
PEER REVIEW PAPER

Quality Management for a Nationwide Fleet of Rental Biomedical Equipment

Binseng Wang, ScD, CCE*; Elliot B. Sloane, PhD**; Bhavesh Patel, MSEE***

*MEDIQ/PRN Life Support Services, Inc. One MEDIQ Plaza, Pennsauken, NJ 08110

**College of Commerce and Finance, Villanova University, Villanova, PA 19085

***Biomedical Engineering Department, Washington Hospital Center
110 Irving Street, NW, Washington, DC 20010

Abstract

A fleet of about 200,000 ventilators, IV pumps, monitors, and other moveable critical-care devices from various manufacturers is available for rent by American healthcare providers. This equipment is delivered around the clock by 106 branches covering all 50 states, usually within 2-4 hours of request. A PC in each branch and a central computer are used to track each device identified by a unique barcode tag. Simple repairs and PMs are performed in branches by qualified biomedical technicians; more extensive repairs are performed at three service centers strategically located. To ensure safety and performance, a comprehensive quality management program has evolved. Each unit is inspected before delivery, no matter how recently it was inspected for the previous rental. Recalls and patient incidents are centrally managed and documented, even if performed in the field. Equipment serviced at service centers and service reports filed by every biomedical technician are audited by an independent quality-assurance staff. In addition, service quality is also monitored when equipment is transferred between branches and rented to customers. A complaint system follows up on any reported problem. Some of the indicators used to identify opportunities for quality/reliability improvement are: a) number of problems found in audits, b) number of confirmed problems reported within 7 days of delivery, and c) number of confirmed problems per hundred units delivered. Branch compliance to the quality program is further reinforced by unannounced random on-site visits. This stringent quality program provides the users with confidence that the equipment is safe and can be used immediately on a patient.

1. INTRODUCTION

MEDIQ/PRN Life Support Services, Inc. is currently the largest biomedical equipment rental company in the United States. It has available for rent approximately 200,000 pieces of moveable equipment such as infusion pumps, ventilators, apnea and patient monitors, sequential compression devices, neonatal and pediatric equipment, and air therapy systems. The equipment is rented by hospitals and other healthcare providers whenever they have a shortage within their organizations or when they prefer not to bear the costs and risks of owning and operating technology.

This company was started about 25 years ago by an intensive-care physician who experienced occasional shortages of ventilators. The hospital where he worked could not afford to purchase enough life support equipment that was used only during peak periods and would sit idle for the rest of the year. He decided to purchase one ventilator and rent it to that hospital as well as to neighboring institutions. From this humble beginning, the business grew steadily

until it was acquired by MEDIQ Incorporated, a holding company that owned several other healthcare related businesses. MEDIQ called the rental division PRN, which are the initials of the Latin words *Pro Re Nata* (as needed).

The company grew rapidly in the early 1990s through acquisition of some of its national and regional competitors. In this manner, it was not only possible to amass the largest fleet of equipment, but also to congregate the best professionals in this field. Currently there are about 1,500 employees nationwide serving approximately 10,000 customers. The gross revenue of fiscal year 1999 was near 250 million dollars.

This article describes how this fleet of equipment is managed to assure safety and performance according to its original specifications and discusses the quality management program that evolved for almost a decade. Before delving into the quality management, a brief discussion of the benefits and disadvantages of rental as compared to ownership is probably useful for those who are not familiar with this form of technology incorporation.

2. THE RENTAL CONCEPT

It is difficult to predict the exact amount of equipment that any healthcare institution should acquire. The number of patients seeking care varies daily and may depend on weather and other unpredictable events. During winter months, for example, many elderly patients are affected by influenza and may require ventilatory assistance. Ice and snow often lead to increased automobile accidents, broken bones from falls, and heart attacks, all of which increase patient census and acuity. In addition, natural disasters, aviation accidents, industrial disasters, and even terrorist attacks may produce large numbers of unexpected trauma patients requiring multiple types of equipment. However, most organizations plan acquisitions based on their "everyday" census and epidemiological data but not for peak seasonal demands and unexpected disasters. This works well for most diagnostic technologies but is often inadequate for therapeutic and certain monitoring technologies, particularly in the critical care area. It is very difficult to estimate how many pieces of life-support equipment are needed. Also, critically ill patients cannot wait for treatment for an extended period of time without jeopardizing their health or life. Moving the patient to another facility is risky in many cases and can degrade the organization's reputation.

Many healthcare organizations have opted to acquire the optimum baseline amount of equipment required for daily use. Any additional needs are then filled by short-term rentals. Using this approach, organizations are able to save precious capital resources that otherwise would be used to purchase seldom-used sophisticated equipment. In addition to the acquisition costs, one has to consider the costs and risks of ownership. A periodic inspection and, often, preventive maintenance (PM) is required for each piece of purchased equipment. Special training, tools, spare parts, and/or service contracts are also required. Furthermore, there are "hidden" costs associated with product upgrades, recalls, and regulatory compliance tasks such as medical device tracking, as described later. The cost of malpractice insurance normally rises with the amount of equipment the organization owns and maintains, particularly for life-support equipment whose failure could result in large claims. By eliminating excess equipment inventory, organizations can reduce its total life-cycle costs and concerns when it is time to replace equipment. There will be less new equipment to buy and less old equipment to safely dispose of.

Some organizations have decided to totally renounce direct ownership of certain classes of portable technology. Instead, they have elected to use rentals as their primary means of access to this complex equipment. In this approach, the organization not only reduces its investments and maintenance costs, but is also able to move on to newer technologies with minimum penalty. This model is particularly interesting for new organizations that have limited capital resources or ones that are uncertain whether a new technology will be cost-effective. Recently, some subacute orga-

nizations have used this approach very successfully as it also allows balancing their equipment costs to the exact number and types of patients they are treating each day. Another segment of healthcare industry that has embraced this idea is home care. Individual physicians tend to prescribe specific brands and models of equipment for each patient, and it becomes very onerous for the home-care agencies to maintain a large inventory of expensive equipment that has unpredictable usage. Furthermore, the costs of labor, facilities, and specialized test equipment required for proper maintenance of a diverse mixture of equipment would make many small home-care agencies unprofitable, if not unsustainable.

On the other hand, if equipment usage is very high (e.g., above 70-80%), and the organization has the investment resources, it may be more advantageous for it to buy and maintain the technology. However, even this high-utilization scenario may have to be supplemented by rental support. This may be especially true if the patient requirements are seasonal or widely variable for other reasons. Also, technological changes may suggest that the equipment may need to be replaced well before lease payments or capital depreciation are complete which is often prohibitively expensive. Naturally, the rental model is only applicable for moveable equipment. Anything that requires installation and a special environment is only economically viable for long-term rental or lease.

3. RENTAL OPERATIONS

3.1 *Equipment Delivery and Pick-Up*

Equipment available for rent is stored in each of the approximately 100 branch offices around the country. Each unit has received a documented Safety and Performance Inspection (SPI) within the previous 3 months. The inspection is performed by one of the branch customer service representatives (CSRs) using a written SPI procedure specifically prepared for this purpose (described in more detail later). If it relies on rechargeable batteries, the equipment is plugged into an electrical outlet to ensure that it is fully charged and ready for customer use.

After receiving a customer's request through a telephone call placed to the central customer service department or directly to the branch office, a CSR loads the equipment into a vehicle and drives to the customer's site. Once there, the CSR takes the equipment to the department that had requested the equipment (or other location determined by the customer). The CSR obtains a receipt for the equipment and accessories delivered and provides a copy of the SPI document. In cases of emergency requests, the delivery is made within 2-4 hours of the call for customers located within 100 miles of the branch office. For non-emergency situations or distances further than 100 miles, the delivery is made within the prearranged period, usually within 24 hours. Orders and delivery services are provided 24 hours

per day, 365 days per year. In order to provide this service, our central customer service department is staffed around the clock. There are at least two persons on call during off-hours at each branch office.

While at the customer site, the CSR will pick up any rental equipment that is no longer needed, due for scheduled periodic inspection or PM, or in need of repair. Pick-ups and deliveries are arranged in such a way to optimize the route.

3.2 Equipment Tracking

Every piece of equipment is tagged with a metal barcode. The barcode is scanned every time a delivery or pick up is performed. Together with the equipment barcode, the customer's identification barcode is also scanned. The information acquired by a handheld barcode reader is uploaded into a PC when the CSR returns to the branch. The PC sends this and other pertinent information to a central computer located at the corporate office in which a sophisticated asset-management program (TelStar) is used to control the entire inventory.

Besides tracking the equipment delivered to, or picked up from, customers, each transfer of equipment from one branch to another is similarly tracked. In addition, a status is attributed to each piece of equipment. The main status codes are: A - available for rental; R - on rent; S - in service; and T - in transit. In other words, at any time it is possible to know the precise location and status of every unit within the vast inventory.

The accuracy of the tracking system is verified by an annual physical inventory. Verification of certain equipment types is performed every few weeks to ensure that no significant discrepancy is found at the annual inventory.

3.3 Equipment Cleaning & Decontamination

Customers expect rental companies to deliver properly decontaminated equipment to reduce the risk of cross-contamination to their patients and staff. In addition, the rental company is also required by Occupational Safety and Health Administration (OSHA) to protect its own employees against infections, especially bloodborne pathogens. A detailed description of the cleaning and decontamination process is described in section 7.1.

4. QUALITY MANAGEMENT

A formal Quality Assurance (QA) Program was started about 10 years ago when the inventory grew to the point it was no longer possible for a few technicians to know each piece intimately. The primary goal of the QA Program is to provide safe, effective medical equipment so the healthcare professionals can use the equipment without asking their own biomedical technicians to perform yet another incoming safety and performance inspection (Davis & Furst, 1988; Putnam, 1990).

Every piece of equipment is included in this rigorous and comprehensive program. The QA Program complies with, or exceeds, most of the requirements set forth by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO, 1999), regulations issued by the Food and Drug Administration (FDA) and OSHA, and recommendations made by the Centers for Disease Control (CDC) and equipment manufacturers.

The QA Program consists of six components: pre-acquisition equipment analysis, inspection and maintenance, infection control, regulatory compliance, staff development, and quality monitoring and improvement. Each of these components is described below.

5. PRE-ACQUISITION EQUIPMENT ANALYSIS

Only equipment that has been approved by the FDA for sale and clinical use in the United States is included in MEDIQ/PRN's rental fleet. FDA approval is granted after the respective manufacturer has provided enough evidence to prove a device's safety and efficacy following extensive experience and/or clinical studies (FDA, 1990). Furthermore, virtually all of this equipment has been tested and is listed by internationally recognized organizations such as the Underwriter Laboratories (UL), ECRI (formerly the Emergency Care Research Institute), and the Canadian Standards Association (CSA). Most of it has also been approved for sale in the European Community as documented by their CE marks.

Whenever possible, we perform a critical analysis of each medical device before purchase. This analysis allows an opportunity to consider any special testing, training, parts, or maintenance procedures that will be needed to support the equipment. However, unlike most healthcare organizations, we are rarely in a position to reject, outright, a piece of equipment because of complexity, design, or manufacturing issues. This is because we have to provide rental support for a device that our customer is already using.

6. INSPECTION AND MAINTENANCE

To ensure that all rental equipment continues to perform within the parameters specified by the respective manufacturer after acquisition, we perform the following four types of inspection and maintenance services on every piece of equipment:

6.1. Inspection and Maintenance Categories

6.1.1. Safety and Performance Inspection (SPI)

The SPI consists of a set of qualitative and quantitative tasks designed to verify the safety and performance of each piece of equipment prior to the incorporation of new equipment into the rental fleet (also known as *incoming inspection*), before each rental, and on a periodic basis (see section 6.3 for details on the development of the procedures). An electrical safety test (often known as *EST*) is performed as part of the SPI. The incoming SPI provides assurance that

the safety and performance of the equipment have not been adversely affected by prior storage, shipment, or handling, or other problems not detected by the manufacturer. If the newly acquired equipment passes the incoming inspection, a permanent barcode tag is affixed to the equipment, and its basic data, such as the model and serial number, are entered into the equipment inventory system. The barcode tag helps us to comply with the FDA's Device Tracking regulation, as discussed later.

An SPI is also performed after each repair, update, or upgrade to verify the unit's safety and performance, no matter who (MEDIQ/PRN, the OEM, or a third party) performed the service. An SPI must be performed following all transfers of equipment between branches to screen against potential damage due to shipment or improper handling. Each SPI is valid for 6 months if the equipment has not been actively rented; otherwise, it must be repeated at specified intervals (see section 6.2). A signed copy (green) of the completed SPI report (also known as the pre-delivery inspection document) is delivered with each piece of rental equipment.

6.1.2. Preventive Maintenance (PM)

A PM is performed only when calibrations, internal measurements, and/or periodic replacement of internal parts are needed. After the required service is completed, an SPI is performed.

6.1.3. Reconditioning

Reconditioning is recommended by some manufacturers for specific pieces of equipment — typically mechanical/pneumatic devices such as ventilators — that need more extensive replacement of critical parts following several years (or tens of thousands of hours) of use.

6.1.4. Repairs

Repairs are performed on an as-needed basis using manufacturer-recommended techniques. After every repair the technician performs a full, documented SPI procedure to ensure proper safety and performance of the equipment before returning it to patient use.

6.2. Inspection and Maintenance Schedule

A detailed analysis of all equipment is performed to determine the proper inspection and maintenance interval as recommended by JCAHO (JCAHO, 1999) based on the experience of numerous healthcare organizations (see, e.g., Fennigkoh & Smith, 1989; Hertz, 1990; ECRI, 1995; Gordon, 1995; ASHE, 1996; Gullikson et al., 1996; Furst, 1997; and Wang & Levenson, 2000). The following factors are used in this analysis: risk of injury to patients, previous service experience with each brand/model of equipment, and frequency of problems found in previous inspections. Based on this analysis, certain equipment types are excluded from the inspection program (but not from the asset tracking program). These would include items such as IV poles, ventilator stands, and equipment carrying bags. These products are only visually inspected for obvious problems. All other equipment is included in the maintenance program.

Low-risk devices such as wall suction units and air-therapy mattresses are scheduled for SPIs every 36 months. Medium-risk devices such as non-powered cribs are required to be inspected every 24 months. All other equipment is scheduled for an SPI at least every 12 months. More stringent requirements (3 and 6 month intervals) apply to specific brands and models.

The four types of services described in section 6.1 are presented in ascending order of significance with the exception of repairs. Whenever a higher order of service is performed, the periodicity clock is reset for all lower level works. In other words, whenever a PM is carried out, all SPI tasks are also performed, so there is no need to carry out another SPI in the next 6, 12, 24, or 36 months (depending on the SPI frequency).

6.3. Inspection, Maintenance and Repair Procedures

All of the SPI and PM procedures we use are derived from written recommendations provided by equipment manufacturers. In some cases, we have included additional safety and functional checks based on recommendations of independent organizations such as ECRI, UL, NFPA, and AAMI. In fact, our SPI and PM programs dovetail with the *Inspection and Preventive Maintenance System* produced by ECRI (ECRI, 1995) and adopted by the majority of hospitals in North America. Presently, we have procedures for about 250 different brands and models, covering about 90% of all rental equipment. The remaining 10% are composed of various lower risk equipment types, or equipment that we only have in very small quantity. In these cases, we use the documentation provided by the manufacturer (operating and/or service manual) to perform inspections, tests, and repairs. New procedures are continuously added to cover newly acquired equipment, and revisions of the existing procedures are made whenever needed.

In addition to the QA manuals, our technical staff has access to libraries of operating and service manuals published by the manufacturers. These manuals are used for repairs and as reference material for inspections. Updates received from manufacturers and additional technical information are provided to our staff through technical bulletins. All this information is available at our Intranet web site so it may be accessed by our staff at any time from any location.

6.4. SPI, PM and Repair Records

There is a unique service form for each broad class of equipment (e.g., infusion pumps, ventilators, etc.) with common qualitative and quantitative task features arranged for easy notation. For the remaining classes of equipment that do not have enough volume to justify a unique form, a "universal form" is used. On this "universal form" only the basic qualitative and quantitative tasks are printed, while providing blank spaces for the employee to record specific tasks

as required by the SPI procedure for that particular piece of equipment.

All completed service forms are scanned and archived in a digital document imaging system. The entire form, including the signature of the person who performed the service, is scanned and saved as a digital image. These images are stored on large capacity write-once-read-many (WORM) optical disks to ensure that the images cannot be altered. After a WORM disk is filled, a back-up disk is made for routine use, while the original is stored elsewhere for security reasons. From each service document, certain essential data are extracted and used to index the scanned image so the service document can be retrieved whenever needed. A rigorous process of computerized and clerical crosschecks is used to ensure the accuracy of the indices. Without this process, the error rate of automated scanning and optical character recognition of handwritten alphanumeric characters can exceed 5% thereby resulting in misfiled documents.

The optical archiving system has also greatly reduced the labor of sorting and filing the forms received daily. Due to the large amount of rental equipment inspected and delivered daily, there are typically 800-1600 service reports that need to be archived every working day. Without an automated system, a much larger staff would be required to manually file these reports and possibly higher rate of misfilings would occur.

These records are available to our customers, JCAHO, and government agencies for a period of up to 7 years after which the images are deleted in accordance with our corporate document retention policy. The SPIs and PMs are also recorded in our computerized asset management system (TelStar) to allow for prompt verification of the last service date and scheduling of future inspections.

6.5. Test Equipment Calibration

Each piece of test and measurement equipment used by our staff for inspections and service is tested and recalibrated every year. The calibration is performed by a contractor who uses calibration standards traced to the National Institute of Standards and Technology (NIST). Calibration of test equipment is also performed after it is repaired.

7. INFECTION CONTROL

As mentioned above, rental equipment must be properly decontaminated to minimize the risk of cross-contamination to patients and users. In addition, incoming cleaning and decontamination is essential to protect our own employees against infections, especially bloodborne pathogens. The actions we take to achieve both objectives are described below.

7.1 Incoming Cleaning and Decontamination

According to OSHA guidelines for bloodborne pathogens and general infection control practices, each piece of

equipment must be cleaned and disinfected by the user before returning to the rental company. To provide further protection for our employees, we have decided to perform an incoming decontamination on all equipment. Every returned device is cleaned and decontaminated upon arrival at our branch office — even if the equipment was never used — before any employee is allowed to inspect or service it.

A detailed procedure has been developed so that our CSRs can perform the cleaning and decontamination in the proper manner. This procedure is actually in the introductory part of an extensive employee orientation program developed by MEDIQ/PRN to train its staff on equipment handling and inspections nationwide.

7.2. Outgoing Cleaning and Decontamination

After the equipment is inspected or serviced, it is again cleaned and decontaminated by the CSR or biomedical technician to ensure that no infectious agent is left on the unit. The unit is then placed inside a plastic bag or, when it is too big or equipped with casters, covered by a plastic bag to keep it clean and protected against dust and other pollutants during storage and shipment.

7.3. Support Surface Products

Support surface products (e.g., air-therapy mattress systems and specialty beds) are also required to be cleaned and decontaminated between rentals. As with other rental equipment, this is performed upon arrival at our branch office. All soft goods that can be laundered are processed in a washer with appropriate disinfectant solution and dried in a dryer. Items that cannot be laundered, including the bed frames and the control units (also known as pumps), are thoroughly sprayed with disinfectant solution and wiped down after specified exposure time. Sometimes the laundry operation is repeated with a detergent or bleach to further remove odor or stains.

7.4. Disinfectants Used

Only hospital-grade chemical disinfectants that are registered with the Environment Protection Agency (EPA) are used. Due to the large number of respiratory products within our inventory, we use products that are effective against both HIV-1 and mycobacterium tuberculosis (TB). Currently, we use two phenol-based products that have these properties. One is a concentrate that is diluted with water, while the other is a foaming spray aerosol. The first is used to soak and wash parts and accessories that are immersible, while the latter is for cleaning and decontaminating surfaces that are not waterproof. For customers who have concerns about the use of phenol-based products on infant care products, we can use bleach to process equipment delivered to them.

When the equipment manufacturer recommends against using phenol-based products, we use disinfectants based on quaternary ammonium compounds that are effective.

tive against HIV-1 and numerous other pathogens. These disinfectants are used to wash and disinfect non-respiratory products such as the support surface products that must not be cleaned with phenol-based chemicals.

No matter which disinfectant is used, MEDIQ/PRN employees are trained to make sure that all parts and surfaces to be decontaminated are wet with the disinfectant for at least 10 minutes before they are washed and rinsed. Without the proper exposure, one cannot be assured of the disinfection effectiveness.

8. REGULATORY COMPLIANCE

An aggressive regulatory compliance program complements our multi-component inspection program. A detailed standard operating procedure (SOP) has been prepared and implemented for each of the regulations issued by the FDA following the **Safe Medical Device Act of 1990** (SMDA'90). Furthermore, all our facilities are compliant with OSHA standards on bloodborne pathogens and chemical safety. A brief summary of the main features of our compliance SOPs is provided below.

8.1. Medical Device Recall

MEDIQ/PRN subscribes to numerous medical technology and clinical care newsletters, magazines, and publications including the *Health Devices* system published by ECRI. Our corporate senior clinical engineering and quality staff screens these publications to keep abreast of potential hazards related to medical devices. Whenever a recall is found or a communication is received from the manufacturer, the information is reviewed to determine the appropriate remedial actions. A technical bulletin (TB) is then distributed to the branch offices (and posted on the Intranet) with clear and specific instructions for action. If the recall only involves revised training or usage instructions, the information is forwarded with each rental device to help ensure effective communication to the customer.

Each recall action is also recorded in the TelStar system which provides a way to manage the progress of remediation. This is a very important process because of the logistical complexity of ensuring the completion of recall actions on a huge fleet of medical equipment that is dispersed throughout 100 cities and thousands of customers. Every piece of affected equipment, by individual serial number, is flagged in the TelStar system. Depending on the severity of risk, the equipment is immediately retrieved from customers or an alternate scheduling mechanism will be elected. The progress of recalls is monitored until 100% completion is documented for each one.

8.2. Medical Device Tracking

As mentioned above, we use a computer program (TelStar) to control our ever growing inventory. This system

enables us to determine the exact location and status of each unit at all times. This information is provided to the manufacturers and FDA, whenever requested, to comply with the medical device-tracking requirement established by SMDA'90. Furthermore, we routinely report to the respective manufacturers the acquisition of all tracked devices.

8.3. Incident Reporting

Per company policy, all our personnel are required to immediately notify the Quality Assurance Department whenever they receive any report of equipment problems involving patient death, serious injury, or when clinical intervention was needed to prevent death or injury. The Quality Assurance Department initiates and coordinates an investigation to confirm the reported problem and its cause. Qualified branch personnel are selected to assist in the investigation by gathering information and documents, testing the device, and contacting the customer for follow-up. If no qualified personnel are available locally, we dispatch an appropriate person from a nearby city or from one of the corporate service centers. Following the investigation, a report is generated and filed in the corporate office.

8.4. Infection Control and Bloodborne Pathogens

In addition to the decision to perform an incoming decontamination on all equipment (see section 7.1), we have a detailed exposure control plan to protect our employees. This plan includes free hepatitis B vaccinations for potentially exposed employees and required training before performing any task that involves potentially contaminated equipment. During the training program, employees learn the concepts and methods of universal precautions, engineering and safe work practices, and personal protective equipment usage. Post-exposure evaluation and follow-up procedures are also included in the control plan.

8.5. Material Safety and Hazard Communication

A detailed and comprehensive policy on material safety has been developed to protect our employees against hazardous chemicals used within our facilities and branches. This policy complies with OSHA regulation on hazard communication and with the Employee Right-to-Know regulation enacted in many states. Each branch must have an MSDS binder in which are kept the material safety data sheets (MSDS) on all chemicals used in that facility. Branch personnel are required to be trained before performing any task that involves hazardous chemicals. Whenever a new chemical is introduced, each employee must be trained on its potential hazards and proper precautions. The chemical control plan also includes inventory of chemicals, replacement or elimination of hazardous chemicals, information collection and dissemination, and communication through labels and postings.

9. STAFF DEVELOPMENT

We are fortunate to have a very dedicated and competent staff, with over 250 biomedical technicians and 500 CSRs throughout the country. Because we firmly believe that our employees are our most valuable asset, we make every effort to recruit and retain the best professionals in the industry. Many of our employees have more than 10 years of experience. Some started with the company many years ago, while others joined when their former employer was acquired or merged with MEDIQ/PRN. All CSRs must maintain pristine driving records. Regardless of their experience and background, all employees are required to observe the company's policies and procedures to ensure the standards of excellence that our customers have come to expect.

A team of trainers from our Human Resources Department is specially selected and trained to provide orientation and training to our employees. A modern self-study program complemented by supervised training has been created to teach our field operations personnel (including the branch managers (BMs), CSRs, and biomedical technicians) how to perform SPIs on the most commonly rented equipment. Customer service operators and other administrative staff at the corporate office are regularly offered seminars to learn the terminology and purpose of each type of medical technology. Biomedical technicians receive further training in-house with more experienced colleagues and at manufacturers' schools. They are also encouraged to achieve certification by the International Certification Commission (ICC). In addition to a bonus, all the expenses associated with ICC certification are reimbursed. Our systematic service-center and branch-office inspection program, described in the next section, helps to identify when and where additional training may be necessary.

10. QUALITY MONITORING AND IMPROVEMENT

We have developed the following nine complementary programs to assure a continuous process of quality assurance and improvement:

10.1. Service Center Inspections

We have two service centers, one on each coast (Pennsauken, NJ, and Santa Fe Springs, CA). In addition to the highly qualified biomedical service technicians, each center has a separate Quality Assurance staff dedicated to inspecting the equipment serviced there. Every piece of reconditioned equipment is inspected prior to releasing it for clinical use. All other serviced equipment is randomly reinspected to provide a basis for ongoing quality improvement activities.

10.2. Branch Inspections

A corporate manager inspects every branch at least once a year. These unannounced inspections check both the con-

dition and quality of the equipment available for rent and the actual operations of the branch. Particular emphasis is given to such items as layout and maintenance of the cleaning area, documentation filing, CSR and biomedical technician training and competence, and compliance with OSHA and other safety regulations. The results of each visit are provided to the respective region Business Unit Director and Area Vice President, the Human Resources Department, and the Quality Assurance Department. This allows appropriate training programs to be implemented when needed.

10.3. Service Report Audits

Every month the service reports received from several branch and service center biomedical technicians are sampled for detailed analysis by the QA Department. These audits are designed to detect oversights and signs of insufficient training. After completing the audit, the QA auditor calls the biomedical technician to discuss any deficiencies that were found and to create a remedial plan. A summary report is provided to the management on a regular basis unless immediate action is needed.

10.4. Service Data Entry Audits

Every month 10% of the service reports received from each branch and service center are sampled at random. They are compared with the data entered into the TelStar system. The purpose of this audit is to verify that the data within the computer have been promptly and properly entered. The accuracy and currency of data entry are vital for our TelStar computerized equipment management and tracking system. Reports of the audit are sent to branches and corporate management.

10.5. Overdue Inspections

Each branch is required to monitor the inspection due dates of all equipment on rent or available for rent. When a piece of equipment is due for inspection, the branch will notify the customer to arrange replacement with another unit so we can perform the necessary inspections. Occasionally, the inspections will be performed at the customer's site, if this is the best alternative for both the customer and our service staff. The Quality Assurance Department also monitors overdue inspections and alerts the branch if an excessive number becomes overdue.

10.6. Unsatisfactory Transfer Among Branches

We frequently move equipment from one location to another to satisfy the demand of our customers. Our policy is to only ship equipment that has been inspected for safety and performance and is complete with all basic accessories. We monitor the quality of the equipment transferred as a complement to our customer complaint program. If the received equipment is defective, missing accessories, improperly packaged, or in an otherwise unacceptable condi-

tion, the receiving branch issues an "unsatisfactory transfer" report naming the sending branch or service center, and sends a copy to the Quality Assurance Department. A copy of the response of the sending branch is also provided to the Quality Assurance Department, which compiles statistics of these unsatisfactory transfers and alerts senior management if retraining or disciplinary actions are needed.

10.7. Customer Complaints and Surveys

Customer satisfaction and the quality of delivered products are closely monitored. Each and every customer report of a problem encountered with a piece of equipment is registered as a "Product Performance Complaint" (PPC). After the QA Department logs the PPCs, a copy is faxed to the respective branches for follow-up. Each branch that receives a PPC is required to test the equipment and then report the findings back to the QA Department using the PPC follow-up form. Cases that involve patient death or serious injury and those that required clinical intervention to prevent death or injury are treated as described earlier (section 8.3 above).

A QA Program would be incomplete without continuous quality improvements based on accumulated experience and feedback from customers. In addition to the PPC program described above, our marketing and sales staff continuously monitors customer satisfaction. Any problem detected in the field is referred to the corporate office for analysis and follow-up, and corrective actions are promptly taken. Every piece of rental equipment is delivered with a customer satisfaction survey postcard. Each card returned is read and acted upon by senior management to ensure that all possible steps are taken to meet our customers' needs. Similarly, a customer satisfaction survey is mailed to every ventilator-reconditioning customer to allow us to benefit from his/her suggestions. Randomized telephone polls are conducted to monitor customer satisfaction and acquire feedback.

10.8. Employee Feedback

The QA Department actively seeks feedback from the employees who use the QA policies and procedures. A specific QA Feedback Form has been developed for this purpose. Comments, criticisms, and suggestions received from field personnel (CSRs, biomedical technicians, and branch managers) regarding equipment management methods and tools are used to improve our policies and procedures. Most changes and additions are introduced through technical bulletins, while others are communicated through revisions of SOPs and other relevant documents. All are available through our Intranet.

10.9. QA Program Revision and Improvement

The QA Program is managed by the National Quality Director who is assisted by a highly qualified team of clinical engineers, biomedical technicians, and administrative

assistants. The National Quality Director also participates in the formulation of company-wide operational policies and procedures. Reviews of the various elements of the QA Program are carried out on an ongoing basis, but not less than annually. Revisions are published whenever necessary.

11. JCAHO COMPLIANCE

Our QA Program complies with, or exceeds, the current JCAHO standards and manufacturers' recommendations. MEDIQ/PRN is not accredited by JCAHO only because the Joint Commission has not developed standards for equipment rental companies to date; thus we cannot apply for, nor receive, accreditation. In fact, JCAHO accreditation is only available to institutions such as our customers who provide services directly to patients.

To assist our customers in their task of qualifying their rental providers, we provide a detailed comparison of our QA Program with JCAHO's 2000 Environment of Care standards for hospitals (JCAHO, 2000) on table 1. In this table, the JCAHO standards are listed in the left column together with the clarifications provided by JCAHO. In the right column, next to each standard or clarification, the relevant section(s) of our QA Program or an explanation is provided. Our customers know that this unusually stringent QA Program not only assists them in obtaining and maintaining their JCAHO accreditation, but also contributes to the reduction of their liability exposure.

12. DISCUSSION

Biomedical equipment rental business fills an important niche within the American health system. Unlike many other developed and developing countries, the US does not have a central coordination of health care delivery. Most American hospitals are autonomous, non-profit organizations chartered to act independently of each other. Competition is often fierce among institutions located in the same geographical area. Within this unique environment, equipment rental is one of the few possible ways healthcare organizations can share resources without a central logistical coordination or political imposition.

The rapid evolution of equipment rental in the last two decades is a consequence of the profound changes that have occurred within health care. The drastic reductions in reimbursement and rapid escalation of costs made most institutions keenly aware of the need to be judicious in their expenditures. Purchasing enough equipment to cover all foreseeable patient demand is simply impossible. In addition, the burden of maintaining seldom-used equipment is prohibitive. More and more organizations prefer to outsource non-core services and lease or rent capital equipment. In fact, a careful financial analysis will show that rental can be a very advantageous alternative to acquisition for most organizations because of the accounting rules and reimbursement models (Wang, Patel & Sloane, 1999).

Establishing a quality assurance program for such a widespread enterprise turned out to be a very expensive and challenging endeavor. As explained before, JCAHO does not have any standards that are directly applicable to rental companies. Even among the clinical engineering departments of organizations accredited by JCAHO, there has been little consensus in adopting a universal standard (Keil, 1989) and a "recommended practice" document was only published recently (AAMI, 1999). The FDA also has very few regulations applicable to rental companies. The ISO-9000 quality standards became widely accepted only in the last few years in the service industry and are only now beginning to be applied to healthcare organizations in the US (Simmons, 1998). The ISO-9000 originally focused on manufacturing-related processes and lack of specific performance requirements makes its application to a rental or repair operation very complex. However, as the standard evolves, it may eventually become more widely adopted.

Very few industries face similar challenges in their quality programs. Commercial nuclear power plants, for example, do not have equipment that leaves their facilities, and at each plant the operators and the maintenance staff work together under a single command. Furthermore, they all follow a single set of rules established by the Nuclear Regulatory Commission (NRC). The passenger airline industry also follows a single set of rules and regulations established by the Federal Aviation Administration (FAA) and has the advantage of dealing with a more limited number of brands and models of equipment than medical devices. Even so, the National Transportation Safety Board has begun to consider requiring the FAA to monitor aircraft maintenance activities due to the increasing use of third-party maintenance companies (McKenna, 1997). Car rental companies are probably the most similar to medical-equipment rental companies. However, automobiles offer the advantage of differing much less from each other than medical equipment. Other rental businesses with similar challenges are those that rent farming and construction equipment. Yet, few have such a large inventory scattered around the country and are required to work around the clock; furthermore, a malfunction of their equipment is much less likely to immediately cause serious injury or death.

In the absence of any immediately applicable standards, we started with those traditionally adopted within healthcare organizations, in particular the hospital accreditation standards created by JCAHO and the widely-accepted policies and procedures recommended by ECRI. Several important discrepancies became immediately apparent while attempting to apply these standards and recommendations and are worth discussing. Some of the discrepancies worked against us, while others worked in our favor. For example, it is not possible to set up an equipment acquisition committee composed of users, technical staff, and management representatives. Besides the impracticality of bringing together representatives of the thousands of users

at far-flung facilities, most institutions have already standardized on certain brands and models. Therefore, it would be unlikely, if not impossible, to reach a consensus. As a consequence rental companies are simply required to buy the devices the customers demand, although sometimes our staff or other users may believe there are better alternatives. On the other hand, this plurality of equipment allows our customers to standardize on few brands and models to reduce their acquisition and maintenance costs, while still being able to bring in other brands and models whenever a special need arises.

Another aspect unique to the rental business is the need to reinspect every piece of equipment that is returned. One cannot assume that the user will always notify the rental company that something is wrong with a piece of equipment. Sometimes the user is no longer on the premises when the equipment is picked up. Sometimes the user may be uncertain about the failure. In any case, the only prudent measure is to reinspect all equipment between rentals. This is rarely done when the equipment is moved from one department or floor to another within an institution. Although rental equipment could be damaged by shipping and handling it from one facility to another, similar risks also exist for equipment moved from one location to another within the same organization. Obviously, this approach results in more frequent inspections for rental equipment than equipment owned by institutions. This is true even when taking into consideration that we have adopted a "sliding" inspection schedule instead of the traditional "fixed" schedule. In the latter case, a piece of equipment is always inspected in the same calendar week or month of the year; whereas in the "sliding" scheme, a newly inspected unit only needs to be inspected again after the entire inspection interval is lapsed. The "sliding" scheme is more difficult to implement than the fixed schedule, but the widespread availability of computers makes this task manageable with suitable software.

To balance the increased inspection frequency and distribute the workload, we limit the SPIs to external inspections and tests (sometimes known as "black-box tests") that can be mostly performed by trained CSRs. Only qualified biomedical technicians are allowed to open the equipment for PMs and repairs, and perform SPIs on certain critical equipment. This is because tasks that involve intrusion into the equipment are potentially risky. For example, according to a study on fossil power plants, 56% of the forced outages occurred within one week after an intrusive type of maintenance task had been performed (Corio and Costantini, 1989). While we are not aware of similar statistics for medical equipment, we prefer to be conservative on this issue.

Unlike hospitals, rental companies have the opportunity to put aside equipment that is not needed and only perform an inspection just before releasing it into the active pool. This is particularly useful for seasonal-demand units like adult ventilators, which are typically in high demand

during the winter months and not usually needed in the summer. As there is no risk of a clinician taking any uninspected equipment and using it on a patient, the rental company can afford to keep it in a warehouse until demand justifies bringing it out again.

The adoption of certain ECRI recommendations is sometimes challenging. For example, ECRI has suggested eliminating the due dates on inspection labels, not performing hi-pot testing of devices, adopting 5% accuracy range for most infusion devices, and reducing the inspecting frequency of low-risk devices (ECRI, 1995). Some healthcare organizations, however, have opted not to accept these recommendations. Therefore, we are occasionally obliged to perform special tasks above and beyond our own QA policies and procedures for certain customers who demand that we conform to their policies and procedures.

Instead of adopting the inspection procedures published by ECRI for generic groups of products, we have decided to develop brand and model specific inspection procedures because of the large number of units we own. With a uniform procedure, it is easier to train our staff and ensure that all inspections are performed in the same manner, regardless of the person or location where it was performed. Furthermore, this approach reduces the number of manufacturer manuals that need to be available at each location. Only biomedical technicians require access to the service manuals to allow them repair a piece of equipment. On the other hand, a tremendous amount of field experience and editorial work is required to create and maintain our customized procedure library. The sheer complexity of some manufacturers' procedures also makes it difficult to adapt them to the intentional rigidity of ECRI's IPM system (ECRI, 1995). Clearly, this approach is only feasible because the variety of equipment that is owned by a rental company is typically quite limited as compared to what is found in a hospital. Although a few rental companies do provide large or heavy equipment that requires installation, most rental equipment is small or, at least, transportable. In addition, as explained above, most rental equipment is in the therapeutic category. Consequently, we manage a large number of units of the same brand and model. For example, we have nearly 3,000 Puritan Bennett 7200 series ventilators and several thousand Baxter Flo-gard® infusion pumps.

Another aspect that is unique to the rental business is the opportunity to decontaminate every piece of equipment upon return and after each SPI, no matter whether used or not. This helps to reduce the spread of infection within and among hospitals. In spite of OSHA regulations, some healthcare organizations are not able to routinely decontaminate the equipment before returning them to a rental company. Furthermore, patient confidentiality requirements prevent us from asking whether the equipment may have been exposed to bloodborne pathogens or other types of infectious material.

In general, our investment in developing a QA program consistent with JCAHO standards and ECRI guidelines has had tremendous benefits. For the customers, this approach provides the benefit of eliminating the need for performing incoming inspections on our rental equipment. As described by Davis & Furst (1988) and Putnam (1990), healthcare organizations can prequalify their rental providers by reviewing their QA programs to verify that they are comparable to their own QA policies and procedures, or to well-known, proven standards. This practice of accepting rental equipment from a properly qualified supplier has proven to be as safe as using the hospital's own equipment. Our data show that less than 0.5% of our rental equipment fails within the first week after rental delivery (Patel, Wang & Sloane, 1997). Furthermore, estimates made by Putnam (1990) shows that a healthcare organization can save as much as \$100,000 per month in unnecessary, redundant incoming inspections if they rent an average of 150 units in that period of time. The elimination of redundant inspections also has an important efficiency advantage. This is particularly evident when life-support equipment is delivered at nights and weekends when the clinicians can seldom afford to wait for the in-house clinical engineering staff to get back to the hospital to perform incoming inspections, while the patients are being manually ventilated, infused, or monitored. On the other hand, when renting from unqualified providers, hospitals have no choice but to reinspect every piece of newly-delivered rental equipment (Tackel & Bell, 1988).

Basing our QA program on JCAHO standards and ECRI guidelines has also provided significant benefits for the company as well. First, our staff has a single, consistent format to follow instead of a multitude of formats and terms on which the medical device industry has yet to standardize. Furthermore, they can rely on a single set of widely available test and measurement equipment, instead of depending on special, proprietary test apparatus for each brand and model. An additional benefit is the consistent method of documenting the service performed. These documents provide valuable legal evidence, too, if the product is involved in a patient incident. Finally, this comprehensive and rigorous approach has helped to reduce significantly our liability exposure. This combination of safety and quality is also being adopted in other industries with the same objectives and achieving good results (Cooper & Phillips, 1995).

We are, however, unable to rely solely on JCAHO standards and ECRI guidelines to manage branch locations that are several thousand miles apart and across six time zones. The management methods and tools deployed by hospital-based clinical engineering departments are generally limited to single institutions or multiple organizations located in a limited geographical region. We, therefore, have to adopt approaches similar to those used by nationwide or multinational service companies or the service divisions of equipment manufacturers. The inspection of equipment serviced

(continued on page 20)

2000 JCAHO STANDARD FOR HOSPITALS

EC.1 The hospital plans for a safe, accessible, effective, and efficient environment of care consistent with its mission, services, law and regulation.

Intent of EC.1

The intent of this standard is self-evident.

EC.1.1 The hospital plans for a safe environment.

Intent of EC.1.1

The hospital identifies how it establishes and maintains a physical environment free of hazards, and manages staff activities to reduce the risk of injuries. Safety planning includes identifying processes for

a. conducting a risk assessment that proactively evaluates the impact of buildings, grounds, equipment, occupants, and internal physical systems on patients and public safety;

...
c. ongoing monitoring of performance regarding actual or potential risks related to one or more of the following:

- staff knowledge and skills;
- level of staff participation;
- monitoring and inspection activities;
- emergency and incident reporting, and
- inspection, preventive maintenance and testing of equipment.

i. maintenance and supervision of all grounds and equipment.

...
A management plan describes all the processes required in safety planning.

EC.1.6 The hospital plans for managing medical equipment.

Intent of EC.1.6

The hospital identifies how it will establish and maintain an equipment management program to promote the safe and effective use of equipment. Equipment planning includes identifying processes for

a. selecting and acquiring medical equipment;

b. establishing criteria for identifying, evaluating, and taking inventory of equipment to be included in the management program before the equipment is used. These criteria address

1. equipment function (diagnosis, care, treatment, and monitoring),
2. physical risks associated with use,
3. maintenance requirements, and
4. equipment incident history;

Note: All medical equipment may be included in the program rather than a limited selection based on risk criteria.

MEDIQ/PRN QA PROGRAM

MEDIQ/PRN Rental Equipment QA Program

MEDIQ/PRN Rental Equipment QA Program

Section 2.2

Section 5

Section 6.7 and 6.8

Section 6

Section 4.3

Section 2

Section 2

MEDIQ/PRN Rental Equipment QA Program

Section 1

All MEDIQ/PRN rental equipment is included in the QA Program (section 2.2)

c. monitoring and acting on equipment hazard notices and recalls;
 d. monitoring and reporting incidents in which a medical device is connected to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990;
 e. reporting and investigating equipment management problems, failures, and user errors;
 f. assessing and minimizing clinical and physical risks of equipment use through inspection, testing, and maintenance;
 g. how an annual evaluation of the equipment-management plan's objectives, scope, performance, and effectiveness will occur.
 h. an equipment orientation and education program for maintainers of equipment; and
 i. emergency procedures that address
 1. specific procedures in the event of equipment disruption or failure;
 2. when and how to perform emergency clinical interventions when medical equipment fails;
 3. availability of backup equipment; and
 4. how to obtain repair services.

In addition, equipment planning establishes
 j. an equipment orientation and education program for users of equipment;
 k. ongoing monitoring of performance regarding actual or potential risks related to one or more of the following:
 • staff knowledge and skills;
 • level of staff participation,
 • monitoring and inspection activities,
 • emergency and incident reporting, and
 • inspection, preventive maintenance and testing of equipment.
 A management plan describes all the processes required for equipment management planning.

EC.2 The hospital provides a safe, accessible, effective, and efficient environment consistent with its mission, services, laws and regulation.

Intent of EC.2

The intent of this standard is self-evident.

EC.2.1 The hospital implements its safety plan.

Intent of EC.2.1

The hospital implements the safety planning activities described in EC.1.1.

EC.2.6 The hospital implements its medical equipment management plan.

Intent of EC.2.6

The hospital implements the medical equipment management plan activities described in EC.1.6.

Section 4.1
 Sections 4.3 and 6.7

Section 6, except part 6.7
 Sections 2, parts 2.1, 2.2, 2.3 and 2.4
 Section 6.9

Section 5

Not applicable.

Not applicable.

MEDIQ/PRN provides back-ups, replacements, and repair services whenever needed.

MEDIQ/PRN will, at customer request, arrange for in-service training provided by qualified manufacturer representatives.

Section 5

Section 6.7 and 6.8

Section 6

Section 4.3

Section 2

MEDIQ/PRN Rental Equipment QA Program

MEDIQ/PRN Rental Equipment QA Program

MEDIQ/PRN's QA Program has been implemented for over 20 years.

MEDIQ/PRN's QA Program has been implemented for over 20 years.

EC.2.10.3 Medical equipment is maintained, tested, and inspected.

- Intent of EC.2.10.3
 The hospital maintains documentation of
- a. a current, accurate, and separate inventory of all equipment identified in the equipment management plan, regardless of ownership;
 - b. performance and safety testing of all equipment identified in the management plan prior to initial use and at least annually thereafter;
 - c. preventive maintenance and inspection of equipment according to a schedule based on current hospital experience and ongoing monitoring and evaluation;
 - d. performance testing of all sterilizers used, and
 - e. chemical and biological testing of water used in renal dialysis and other applicable tests based upon regulations, manufacturers' recommendations, and hospital experience.

Note: An equipment time frame longer than 12 months may be justified based on previous experience and safety committee approval. The specification of an annual testing interval is not intended to be a single standard of testing needs. It is expected that hospitals will apply professional judgment in establishing intervals so that risks and hazards are adequately managed.

Sections 2.2 and 4.2.
 Sections 2.1 and 2.2.
 NOTE: Some hospitals accept our SPI in lieu of their incoming inspection.
 Section 2.2.

MEDIQ/PRN does not rent sterilizers.
 Not applicable.

Section 2.2

EC.4 The hospital evaluates and improves conditions in the environment.

Intent of EC.4
 The intent of this standard is self-evident.

EC.4.1 The hospital collects information about deficiencies and opportunities for improvement in the environment.

Intent of EC.4.1

- The hospital's leaders assign an individual to monitor and respond to in the hospital's environment. The individual
- a. directs ongoing, hospitalwide collection of information about deficiencies and opportunities for improvement in the environment of care;
 - b. reviews summaries of deficiencies, problems, failures, and user errors related to managing
 - ... 6. medical equipment; and
 - ...
 - c. draws on other sources of information, such as published hazard or recall reports;
 - d. reports on findings, recommendations, actions taken, and results of measurement;
 - e. regularly participates in hazard surveillance and incident reporting; and
 - f. participates in the development of safety policies and procedures.

Section 6, all parts.

Section 6, parts 6.1-6.8

MEDIQ/PRN's National Quality Director is responsible for our QA Program and is available to work with our customers' Safety Officer or Committee.

Section 6.1-6.7

Section 4.1

Section 6

Sections 4.1 and 4.3

Section 6.9

This individual reports on findings, recommendations, actions taken, and results of measurement.

Notes:

1. *Incidents involving patients may be reported to staff in quality assessment, improvement, or other functions. However, at least a summary of incidents is shared with the individual appointed to direct the safety program.*
2. *The review of incident reports often requires that various legal processes be followed to preserve the confidentiality of information documented in the reports. Opportunities to improve care or to prevent future similar incidents are not lost as a result of the legal process followed.*

EC.4.2 The hospital analyzes identified environment issues and develops recommendations for resolving them.

Intent of EC.4.2

Safety issues are analyzed in a timely manner. Recommendations are developed and approved. Safety issues are communicated to the leaders responsible for performance improvement activities. Based on the ongoing monitoring of performance in each of the seven management areas, recommendations for one or more performance improvement activities are communicated at least annually to the hospital's leaders.

A multidisciplinary process is established and followed for resolving environment of care issues involving representatives from clinical, administrative, and support services, when applicable, to resolve environmental issues in the hospital. A multidisciplinary improvement team meets at regular intervals to address issues related to managing the environment of care. The hospital applies reasonable and prudent professional judgment when establishing meeting frequency of the team so that risks hazards, problems, failures, accidents, and incidents are minimized and resolved in a timely manner...

EC.4.3 The hospital works to implement recommendations to improve the environment and monitor the effectiveness of the recommendation's implementation.

Intent of EC.4.3

Appropriate staff participate in implementing recommendations and monitoring their effectiveness. Measurement guidelines are established by appropriate staff, and results of measurement are reported through appropriate channels, including the hospital's leadership, and to the multidisciplinary improvement team that is responsible for resolving environment of care issues.

HR.4 An orientation process provides initial job training and information and assesses the staff's ability to fulfill specified responsibilities.

Intent of HR.4

The orientation process assesses each staff member's ability to fulfill specific responsibilities. The process familiarizes staff members with their jobs and with the work environment before the staff begins patient care or other activities. In this way, the process promotes safe and effective job performance. When the hospital uses volunteer services ...

HR.4.2 Ongoing in-service and other education and training maintain and improve staff competence.

Upon request, MEDIQ/PRN will be glad to provide information to the customer's Safety Officer and Committee.

Section 6

Section 6.7 and 6.9

Upon request, MEDIQ/PRN will be glad to provide information to the customer's Safety Officer and Committee.

MEDIQ/PRN's QA Department (Section 6.9)

Section 6.9

Section 6.9

Section 5

Section 5

Intent of HR. 4.2

The hospital ensures that each staff member participates in ongoing in-service education and other training to increase his or her knowledge of work-related issues. The hospital periodically reviews the staff's abilities to carry out job responsibilities, especially when introducing new procedures, technique, technology, and equipment. Ongoing in-service and other education and training programs are appropriate to patient age groups served by the hospital.

HR. 4.3 The hospital regularly collects aggregate data on competence patterns and trends to identify and respond to the staff's learning needs.

Intent of HR. 4.3

The hospital regularly collects and analyzes aggregate data from a variety of sources to assess staff competence and pinpoint training needs. The hospital may extract data from performance evaluations and performance-improvement reports, it may survey the staff, or may conduct other needs assessment. The hospital analyzes patterns and trends, then responds by offering ongoing in-service education, training, and other teaching to meet identified needs. The hospital reports at least annually to the governing body on levels of competence, patterns and trends, and competence maintenance activities.

HR. 5 The hospital assesses each staff member's ability to meet the performance expectations stated in his or her job description.

Intent of HR. 5

The hospital has a system to conduct periodic competence assessment and document findings for each staff member. When appropriate, the hospital considers special needs and behaviors of specific patient ...

Section 5

Section 5

IC. 1 The organization uses a coordinated process to reduce the risks of endemic and epidemic nosocomial infections in patient and health care workers.

IC.1.1 The infection control process is managed by one or more qualified individuals.

Intent of IC.1 and IC.1.1

...

The hospital's infection control program addresses issues defined by that hospital to be epidemiologically important. Depending on the hospital, these may include

- device-related infections, especially those associated with intravascular devices, ventilators, and tube feeding;

...

IC. 4 The hospital takes action to prevent or reduce the risk of nosocomial infections in patients, employees, and visitors.

Intent of IC.2 through IC.5

The hospital's infection control process is comprehensive, encompassing both patient care and employee health services. The mechanisms that support this process are based on current scientific knowledge, accepted practice guidelines, and applicable law and regulation. They address the infection issues that are epidemiologically important to the hospital.

Section 3

MEDIQ/PRN's QA Department

Sections 3.1, 3.2, 3.3, and 3.4

Sections 3 and 4.4

NOTES: 1. The 2000 JCAHO Hospital standards cited above are up-to-date as of August 2000. Since updates are published quarterly by JCAHO, some items may have been revised by JCAHO by the time this article is published.

2. Although the standards above were written by JCAHO specifically for hospitals, most of them are similar, if not identical, to those established by JCAHO and other similar organizations for home care, long-term care (including subacute), and ambulatory care providers. These providers have been satisfied MEDIQ/PRN customers for rental equipment of many years.

(continued from page 15)

at service centers and *in situ* branch inspections illustrate what we have learned from the service industry. Whenever on-site inspection is not sufficient or feasible, we use remote monitoring tools such as service report audits, statistics of overdue inspections, unsatisfactory transfers among branches, and customer complaints. Our experience has shown that, in spite of all the efforts spent to prevent problems from developing while equipment is in the customers' hands, the reality is that random failures, shipment and handling damages, and human errors are impossible to eliminate. Collecting and analyzing failure information provides an invaluable source of opportunities for system revision, customer training, staff retraining, and, if necessary, disciplinary action. Only through perpetual improvement of the QA program can we continue to reduce the problems and enhance the quality of our products and services.

Many obstacles continue to challenge us despite more than a decade of evolution. Some of the continuing challenges are staff training and turnover, constant volume growth, seasonal demand fluctuations, customer competence and cooperation, and the strict financial constraints of the healthcare marketplace. For example, the recruiting, training, and retention of CSRs is one of the perennial challenges. Our CSRs have to learn very quickly a variety of tasks so they can clean and decontaminate an ever-growing assortment of equipment and inspect it for safety and performance. They must carefully document their work, deliver the equipment on time, be courteous to customers, and be on call in the evenings, weekends, and holidays. Their job is often complicated by stressful situations they encounter, in which a critical piece of life-support equipment is urgently needed, regardless of weather, traffic, or other circumstances. They are really among the unsung heroes of this organization. In fact, many successful CSRs have risen to become branch managers, district sales managers, and regional directors because of what they were required and able to learn.

The ever-decreasing financial resources for healthcare are forcing everyone to find more efficient ways to manage technology. As a for-profit company, MEDIQ/PRN has a very efficient operation that takes advantage of our business volume, years of accumulated experience and, above all, dedicated staff. The challenge we live every day is how to continue to decrease rental fees and provide ever safer and more reliable service. The adoption of new computerized document scanning technology to archive service reports is one example how we constantly seek to decrease the costs while increasing efficiency. Similar efforts at reducing costs and improving quality are being attempted in a variety of other industries (see, e.g., Mirghani, 1996; Spires, 1996; Phillips, 1997; and Erwin, 2000).

In closing, it is worthwhile to mention that, although the for-profit rental business model may have limited appli-

cability outside of developed countries, it would not be surprising if the basic elements of our quality management model can be used even in the poorest countries. As described above, the role of a rental company is to share limited resources among many organizations. It is, in principle, perfectly feasible for a governmental health authority to create a national or regional coordination office to distribute equipment to its care delivery facilities on an as-needed basis. Obviously, this assumes that there is enough equipment to be distributed and that the coordination unit can be managed in a professional manner with minimal political interference. Unfortunately, equipment ownership is still often considered a status symbol in less-developed countries (Wang, 1990) and very few healthcare decision-makers are aware of this type of resource-sharing possibility. Besides describing our quality management experience, we hope this article may contribute to a more widespread adoption of this concept in other countries.

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BIOGRAPHY

Binseng Wang earned his Sc.D. from MIT. He is a certified clinical engineer (CCE) and Quality Management System (QMS) Provisional Auditor. He worked over 20 years in Brazil, first at the State University of Campinas, where he was a faculty member and the founder and first director of the Center for Biomedical Engineering (CEB), later designated a collaborating center of the World Health Organization (WHO). Later, he served as the Special Advisor on Equipment to the Secretary of Health of Sao Paulo State, Brazil, where he established a comprehensive policy for technology planning, management, and service. He was a visiting scientist at the National Institutes of Health (NIH), Bethesda MD, where he developed a method for integrating three-dimensional data obtained from electro-magnetic recordings and stimulation with MRI and PET

images of the brain. In 1992, he joined MEDIQ/PRN Life Support Services, Inc. and currently he holds the position of National Quality Director. He has worked in several Latin American and Caribbean countries as a consultant to international organizations, health authorities and organizations, and manufacturers.

Elliot B. Sloane is a clinical engineer and information scientist who recently successfully completed his Ph.D. at Drexel University's College of Information Science and Technology. He originally worked at the Emergency Care Research Institute (ECRI) for 15 years, where, as vice president of laboratory operations, he was responsible for medical device evaluations, accident investigations, and information systems design and development. He spent the next 10 years of his career as a vice president for MEDIQ/PRN Life Support Services, Inc. where he was responsible for nationwide medical equipment service, support, regulatory compliance, and quality assurance. Since 2000, he has been an assistant professor of information systems at Villanova University and a senior consultant for regulatory assurance and clinical engineering projects to the medical and pharmaceutical industries with OCS, Inc. For the past two decades he has served in Australia, Latin America, the Caribbean, and both Western and Eastern Europe as a healthcare and information technology consultant to intergovernmental and humanitarian agencies. He is frequently invited as a presenter at numerous national clinical engineering and information science conferences, and he advises the Ben Franklin Technology Partnership on regional business investments for biomedical technology companies.

Correspondence and reprint request address:

Binseng Wang
 MEDIQ/PRN Life Support Services, Inc.
 Pennsauken, NJ 08110.
 Telephone: 856-662-3200, x5516
 Fax: 856-661-1635 or 856-661-0278
 E-mail: binseng@alum.mit.edu

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