality assurance teams, and with oversight from the Environment of Care or Patient Safety committee, has been determined to be a more effective equipment management process. Manufacturer recommendations are useful as a reference in the development of a comprehensive equipment management process. Evidence-based maintenance programs allow organizations to experience reductions in the cost of equipment service, while the quality of service and the outcomes remain the same or even improve.

A more comprehensive clarification from CMS, to allow the continued use of evidence-based maintenance strategies would be received as a very positive communication by healthcare organizations. The development of a surveyors’ guide, which could be a shared communication tool for use by those who are responsible for assuring compliance with the healthcare facilities, would contribute greatly to the efforts to standardize the processes of equipment risk analysis.
and maintenance strategies. AAMI and ASHE are committed to providing information and resources to support CMS efforts to improve the quality of care for all patients.
Exhibit A: Zoll Letter
September 14, 2011

Karen Waninger  
Bio Medical Engineering  
Community Hospital Health System  
Indianapolis, Indiana

Dear Karen:

We understand that there may be some additional explanation required regarding the frequency of defibrillator checks (on our M Series Model), and our recommended intervals on performing these checks. As a review, there are two primary reasons that we suggest that hospitals perform a defibrillator check once per shift:

1) To insure that each person operating an M Series Defibrillator is familiar with the product, and its use.
2) To insure that the operational performance of the M Series in question is checked, to be certain it is ready to use if required.

This testing recommendation listed in our Operating Guide is our recommended practice. However there are a number of things which could impact your individual institutions decision to modify how you actually perform these defibrillator checks. Different length shifts for example-an 8 hour versus 12 hour shift would dictate the frequency of these defibrillator checks. Another item which may impact these checks would be the training and familiarity of your staff with the defibrillator, and if you believe that your staff training is excellent, you may decide in your procedures to change the time intervals between defibrillator checks. And yet another parameter which may impact your decision to alter these time intervals is the frequency of use of the defibrillator in question and the number of defibrillators and their location throughout your facility.

There are a host of environments and situations that our equipment may be used within, therefore what we state in our Operating Guide is a recommendation, and ultimately how you conduct your defibrillator checks is your decision based on these factors. We would not recommend decreasing the frequency of a defibrillator check to be be less than once per day.

I hope that this correspondence clarifies any potential confusion, and if you should have any additional questions, please do not hesitate to contact me.

With every good wish,

ZOLL Medical Corporation

Jim O'Malley  
Vice President Hospital Sales
Exhibit B: Excerpts from the 2009 ASHE Maintenance Management Handbook
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In order to understand many of the concepts contained in this book, it is necessary to begin with definitions of basic terms associated with the maintenance of equipment. The following definitions will be used for the book.

Scheduled equipment maintenance: Work performed on equipment under a scheduled, rather than a user-demand, basis. The purpose of the procedure may be a mixture of one or more of the following:

- **Preventive maintenance**—To clean, lubricate, adjust, check for wear, and replace components that might cause total breakdown or serious functional impairment of the equipment before the next scheduled inspection. In addition a major advantage of true preventive maintenance, is a reduction of economic costs associated with demand repair work and loss of revenue while the equipment is nonfunctional.

- **Functional testing, performance verification, and calibration**—To verify that equipment is fully operational and performing within reasonable, previously specified limits. Depending on the device, it may be appropriate to specify several different levels of functional testing and performance verification; for example, the simplest level consists of visual inspection of the device. Calibration usually implies that the device is compared against a reliable standard.

- **Safety testing**—To verify that the equipment is in compliance with one or more specified safety requirements. Such checking is frequently limited to electrical safety testing at the time of initial inspection and after major repairs.

Environmental Rounds: Work performed within a designated area on a scheduled basis. The purpose of the procedure is a mixture of those items mentioned under scheduled equipment maintenance, but the emphasis is changed from equipment to the area in which equipment is found and minor equipment items not inventoried. Environmental maintenance includes appearance and the integrity of an area. Examples of items that are environmental in nature include paint, plumbing, lighting, electrical outlets, and minor equipment such as table lamps and electronic calculators.

Corrective maintenance: Work performed on a piece of equipment or environment to restore it to proper condition. Such work generally is not scheduled and is performed at the request of the equipment operator or personnel conducting scheduled maintenance. In the latter case, the repairs are different from those required by scheduled maintenance procedures even though these procedures may have been instrumental in identifying the repair.

Maintenance inventory: A list of equipment requiring more care than allowed for under the provisions of environmental maintenance. Maintenance inventory differs from property or equipment inventories in that it is specifically designed as a tool for developing an efficient and effective facilities maintenance management function. In developing the maintenance inventory, a hospital is divided into environmental units.

Maintenance Philosophy

As outlined in the preface, a maintenance philosophy should achieve the goals of ensuring a safe, functional environment by maximizing equipment maintenance, providing essential documentation, and easing management and cost by minimizing the required maintenance and documentation time.

In this book, these goals have been translated into two approaches to scheduled maintenance. These are:
1. Provision of one major maintenance procedure, such as inspection, lubrication, calibration or testing for wear, per item per determined frequency. This procedure is supplemented by as many minor procedures as are required to keep the performance of the device within what the hospital considers to be reasonable limits and to meet the requirement of the Joint Commission for periodic testing of the facilities’ equipment.

2. Provision of a major maintenance procedure every time the device is inspected. This approach requires a considerable work force and is therefore not considered to be cost-effective.

The middle-of-the-road approach, listed first above, was selected because it appears to make the most cost-effective use of all resources and meets the goals established for effective facilities maintenance. The second, more time-consuming approach produces no better results than the first; maintenance procedures involving a major overhaul are not required more than once per year except in unusual operational settings.

The middle-of-the-road approach coincides with the maintenance level that is necessary under normal operational circumstances to keep equipment operating properly, safely, and most economically. A judgment on how these requirements are best balanced is reflected in the attached procedures. As more information becomes available, these inspection formats and/or their frequencies may need to be revised.

**Maintenance Inventory Control Concepts**

Even using the middle-of-the-road approach, the workload and paperwork would be overwhelming if every piece of equipment in a hospital, including such things as electronic calculators and table lamps, were given a separate maintenance schedule. Recognizing this, several concepts have been developed in order to limit the inventory. For example, such noncritical items as calculators and table lamps are incorporated into environmental units, and an entire environmental unit is placed on a maintenance schedule rather than each piece of equipment within the unit. This concept, along with two other inventory control concepts, is further explained in this book.

**Use of Procedures**

The procedures in this book are intended to provide a middle-of-the-road guideline to scheduled maintenance. They are not intended as industry standards, but rather are to be used as models from which each hospital can develop procedures appropriate for its own equipment and special needs. Neither the procedure content nor the frequency should be considered as a fixed standard; instead, they should be varied as necessary to reflect the hospital’s own environment, staff complement, equipment utilization, and skill levels of its personnel. The procedures are intended only to define the scope of the maintenance performed, not to be used for detailed instructions or for training purposes. Detailed procedures for these functions should be obtained from other sources, such as the equipment manufacturer.

The procedures section covers only those tasks that are related to the scheduled maintenance of facilities’ equipment and then only within the normal hospital setting. The allocated labor levels include a nominal amount of time for such activities as traveling between areas of the hospital, locating the equipment, and completing paperwork. If the procedure is modified or if the nominal time allowance does not appear to take into account the specific circumstances within the hospital, the allocated labor level should be modified accordingly.

Other activities, however, must also be taken into account in determining the productivity of an organization or an individual. Identification of such activities and a formula for determining productivity are discussed on page 8.

**MAINTENANCE INVENTORY CONTROL AND DOCUMENTATION**

**Maintenance Inventory Control**

Experience shows that, unless equipment inventories are limited only to essential equipment, a massive paperwork system is created with demands that are not easily satisfied. Placing items such as card embossers on the same inventory as chillers forces maintenance departments to provide individual attention and documentation for minor equipment at the expense of time needed for maintaining essential equipment. The necessity, however, to retain some maintenance control over minor equipment is still recognized. The key to maintenance inventory control is utilization of three maintenance and documentation concepts: the environmental concept, the functional-unit concept, and the grouping concept.

**The Environmental Concept**

The premise of the environmental concept is that the basic requirement of any maintenance system is evidence that a
safe and functional environment exists throughout a medical center. Using this premise, this manual is written to make provisions for the documentation of maintenance on the basis of facilities divided into environmental units rather than on individual equipment within these units. Through the environmental concept approach, maximum maintenance coverage is obtained, yet the number of files needed to document this activity is kept to a minimum.

An environmental unit is a space of manageable size identified by a maintenance identification number. Manageable size is defined in terms of either a unit’s function, such as an intensive care unit (ICU), or the time required to perform the maintenance procedure, for example, half a general nursing floor. The entire hospital is divided into environmental units, and the equipment found in an environmental unit is considered part of the unit.

Under the environmental maintenance concept, maintenance protocols and documentation are not required for individual pieces of equipment unless deemed necessary by a set of guidelines that are outlined later in this section. Instead, scheduled maintenance programs are developed for the environmental units of the hospital, and documentation is recorded for each environment. The task list includes such items as the condition of outlets, plumbing, lighting, and paint. Equipment checks for minor equipment are part of the environmental task list and are maintained as part of the environmental unit. Examples of nonessential equipment included in environmental testing are listed in Figure 1, below. According to a schedule, maintenance work orders are issued for the environmental unit, and the entire unit, including all equipment on its task list, is checked or maintained at one time. Corrective maintenance done to equipment in a unit is documented under the identification number of the environmental unit and through the use of the model and serial number (if any) of the repaired item.

The areas of a hospital are divided into hospital units and are classified according to the type of patient and activity use of the area. All areas of a hospital will fit into one of these classifications. The five types of environmental units in general use today and two others that have been found useful to create are as follows:

<table>
<thead>
<tr>
<th>Items Generally Included in Environmental Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audiovisual Equipment</td>
</tr>
<tr>
<td>Baby Cribs</td>
</tr>
<tr>
<td>Bassinets</td>
</tr>
<tr>
<td>Bed Lamps</td>
</tr>
<tr>
<td>Buffers</td>
</tr>
<tr>
<td>Coffee Makers</td>
</tr>
<tr>
<td>Doors</td>
</tr>
<tr>
<td>Electrical Outlets</td>
</tr>
<tr>
<td>Exam Tables</td>
</tr>
<tr>
<td>Exit Lighting</td>
</tr>
<tr>
<td>Eye Washers</td>
</tr>
<tr>
<td>Floor Coverings</td>
</tr>
<tr>
<td>Floor Machines</td>
</tr>
<tr>
<td>Floor and Roof Drains</td>
</tr>
<tr>
<td>General Lighting</td>
</tr>
<tr>
<td>Gurneys</td>
</tr>
<tr>
<td>Heaters</td>
</tr>
<tr>
<td>Heat Sealing Units</td>
</tr>
<tr>
<td>Immersion Heaters</td>
</tr>
<tr>
<td>Insect Controllers</td>
</tr>
<tr>
<td>Laundry Chute Doors</td>
</tr>
<tr>
<td>Laundry Scales</td>
</tr>
<tr>
<td>Master Clocks</td>
</tr>
<tr>
<td>Mechanical Beds</td>
</tr>
<tr>
<td>Medical Gas Outlets</td>
</tr>
<tr>
<td>Medical Vacuum Outlets</td>
</tr>
<tr>
<td>Motorized Tables</td>
</tr>
<tr>
<td>Morgue Table</td>
</tr>
<tr>
<td>Nonelectric Food Carts</td>
</tr>
<tr>
<td>Operating Room Lamps</td>
</tr>
<tr>
<td>Parallel Bars</td>
</tr>
<tr>
<td>Patient Lifts</td>
</tr>
<tr>
<td>Patient Scales</td>
</tr>
<tr>
<td>Portable Exam Lamps</td>
</tr>
<tr>
<td>Portable Heat Lamps</td>
</tr>
<tr>
<td>Room Furniture</td>
</tr>
<tr>
<td>Sewers</td>
</tr>
<tr>
<td>Showers</td>
</tr>
<tr>
<td>Signs and Lighting</td>
</tr>
<tr>
<td>Sinks</td>
</tr>
<tr>
<td>Time Clocks</td>
</tr>
<tr>
<td>Trash Chute Doors</td>
</tr>
<tr>
<td>Televisions</td>
</tr>
<tr>
<td>Ultrasonic Cleaners (small)</td>
</tr>
<tr>
<td>Vacuum Cleaners</td>
</tr>
<tr>
<td>Warming Cabinets</td>
</tr>
<tr>
<td>Wheelchairs</td>
</tr>
<tr>
<td>X-Ray View boxes</td>
</tr>
</tbody>
</table>
1. **Anesthetizing location:** Area of the hospital that has been designated by the hospital to be normally used for the administration of an inhalation anesthetic agent. In most cases, this area refers only to operating rooms and delivery rooms.

2. **Critical care area:** Patient care area, classified by hospital policy, where patients are subjected to invasive procedures and directly connected to line-operated medical devices. In addition to the operating room and delivery room, this class includes intensive care and catheterization areas. With a few exceptions, electrical construction provisions of these areas have basically the same requirements as the general care areas.

3. **Wet location:** Patient care area normally subject to wet conditions, including standing water on the floor or routine dousing or drenching of the work area. Routine housekeeping procedures and incidental spillage are not cause to designate an area as a wet location. Generally, this classification refers only to the hydrotherapy tank rooms of physical therapy departments.

4. **General patient care area:** Patient care area where patients are expected to come in contact with ordinary electrical appliances (lamps, beds, televisions, and so forth) or be connected to medical devices. This does not include nursing stations.

5. **Non-patient care area:** Area where patients are not normally cared for or treated, such as administrative office areas, laboratories, nursing stations, storage areas, kitchens, or medical office areas.

6. **Mechanical area:** Area of restricted access containing building equipment.

7. **Grounds:** Areas surrounding facility building, including parking, parking structures, loading docks, sidewalks, lawns and gardens.

A key to maintaining minimum environmental maintenance scheduling is proper classification of an environment. Incorrect classification can result in twice the number of maintenance inspections than required.

Although we should ideally be able to maintain the hospital adequately by using the environmental approach, some equipment cannot be maintained appropriately as part of the environment. Such equipment, labeled “significant equipment,” is excluded from scheduled environmental maintenance and is assigned an independent inspection frequency, instruction set, and documentation file. Equipment considered essential for the purpose of this book is listed in the classification tables that separate the instruction sets for each category starting in Part II on page 11. To be classified as significant equipment, a piece of equipment should meet one or more of the following criteria:

- Equipment known to be involved in incidents. Items such as boilers, which normally have a higher incident risk associated with their use.
- Significant components of utility systems. Includes items that are significant in their support of the artificially created internal environment for both general comfort as well as infection control (for example, HVAC) and those systems that are centrally established for use throughout the facility (for example, communications, gas systems).
- Equipment needing a more intense maintenance schedule. The more mechanized a piece of equipment or the more often it is used, the less likely the equipment can be appropriately maintained by the environmental approach. This equipment may generally need a more complex set of maintenance instructions or a more intense maintenance schedule than can be provided by the environmental inspection.
- Equipment being maintained by an external vendor. Equipment being maintained externally becomes “transparent” to the environmental maintenance of the area and, therefore, is not part of the scheduled maintenance and documentation program.

In treating equipment as part of an environment, two questions arise: (1) what procedure should be followed when equipment checking would interfere with patient care and (2) if a piece of equipment frequently moves from one environmental unit to another, how can its inspection be verified? For example, how can one be sure that all hospital beds in an environment have been inspected when one bed may have been occupied by a critically ill patient or out of the unit during checking? To be sure, such equipment will occasionally be missed. This problem can be minimized if the environmental units are kept relatively large (for example, a wing rather than an individual room). However, even allowing for occasional misses, the hospital can still be certain that in general all equipment of one type (hospital beds, for example) is safe and functional and that problem patterns for that class of equipment can be identified. The environmental unit concept assumes that the same principles of quality control used in manufacturing, work for hospitals as well. Portable equipment moved from environment to environment is not expected to be tested at the same frequency as the environment the equipment is in.
However, testing a large number of minor devices of a similar type is expected to alert engineers to any generic problem that may exist, and a subsequent sweep of the hospital would then eliminate the problem. If a particular type of equipment is found to be particularly troublesome, it can always be taken off the environmental list and given its own maintenance instruction and schedule.

**The Functional-Unit Concept**

Developing control over the maintenance inventory by classifying the facility into environmental units is the first concept in the middle-of-the-road approach to facilities’ maintenance management. The second, the functional-unit concept, provides a method for controlling the maintenance inventory of essential equipment, which is excluded from scheduled environmental maintenance. This concept applies to a piece of equipment, or easily identifiable system, composed of several parts of modules. If the parts or modules always occur together and require each other to be functional, the entire system can be considered as one piece of equipment on the inventory. A chiller, for example, is a system composed of a compressor, condenser, pumps, and valves that can be treated as one piece of equipment. In this way, only one maintenance protocol is developed so that the entire system is inspected at one time rather than individual parts being inspected separately. Documentation is kept on a system rather than on each individual part.

**The Grouping Concept**

A third method for minimizing the essential equipment inventory while ensuring necessary maintenance is the grouping concept, which applies to a class of equipment that qualifies as essential equipment but occurs in such large numbers that individual treatment is unmanageable. An example of such a class of equipment is a fire extinguisher. Fire extinguishers qualify as essential equipment because regulations require them to be inspected more frequently than the environmental inspection generally provides, yet, to require work orders and documentation for each fire extinguisher in a hospital would be unmanageable. Under the grouping concept, all fire extinguishers would be considered as one item on the maintenance inventory. One work order would be issued and all fire extinguishers would be inspected (and results documented) in a sweep of the entire building.

**Documentation**

While a facilities’ maintenance management program is designed to provide a safe and functional environment, documentation of maintenance activity has also become an important part of a complete program. As various accrediting and regulatory agencies have required more thorough documentation, hospitals have developed documentation systems, many involving substantial time and paperwork to maintain. Although this book does not prescribe a specific system for documentation, the following can be used as guidelines are provided for developing an acceptable documentation system using the concepts described earlier.

Documentation provides evidence that maintenance is being performed in a prescribed and acceptable manner. To determine whether documentation is adequate, a breakdown of the maintenance system into its work elements is necessary. If evidence can be produced that the work involved in maintenance activities is currently and historically being performed, documentation can be considered adequate.

The functions that form the basis for a facility’s maintenance activity are installation of equipment or addition of environments, scheduled maintenance, and corrective maintenance. Using the approach to maintenance outlined in this manual, the following work occurs within these three activities:

1. Addition of environmental units and equipment
   a. A verbal or written communication is sent notifying the engineering office of receipt of new equipment (or the addition of environmental units).
   b. Electrical safety tests are performed on all incoming equipment (see Appendix B, Electrical Safety Test No. 3) and the results documented. An environmental unit will receive its initial survey using the instruction set for its classification.
   c. New equipment is inspected and, if determined to be essential, is assigned an identification number and added to the maintenance inventory. Otherwise, it is considered to be part of the environmental task list. Environmental units also receive an identification number and are added to the maintenance inventory.
   d. When a piece or an environmental unit is assigned a number, a maintenance instruction and a maintenance schedule are assigned (or prepared if the instruction and schedule do not exist).
   e. The description, identification number, maintenance instruction, and schedule are entered into the file, along with supplemental information for equipment such as manufacturer, serial number, date purchased, model number, vendor, user department, location, cost, and purchase order number.
f. This information is then used to produce work orders for scheduled maintenance at the frequency of the assigned schedule.

2. Scheduled maintenance
   a. A work order and procedure are sent to the maintenance personnel to whom the work is assigned.
   b. Maintenance is performed, and results of this maintenance are recorded (including completion date and notation of any special or unusual occurrences) and sent to the engineering office for filing. If scheduled maintenance cannot be completed, for example, if parts are not available, the reason is recorded and kept in a file “jobs labeled outstanding.”
   c. From these files, user departments are notified what maintenance, if any, has been performed. A follow-up work order is sent to maintenance personnel as a reminder if no scheduled maintenance report was submitted or if a jobs-outstanding report was submitted.

3. Corrective maintenance
   a. The user department notifies the maintenance department orally or in writing about what corrective maintenance needs to be performed. This request is filed.
   b. The repair is performed.
   c. The results and the completion date of the repair are filed. From this file, reports are issued to the user department notifying them of corrective work done. If no record of results has been filed, a jobs-outstanding report is issued to both the user department and the maintenance department.

An analysis of this work-flow process provides the following list of essential items that ensure an acceptable level of documentation:

- A separate identification number for each item on the maintenance inventory
- A maintenance protocol (procedure and testing schedule) for each inventory item
- A permanent record of maintenance performed
- A record showing reasonable adherence to designed protocol
- A record showing completion of requested follow-up actions
- A history of essential information relating to the serviceable life of the environmental units and the equipment
- A system to notify the departmental personnel of environmental and equipment conditions

As mentioned previously, maintenance and documentation systems often fail because of the excessive time and paperwork required to keep the system functioning. This generally occurs when a hospital attempts to provide the “perfect” system, which would provide maintenance protocols and complete documentation for each individual piece of equipment in the inventory, including such minor items as calculators, coffee makers, and furniture. Often, in attempting to keep up with minor items, essential items are neglected.

The maintenance program outlined in this chapter ensures that minor equipment receives function and safety testing without burdensome requirements of time and documentation. Essential equipment receives separate priority coverage, and the inventory control concepts of environmental maintenance, the functional-unit concept, and the grouping concept ensure minimal paperwork. This approach to maintenance will provide an efficient maintenance inventory and a well-documented maintenance program with reasonable

**USING THE PROCEDURES SECTION IN A FACILITIES MAINTENANCE MANAGEMENT PROGRAM**

The maintenance data tables and procedures section of the book is divided into three parts, one for environmental units and two for equipment.

The category of environmental units is designed to cover each area with a set of instructions that provides adequate testing and inspections for minor electrical and mechanical equipment, as well as environmental systems, in areas that have been classified according to the type of patient frequenting the unit. Building systems equipment is stationary equipment required to provide a functional and acceptable environment for the building and grounds. Hospital service equipment supports the nonclinical function of the hospital and is normally used by departmental personnel and maintained by the engineering department.
Each group has been subdivided as much as possible into sections of related items. For each section, a summary table listing environmental units of equipment is followed by scheduled preventive maintenance procedure sheets for that environment or equipment. The tables and procedures are correlated to produce a total approach to scheduled maintenance.

**Maintenance Data Tables**
The maintenance data tables contain the recommended number of preventive maintenance procedures per year. No values are given for annual corrective maintenance. Estimates for corrective maintenance are difficult to provide primarily because of the complex nature of the equipment (especially building systems equipment) and the elusive definition of a “standard” environmental unit. To develop repair time values for equipment requires a more complex analysis, which should include an itemized listing of known ways the equipment fails. For each type of failure, a time value for corrective maintenance can then be developed. With the almost universal use of computerized maintenance systems, it is now possible to develop a database of actual in-house repair times. The next step is to predict how often each failure occurs, and, from those data, to produce annual values for corrective maintenance labor. This would be a more realistic criteria than relying on outside benchmark data.

Once environmental units have been defined and some experience gained in performing environmental maintenance, the engineering department will be able to estimate more accurately their annual corrective maintenance and labor requirements.

The following columns are found on the maintenance data tables:

**Class code:** A number identifying the type of environment or equipment used for cross-referencing maintenance data tables to the procedure pages.

**Description of environment equipment:** A general description only; a more detailed definition, when necessary, will be found in the comments column.

**Maintenance schedule:** The letter codes used in this column are M for monthly, Q for quarterly, S for semiannual, A for annual. A class of equipment with both quarterly (Q) and annual (A) schedules is maintained every three months, but every 12 months, the annual set of instructions is used rather than the quarterly. The annual instructions include the quarterly procedures plus the more rigorous annual procedures. Within one year, this piece of equipment receives three quarterly inspections and one annual inspection.

**Maintenance Procedures**
The maintenance procedures correspond to the required scheduled maintenance hours shown in the tables and are simplified. They are intended to define the scope of the maintenance performed and to be used by personnel familiar with the equipment, not by trainees with no previous experience. Neither the tables nor the procedures include the regular maintenance duties that should be performed by personnel operating the equipment, such as daily and weekly operational routines.

Throughout the procedures, references are made to following an electrical safety procedure or to the performance of electrical safety tests. The procedure and tests are found in appendixes A and B.

For proper utilization of the tables and procedures in a facility’s maintenance management program, the following steps are recommended:

1. Review the content of the procedures and determine whether they are appropriate in your hospital’s environmental and operational setting. Because the tables and procedures are guidelines consistent with the middle-of-the-road approach, they may need to be altered to fit any unusual circumstances or singular equipment usage or abuse. For example, certain equipment may receive less use in a small or rural hospital than in a large urban one. Normal or abnormal weather conditions such as prolonged periods of high humidity or dusty conditions may also affect the maintenance schedules and procedures.

2. Determine which equipment will be served by your program and develop the maintenance inventory. Use the inventory control concepts presented previously in this book. All hospital locations must be classified according to the type of environment. Only equipment that qualifies as essential equipment should be listed individually.

**DETERMINING PERSONNEL REQUIRED**

It has been determined previously that this manual can be used as a management tool; in this mode, its data can be used to estimate the number of FTEs necessary to run a maintenance program of the type proposed here. Before outlining how this estimate can be calculated, some information concerning productivity must be explained.
**Definition of Productivity**

For the purpose of this book, productivity is determined by the following formula:

\[
\text{Productivity (\%)} = \frac{\text{time worked}}{\text{time available}} \times 100
\]

Time worked equals all hours charged to work orders for scheduled maintenance, repairs and clinical engineering activities, and time available equals total time paid less vacation, holiday and sick leave.

The productivity figure provides key information about the relationship between direct labor (time worked or productive time) and indirect labor (time available minus time worked or nonproductive time). It can be used as one measure of the performance efficiency of an organization or an individual.

**Productive and Nonproductive Activities**

No attempt has been made in this book to provide estimates of annual man-hours for the productive activities not related to maintenance and repair. The required hours vary greatly from hospital to hospital on the basis of the equipment complement and the nature of the hospital’s program. Productivity (direct labor) activities are:

- Preventive maintenance
- Incoming inspection
- Repairs
- Necessary travel time
- Performance verification
- In-service training
- Safety testing
- Operator errors
- Conductivity testing
- Safety modifications
- Line isolation monitor testing
- Design modifications
- Prepurchase evaluation
- Documentation of productive activities

In addition to such productive activities, a hospital department must engage in many necessary administrative and overhead-type functions. Tasks are considered nonproductive by definition and include at least the following:

- Maintenance of inventory
- Public relations efforts
- Training of personnel
- Calibration of test equipment
- Vendor control
- Documentation of nonproductive activities
- Keeping up with the field
- Maintenance of technical libraries
- Conventions/seminars
- Personal time, breaks
- Supervision
- Budgeting
- Repairs/callbacks
- Committee meetings

Similarly no attempt has been made to provide estimates of annual man-hours for these necessary but administrative and overhead functions. These lists are not meant to be exhaustive, but they should provide insight into the determination of productive and nonproductive time.

**Evaluating Productivity**

As previously mentioned, the manual does not provide estimated time allocations for any of the other productive activities that might be involved. Consequently, it is necessary to establish time estimates for these other productive services before any type of productivity determination can be made. These productive activities must be undertaken at the hospital; they may, however, be performed by outside agents, depending on the size of the hospital’s maintenance staff.

The most accurate means of determining productivity involves using completed work orders. This method ensures that each action of each person on a maintenance assignment is documented on a separate work order describing the work performed, the time spent, and the material used. These work orders are then summarized over a specific period of time, usually a month, to provide a figure for time worked. Time available for the same period is calculated from time cards, or whatever other mechanism is used to determine time for payroll purposes, less time off for vacation, holidays, or sick leave.

Once these figures have been calculated, time worked can be divided into time available to calculate percentage productivity. For example, 1,920 hours of time available divided into 1,400 hours of time worked equals a productivity level of 75 percent.
Interpreting Levels of Productivity

On the basis of previous data, the following breakdowns can be made for productivity levels:

- More than 85% = Questionable
- 75-85% = Excellent
- 60-74% = Acceptable
- 55-59% = Borderline
- Less than 55% = Unacceptable

Productivity of more than 85 percent is questionable because it is difficult to achieve without the use of unpaid overtime, improper documentation of time worked, or an increasing level of repeat calls. Experience has shown that if a group accounts for its work by individual job and sustains a real level of productivity of more than 85 percent for three to six months, the result will be a rash of recalls and complaints.

Productivity of less than 55 percent indicates that productive time per person is less than 4.5 hours per day. This work load would be insufficient to justify an in-house maintenance staff unless sources of outside service were a considerable distance away.

Productivity that is lower than expected generally indicates special problems requiring management attention. A partial list of such problems includes:

- Lengthy periods spent waiting to gain access to equipment. This problem requires some discussion with department managers to arrange a mutually acceptable solution.
- Long periods of time spent tracking down equipment that has been relocated.
- Use of hospital engineering personnel to perform clerical functions that are more easily handled by clerical staff.
- Use of inefficient test forms, requiring more time than is necessary to complete overly detailed service reports.
- Inefficient maintenance practices, such as taking back equipment to the shop for maintenance work that could be done on the floors or routinely returning to the shop between work orders.

There is no doubt that an efficient, well-managed internal maintenance program can provide most hospitals with cost savings and other additional benefits. The challenge is in maintaining the consistently high level of management oversight needed to keep the program running optimally.
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**Maintenance Management for Health Care Facilities**

## COMPRESSORS

### Medical Air-Compressor Unit

**204F**

**PROCEDURE**

- Check pressure drop across main air-line filter. Change or clean annually or if pressure drop exceeds 20 psi.  
  - SCHEDULE: A,S,Q
- Check pressure gauges; calibrate or replace as needed. Check pressure regulating valve operation.  
  - SCHEDULE: A,S,Q
- Drain moisture from air receivers and traps.  
  - SCHEDULE: A,S,Q
- Manually lift safety relief valves.  
  - SCHEDULE: A,S,Q
- Clean air intake filters.  
  - SCHEDULE: A,S,Q
- Check oil level.  
  - SCHEDULE: S
- Follow electrical safety procedures.  
  - SCHEDULE: A,S,Q
- Cycle unit off/on; check operation of unloaders, water valves, float valves, flow switches, controls and alternator.  
  - SCHEDULE: A,S,Q
- Check all electrical connections for tightness.  
  - SCHEDULE: A,S,Q
- Check motor/compressor alignment. Check V-belts; change or adjust as needed.  
  - SCHEDULE: A,S,Q
- Change oil.  
  - SCHEDULE: A
- Clean unit. Check all piping, guards and mounts for tightness.  
  - SCHEDULE: A,S,Q
- Record amperage and voltage with unit operating.  
  - SCHEDULE: A,S
- Check shaft seals and packing. Replace or repack as needed.  
  - SCHEDULE: A,S
- Record cut-in and cut-out pressures.  
  - SCHEDULE: A,S
- As applicable, remove, inspect and clean or replace compressor valves cooling water control valves, control tubing and float valves. Flush water chambers and cylinder water jackets.  
  - SCHEDULE: A

**Procedures**

The letters in the Schedule column in the procedures refer to:

- **A** - Annual
- **S** - Semi-annual
- **Q** - Quarterly
- **M** - Monthly
## Medical Vacuum Unit

### 205F

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>SCHEDULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Follow electrical safety procedure.</td>
<td>Q,S</td>
</tr>
<tr>
<td>• Check oil level.</td>
<td>Q,S</td>
</tr>
<tr>
<td>• Blow discharge drip leg.</td>
<td>Q,S</td>
</tr>
<tr>
<td>• Check unit for unusual vibration.</td>
<td>Q,S</td>
</tr>
<tr>
<td>• Check V-belt, adjust as needed.</td>
<td>Q,S</td>
</tr>
<tr>
<td>• Check pump rotation for direction and free operation.</td>
<td>Q,S</td>
</tr>
<tr>
<td>• Record vacuum pump cut-in and cut-out pressures.</td>
<td>Q,S</td>
</tr>
<tr>
<td>• Note unit pump down-running time.</td>
<td>Q,S</td>
</tr>
<tr>
<td>• Check alternator operation.</td>
<td>Q,S</td>
</tr>
<tr>
<td>• Check cooling water flow and drain.</td>
<td>Q,S</td>
</tr>
<tr>
<td>• Drain liquid from vacuum tank.</td>
<td>Q,S</td>
</tr>
<tr>
<td>• On reciprocating units, remove, clean and reinstall vacuum pump valves.</td>
<td>Q,S</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>• Clean unit.</td>
<td>Q,S</td>
</tr>
<tr>
<td>• Inspect electrical connections and control contacts.</td>
<td>S</td>
</tr>
<tr>
<td>• Check low oil switch operation.</td>
<td>S</td>
</tr>
<tr>
<td>• Change oil.</td>
<td>S</td>
</tr>
<tr>
<td>• Record suction-line filter pressure drop. Change filter as needed.</td>
<td>S</td>
</tr>
</tbody>
</table>

**Procedures**

The letters in the Schedule column in the procedures refer to:

- **A** - Annual
- **S** - Semi-annual
- **Q** - Quarterly
- **M** - Monthly
## Centrifugal Chiller

### 304F

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>SCHEDULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review machine logs.</td>
<td>A,Q</td>
</tr>
<tr>
<td>Check refrigerant level.</td>
<td>A,Q</td>
</tr>
<tr>
<td>Check oil level.</td>
<td>A,Q</td>
</tr>
<tr>
<td>Check refrigerant condensing liquid temperature and condensing pressure at full load. Refer to manufacturer’s service manual to interpret these for indication of a need to purge or of presence of fouled tubes.</td>
<td>A,Q</td>
</tr>
<tr>
<td>Check water flow through operator purge condenser and bearing oil cooler by flushing.</td>
<td>A,Q</td>
</tr>
<tr>
<td>Record amperage and voltage with compressor operating.</td>
<td>A,Q</td>
</tr>
<tr>
<td>Clean bearing oil cooling water strainer.</td>
<td>A,Q</td>
</tr>
<tr>
<td>Check bearing oil temperature. Backflush bearing oil cooling water control valve.</td>
<td>A,Q</td>
</tr>
<tr>
<td>For electrical check:</td>
<td>A</td>
</tr>
<tr>
<td>- Follow electrical safety procedure.</td>
<td></td>
</tr>
<tr>
<td>- Check magnetic starters. Clean starter panel.</td>
<td></td>
</tr>
<tr>
<td>- Check all electrical connections for tightness.</td>
<td></td>
</tr>
<tr>
<td>- Check safety controls and log cut-in and cut-out points: Low oil pressure, condenser high pressure, cut out, chill water low temperature cut out, anti-cycle time delay and flow switches.</td>
<td></td>
</tr>
<tr>
<td>- Check guide vane operation.</td>
<td></td>
</tr>
<tr>
<td>- Check demand limiter and transformer.</td>
<td></td>
</tr>
<tr>
<td>- Check compressor windings with megohmeter.</td>
<td></td>
</tr>
<tr>
<td>- Check oil pump.</td>
<td></td>
</tr>
<tr>
<td>- Check lube oil sump heater.</td>
<td></td>
</tr>
<tr>
<td>- Record lube oil pump amperage and voltage.</td>
<td></td>
</tr>
</tbody>
</table>
Centrifugal Chiller - continued

- For condenser:
  - Refer to manufacturer’s maintenance manual. Establish
device flow through machine at full load. Establish
85°F condenser water supply. Determine if refrigerant
condensing temperature is excessively high. If so, record
temperature then proceed with these instructions:
  - Drain condenser and pull heads. Clean tubes, inspect for
  excessive pitting, scale or corrosion. Note conditions found.
  Reassemble.
  - Perform condenser instructions.

- For lubrication system, refrigerant R-11 machines.
  - Refer to manufacturer’s instructions for changing oil.
  Pressurize with nitrogen. Do not exceed 5 psig on refrigerant for
  all machines, as damage to rupture disc may occur. Remove oil.
  - Take oil sample; perform acid test. Note results.
  - Break machine to atmospheric pressure after all oil is removed.
  - Change oil and lube oil sump filter.
  - Change bearing oil filter.
  - Pressurize machine with nitrogen to 5 psig.
  - Check entire machine for leaks. Repair all leaks.
  - Break pressure. Run purge until proper vacuum is established.
  - Record usable lube oil pressure and lube oil pump running
  amperage and voltage.

- For purge unit
  - Change oil in purge compressor and in oil separator.
  - Check overall operation of purge unit, solenoid valve, air relief
  valve, oil separator, purge heater and leak check.
  - Adjust purge drive belt tension.
  - Oil purge motor. Check motor mounts.
  - Check and record motor voltage and amperage.
  - Drain water from purge drum. Clean internals every other year.
  - Check float operation.
  - Check purge compressor for wear.

- Clean entire unit. Touch up paint as needed.

Procedures
The letters in the Schedule column in the procedures refer to:
A - Annual  S - Semi-annual  Q - Quarterly  M - Monthly
# Cooling Systems

## Cooling Tower Unit

### 305F

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>SCHEDULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow electrical safety procedure.</td>
<td>A,S,Q</td>
</tr>
<tr>
<td>Inspect entire unit for general preservation and cleanliness.</td>
<td>A,S,Q</td>
</tr>
<tr>
<td>Check V-belt tension and alignment.</td>
<td>A,S,Q</td>
</tr>
<tr>
<td>Check spray tree nozzles and top eliminators.</td>
<td>A,S,Q</td>
</tr>
<tr>
<td>Brush tower slats to remove solids buildup.</td>
<td>A,S,Q</td>
</tr>
<tr>
<td>Brush tower water distribution tray and clear distribution orifices at top of unit.</td>
<td>A,S,Q</td>
</tr>
<tr>
<td>Check makeup float valve operation.</td>
<td>A,S,Q</td>
</tr>
<tr>
<td>Check tower bleed valve operation.</td>
<td>A,S,Q</td>
</tr>
<tr>
<td>On evaporative condensers, check tube bundle for visible signs of corrosion and support brackets for tightness and verify pump operation.</td>
<td>A</td>
</tr>
<tr>
<td>Check fan and motor mounts for tightness and correct alignment.</td>
<td>A</td>
</tr>
<tr>
<td>Review chemical logs for proper chemical treatment residuals.</td>
<td>S,Q</td>
</tr>
<tr>
<td>Check water filters. Clean filter pump suction strainers as applicable. Observe filter backwash cycle. Replace filter media as needed.</td>
<td>S</td>
</tr>
<tr>
<td>Check drive line and transducer oil level.</td>
<td>A,S</td>
</tr>
<tr>
<td>Change transducer oil.</td>
<td>A</td>
</tr>
<tr>
<td>Lubricate fan bearings.</td>
<td>A,S</td>
</tr>
<tr>
<td>Lubricate motor bearings.</td>
<td>A</td>
</tr>
<tr>
<td>Inspect all motor electrical controls and connections for tightness and proper operation.</td>
<td>A</td>
</tr>
<tr>
<td>Record amperage and voltage of motors operating at each speed.</td>
<td>A</td>
</tr>
<tr>
<td>Clean entire cooling tower, including basin and sump.</td>
<td>A</td>
</tr>
<tr>
<td>Clean all water strainers.</td>
<td>A</td>
</tr>
<tr>
<td>As installed: Check water filter and backwash cycle. Refrigerate/flush/change filter as needed.</td>
<td>A</td>
</tr>
</tbody>
</table>

Procedures

The letters in the Schedule column in the procedures refer to:

- **A** - Annual
- **S** - Semi-annual
- **Q** - Quarterly
- **M** - Monthly
Exhibit C: Sample Utilities Management Assessment Policy, Sample Utilities Hazard Assessment Worksheet, Sample PM Criteria
# Utility System Preventive Maintenance Prioritization Chart

<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Utility Function</th>
<th>Physical Risk</th>
<th>Maintenance Requirement</th>
<th>Incident History</th>
<th>Total Score</th>
<th>Contract</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air Handling Units</td>
<td>9 3 3</td>
<td>2</td>
<td>17</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beds</td>
<td>5 2 1</td>
<td>1</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boilers</td>
<td>9 3 3</td>
<td>1</td>
<td>16</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Building Automation</td>
<td>7 3 3</td>
<td>2</td>
<td>15</td>
<td>Johnson Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chillers</td>
<td>7 3 3</td>
<td>1</td>
<td>14</td>
<td>York</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clocks</td>
<td>5 1 1</td>
<td>1</td>
<td>8</td>
<td>Simplex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compressor - Clinical Air</td>
<td>7 3 3</td>
<td>1</td>
<td>14</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compressors - Control</td>
<td>7 3 3</td>
<td>1</td>
<td>14</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooling Tower</td>
<td>5 3 3</td>
<td>1</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dishmachine</td>
<td>5 3 1</td>
<td>1</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Doors - Automatic</td>
<td>5 2 3</td>
<td>3</td>
<td>13</td>
<td>Stanley</td>
<td></td>
<td></td>
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<tr>
<td>Electric Panels</td>
<td>10 3 1</td>
<td>1</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elevators</td>
<td>7 3 3</td>
<td>2</td>
<td>15</td>
<td>Montgomery</td>
<td></td>
<td></td>
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<tr>
<td>Fan - Exhaust</td>
<td>7 2 3</td>
<td>1</td>
<td>13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fan - Isolation</td>
<td>9 3 3</td>
<td>1</td>
<td>16</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Fan - Supply</td>
<td>7 2 3</td>
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<td>13</td>
<td></td>
<td></td>
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<tr>
<td>Fan Coil Unit</td>
<td>7 2 3</td>
<td>1</td>
<td>13</td>
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<td></td>
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<tr>
<td>Fire Alarm System</td>
<td>10 5 3</td>
<td>3</td>
<td>21</td>
<td>Simplex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freezers</td>
<td>5 1 1</td>
<td>1</td>
<td>8</td>
<td>Nwtown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generators</td>
<td>10 3 3</td>
<td>2</td>
<td>18</td>
<td>Patten/Charles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ice Machines</td>
<td>5 1 1</td>
<td>1</td>
<td>8</td>
<td>Nwtown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pump - Booster Coil</td>
<td>7 3 1</td>
<td>1</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pump - Condensate</td>
<td>7 3 1</td>
<td>1</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pump - CW circulating</td>
<td>7 3 1</td>
<td>1</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pump - Fire Jockey</td>
<td>7 3 1</td>
<td>1</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pump - HW circulating</td>
<td>7 3 1</td>
<td>1</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pump - Sewerage</td>
<td>7 3 1</td>
<td>1</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pumps - Chilled Water</td>
<td>7 3 1</td>
<td>1</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pumps - fuel Oil</td>
<td>7 3 1</td>
<td>1</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pumps - Sump</td>
<td>7 3 1</td>
<td>1</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiator - Cooling</td>
<td>7 3 1</td>
<td>1</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refrigerators</td>
<td>5 1 1</td>
<td>1</td>
<td>8</td>
<td>Nwtown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterilizer &amp; Washer</td>
<td>9 3 3</td>
<td>2</td>
<td>17</td>
<td>Amsco</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermostat</td>
<td>7 2 1</td>
<td>1</td>
<td>11</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Translogic</td>
<td>5 3 3</td>
<td>2</td>
<td>13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vacuum Compressors</td>
<td>10 3 3</td>
<td>2</td>
<td>18</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water Coolers</td>
<td>5 1 1</td>
<td>1</td>
<td>8</td>
<td>Nwtown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wheelchairs</td>
<td>5 4 3</td>
<td>2</td>
<td>14</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
UTILITIES MANAGEMENT ASSESSMENT

POLICY:

There is a Utilities Management Program designed to assure operational reliability, assess risks, and respond to failures and train users and operators of utility system components.

1. The Utilities Management Program shall include equipment that meets the following criteria:

   A. Equipment that maintains the climatic environment in-patient care areas.

   B. Equipment that constitutes a risk to patient life safety and support upon failure.

   C. Equipment that is a part of a building system which is used for infection control.

   D. Equipment that is part of the communication system which may affect the patient or the patient care environment.

   E. Equipment that is an auxiliary or ancillary part of a system control or interface to patient care environment, life safety, support, or infection control.

2. The following systems are included in the Utilities Management Program:

   A. Electrical Distribution System
   B. Emergency Power System
   C. Vertical and Horizontal Transport
   D. Heating and Ventilation Systems
   E. Plumbing and Water Delivery Systems
   F. Boilers and Steam Delivery Systems
   G. Medical Gas Distribution
   H. Medical and Surgical Vacuum and Air Delivery Systems
   I. Communication Systems
   J. Sewerage Removal Systems
PROCEDURE:

All utilities and their components will be evaluated following the procedure defined herein to determine if it will be included in the utilities management program and to assist in the prioritization of preventive maintenance and inspections.

1. The Director will evaluate each utility system or component and assign a numerical score in each of four categories; utility function, physical risk, maintenance requirements, and incident history.

2. The most appropriate value from each of the attached four Tables (Numbered Table 1-4) will be selected and entered into the equipment-scoring chart shown below.

3. The total score shall be the UM# for that utility or component. Utility or Component having an UM# of 12 or greater shall be included in the Utility Management System and shall be tested and maintained according to hospital policy, manufacturers, guidelines, and any other applicable regulations.

   TOTAL SCORE (UM#) = Utility Function + Physical Risk + Maintenance Requirement + Incident History

4. Utility or Component having an UM# of 11 or less shall be omitted from the program (however the Maintenance Facilitator or Chief Engineer may, at his/her discretion, require periodic safety testing and/or previous maintenance for any piece of equipment).

<table>
<thead>
<tr>
<th>Table 1 - Criteria: Utility Function</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Element or Item supports Life Support</td>
<td>10</td>
</tr>
<tr>
<td>Element or Item supports Infection Control</td>
<td>9</td>
</tr>
<tr>
<td>Element of Item required for Environmental Controls or Comfort</td>
<td>7</td>
</tr>
<tr>
<td>Element or Item necessary for support of above equipment</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2 - Criteria: Physical Risk</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>A failure in this element or item could cause:</td>
<td></td>
</tr>
<tr>
<td>Patient or Staff Death</td>
<td>5</td>
</tr>
<tr>
<td>Patient or Staff Injury or Illness</td>
<td>4</td>
</tr>
<tr>
<td>Minor Injury or Serious Inconvenience</td>
<td>3</td>
</tr>
</tbody>
</table>
Slight Inconvenience 2
No significant risk or inconvenience 1

Table 3 - Criteria: Maintenance Requirement
<table>
<thead>
<tr>
<th>Maintenance Requirements are:</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extensive (Daily or Weekly)</td>
<td>5</td>
</tr>
<tr>
<td>Average (Monthly or Quarterly)</td>
<td>3</td>
</tr>
<tr>
<td>Minimal (Annual or longer)</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 4 - Criteria: Incident History
<table>
<thead>
<tr>
<th>Problems with this item or element have occurred:</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequently (Daily, Weekly)</td>
<td>3</td>
</tr>
<tr>
<td>Average (Quarterly to Annually)</td>
<td>2</td>
</tr>
<tr>
<td>Minimally (No problems in past years)</td>
<td>1</td>
</tr>
</tbody>
</table>

5. Devices included in the utility program are assigned an individual control number to which all work orders and preventive maintenance forms are referenced. Preventive maintenance inspections are handled in one of the following ways:

   A. Depending on maintenance requirements, devices will receive a PM inspection weekly, monthly, bi-monthly, quarterly, or annually. Most PM's are scheduled by the area in which the devices are located.

   B. Devices that a manufacturer-recommended PM interval based on hours of use are scheduled and given preventive maintenance accordingly.

6. Written test procedures for all equipment on the Utility Management inventory are developed to ensure a high level of inspection and documentation consistency. These procedures are printed on TMA generated work orders at the proper PM intervals. More detailed Preventive Maintenance procedures for each task code is in the equipment manual or in the manufacturer's service manual. References may be made to the service or procedure manual when ever due to the length of the PM procedure, or the complexity involved in completing the PM, there is too much information for a single work order.
## Risk Assessment for Utility System Management

<table>
<thead>
<tr>
<th>Risk Scale</th>
<th>Electrical Failure</th>
<th>Medical Gas</th>
<th>Vaccum</th>
<th>Computer</th>
<th>Water</th>
<th>Sewer</th>
<th>Steam</th>
<th>A/C</th>
<th>Lighting</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
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<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>1</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 West
2 North
2 South
3 North
4 North
5 North
6 North
7 North
8 North
Administration
Admitting
BGTC
Birth Care
Business Office
Cardiology
Chaplains
Day Surgery
Employee Health
Facility Support
Gift Shop
Human Resources
ICU
IMT
Lab
Library
LZTC
Material Management
Medical Records
Medical Staff
Nuerodiagnostic
Oncology
Percent Passing
Pharmacy
PM&R
QMI
Radiology
Resp Care
STC
Surgery
Training & Develop
Food Service

g:\JCAHOLife Safety\1998 Haz Surveillance
Exhibit D: ECRI Institute’s Sample Device Inspection Procedure
Sample ECRI Institute inspection and preventive maintenance procedure from BiomedicalBenchmark™

**Procedure No. 416-20081015**

✓ Acceptance ✓ Major _Minor_

### General-Purpose Infusion Pumps

#### Also Called
Large-volume pumps

#### Commonly Used In
All patient care areas, homes

#### Scope
Applies to general-purpose infusion pumps

#### Risk Level:
High

<table>
<thead>
<tr>
<th>Type</th>
<th>Interval</th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major</td>
<td>12 Months (see Notes)</td>
<td>0 Hours</td>
</tr>
<tr>
<td>Minor</td>
<td>NA</td>
<td>0 Hours</td>
</tr>
</tbody>
</table>

#### Overview
Infusion pumps are often used when accurate delivery rates are required over long periods of time. Most general-purpose infusion pumps have a flow range of 0.1 to 999 mL/hr. Some general-purpose infusion pumps are multichannel models, offering two or more general-purpose pumps within one chassis.

#### Test Apparatus and Supplies
- Electrical safety tester
- Pressure meter (≥50 psi)
- Infusion pump tester - optional
- 50 mL graduated cylinder (1 mL graduations)
- Electronic balance (200 g range, 0.1 mg resolution)
- 5 mL pipette (0.1 mL graduations)
- Stopwatch or watch that displays seconds

#### Procedure
Be sure that you understand how to operate the equipment, the significance of each control and indicator, and the alarm capabilities. Before beginning an inspection, carefully read this procedure, the operators manual, and the inspection and preventive maintenance procedures recommended by the manufacturer (typically included in the service manual). Use the BiomedicalBenchmark Support Assessment Form to document a maintenance decision that reflects past experience with this type of equipment and the environment where it is used. Then use the IPM Procedure Customization Tool to modify this procedure as needed; the program will generate a documentation form with the corresponding changes. Also see: *Inspecting Infusion Pumps: How Often is Enough?* (in IPM Guidance article Optimizing the IPM Program).

Use the disposable accessory (e.g., IV tubing set) specified for the infusion pump to be inspected. Disposable accessories should be replaced at least weekly and more frequently with heavy use. Use degassed water or, when available, bags of outdated (i.e., clinically unusable) IV solutions.

For settings ≥1 mL/hr, flow accuracy is most conveniently determined with an infusion pump tester. If a tester is not available, calculate flow rate by dividing the volume collected in a 50 mL graduated cylinder (1 mL graduations) by the delivery time measured with a stopwatch. For settings less than 1 mL/hr, calculate flow rate by dividing the mass obtained in a small beaker on an electronic balance (200 mg range and resolution to 0.1 mg) by the measurement time. If a balance is not available, use a 5 mL pipette (0.1 mL graduations) attached to a vertical mounting stand and divide the volume collected by the delivery time. Operate the pump on battery power during a flow accuracy measurement if not during the entire inspection to check that the battery has been charged and can hold a charge. If a low-battery alarm occurs, verify that the alarm is properly displayed and then continue the inspection on line power. Note how long the pump was operating on battery power and the conditions under which the low-battery alarm occurred. Fully charge the battery before returning the pump to use.
Qualitative Tasks

**Chassis/Housing (Acceptance)**
Check for shipping damage; report any damage to the manufacturer, shipper, or service organization, and arrange for repair or replacement.

Check that the infusion pump is suitably constructed to withstand normal hospital use and abuse. For instance, a unit with venting on the top of the housing or poorly protected or sealed controls and indicators may be prone to fluid entry.

Examine the exterior of the infusion pump for cleanliness and general physical condition. Ensure that plastic housings are intact, that all assembly hardware (e.g., screws, fasteners) is present and tight. Check that labels and markings are legible.

**Chassis/Housing (Major)**
Examine the infusion pump for overall condition. The chassis should be clean and free from IV or enteral solution residue, especially near moving parts (e.g., thumbwheel switches, pump or controller mechanisms). Also check for dried solution deposits on accessible air-in-line sensors, pressure sensing mechanisms, and infusion set/cassette locking mechanisms. Check that labels and markings are legible.

**Mount (Acceptance, Major)**
Screws and brackets that attach the infusion pump to an IV pole should be secure and functioning. If the pump is mounted on a stand or cart, examine the condition of the mount. Also examine the pole, stand, or cart.

**Casters/Brakes (Acceptance)**
If the infusion pump is mounted on a dedicated IV pole, stand, or cart that moves on casters, check their condition. Check the operation of brakes and swivel locks, if so equipped.

**Casters/Brakes (Major)**
If the infusion pump is mounted on a dedicated IV pole, stand, or cart that moves on casters, check their condition. Look for accumulations of lint and thread around the casters and be sure that they turn and swivel, as appropriate. Check the operation of brakes and swivel locks, if so equipped.

**AC Plug (Acceptance)**
A solidly constructed, good quality plug with adequate strain relief is acceptable, but the use of a Hospital Grade plug (identifiable by a green dot and/or labeling) will eliminate guesswork and ensure a plug of acceptable construction quality. Right-angle plugs are unacceptable for devices that are moved frequently. A good quality two-prong plug is acceptable for double-insulated devices. Replace the plug or have the supplier replace it if it is not Hospital Grade or otherwise suitable. Hospital Grade molded plugs are acceptable.

Examine the AC power plug for damage. Attempt to wiggle the blades to determine if they are secure. Shake nonmolded plugs and listen for rattles that could indicate loose screws.

If the pump or its IV pole has electrical receptacles for accessories, examine them by inserting an AC plug into each and checking that it is held firmly.

**AC Plug (Major)**
Examine the AC power plug for damage. Attempt to wiggle the blades to determine that they are secure. Shake the plug and listen for rattles that could indicate loose screws. If any damage is suspected, open the plug and inspect it.

If the pump or its IV pole has electrical receptacles for accessories, inspect them by inserting an AC plug into each and checking that it is held firmly. If accessories are plugged and unplugged often, consider a full inspection of the receptacle.

**Line Cord (Acceptance)**
Ensure that the line cord is long enough for the infusion pump's intended application; an extension cord should not be required. (A length of 10 ft [3 m] is suitable for most applications, although 18 ft [5.5 m] has been suggested for operating room equipment.)
The cord should be of suitable quality and current-carrying capacity. Hard Service (SO, ST, or STO), Junior Hard Service (SJO, SJT, or SJTO), or an equivalent-quality cord should be used.

Verify that the pump has adequate protection against power loss (e.g., from accidental disconnection of a detachable power cord, disconnection of the power cord from the wall, or depleted battery if a battery-powered pump is not plugged in). Equipment having a detachable power cord should also have adequate capture devices, cleats, or channels to hold the cord in place. If these are absent, request that the supplier provide suitable means of securing the cord. Verify that the infusion pump has adequate alarms or indicators for line-power loss and battery depletion and an adequate battery-charging indicator.

**Line Cord (Major)**
Inspect the cord for signs of damage. If damaged, either replace the entire cord or, if the damage is near one end, cut out the defective portion.

**Strain Reliefs (Acceptance, Major)**
Examine the strain reliefs at both ends of the line cord. Be sure that they hold the cord securely.

**Fittings/Connectors (Major)**
Examine any electrical cable connectors (e.g., data transfer, nurse call) for general condition. Electrical contact pins or surfaces should be straight and clean. Check any spill-protection connector caps for signs of damage.

**Controls/Switches (Acceptance)**
Verify that software setup parameters accessible through hidden or service menus are correctly set for the appropriate application and are consistent for all similar infusion pumps.

Examine all controls and switches for physical condition, secure mounting, and correct motion. If a control has fixed-limit stops, check for proper alignment, as well as positive stopping. Ensure to check that each control and switch performs its proper function.

**Controls/Switches (Major)**
Examine all controls and switches for physical condition, secure mounting, and correct motion. Where a control should operate against fixed-limit stops, check for proper alignment, as well as positive stopping. Check membrane switches for membrane damage (e.g., from fingernails, pens). During the course of the inspection, be sure to check that each control and switch performs its proper function. Verify operation of the front keypad lockout switch, located on the back of most models.

**Battery (Acceptance)**
Determine the replacement interval for all batteries and document the interval(s). Be sure to include batteries/cells for clocks and/or memory logs.

Operate the infusion pump on battery power for several minutes to verify that the battery is charged and can hold a charge. Activate the battery test function, if so equipped. Check the condition of the battery charger, and verify that battery charge indicators function. Ensure that the battery is fully charged before putting the infusion pump into service.

**Battery (Major)**
If so equipped, check the pump’s battery log for battery status. Operate the pump on battery power during a flow accuracy measurement if not during the entire inspection to check that the battery has been charged and can hold a charge. If a low-battery alarm occurs, check to ensure that it is properly displayed and then continue the inspection using line power. Note how long the infusion pump has been operating and the conditions under which the low-battery alarm occurred. Fully charge the battery before returning the pump to use. When it is necessary to replace a battery, label it with the date.

**Indicators/Displays (Acceptance, Major)**
During the course of the inspection, confirm the operation of all lights, indicators, meters, gauges, visual displays, and display backlighting, if so equipped. Be sure that all segments of a digital function. (Many infusion pumps automatically check indicator and display function when turned on or during a manually activated self-test.)

**Self-Test (Acceptance, Major)**
For units with a self-test mode, activate it and determine if the expected response is produced.
Time/Date Settings (Acceptance, Major)
Verify that the time and date settings on the unit are correct.

Network/Wireless Interfaces (Acceptance)
Assess the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic information stored or transmitted by the device or system and take appropriate preventive measures. Make sure that necessary information, including device identification, operating system, IP (internet protocol) address, is documented in the appropriate log. As appropriate, verify that confidentiality (e.g., password protection) and malicious software protective (including mechanisms for future operating system and virus protection patches and upgrades) measures are implemented. Determine if a VPN (virtual private network) is needed. For wireless devices, ensure that appropriate wireless security measures have been implemented and that requirements of the healthcare organization's wireless management policies have been met. Verify that data backup processes are activated and verified.

Network/Wireless Interfaces (Major)
Review measures taken to ensure protection against the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic information stored or transmitted by the device or system and verify that preventive measures are still active. For example, are passwords being applied correctly, have operating system and virus protection patches and upgrades been installed, is the device still operating on a VPN (virtual private network) and are wireless security measures still in place. Verify that data backup processes are activated and that data can be retrieved from backups.

Alarms (Acceptance, Major)
Many infusion pump alarm capabilities can be checked qualitatively. The following tasks include tests for the most common alarm conditions. Check the instruction manual to see how the alarm should work. When an alarm occurs, check to see that both audible and visual alarms are activated and that flow stops or is reduced to a keep-vein-open rate (e.g., <5 mL/hr). Confirm appropriate alarm volume, as well as the operation of any volume control.

Audible Signals (Acceptance, Major)
Operate the pump (e.g., press rate switches) to activate any audible signals. Confirm appropriate volume, as well as the operation of the volume control, if so equipped.

Open Door/Misloaded Infusion Set (Acceptance, Major)
Check this alarm during setup and operation.

Flow-Stop Mechanism(s) (Acceptance, Major)
Turn the power off with the infusion set primed and loaded in the device. With all tubing clamps open, the fluid container two feet or more above the device, and the tubing hanging to the floor, verify that no fluid flows out of the distal connector.

If the device incorporates a mechanism that automatically closes the set or requires the set to be manually closed before it is removed from the device, verify the operation of this mechanism.

Empty Container (Acceptance)
Simulate an empty fluid container while the pump is infusing. The simulation method will depend on the type of sensor that is used in the alarm system. For most infusion pumps, inverting the fluid container will cut off the supply, empty the tubing leading from the container, and trigger an (air) alarm.

Occlusion (Acceptance, Major)
Verify upstream occlusion detection by activating infusion with the tubing clamped just below the fluid container. Verify operation of downstream occlusion detection by activating infusion with the infusion set's distal connector capped.

Infusion Complete (Acceptance)
Set the total volume or dose to be infused to a low volume/dose (e.g., 10 mL), and operate the pump at a high-flow setting. An end of infusion alert should be triggered and the rate should drop to a keep-vein-open rate (typically ≤5 mL/hr).

Nurse Call (verify only if this function is used) (Acceptance, Major)
Some pumps have a relay contact closure that activates a nurse-call system when an alarm condition occurs. This requires a special cable that connects the pump to the nurse-call system. If the infusion pump
Sample ECRI Institute inspection and preventive maintenance procedure from BiomedicalBenchmark™

has this capability and it is used in any clinical location, connect the cable, and simulate one or more of the above alarm conditions to determine whether they activate the nurse call. Alternatively, use an ohmmeter to check that a change in resistance (either low to high or high to low) occurs between the two conductors of the cable when an alarm condition is created.

**Labeling (Acceptance, Major)**
Check that all necessary placards, labels, and instruction cards are present and legible.

**Accessories (Acceptance)**
A copy of the operators and service manuals (electronic or hard copy), including schematics, should be shipped with the equipment. Manuals should be filed in the central equipment file and clinical instructions should be kept in the patient care area for easy access by clinicians.

**Quantitative Tasks**

**Grounding Resistance (Acceptance, Major) ≤0.5 Ω**
Measure the resistance between the grounding pin of the power cord (if so equipped) and exposed (unpainted and not anodized) metal on the chassis. Grounding resistance should not exceed 0.5 Ω. If the unit is double insulated, grounding resistance need not be measured.

**Chassis Leakage Current (Acceptance) ≤500 μA**
Leakage current must be measured with the device powered by a conventional (grounded) power system, even if it is normally used in an area with isolated power. ECRI Institute does not recommend chassis leakage current tests of double-insulated devices.

With the polarity of the power line normal and the equipment ground wire disconnected, measure chassis leakage current with the device operating in all normal modes, including on, standby, and off. Maximum leakage current should not exceed 500 μA.

Inspect AC adapters used to power (or recharge) certain devices for CE mark or UL (or other testing laboratory) listing and to verify that it is labeled to identify the device with which it is to be used. ECRI Institute recommends testing of adapters, particularly those that are not listed, by measuring the leakage current from each secondary (low voltage) connection to ground. The leakage current should not exceed the limits for the device chassis leakage current to ground.

**Flow Accuracy (Acceptance) ±5%**
Record any test variables (e.g., infusion set catalog number) for the pump to facilitate the comparison of results with those obtained during future inspections. Determine the flow accuracy at two typical flow settings (e.g., 10 and 100 mL/hr) and at minimum and maximum flow settings. Note: It is probably unnecessary to perform testing at minimum and maximum settings for more than a small (e.g., 5%) sample of an infusion pump shipment.

For flow settings ≥1 mL/hr, use an infusion pump tester or collect the output in a graduated cylinder. Use a stopwatch or a watch that displays seconds to time the delivery into the graduated cylinder until at least 10 mL is collected. Record the time interval and volume collected, and calculate the delivery rate in mL/hr.

For flow settings <1 mL/hr, use an infusion pump tester if it is capable of measuring this flow. Otherwise, use an electronic balance to gravimetrically determine pump accuracy by weighing a small beaker (covered with a film of plastic wrap to minimize evaporative losses) before and after collecting a mass of at least 1.5 g. Convert the mass to volume (1 g H2O = 1 mL; 1 g/mL can be used for most other test solutions [e.g., normal saline], although the mass per unit volume of some fluids may differ significantly). Divide the calculated volume by the collection time in hours (e.g., 1.5 mL / 15 hr = 0.1 mL/hr).

If an electronic balance is not available, use a small length of rubber hose to connect the infusion set to the base of a vertically mounted, graduated 5 mL pipette (resolution to 0.1 mL). Divide the collected volume (1.5 mL, minimum) by the collection time to calculate the infusion rate.

To calculate flow error, use the following formula:

\[
\text{% Error} = \frac{\text{Actual rate} - \text{Desired rate}}{\text{Desired rate}} \times 100\%
\]
Most intravenous infusion pumps are specified to deliver within 5% of the flow setting. Note: Negative and positive flow error represents underdelivery and overdelivery, respectively.

**Flow Accuracy (Major) ±5%**
Determine the flow accuracy at two typical flow settings ≥1 mL/hr (e.g., 10 and 100 mL/hr).
Use an infusion pump tester or collect the output in a graduated cylinder. Use a stopwatch or a watch that displays seconds to time the delivery into the graduated cylinder until at least 10 mL is collected. Record the time interval and volume collected, and calculate the delivery rate in mL/hr.

To calculate flow error, use the following formula:
\[
\text{% Error} = \frac{\text{Actual rate} - \text{Desired rate}}{\text{Desired rate}} \times 100\%
\]

Most infusion pumps are specified to deliver within 5% of the flow setting.
Note: Negative and positive flow error represents underdelivery and overdelivery, respectively.

**Maximum Pressure (Acceptance) ±1 psi of manufacturer specification**
Determine the pump's downstream occlusion alarm pressure specification if a maximum pressure is not specified. For most pumps, maximum pressure will be equivalent to occlusion alarm pressure. However, it is important to understand what is happening when a pump's occlusion alarm activates to properly measure maximum infusion pressure. Each pump model is likely to use one of three pressure references for triggering its occlusion alarm: 1) a single fixed pressure, 2) user-adjustable occlusion pressures, or 3) occlusion pressures that are benchmarked from operating infusion pressures. For pumps with user-adjustable pressure, this test should be performed at the highest setting. For pumps that reference occlusion alarms to increases in baseline operating pressure, it will be necessary to restart the pump several times after serial occlusion alarms until a maximum pressure is obtained. The maximum pressure of most pumps is less than 20 psi.

Connect the distal end of the primed infusion set to a pressure meter or use an infusion pump tester (if equipped to perform this task), and start infusion. Determine maximum pressure and the time to occlusion alarm activation at two commonly used flow settings (e.g., 10 and 100 mL/hr). Restart the pump after each occlusion alarm to ensure that maximum infusion pressure has been attained.

It may be desirable to also measure and record the time to occlusion alarm for future reference. If this is done, record the length and type of infusion set (i.e., standard or microbore tubing) that was used.

**Maximum Pressure (Major) ±1 psi of acceptance test pressure**
Reference the pump's maximum pressure determined during acceptance testing. Connect the distal end of the primed administration set to a pressure meter or use an infusion pump analyzer (if equipped to perform this task). Start infusion at a commonly used flow setting (e.g., 10 or 100 mL/hr) and record the maximum pressure. Restart the pump after each occlusion alarm to ensure that maximum infusion pressure has been attained. The maximum pressure of most pumps is less than 20 psi.

**Air-in-Line Detection (Acceptance, Major) 50 to 100 μL**
Inject 100 μL air into an injection port of the IV tubing with a U-100 insulin syringe between the fluid container and the air-in-line detector. 100 μL can be approximated by 10 units from a U-100 insulin syringe. Sensitivity to air volumes of less than 50 μL is likely to result in nuisance alarms. Most pumps will trigger an alarm for 50 to 100 μL air.

**Preventive Maintenance**

**Replace (Major)**
Replace the primary battery and/or the clock/memory battery/cell, if necessary, and label it with the date.

**Notes**
It may be possible to establish a longer inspection interval or eliminate scheduled inspections of general-purpose pumps.
Exhibit E: Equipment Service History—Community Hospitals of Indianapolis
<table>
<thead>
<tr>
<th>Equipment Support Details</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Service Expenses</td>
<td>$5,089,505</td>
<td>$4,727,483</td>
<td>$4,536,097</td>
<td>$4,198,448</td>
<td>$4,485,543</td>
<td>$4,787,329</td>
<td>$5,783,357</td>
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<tr>
<td>Estimated Equipment Acquisition Value</td>
<td>$72,000,000</td>
<td>$83,938,000</td>
<td>$93,460,000</td>
<td>$126,000,000</td>
<td>$139,253,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Service Cost as % of Acquisition Value</td>
<td>6.30%</td>
<td>5.00%</td>
<td>4.80%</td>
<td>3.80%</td>
<td>4.15%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Active Devices</td>
<td>11954</td>
<td>13020</td>
<td>13749</td>
<td>13680</td>
<td>13894</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Safety Assessments Completed</td>
<td>38</td>
<td>83</td>
<td>61</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Equipment Related Incidents</td>
<td>14</td>
<td>11</td>
<td>9</td>
<td>5</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average Service Cost per Active Device</td>
<td>$379.46</td>
<td>$322.46</td>
<td>$326.25</td>
<td>$349.95</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Repair Requests on Scheduled Devices</td>
<td>5924</td>
<td>5866</td>
<td>5481</td>
<td>3903</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average Service Cost per Repair Request on Scheduled Devices</td>
<td>$765.72</td>
<td>$715.73</td>
<td>$818.38</td>
<td>$1,226.58</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total # Repair Requests</td>
<td>6800</td>
<td>6924</td>
<td>6434</td>
<td>7366</td>
<td>7184</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repair Requests per Active Device</td>
<td>0.57</td>
<td>0.53</td>
<td>0.47</td>
<td>0.54</td>
<td>0.52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total # Device Service Events</td>
<td>12940</td>
<td>13665</td>
<td>13501</td>
<td>13339</td>
<td>13204</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average Service Event per active Device</td>
<td>1.08</td>
<td>1.05</td>
<td>0.99</td>
<td>0.98</td>
<td>0.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average Cost per Service Event</td>
<td>$350.55</td>
<td>$307.24</td>
<td>$332.24</td>
<td>$358.90</td>
<td>$438.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total # Productive Paid Hours</td>
<td>39,302</td>
<td>38,957</td>
<td>39,436</td>
<td>38,765</td>
<td>38,175</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average Cost per Productive Hour</td>
<td>$115.42</td>
<td>$107.77</td>
<td>$113.74</td>
<td>$123.50</td>
<td>$151.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average Productive Hours per Active Device</td>
<td>3.29</td>
<td>2.99</td>
<td>2.87</td>
<td>2.83</td>
<td>2.75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual Year End Paid FTE</td>
<td>20.68</td>
<td>20.72</td>
<td>20.95</td>
<td>20.84</td>
<td>20.42</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year End Paid Hours</td>
<td>430,144.40</td>
<td>430,976.00</td>
<td>435,766.00</td>
<td>433,472.20</td>
<td>424,330.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Labor Only Cost per Paid Hour</td>
<td>25.74</td>
<td>28.54</td>
<td>30.80</td>
<td>28.73</td>
<td>28.56</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average # Active devices per Paid FTE</td>
<td>578</td>
<td>628</td>
<td>656</td>
<td>656</td>
<td>680</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acquisition Cost per Technician</td>
<td>$3,481,625</td>
<td>$4,051,062</td>
<td>$4,461,098</td>
<td>$6,046,068</td>
<td>$6,819,442</td>
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</tr>
</tbody>
</table>

Note: Total Active Device Count is relatively constant. As the number of Scheduled Inspections decreased due to expanded inspection intervals, the number of Service Events per active device trends down. More time was available to spend on Safety Assessments. The number of Device Related Incidents has trended down, and the number of Repair Requests per active device is effectively unchanged.
Exhibit F: Trinity Health Medical Equipment Management—Post-Implementation Results
Trinity Health Medical Equipment Management — Post-Implementation results of an Evidence-Based Maintenance process

This document summarizes the post-implementation results since December 2009 for Trinity Health’s Evidence-Based Maintenance process. THCE uses both OEM and in-house inspection validation methods to ensure the safe support for the various types of medical equipment managed by its centrally managed Clinical Engineering program. The following are the notable results of the implementation of the THCE evidence-base maintenance process:

- Reduction in age-related device failures
- Reduction in reported device incidents
- Measured increase in number of hours technical staff spent rounding with clinicians
- Measured increase in customer satisfaction scores
- Recognition by several States and by ECRI Institute as addressing patient safety needs
- Reproducible results and audit trails for validation

Trinity Health Clinical Engineering (THCE) uses an Evidence-Based Maintenance process with a scoring system to identify risk for each device type in its inventory, and incorporates the actual service experience for planned (PM) and corrective maintenance (CM) to determine program inclusion status. This includes identification of device types that THCE classifies as “Life Support,” and those high-risk devices that THCE feels can contribute to “potential patient death” if not properly maintained. This approach, using a defined scoring system and actual service experience to determine maintenance needs, follows what is outlined in the recommended process identified by ANSI/AAMI EQ56: 1999/(R) 2008, “Recommended practice for a medical equipment management program”, Section 4-4.2.2.

THCE may not use the exact same brand of test device as specified by an OEM. Where it does not, THCE will use a commercially produced test device that is analogous in capabilities to the OEM-specified device, thus insuring accuracy and relevance of measurements. Test equipment is calibrated annually to ensure it meets the National Institute of Standards and Technology (NIST) for accuracy of measure and is traceable.

The actual method utilized by THCE for performing a PM inspection is a mix of both OEM Methods and THCE procedures — depending on device type, equipment function, and clinical application risk — to ensure appropriate device parameters, referred to in the medical device service industry as “critical failure modes”, are being checked to maintain a high level of patient safety. THCE mandates compliance with manufacturer-specified tolerances for its procedures. Because THCE focuses on the actual performance parameters when validating a device, this may result in THCE taking significantly less time to perform an inspection due to the consolidation of procedural steps. It is to be stressed that the performance validation for parameters that directly impact patient safety are not skipped.

In December 2010, ECRI Institute, designated as an Evidence-Based Practice Center by the U.S. Agency for Healthcare Research and Quality and listed as a federal Patient Safety Organization by the U.S. Department of Health and Human Services, had reviewed a Trinity Health facility for its hospital-wide implementation of the THCE program and policies, which included its evidence-based maintenance process. Their findings stated:

“In its review, ECRI Institute found that the THCE medical equipment management program to be well-designed with patient safety a primary concern” and “ECRI Institute finds that the safety of the THCE program is well-established.”

THCE was also granted written waivers by several States from their own administrative codes as related to their Department of Public Health requirements for medical device maintenance. Those waivers provided the written acknowledgement that those states felt the THCE approach to medical equipment maintenance was effective in
ensuring proper operation of the devices supported and, more importantly, that the approach did not compromise patient safety.

THCE’s initial assessment and modeling performed in early 2009 consisted of a review spanning three years of service data for each device type in the consolidated THCE service database supported under its original implementation of the Fennigkoh-Smith model for risk-based maintenance. This covered 300,000 work orders for approximately 200,000 medical device records, both for active and inactive devices. THCE identified the need to filter out non-relevant CM’s (damage, use error, software, could not duplicates, recalls, etc) and take the position that all PM failures (major and minor) were relevant. Equipment function and clinical application were deemed important factors when assessing service histories for potential impact on patient safety.

THCE was unconcerned about the actual repair costs and hospital service line revenue; as such those were not factors considered when assessing what to inspect. THCE tracked the following failure types: Electrical, Image Quality, Mechanical, and Deterioration. Failures measured were not related to the user through misuses (work orders coded as Use Errors, Damage, or Unable to Duplicate). THCE focused on the operational reliability, function, and clinical application of the device driving the need for a PM at all. This process also addresses the concern that certain types of equipment will require more service support as they age, as actual service data is measured annually for PM inclusion and frequency consideration.

THCE had compared its pre-December 2009 risk-based PM inclusion statuses for equipment against the new evidence-based maintenance processes PM inclusion scores for reasonableness. Post-implementation evaluation of the process indicated that only about five percent of all 475-device types were experiencing a change to their corresponding PM inclusion statuses — about 12,000 items out of the current total inventory of 155,000 active devices. The majority of items that experienced a change are infusion devices. Some experienced CM failures later identified as part of a national safety recall for an internal design flaw. Another large quantity had physically deteriorated due to disinfecting agents damaging the housing that were part of another design issue with a different OEM. PM failures were not a driving issue for this change in inclusion status. The age-related CM’s were captured in the process, driving up the corresponding PM inclusion status scores.

Since implementation in December 2009, THCE has tallied another 305,000 PM and CM work orders for its internal analysis, along with 183,000 additional work orders for Rounding, Special Projects, Device Incidents, etc. Total work orders currently in the unified THCE database represent approximately 1.5 million service events available for THCE review. The analysis of the post-implementation of the evidence-based maintenance process has shown a measurable, favorable decline in several metrics, including age-related CM work orders, Use Errors, and reported Device Incidents (see attached graphs).

THCE Senior Leadership (SLT) continued ongoing education of its technical staff for items they supported, performing documentation-related training as identified, and completing annual program-performance reviews at the hospital level to ensure the integrity of the service documentation and program implementation. THCE felt this attention to detail supported accurate, reproducible results for the program analysis going forward. The THCE program grew in size between 2009 and 2011, when active equipment support went from 104,000 devices to over 155,000 devices; at the same time, technical staffing increased from eighty-six technicians to over 160.

THCE identified training on use of service codes as a need for the hospitals that joined the THCE program, as the new technicians were coding Use Errors for items that by THCE definition, should have been coded differently. Important here is the fact that THCE requires any Use Errors to have a clinician identified so that proper in-servicing can be performed to ensure communications are a closed-loop process and that ongoing patient safety is maintained. THCE addressed the issue with the new technicians, and a drop in Use Errors has been observed since that time, supported by the increase in customer satisfaction scores and the number of hours spent rounding with clinical staff.

THCE feels the positive trends in its metrics are due to two primary factors. First, THCE technical staff is effectively addressing non-life support and lower-risk items that have demonstrated an actual need for a PM. This results in more time to be with the clinical staff THCE supports, and was reflected by its higher measured customer
satisfaction scores since implementation of the new process. Second, since many items not receiving a PM prior were identified as needing a PM, this contributed to a drop in age-related failures for CM work orders. The lack of an increase in age-related CM when taking many devices off a PM schedule further supports the effectiveness of such an approach. The availability of technical staff is augmented by THCE using its approach for methods when measuring and validating the parameters related to a device’s safe operation.

Though the evidence-based process used by THCE is dynamic for items moving both in and out of program, THCE knew not all situations could be completely addressed. To meet this need, THCE also introduced a PM variance request process for items impacted by unique hospital specific environmental issues, utilization, or special accreditation needs. This addressed potential items that may not readily fall in — or out — of a PM program. Audit trails support the reproducibility of the process results, PM variance request approvals, and the final PM inclusion status for every device in its inventory. Documentation is made available to THCE staff via the team website at Trinity Health.

In summary, THCE feels that its use of an evidence-based maintenance process applied uniformly and consistently — along with its approach to using a mix of OEM and in-house methods for validating medical devices — is sound in process. With a large consolidated repository of available data, THCE can show its results are reproducible and traceable, and ensure patient safety needs are never compromised.

Attachments:
Graphs of results
We serve together in Trinity Health, in the spirit of the Gospel, to heal body, mind and spirit to improve the health of our communities and to steward the resources entrusted to us.

Respect • Social Justice • Compassion • Care of the Poor and Underserved • Excellence

Sponsored by Catholic Health Ministries
Several new hospitals were added in the 2009-2011 timeframe, resulting in an increase in the number of CM work-orders relating to the items incorporated into the THCE program. As the number of scheduled PM work orders dropped per 1,000 devices, the occurrence of CM work orders also fell at a respective rate. More importantly, the number of Age-related CM work orders measured per 1,000 devices in inventory did not see an increase. THCE feels this validates the process for more accurately assigning a PM, and clearly shows there were no shifting of how service events/maintenance needs were being accounted for. All PM’s and CM post-repair validations are performed with a mix of OEM and in-house inspection Methods, dependant upon the device type, repair, equipment function, and clinical application risk.

Since several new Hospitals were added in the 2009-2011 timeframe, this resulted in an increase in the number THCE technical staff that had to be trained on the use of proper codes (specifically appropriate documentation for Incident and Use Error). THCE was able to train technical staff to do more work in house, eliminate contracts, and in some cases hire more staff. This resulted in THCE providing more time for technical staff to perform rounding (a 4,000 hour increase since 2009), helping contribute to a reduction in reported device incidents.

*A review of each device incident work order was performed to identify the nature of the incident. THCE was able to determine that no reported incidents were caused by incomplete or improper maintenance of the devices in question.*
Exhibit G: Schedule Change Worksheet Used by Community Hospitals of Indianapolis; Equipment Schedule Assessment Policy; and Medical Equipment Maintenance Intervals Policy (with decision flowchart)
# Device Inspection Schedule Change Worksheet

Note: A spreadsheet of selected inventory may be submitted in lieu of or in addition to this worksheet. For any such submittal, the Clinical Engineering Director is responsible to ensure that all requirements for compliance are met.

| Department Contact: | 
| Date Submitted to EOC: | 
| Date Approved by EOC: | 
| Date Submitted to Risk Management: | 
| Submitted by: | 
| Database Changes Authorized: Yes No |

| Equipment Management (EM) Process Key | 
| Required Processes | Key |
| Active medical equipment management strategy, inventory review process | A |
| Staff knowledge and device set up monitored during environmental safety rounds | S |
| Service scheduled as necessary based on maintenance requirements | S |
| User Competency Evaluation, Training Plan, Staff Orientation as appropriate | U |
| Routine visual check/activation during technician/clinician rounds to ensure performance | R |
| Emergency clinical response protocols for alternative patient care if applicable | E |
| Documented policies/procedures addressing use, service, and/or reliability | D |

|-------------------|-------------|--------------|-------|---------------------|-------------------------------|------------------------------------|----------------------------------|

Community Health Network Confidential 7/11/2012 Page 1
TITLE: MEDICAL EQUIPMENT – EQUIPMENT INSPECTION SCHEDULE ASSESSMENT

POLICY

As part of our comprehensive Medical Equipment Management Program, the Clinical Engineering department utilizes a process of scheduled service for routine maintenance of medical systems and equipment. The inspection schedule for each device is reflected in the medical equipment management database.

Over a period of time, the frequency of the scheduled inspections may be adjusted based on what is noted from a review of the equipment service history or from any safety related concerns. The intent is to do scheduled service on equipment based on intervals that are appropriate in terms of extending the useful life of the equipment or for providing a positive impact to safety.

PROCEDURE

1. For the equipment included in the medical equipment database, the inspection schedule is initially established based on manufacturer recommendations.
   a. New equipment that is added to the inventory will be placed on an inspection schedule of the same interval as any other devices of the same manufacturer/model that are already shown in the inventory.
   b. If the device is a completely new type (manufacturer/model) that is not already in the database, the schedule will be assigned based on manufacturer recommended intervals.
2. If there is a perception that a device is failing frequently, and that increased maintenance may be appropriate to prevent failures, the interval between inspections may be shortened.
3. If there is any safety related concern for a device where it is determined that a scheduled inspection may have a positive impact to safety, the interval between inspections may be shortened.
4. When there are two years or more of history available on a device, if the device is perceived to have been reliable, and there is no specific safety concern on the device, Clinical Engineering may elect to recommend the inspection interval for that device be lengthened.
   a. When there is a recommendation that the inspection interval be lengthened, the service history for the entire inventory of active devices of
that type will be reviewed, to determine if there have been any Maintenance Preventable Failures (MPFs) on the devices.

i. If there are no records indicating MPFs on the devices, Clinical Engineering will take the recommendation for the interval change to the Network Environment of Care (EOC) Committee for review.
   1. Typically, the inspection interval will be extended by six months or one year, depending on the actual device maintenance history and procedures involved in the scheduled service.
   2. For some devices, the recommendation may be to take the device off of an inspection schedule completely. In those cases, the service on the device will still be tracked, and if there are any future instances of maintenance preventable failures, the device will be put on a schedule again at that time.

ii. The recommended changes will be identified on the Inspection Interval Change Form, attached to this policy for reference.

iii. If there are any MPFs found during the service history review, the details of those findings, specifically the average number per device per year, will be evaluated using the MPF Tracking Spreadsheet which is attached to this policy for reference.
   1. For devices where the average number per device per year is less than 0.1, the recommendation will be to extend the inspection interval by a length of time equal to the current interval, and the history will be evaluated again after one interval.
   2. For devices where the average number per device per year is greater than 0.1, there will not be a recommendation to change the interval at this time, and the history will be evaluated again at a later time.

b. If the EOC Committee agrees with the recommendation from Clinical Engineering, the schedule will be changed for the devices at the time of the next scheduled inspection for each affected device.

c. If the EOC Committee does not agree with the recommendation, the schedule will not be changed.

d. A copy of the Inspection Interval Change Form will be forwarded to the Director of Risk Management for devices that will have the schedule changed.

NOTE: This process was not in place when the initial schedules were set for many of the devices in the inventory. Those schedules were based on a Risk Assessment Scoring and Inspection Scheduling process. A copy of that process, and the resulting device categorization is on file in Clinical Engineering. The Medical Equipment Database also still reflects that Risk Assessment Result for Non-Life Support devices. During 2012, an updated Risk Assessment process is being applied to all devices in the inventory. Upon completion, the maintenance
intervals will reflect the application of the 2012 Medical Equipment Maintenance policy.
TITLE: MEDICAL EQUIPMENT MAINTENANCE INTERVALS

Purpose: To establish criteria by which to determine the appropriate inspection intervals for medical equipment.

Policy Statement:

It is the policy of Community Health Network, as part of our comprehensive Medical Equipment Management Program, to define and verify appropriate performance and maintenance of medical systems and equipment. The medical equipment is evaluated to determine the risk classification, and then subsequently evaluated for inclusion on a schedule for routine inspections of appropriate intervals. Routine service may include calibration, inspection, maintenance, general and electrical safety testing or other scheduled services or functions.

Definitions:
1. Medical equipment – Equipment used for the diagnosis, treatment, or monitoring of patients. The equipment may be powered or not powered by electricity, mechanical, or other means.

Procedure:

RECOMMENDED MAINTENANCE STRATEGY

Determination of a maintenance strategy and the intervals for applying it are based on several factors, separate from the Risk Classification of the device. The factors considered as part of the medical equipment management program are equipment reliability/history, manufacturer recommendations, and accreditation or regulatory requirements. Using these factors as a guide, the Director of Clinical Engineering will determine the best strategy for each type of equipment included in the medical equipment management active inventory, and the intervals at which the strategy will be applied. The standardized recommendations will be applied as the baseline for each type of equipment, although specific device schedules may vary from that based on factors such as device location, utilization, or manufacturer/model specific nuances or features.

Typical strategies include interventional maintenance, proactive or preemptive maintenance, calibration, system inspection, performance assurance and/or electrical and general safety testing. Scheduled intervals may be based on or include calendar increments of time, and may be related to use cycles or use hours.
1. EQUIPMENT RELIABILITY

Equipment reliability has been divided into three (3) categories. Equipment reliability is an evaluation of whether the rate of repairs indicates a need for scheduled interventional maintenance to address a predictable failure. Equipment reliability is evaluated as part of the process for determining the appropriate maintenance strategy and frequency. The equipment reliability criteria are based on the number of repairs that are determined to be maintenance preventable. The equipment reliability score is determined by dividing the total number of maintenance preventable repairs that occur during the previous 24 month period by the total number of units in the equipment category, as a percentage.

**Maintenance Preventable Repairs per Year (MPRPY)** = Total maintenance preventable repairs during the previous 24 months / the number of pieces of the equipment type (if more than one manufacturer or model of equipment makes up an equipment type, the reliability for each manufacturer or model should be calculated separately)

For manufacturer and model specific device analysis, per 24 month period

- **a.** \(<= 1\% \text{ maintenance preventable repair (MPR)}\)
- **b.** \(>1\% \leq 3\% \text{ MPR}\)
- **c.** \(>3\% \text{ MPR}\)

(Note: use 24 months of data; if less than 24 month history is available, inspection intervals will be set to manufacturer recommendations)

<table>
<thead>
<tr>
<th>Reliability Category</th>
<th>Maintenance Interval Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>No regular inspection or maintenance is required, except on Critical or Life Support equipment</td>
</tr>
<tr>
<td>b.</td>
<td>Visual inspection during environmental rounds by engineering staff. No device specific documentation required.</td>
</tr>
<tr>
<td>c.</td>
<td>Scheduled inspection required. The frequency and content of the inspection or maintenance will be determined by manufacturer recommendation, accreditation or regulatory requirements, and/or the recommendations from the Director of Clinical Engineering.</td>
</tr>
</tbody>
</table>
2. MANUFACTURER RECOMMENDATIONS

Manufacturer recommendations will be considered when determining appropriate maintenance strategies for medical equipment. Recommended actions that include calibration, replacement of worn parts, mechanical adjustments, and similar actions will be given higher weight than periodic functional or safety checks of equipment that has no owner adjustable physical or electronic components.

<table>
<thead>
<tr>
<th>Manufacturer Recommendation</th>
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<tr>
<td><strong>Recommended Activity</strong></td>
</tr>
<tr>
<td>a. No recommended periodic activity</td>
</tr>
<tr>
<td>b. Periodic functional and/or safety check</td>
</tr>
<tr>
<td>c. Periodic cleaning and/or calibration check</td>
</tr>
<tr>
<td>d. Replacement of wearing parts and/or mechanical adjustment of components</td>
</tr>
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3. KNOWN ACCREDITATION / REGULATORY REQUIREMENTS

<table>
<thead>
<tr>
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<td>Centrifuges</td>
<td>CAP</td>
<td>Periodic verification / documentation of timer and speed</td>
</tr>
<tr>
<td></td>
<td>Blood Warmers</td>
<td>CAP, AABB</td>
<td>Periodic steady state and alarm temperature verification / documentation</td>
</tr>
<tr>
<td></td>
<td>Line Isolation Monitors</td>
<td>NFPA 99</td>
<td>Monthly verification of trip point and alarms</td>
</tr>
</tbody>
</table>

The recommended maintenance strategy is determined by evaluating the Equipment Reliability, Manufacturer Recommendations, and Accreditation Requirements using the following flowchart as a guide. The Director of Clinical Engineering must review all recommended strategies before they are finalized as part of the equipment history file.
4. DEVICES INCLUDED FOR SCHEDULED INTERVENTIONS

Each piece of equipment included in the medical equipment management inventory program is assigned a Clinical Engineering Item Number (Item #). Scheduled and unscheduled work orders for each piece of equipment in the inventory are referenced to the Item # for the device, or for the area where the work was performed if not related to a specific device. For devices which need routine service, a specific schedule for that service is established in the Equipment Management Database, and work orders are automatically generated to track the scheduled service activities for those devices. Any changes to the inspection intervals will follow the Clinical Engineering policy for Equipment Inspection Schedule Assessment.

5. DEVICES NOT INCLUDED FOR SCHEDULED INTERVENTIONS

Equipment determined not to need any scheduled interventions will undergo an initial safety inspection. The equipment will be added to the medical equipment inventory, in accordance with the Inventory Management process, for tracking of warranty, repair history, etc. Following any repair, the device will receive a performance assurance inspection. An assessment of repair history and other performance issues may be used to determine if the equipment should be transferred to a scheduled maintenance status.

6. LOANED, LEASED AND RENTED EQUIPMENT

All leased or rented equipment will be evaluated utilizing the medical equipment inventory system. Equipment that is not expected to remain on site for any extended period of time will be tagged with a sticker to indicate the unit is a “LOANER” and will have a due date of 6 months from the date of inspection, as a visual reminder in the unlikely event that one of these devices does remain on site for an extended period of time. Any of this equipment that is expected to be “long term” will be included in the medical equipment management program. Long-term loaned, leased or rented equipment is defined as items expected to remain in the facility for more than 6 months. Those items will be added to the inventory. All such devices will be placed on an annual schedule, as a notification at time to validate the item is still on site and has received the necessary maintenance from the supplier.

The leasing department will inform Clinical Engineering when the equipment is returned to the manufacturer or supplier for exchange under the terms of the lease or rental agreement, or when a repair is required. Clinical Engineering will work with the leasing department to be responsible for collecting the manufacturer or leasing agent’s maintenance documentation on site through the term of the lease.

7. PATIENT OWNED EQUIPMENT

Patient owned equipment, including personal medical devices such as CPAP and LVAD units, is evaluated upon the patient’s arrival in the clinical care area, by the clinical care staff, in accordance with Policy N-003. Clinical Engineering is consulted if there are any
questions or concerns regarding such devices. Patient owned equipment is not evaluated under this process nor tracked as an individual Item # through the Medical Equipment Management Database.

8. EQUIPMENT TAGS AND LABELS

The Clinical Engineering department utilizes a variety of equipment identification tags and stickers to serve as a tracking method for Clinical Engineering and as a communication aid for the clinical users. Refer to the current Clinical Engineering Policy for specific details regarding the identification tags and inspection labels that are affixed to the medical equipment.

Formulated by:  Karen Waninger, Director of Clinical Engineering

Reviewed by: Community Health Network EOC Committee 3/1/2012

_______________________________
(signature on filed copy)

APPROVED BY:   Tom Malasto
President / CEO
Community Hospitals of Indiana, Inc.
Response to June 28 Meeting

Exhibit H: Maintenance Strategy Adherence—Trinity Health
SUBJECT: MAINTENANCE STRATEGY ADHERENCE

PURPOSE:
To ensure the Planned Maintenance (PM) and Corrective Maintenance (CM) strategies are in alignment with the Medical Equipment Management Program, Policy 1001.

INTRODUCTION:
THCE has implemented a planned maintenance strategy that incorporates both risk and reliability calculations. The placement of a device into a maintenance strategy is based on an analysis of equipment function, clinical application, parts/regulatory - required maintenance and the service history of a type of equipment, analyzed at a minimum of every three (3) years (see Policy 1002, Definitions of Maintenance Strategies). Ensuring that each device is accurately categorized for placement involves the CE Director and THCE SLT. Applying the necessary stickers for the strategy is the responsibility of the CE director. As such, information may come forward to show certain equipment may in fact need be moved in or out of the program after additional factors are applied. It is also possible that equipment receiving an inspection may require a change in the inspection frequency.

Examples of such regulatory requirements based upon actual equipment utilization, filter cleaning needs based upon equipment location, and battery replacements based upon equipment type or identified manufacturer/model specific needs.

PROCESS:
Each device type will be reviewed and analyzed for inclusion into a maintenance strategy every three years. The results of the review will be provided to all THCE associates via the web site – PM Risk Assessment. A summary of the results will also be available – PM Inclusion Listing F6003a Workbook, F6003a. The PM Inclusion Listing, Updates, Variance Log and Request Not Approved Tabs will be updated as needed, each time a new device type is added to the THCE program, or when an exception is requested.

To request an exception to any equipments maintenance strategy:

1. The CE Director will complete the Planned Maintenance Exception Form, Form F6003b.
2. The CE Director and Regional director will review the form for completeness and rationale
3. Once reviewed, the form will be sent to THCE Senior Leadership for review.
4. If the requested change is determined to be needed:
   a. THCE Senior Leadership will notify the CMMS department of the required change(s)
   b. The CMMS department will log the change into the workbooks Variance Log.
c. The CMMS department will review the THCE CMMS database system wide for all applicable equipment and update as needed.
   i. Any time a scheduled PM will be removed from a device a notation in the devices’ history will be entered in the CMMS database.

d. The updated workbook will be posted to the THCE Team website.

5. If the request for a variance is determined to not be needed:
   a. The Regional Director will notify the requesting CE Director of the status.
   b. The CMMS department will log the denial into the workbooks Request Not Approved tab.

6. All changes entered into the Planned Maintenance Exception Log will be reviewed in accordance with the internals identified by the Medical Equipment Management Plan, Policy 1001.

The CE director is to review the equipment inventory at a minimum every quarter to ensure newly added equipment have been placed into the correct strategy.

- When a device is removed form the PM program, the “Spot the Dot” sticker is removed from the device and a “not in program” sticker affixed.
- When a device is added to the PM program, the “not in program” sticker is removed from the device and a “Spot the Dot” sticker is affixed.
Exhibit I: AAMI 2009 Medical Equipment Management Manual
How to Be in Complete and Continuous Compliance with the Joint Commission Standards

Robert H. Stiefel, MS, CCE
2009 Edition

Medical Equipment Management Manual

How to Be in Complete and Continuous Compliance with the Joint Commission Standards

Robert H. Stiefel, MS, CCE
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Exhibit J: AAMI EQ 56 Recommended Practice
American National Standard

Recommended practice for a medical equipment management program

ANSI/AAMI EQ56:1999/(R)2008
Recommended practice for a medical equipment management program

Abstract: This recommended practice specifies minimum criteria for a management program designed to minimize certain risks associated with equipment that is used during the routine care of patients in a health care organization. The recommended practice addresses the structure of the program, documentation requirements, staffing, and resources allocated to those responsible for maintaining medical equipment.

Keywords: accreditation, maintenance, medical equipment

AAMI Recommended Practice

This Association for the Advancement of Medical Instrumentation (AAMI) recommended practice implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI recommended practice does not in any respect preclude anyone, whether they have approved the recommended practice or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the recommended practice. AAMI recommended practices are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI recommended practice may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this recommended practice no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI recommended practices by calling or writing AAMI.
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Exhibit K: Excerpt from NFPA 99—2012 Edition
10.5.2.4 Devices Likely to Be Used During Defibrillation. Devices that are critical to patient safety and that are likely to be attached to the patient when a defibrillator is used (such as ECG monitors) shall be rated as “defibrillator proof.”

10.5.2.5 System Demonstration. Any system consisting of several electric appliances shall be demonstrated to comply with this code as a complete system.

10.5.2.6 Electrical Equipment Systems. Purchase contracts for electrical equipment systems, such as nurse call and signaling that consists of interconnected elements, shall require all of the following:

1. The elements are intended to function together.
2. The manufacturers provide documentation for such interconnection.
3. The systems are installed by personnel qualified to do such installations.

10.5.2.7 Appliances Not Provided by the Facility. Policies shall be established for the control of appliances not supplied by the facility.

10.5.3 Servicing and Maintenance of Equipment.

10.5.3.1 The manufacturer of the appliance shall furnish documents containing a least a technical description, instructions for use, and a means of contacting the manufacturer.

10.5.3.1.1 The documents specified in 10.5.3.1 shall include the following, where applicable:

1. Instructions that show the location of controls
2. Explanation of the function of each control
3. Instructions of proper connection to the patient or other equipment, or both
4. Step-by-step procedures for using and proper use of the appliance
5. Safety considerations in use and servicing of the appliance
6. Precautions to be taken if the appliance is used on a patient simultaneously with other electric appliances
7. Schematics, wiring diagrams, mechanical layouts, parts lists, and other pertinent data for the appliance
8. Instructions for cleaning, disinfection, or sterilization
9. Utility supply requirements (electrical, gas, ventilation, heating, cooling, and so forth)
10. Explanation of figures, symbols, and abbreviations on the appliance
11. Technical performance specifications
12. Instructions for unpacking, inspection, installation, adjustment, and alignment
13. Preventive and corrective maintenance and repair procedures

10.5.3.2 Service manuals, instructions, and procedures provided by the manufacturer shall be considered in the development of a program for maintenance of equipment.

10.5.4 Administration of Oxygen Therapy.

10.5.4.1 Electrical Equipment in Oxygen-Enriched Atmospheres. Appliances, or a part(s) of an appliance or a system (e.g., pillow speaker, remote control, pulse oximeter probe), to be used in the site of insensational explosion shall comply with one of the following:

1. They shall be listed for use in oxygen-enriched atmospheres.
2. They shall be sealed so as to prevent an oxygen-enriched atmosphere from reaching electrical component, with sealing material of the type that will seal even after repeated exposure to water, oxygen, mechanical vibration, and heating from the external circuitry.
3. They shall be ventilated so as to limit the oxygen concentration surrounding electrical components to below 25.5 percent by volume.
4. They shall have both of the following characteristics:
   a. No hot surfaces over 300°C (573°F), except for small (less than 2 W) hermetically sealed heating elements, such as light bulbs.
   b. No exposed switching or sparking points of electrical energy that fall to the right of the curve for the appropriate type of circuit illustrated in Figure 10.5.4.1(a) through Figure 10.5.4.1(d), with the dc (or peak ac) open-circuit voltage and short-circuit currents required to be used

10.5.4.2 When only the remote control or signal leads of a device are to be used in the size of insensational explosion, only the control or signal leads shall be required to comply with 10.5.4.1.
Response to June 28 Meeting

Exhibit L: BI&T Article, September/October 2008
Applying Risk Management Principles to Medical Devices Performance Assurance Program—Defining the Process

Tidimogo Gaamangwe, Agustina Krivoy, Petr Kresta

Over the years there has been increasing recognition that performance assurance (PA) program implementation is a risk management issue. To that end there has been concerted effort to identify the key risk categories and define the risk assessment technique, which deals with inclusion of medical equipment in the PA program. However, there is still no general consensus on the risk categories and the inclusion criteria.

Applying Risk Management Principles to Medical Devices Performance Assurance Program—Defining the Process

Program Implementation

Over the years there has been a tremendous shift in PA philosophy, from do it all to do as little as possible. As the pendulum swings to less PA and the concept gains acceptance, the question of how to select devices for inclusion in a PA program arises. Some are beginning to ask if the program is needed at all. These questions have highlighted the fact that PA is implemented for risk management. The risk management aspect is now recognized by most clinical/biomedical engineering departments and associations.

The understanding that a PA program is developed and implemented for risk management is fundamental for clinical engineering departments. It is a necessary and mandatory risk management service performed by clinical engineering for their enterprise. So whether a clinical engineering department does or does not have a PA program is not the real question. The real question is whether there is a methodology for the profession to determine how the program is implemented. This can be controlled by each clinical engineering department based on its own justification or on collective professional justification. But the basis of the program remains the same.

Program Basis

The basis of a PA program is risk management, which has two components: risk financing, which deals with insurance, and risk control, which deals with controlling losses. Risk control is defined as “any conscious action (or decision not to act) that reduces the frequency, severity,
or unpredictability of accidental loss.” Therefore, PA is implemented for risk control. This aspect is recognized by national accreditation/regulatory authorities who in turn have made PA a requirement for any healthcare organization that values accreditation. Specific enterprise policies are often based on these overarching requirements.

In Canada, the program is a requirement of Accreditation Canada (formerly the Canadian Council on Health Services Accreditation or CCHSA), Canadian Standards Association (CSA), and the Canadian Medical and Biological Engineering Society’s Clinical Engineering Standards of Practice for Canada. In the United States it is based on the requirements of the Joint Commission. Thus, the program is implemented as part of a clinical engineering department’s risk management services to meet accreditation/regulatory and legal requirements.

Since the basis of the program is risk management, the management and implementation of the program should follow risk management principles. General risk management principles are addressed in CSA and AAMI documents. A simplified model of a risk management decision-making process is presented in Figure 1.

It is important to understand that effective risk management requires a risk management team. This is because there is a lot of information to take into account: technical, regulatory, stake holder interest, etc., not only during the risk identification and assessment process, but throughout the whole process. For example, risk control measures may introduce unforeseen risks for some stakeholders, whether perceived or real. In addition, monitoring may uncover some issues that will require reassessment of risk, such as changes in technology or a change in the environment where the device is used. Therefore, in line with the risk management decision-making process, it is advisable for a clinical engineering department to consider forming a standing committee that takes responsibility for all PA issues and thus acts as a risk team in PA matters.

Risk Categories
By owning and using medical devices, the enterprise faces a number of risks. Previous authors have identified three categories—function risk, physical risk, and maintenance requirement—as the main risks. While these are valid risks and have been used by a number of clinical/biomedical engineering departments, there is still no general consensus that they are the right categories of risk. In addition, these risks are limited to devices and patient and user safety.

There has, however, been recognition that it is important to take enterprise-level risk into account by including mission criticality as one of the categories. Mission criticality was adopted by Brewin et al. in developing their system. We think this is a step in the right direction, but at this point the categories are not broad enough to address enterprise-level risks. Therefore, there is still a need to define appropriate enterprise-level risk categories.

In this paper we propose new enterprise-level risk categories that are linked to ownership and use of medical devices. The proposed risk categories are:
- financial risk
- legal liability
- patient and staff safety

The importance of these new risk categories is that they are broader than the previously used categories of function risk, physical risk, and maintenance requirement. Fennigkoh and Smith have defined function risk in terms of the main equipment function categories: therapeutic, diagnostic, analytic, and miscellaneous. The authors defined physical risk in terms of the risks emanating from the clinical application of the equipment: death, injury, inappropriate therapy, or misdiagnosis. Maintenance requirement has been defined in terms of the level of maintenance inspection required: extensive, average, and minimal. The definitions of these categories suggest that they fall within the new proposed risk categories.

The use of equipment in any of the function categories as defined above has safety, legal, and financial implications for the enterprise. In addition, the risks emanating from clinical application as defined above also have im-
applications on safety, legal liability, and financial risk. Also, maintenance requirement, as defined above, means that if inspections are not performed, the consequences for the enterprise could be one or all of the following: compromised patient and staff safety, increased legal liability, and financial risk. Therefore, the previously defined risk categories are covered within the new categories.

By addressing risks from the enterprise perspective it is easier to see how actual device risks link to the broader risk categories. The device risks are merely drivers or inputs to the broader risk categories. The newly identified risk categories emanate from a number of contributing factors, some of which are inherent in equipment design, some of which are related to the equipment use, and some of which are regulatory, as illustrated in Figure 2.

The risk contributing factors are elaborated below, under three broad factors:

Equipment design factors
i) Incorrect diagnostic information: Diagnostic equipment that may give the user wrong information without the user being aware. Wrong diagnosis, based on wrong information that the user cannot easily verify, e.g., a blood pressure measuring system giving inaccurate blood pressure measurement, would result in wrong treatment, which poses patient safety, legal liability, and financial risk for the enterprise.

ii) Inappropriate energy output
   a. Therapeutic equipment that has output to patient, which may cause injury to patient and/or staff. Equipment output to patient (thermal, electrical, gaseous, chemical, mechanical) may be dangerously high or low if equipment malfunctions, which may result in injury or endanger patient's life, e.g., hypo/hyperthermia units and defibrillators. This would pose patient safety, legal liability, and financial risk for the enterprise.
   b. Radiation equipment that may harm a patient with high energy output

iii) Maintenance requirement: Equipment that needs regular cleaning/lubricating or replacement of parts to perform without impairment. Some types of equipment have filters that need regular cleaning/replacement. Some have batteries that need replacement on a regular basis because they are used for transport. If the cleaning or replacement functions are not done, there is increased risk of equipment failure and life cycle cost.

iv) Function degradation: Device has a fan or filter and the failure of the device poses risk to patient.

Figure 2. Illustration of how risk categories emanate from risk contributing factors.
Equipment use factors

i) High usage: Equipment that experiences high usage and rough handling. Transport equipment such as infant incubators may experience rough handling and, as a result, there is likelihood of damage to the electrical cable, posing electrical safety risks to both the patient and the staff.

ii) Use area requirement: Equipment where the same models may be used in two areas that have different tolerance for error, e.g., patient scales—errors may be tolerated in the general area of the hospital but not in dialysis or renal program, where accurate patient weight information is used to make treatment decisions.

Regulatory factors

i) Compliance with codes: Devices that are required to be tested for accreditation purposes if used for direct or indirect patient diagnosis or treatment, e.g., biological, radiation, lab.

All the above factors have implications, to varying degrees, on patient safety, legal liability, and financial risk for the enterprise. Before any measures can be taken to mitigate these risk factors, it is important to assess the acceptability of the risk factors through risk assessment.

Risk Assessment

Risk assessment (risk analysis and risk evaluation) allows the organization to estimate the probability and severity of risk and to evaluate the acceptability of risk. There are various risk assessment techniques, but most statistical techniques, such as probability and regression analysis, require data to be able to make an objective decision. The question of which technique to use depends not only on the availability of data but also on the type of data.

Therefore, the risk assessment technique for PA implementation also depends on the availability and type of PA data. Risk assessment is done through inclusion criteria, which defines the delineation process for separating the inventory into two subsets—devices that need to be in the PA program (need regular inspection because they pose unacceptable risk to the organization) and devices that do not need to be inspected on regular basis (excluded from PA). The first task is to define appropriate and acceptable inclusion criteria, which determines the size of each subset.

While reliability engineering methods are used in some industries for identifying possible device failures, the type of analysis involved is normally quite complex and time consuming. These methods include life cycle cost, failure mode and effect analysis (FMEA), mean time before failure, and other analysis techniques. Not all these analysis techniques are appropriate for all the devices. Therefore, they are not generally used in PA programs. One may find some aspects of one or more of the techniques applied in some fashion. Due to the difficulty of applying these strategies to a large and complex inventory of medical devices, there has been concerted effort in clinical/biomedical engineering to develop alternate appropriate inclusion criteria.

Several authors have previously addressed issues of PA inclusion or exclusion criteria. Most of the criteria involve risk-level scoring, which has evolved from the Fennigkoh and Smith model. Their model assigned risk assessment scores to their identified risk categories: function risk, physical risk, and maintenance requirement. A number of shortfalls with this method have been identified and modified versions proposed. While some authors have modified the weighting values of the risk categories, some have also redefined the risk contributing factors and thus produced different inventory subsets. There has also been a proposal to use a decision-making tree algorithm.

The development of several assessment strategies indicates that there is no general consensus on the inclusion criteria because there is no consensus on risk categories, weighing each of the currently used risk categories on the total risk, defining the risk contributing factors, and scoring each risk-contributing factor.

This paper proposes enterprise-level risk categories that others can consider adopting. We propose that the risk categories be equally weighted unless there is direction from the enterprise, taking other information into account. The risk contributing factors to be used are those defined above. We propose criteria that would be based on the risk factors.

Since risk-contributing factors are the cause of risk categories, any changes in the risk-contributing factors or quantities derived from them would cause changes to the risk categories. Therefore, risk-contributing factors or quantities derived from them can be used as indicators for risk or inclusion criteria parameters. The inclusion criteria parameters provide the specification against which risk can be assessed. The specification will determine the types of data required for the risk assessment.

In this case, where the proposed inclusion criteria parameters are derived from risk-contributing factors,
the information required for risk assessment would be available in any healthcare enterprise, with or without historical data. This is important because there are no constraints placed on PA implementation by historical data. Retrospective data from monitoring the program is used for reassessing risk.

The detailed definition of the inclusion criteria and how they are applied is beyond the scope of this paper. What is important to understand about the proposed model at this point is that enterprise-level risk categories flow from the risk contributing factors, which in turn form the basis for the inclusion criteria.

Risk Control Measures
Risk control measures are specific actions or activities intended to reduce the frequency and/or severity of loss. In the risk management decision-making process, before any decision is made on a specific action to control any identified risk, a broad strategy question—whether the risk can be avoided, prevented, or reduced—is usually asked. This process is important because there may be no need for the enterprise to devise any elaborate specific activities, e.g., if the best strategy is to transfer the risk to another party.

There are six recognized broad risk control strategies:3 (a) exposure avoidance, e.g., not manufacturing a device, which reduces probability of loss to zero; (b) loss prevention, e.g., PM, which reduces frequency of loss but not necessarily severity; (c) loss reduction, e.g., rapid alarm activation, which reduces severity of loss; (d) separation of exposure, e.g., maintaining inventory at several warehouses, which reduces severity of individual loss; (e) duplication of exposure units, e.g., providing backup or spare parts reduces overall severity of loss; and (f) contractual transfer of risk control obligation to another party, e.g., service contract, which transfers responsibility to the vendor.

The question of which strategy to use depends on the problem at hand. Clearly, for PA the clinical engineering department is concerned mostly with loss prevention and loss reduction. This is important information because the knowledge of the appropriate control strategy narrows risk control options or measures to be considered.

From a risk control point of view, the subcomponents of PA, as defined under the definition of PA, are actually risk control measures. Depending on the device, these risk control measures (PV, PM, ST) can be applied individually or in combination. Once the risk control measures have been identified, it is important to decide on the appropriate activities to undertake for each measure to be effective.

Implementing the Measures
The activities or detail of inspection undertaken under any of the above risk control measures are sometimes based on manufacturer procedures/protocols or protocols developed in-house, depending on a number of factors, such as whether the devices are specialized, the number of devices in the inventory, etc.

Besides deciding on the activities, it is important to decide on the frequency of activities, i.e., inspection frequency. The inspection frequency is often based on information from a number of factors, such as manufacturer recommendation, facility experience, recalls/alerts, repair, and incidents.

Monitoring
Monitoring is an important part of risk control to ensure that the measures are effective in achieving the desired outcomes and to adapt the program whenever necessary. Monitoring in PA is done for three reasons:

- **Adaptation**: monitoring to ensure that the appropriate risk control measures are always identified to address the risk contributing factors that may arise due to changing circumstances, e.g., change in technology, change in the environment where the device is used, etc.
- **Effectiveness**: monitoring to ensure proper implementation of risk control measures and activities. Monitoring activities ensures that the right inspection procedures are done to address the identified risk contributing factor. Implementation of risk-control measures is monitored through performance indicators. The performance indicators can be established by industry, developed by consensus, or developed from in-house best practices. A number of repair and maintenance indicators have been previously discussed.17 There is still need to develop consensus on the key parameters and their definitions in order to facilitate benchmarking.
- **Communication**: monitoring to ensure that stakeholders understand and perceive the program to be effective. Stakeholders would generally be interested in broader issues such as patient and staff safety, compliance with codes, reduced risk of
failure, reduced life cycle cost, improved clinical outcomes, etc. This is addressed through effective communication with stakeholders. Some of the information communicated is gathered through periodic customer satisfaction surveys. It is important that communication addresses not only the PA relation to the risk categories but any other strategic issues that may arise from time to time. This usually gives them piece of mind.

Information from the monitoring process feeds back to the risk assessment process so that the PA program is continuously driven by current information.

Discussion

As the basis of PA is risk management, it is important for clinical engineering departments to understand that PA has merit on its own, regardless of accreditation requirements. It is clinical engineering risk management prudence to develop and implement PA programs.

While there has been increasing recognition that PA is implemented for risk management, there has been little effort to relate the PA processes to the overall risk management decision-making process—only some PA decisions, such as inclusion criteria, have followed the risk assessment process. In this paper we have defined how PA is linked to the overall risk management decision-making process. The risk management view assists in several ways: defining appropriate risk categories, defining appropriate risk contributing factors, applying appropriate risk assessment techniques, and defining appropriate risk control measures and appropriate monitoring processes. It is hoped that by viewing PA as an overall risk management decision process, clinical engineering departments will consciously relate all their PA decisions to risk management process.

Conclusion

This paper has presented a framework for linking PA to the overall risk management decision-making process. It is hoped that others will adopt this view and start applying risk management principles in PA decisions. It is hoped that with this view, there will be renewed interest to revisit some of the PA issues that have been debated over the years, such as inclusion criteria. The renewed interest should assist in an attempt to build consensus.

References


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Exhibit M: Medical Equipment Risk Assessment—
Community Health Network Indianapolis
TITLE: MEDICAL EQUIPMENT RISK CLASSIFICATION

Related Plans: Safety Management Plan and Medical Equipment Management Plan

Purpose: To establish a numerical scoring system by which the level of risk for medical equipment is determined.

Policy Statement:

It is the policy of Community Health Network, as part of our comprehensive Medical Equipment Management Program, to define and verify appropriate performance and maintenance of medical systems and equipment. All medical equipment is evaluated to determine the need for calibration, inspection, maintenance, testing, and management risks, including medical alarm risks. In addition, the evaluation will determine if equipment meets the definition of life support and if the utilization of such equipment (and any subsequent unplanned failure) requires emergency preparedness planning to mitigate, prepare for, and respond to equipment failures and disruptions.

The relative level of risk for each device is established through this Equipment Risk Assessment process.

Definitions

1. Medical equipment – Equipment used for the diagnosis, treatment, or monitoring of patients. The equipment may be powered or not powered by electricity, mechanical, or other means. The medical equipment is classified into one of the following risk classifications.

   a. Life Support equipment (LS) - intended to sustain life, where failure to perform its primary function is expected to result in imminent death.

   b. Non-life support – All other medical equipment that is not classified as life support will be ranked as High (H), Medium (M) or Low (L) risk based on the following assessment scoring process.

      i. The added classification of Critical (C) may be applied if necessary, for the purpose of clearly demonstrating compliance with CMS expectations per the December 2011 clarification of allowable variance from manufacturer recommendations for inspection intervals. Analysis will be applied to determine whether the failure or disruption of a device’s ability to perform its primary function, when used in accordance with manufacturer instructions and following appropriate clinical use...
guidelines, is likely to result in harm to the patient or staff unless there is a prompt intervention to restore the normal function of the equipment or to initiate an appropriate emergency clinical procedure to continue management of the physiological process.

Procedure:

1. The use of medical equipment for the diagnosis, treatment, and monitoring of patients poses a variety of risks to patients. The risks may be related to the design, use, or field performance of the equipment. The risks may be physical, related to performance of the operator, or related to the environment of use. An evaluation of the equipment and the environment in which it is used is an essential part of both the patient safety program and the medical equipment management program.

2. This procedure addresses the assessment of the risks of any type of medical equipment and is used to determine an appropriate classification of risk. The maintenance strategies are determined separately from the risk classification, and frequencies are based on the concept of whether a scheduled inspection can reduce the likelihood of failure or extend the useful life of the equipment. It also takes into account such factors as equipment reliability, manufacturer recommendations, reported and measured use related errors, incident history and other information from the service history as deemed appropriate. Refer to Policy ADM F 003A for more information regarding maintenance.

3. Each item in the inventory will be classified as indicated above (LS, C, H, M, L). All life support equipment will be considered high priority for completion of the required intervention, with descending priority for the other classifications. Any piece of medical equipment that is determined to require a regularly scheduled inspection or intervention will be assigned to an appropriate schedule.

4. The scheduled interventions may include performance assurance, proactive maintenance, calibration, replacement of wearing parts, or necessary mechanical adjustments. They may also include inspection and testing to assure electrical and general safety and performance of equipment that would not otherwise require maintenance. See Policy ADM F 003 for maintenance schedule details.

DEVICE RISK ASSESSMENT AND SCORING

Patient safety risk is determined by considering the function of the equipment relative to the environment in which it will typically be utilized, and the potential outcome of any adverse event during the normal and intended use of the equipment, such as equipment failure, partial disruption of function, potential error in setup or application of the equipment and other similar factors. The risk classification is determined by the combined evaluation scores, which are assigned according to the following tables.
a. Equipment Function

Equipment function is divided into ten categories. Each is assigned points as a relative measure of risk. Table 1 lists the categories and assigned points.

<table>
<thead>
<tr>
<th>Function</th>
<th>Risk Weight</th>
<th>Function</th>
<th>Risk Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physiological Process Support</td>
<td>10</td>
<td>Non-Invasive Diagnostic</td>
<td>5</td>
</tr>
<tr>
<td>Surgical Procedure / Intensive Treatment</td>
<td>9</td>
<td>General Care (including fluid delivery and most portable patient care items)</td>
<td>4</td>
</tr>
<tr>
<td>Physiological Monitoring</td>
<td>8</td>
<td>Module, not able to function outside of system</td>
<td>3</td>
</tr>
<tr>
<td>Interventional Diagnostic (IVUS, EP Stimulator, etc.)</td>
<td>7</td>
<td>Miscellaneous Direct Patient Care</td>
<td>2</td>
</tr>
<tr>
<td>Energy Delivery for Treatment or Therapy</td>
<td>6</td>
<td>Miscellaneous Indirect Patient Care or Care Related</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 1

b. Use Related Risk

Use related risk is a measure of the severity of the impact of adverse equipment related events relative to patient outcomes. In scoring, assume the worst-case scenario in the event of a single device failure when it is being used for the intended purpose, according to protocol (including the appropriate precautions) and for the intended purpose, while also considering the inherent safety features of the device or technology. This scoring should also take into consideration any known incident history for the type of device being evaluated. Table 2 lists the use associated risks and the assigned points value.
### Use Related Risks

<table>
<thead>
<tr>
<th>Adverse Outcome</th>
<th>Risk Weight</th>
<th>Adverse Outcome</th>
<th>Risk Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>10</td>
<td>Treatable Injury, No Lasting Impact</td>
<td>5</td>
</tr>
<tr>
<td>Permanent Long Term Disability</td>
<td>9</td>
<td>Inaccurate Function, Reading or Diagnosis with No Immediate Impact To Care</td>
<td>4</td>
</tr>
<tr>
<td>Temporary Long Term Disability</td>
<td>8</td>
<td>Possibly Higher Risks Minimized Due to Internal Diagnostics at Start Up and/or During Use</td>
<td>3</td>
</tr>
<tr>
<td>Short Term Disability</td>
<td>7</td>
<td>Delay in Treatment or Diagnosis</td>
<td>2</td>
</tr>
<tr>
<td>Inaccurate Function, Reading or Diagnosis with Immediate Impact to Care</td>
<td>6</td>
<td>Negligible Impact</td>
<td>1</td>
</tr>
</tbody>
</table>

**Table 2**

The overall Medical Equipment Risk Classification is determined by the total relative severity of the equipment function and use related risk. It is calculated by adding the total risk weights determined from Tables 1 and 2. Table 3 lists the classification based on the ranges of the summed weights. Note that a classification of Life Support or Critical is not determined using this scoring method, as explained in the above definitions.

<table>
<thead>
<tr>
<th>Medical Equipment Risk Classification</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Score</td>
<td>Risk</td>
</tr>
<tr>
<td>17-20</td>
<td>High (H)</td>
</tr>
<tr>
<td>10 – 16</td>
<td>Medium (M)</td>
</tr>
<tr>
<td>&lt; 10</td>
<td>Low (L)</td>
</tr>
</tbody>
</table>

**Table 3**
2. MEDICAL ALARM RISK

The Joint Commission has identified management of medical alarms as a critical patient safety issue. The strategy for management of medical alarm risk will be applied for all types of medical equipment that include an alarm function which is related to the utilization of the device for patient care. For each piece of equipment, a determination is made as to whether or not there is an alarm risk associated with the device, and that is indicated by checking a field in the equipment record within the equipment management database. Individual device alarms are evaluated in accordance with the maintenance procedures and intervals deemed appropriate for each device.

Formulated by: Karen Waninger, Director of Clinical Engineering

Reviewed by: Community Health Network EOC Committee 3/1/2012

(Signed copy on file)  
APPROVED BY: Tom Malasto  
President / CEO  
Community Hospitals of Indiana, Inc.
Exhibit N: Risk Assessment Model—Steve Grimes
PROCEDURE

Establishing Risk Scores for Medical Equipment Categories

PURPOSE

The purpose of this policy/procedure is to define a guideline by which this organization assesses relative risks associated with medical equipment failures and effectively mitigates risks that could otherwise compromise the safety of patients, staff or others or that could compromise patient care.

RESPONSIBILITY

Clinical engineering is responsible for the medical equipment risk assessment process and works with owner/operators, information technology and other knowledgeable stakeholders as appropriate to insure an effective risk assessment is conducted on each major medical equipment category.

PROCEDURE

Risk is a function of the severity of failure and probability of failure (i.e., risk = severity x probability).

Each major medical equipment category is given a risk score. The risk score is used to illustrate the relative risk (to patient/staff health, operations or finance) associated with a major failure of an item of medical equipment in that category.

A major failure is defined as any medical equipment failure where the equipment is not operational or has a safety issue that threatens the safety or well-being of patients or staff.

That risk score is the product of the severity score and the probability score. Severity and probability scores are first determined in order to calculate the risk score (risk = severity x probability).

The severity score is given to each major medical equipment category according to how the potential consequences of a major failure are classified. Those severity consequences are classified and scored in one of the following four categories.

<table>
<thead>
<tr>
<th>Classification of Severity</th>
<th>Definition of Severity</th>
<th>Severity Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negligible</td>
<td>no adverse effect on health, finances or operations</td>
<td>1</td>
</tr>
<tr>
<td>Marginal</td>
<td>reversible adverse effect on health, finances or operations</td>
<td>2</td>
</tr>
<tr>
<td>Critical</td>
<td>permanent adverse effect on health, finances or operations</td>
<td>3</td>
</tr>
<tr>
<td>Catastrophic</td>
<td>loss of life, total financial loss, cessation of all operations</td>
<td>4</td>
</tr>
</tbody>
</table>

Clinical engineering, working with the equipment operators and other stakeholders as appropriate, assign a severity score to each major medical equipment category based on the organization’s experience and/or the industry’s experience with that category.

The probability score is given to each major medical equipment category according to how probable a major failure is to occur in the equipment lifetime. The probability of a major failure is classified and scored in one of the following four categories.

<table>
<thead>
<tr>
<th>Classification of Probability</th>
<th>Definition of Probability</th>
<th>Probability Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improbable</td>
<td>extremely unlikely to occur in the equipment lifetime</td>
<td>1</td>
</tr>
<tr>
<td>Remote</td>
<td>unlikely, but possible, to occur in the equipment lifetime</td>
<td>2</td>
</tr>
<tr>
<td>Occasional</td>
<td>likely to occur sometimes in the equipment lifetime</td>
<td>3</td>
</tr>
<tr>
<td>Probable</td>
<td>very likely to occur several times in the equipment lifetime</td>
<td>4</td>
</tr>
</tbody>
</table>
**PROCEDURE**

*Establishing Risk Scores for Medical Equipment Categories*

Clinical engineering, working with the equipment operators and other stakeholders as appropriate, assign a *probability* score to each major medical equipment category based on the organization’s experience and/or the industry’s experience with that category.

The *risk score* for each major equipment category is calculated by multiplying its *severity* score by its *probability* score.

The table below illustrates *risk scores* generated as a product of *severity* and *probability*.

<table>
<thead>
<tr>
<th>Probability of Failure</th>
<th>Severity of Failure (Consequence)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 Negligible</td>
</tr>
<tr>
<td>4 Probable</td>
<td>4</td>
</tr>
<tr>
<td>3 Occasional</td>
<td>3</td>
</tr>
<tr>
<td>2 Remote</td>
<td>2</td>
</tr>
<tr>
<td>1 Improbable</td>
<td>1</td>
</tr>
</tbody>
</table>

The resultant *risk scores* for major medical equipment categories are classified as either *low, moderate, serious* or *high* and are subject to review at an appropriate organizational level according to the following:

<table>
<thead>
<tr>
<th>Risk Score Range</th>
<th>Review level required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Acceptable without review: risk &amp; any mitigation plan require no further review or acceptance</td>
</tr>
<tr>
<td><strong>Risk Score: 1-4</strong></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Acceptable risk with review: risk &amp; any risk mitigation plan must be reviewed/accepted by the committee</td>
</tr>
<tr>
<td><strong>Risk Score: 5-7</strong></td>
<td></td>
</tr>
<tr>
<td>Serious</td>
<td>Undesirable risk: risk &amp; any risk mitigation plan must be reviewed/accepted by the relevant medical director</td>
</tr>
<tr>
<td><strong>Risk Score: 8-11</strong></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Unacceptable risk: risk &amp; any risk mitigation plan must be review/accepted by the organization’s senior management</td>
</tr>
<tr>
<td><strong>Risk Score: 12-16</strong></td>
<td></td>
</tr>
</tbody>
</table>

All medical equipment categories with a *risk score* exceeding 5 are included in the organization’s Medical Equipment Management Plan (MEMP).
**PROCEDURE**

**Establishing Risk Scores for Medical Equipment Categories**

All medical equipment categories included in the organization’s MEMP (i.e., with risk scores exceeding 5) are further reviewed to determine what factors are most probable contributors to a major failure.

<table>
<thead>
<tr>
<th>Potential Factors Contributing to Medical Equipment Failure</th>
<th>Probability of Contributing to Major Failure</th>
<th>Examples of mitigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ hidden alarm failures (e.g., failures not detectable until alarm conditions)</td>
<td>Prevent use testing by operator, scheduled maintenance</td>
<td></td>
</tr>
<tr>
<td>□ wear &amp; tear</td>
<td>Scheduled maintenance (e.g., preventive maintenance, calibration)</td>
<td></td>
</tr>
<tr>
<td>□ spontaneous (unpredictable)</td>
<td>Replace with more reliable equipment and/or obtain backup</td>
<td></td>
</tr>
<tr>
<td>□ inappropriate/inadequate instructions/procedures/process</td>
<td>Re-engineer process, improve training</td>
<td></td>
</tr>
<tr>
<td>□ unqualified operator</td>
<td>Obtain qualified operators and/or educate to achieve necessary qualifications</td>
<td></td>
</tr>
<tr>
<td>□ mishandling / misuse</td>
<td>Establish guidelines, educate, &amp; monitor</td>
<td></td>
</tr>
<tr>
<td>□ damage (fire, smoke, flood, contamination, electrical accident, etc.)</td>
<td>Environmental precautions, training</td>
<td></td>
</tr>
<tr>
<td>□ sabotage / vandalism</td>
<td>Security</td>
<td></td>
</tr>
<tr>
<td>□ unavailability of required utility (e.g., water, electricity, gas/vacuum, network) or other necessary component or element</td>
<td>Establish redundant and backup capabilities, training</td>
<td></td>
</tr>
<tr>
<td>□ inappropriate/inadequate supplies/accessories</td>
<td>Resource management &amp; quality control, training</td>
<td></td>
</tr>
<tr>
<td>□ interference (e.g., EMI) or interaction</td>
<td>Precautions (e.g., distance, shielding and other hardening)</td>
<td></td>
</tr>
<tr>
<td>□ other?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A mitigation plan is developed for any medical equipment category with potential contributing factor(s) whose probability score combined with a medical device category severity score exceeds 5. This mitigation plan is to identify how those risks exceeding a score of 5 and their associated risk factors are mitigated (e.g., scheduled maintenance, training, backup systems), who is responsible (e.g., owner/operator, clinical engineering, clinical education), and a timeframe for mitigation.

The mitigation plan must be signed off at the appropriate level (i.e., the EoC committee may sign off on mitigation plans for medical device categories with risks scores between 5 and 7, the relevant medical director may sign off for risk scores between 8 and 11, and senior management may sign off for risk scores between 12 and 16).

**REVIEW**

Medical equipment category severity, probability and risk scores along with any mitigation plans are reviewed by Clinical Engineering at least annually to assure their relevance and effectiveness and a report of this review is made to the EoC committee.
Exhibit O: AAMI New Work Item Proposal and Outline
1. Project Title

Scheduled Maintenance and Performance Testing Procedures

2. Project Type (e.g., standard, recommended practice, technical information report, monograph, other [describe])

Recommended Practice

3. Scope of the Project

Please describe the technical subject of the standard, recommended practice, technical information report, or other project. For documents, provide a draft scope statement. (Attach an additional sheet, if necessary.)

To create a guidance for the creation of testing procedures of medical equipment (post manufacture) that are based on a consistent structure.

4. Need

Please describe in detail the clinical/healthcare needs to be addressed, providing, if applicable, copies of relevant literature. If the proposed project is the development of a medical device standard, identify the risks to patient health to be addressed and give the FDA classification of the device. (SEE ALSO part 4a).

Currently individual Healthcare Technology Management departments and companies are allowed to modify and create testing procedures for scheduled maintenance and performance testing. These procedures currently vary widely in their construction, and are not based on any outside evidence or collaboration. This has caused a wide variation about what is actually being done to verify these devices & systems are functioning properly and safely. This document would create guidance for the creation of consistent procedures while still allowing flexibility for the HTM organizations.

Also, the recent letter about routine maintenance from CMS brought up a lot of conversations about this issue. AAMI and TJC have told CMS that this work is being proposed as part of the negotiation process with CMS.

4a) International relevance

Please identify any international standards (in progress, or final) that relate to the proposed scope of the project. If any international standards exist or are under development, explain why a U.S. standard or recommended practice is needed, versus adopting the international standard as a U.S. standard or recommended practice. [NOTE: All AAMI technical committees undertaking new work should review any relevant international standards of the ISO or IEC when first beginning the project and throughout its development. The committee should discuss at the outset the possibility of: formally adopting the international standard as a U.S. standard; or deferring any work on a U.S. standard (that is, adopting the international standard as a "de facto" U.S. standard). If neither of these are acceptable to the committee, or there are no international standards (final or in progress), and work proceeds to develop a U.S. standard under AAMI auspices, the AAMI committee should remain current on relevant international standards developments (if any) and, to the extent possible, harmonize its document with any international standards. Committees that have completed U.S. standards or recommended practices for which there is a corresponding international standard (final or draft) will be asked to provide a report, updated as necessary, describing areas of harmonization, and areas of difference between the U.S. and international documents.]

None known

5. Vehicle

Please explain why the standard, recommended practice, technical information report, or other vehicle is the best approach to addressing the clinical/healthcare needs described in part 4. For example, why a standard rather than a recommended practice or technical information report?

A recommended practice seems to be the best choice for this topic because we are recommending how something is
6. **Why AAMI?**

Please explain why AAMI is the appropriate organization to undertake the project. Identify any other organizations that could reasonably be expected to have an interest in the proposed project and/or that already have relevant work in progress.

This proposed document is not aimed at the device manufacturers, but the maintainers of the equipment. This is primarily the hospital based HTM departments, and service providers. I could not imagine another more qualified organization for this than AAMI.

7. **Committee**

If the project is proposed to be undertaken by an existing AAMI committee, please identify the committee and indicate whether or not the existing membership has adequate relevant expertise; if not, identify those experts and/or organizations that should be invited to join the committee. If the proposed project does not fall within the scope of an existing committee, attach a list of potential members of the committee, consisting of roughly equal members of industry, user, and general-interest representatives, and a list of hospital, medical, or trade groups that support and would participate in the project.

The AAMI/EQ, Medical Equipment Management Committee would appear to be the best committee for this. This work would fit very nicely with their other standard, EQ56. Membership is adequate and has the relevant experience, although soliciting outside experts would be a good idea.

8. **Plan of Work**

In the case of a standard, recommended practice, or other technical publication, please describe the prospective readership and attach to this proposal a draft outline of the document. In the case of a proposal to undertake the sponsorship of an educational program, describe the recommended format and prospective audience and attach to this proposal a program outline identifying some or all of the prospective faculty.

Prospective readership should include HTM personnel in hospitals and service companies, regulatory bodies, and government entities.

9. **Schedule of Work**

AAMI policy on completion of new work is that all active projects must have on file a scheduled date of completion (month and year), which has been approved by the Standards Board. For consensus documents, the amount of time from approval of new work to scheduled date of completion shall not exceed five years for standards, four years for recommended practices, or eighteen months for technical information reports, unless authorized by the Standards Board at the proposal stage or shortly thereafter (see 7a below). Other projects are scheduled on a case-by-case basis. See 2.11 of the [AAMI Standards Program Policy and Procedures Manual](#) for additional information.

Please provide a work plan, based on three to six month intervals, that identifies interim steps of the project, then estimate the amount of time that it will take to achieve each interim stage (up to and including final completion of the work). For consensus documents, you **must** include the following four milestones in your work plan: (1) completion of preliminary draft; (2) initiation of committee ballot; (3) document placed on public review (standards and recommended practices only); and (4) document submitted for final approval.

<table>
<thead>
<tr>
<th>Stage of Development</th>
<th>Planned Schedule (number of months from approval of new work)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
9a) Request for extended schedule of completion (consensus documents only)

(Co)chairs, on behalf of a committee, may "negotiate" an extended schedule with the Standards Board by providing a written request c/o the AAMI Vice President of Standards Policy and Programs explaining why an exception is necessary, and how much additional time is needed. If the above schedule is not within the specified maximum period allowed for completion, please provide a detailed explanation of why additional time is needed.

10. Financial Resources

Please describe any extraordinary resources that will likely be needed for the proposed project and how these resources can be obtained; for example, if a user travel fund is planned, explain how it will be established and maintained. Also identify any potential sources of funding, such as government grants, corporate contributions, and the like.

11. Person(s) to Contact for Further Information

11a. Submitted by (Please provide your name, address, phone number and email address here)
Paul W. Kelley, 2000 Mowry Ave., Fremont, CA, 510-791-3493, paul_kelley@whhs.com

11b. On behalf of (Please indicate the company, committee, association, etc. that has officially asked you to submit this proposal on their behalf, if applicable. If not applicable, leave blank or indicate "self.")
AAMI

11c. Other persons to contact for further information. If applicable, please provide the names, addresses, phone numbers and email addresses of other individuals who can be contacted about the proposed project should AAMI staff or the Standards Board have questions or need additional data.

For Office Use Only
Date Received
Date to SB
Action Taken
If Approved, Scheduled Completion Date:
Scheduled Maintenance and Performance Testing Procedures

Introduction & Purpose
- Why and when to deviate from manufacturers recommendations
- Provide descriptions of methodologies used for changing procedures or frequencies away from those indicated in manufacturer recommendations
- Provide a description of the algorithms used to determine PM strategies/procedures, as well as commonalities/differences among the algorithms.
- Identify ‘fail-safes
- Provide examples of documentation of evidence-based maintenance, history, etc.

How to begin
- Manufacturers literature/manuals
- Experience
- Peers/vendors
- Literature review/References

Creating alternative procedures & Frequency of inspections
Considerations
- Potential Factors Contributing to Medical Equipment Failure
  - Risk, Severity, and Probability
  - Total vs. hidden (unnoticed) failure
- Environment of use
  - Life support (critical)
  - Non-life-support (non-critical)
- Environmental conditions
- Reliability
- Performance
- Built-in self testing
- Maintenance quality
- User training
- Management of rechargeable batteries & Accessories
- Examples of mitigation

Types of Maintenance Strategies
- Evidence-Based Maintenance
- Risk-based
- Reliability-centered Maintenance (RCM)
- Run-to-failure

Regular analysis of program
- Adjustments to program
- Adoption of new methodology

Documenting PM Findings

Equipment-related incidents

Critical Thinking Skills

Risk Analysis

Current/Best Practices

References