List of Titles

American National Standard

ANSI/AAMI EQ56:1999

Recommended practice for a medical equipment management program

AAMI Association for the Advancement of Medical Instrumentation

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Developed by
Association for the Advancement of Medical Instrumentation

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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

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Committee representation

Association for the Advancement of Medical Instrumentation

Equipment Management Committee

This recommended practice was developed by the AAMI Equipment Management Committee. Committee approval of the recommended practice does not necessarily imply that all committee members voted for its approval.

The **AAMI Medical Equipment Management Committee** has the following members:

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NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

Foreword

This recommended practice was developed by the AAMI Equipment Management Committee. This recommended practice specifies the minimum required characteristics for a management program designed to minimize certain risks associated with equipment that is used during routine care of patients in a health care organization. The document addresses the structure of the program, the documentation that must be produced by the program, and the staffing and resources allocated to those responsible for maintaining the medical equipment.

This recommended practice should be considered flexible and dynamic. As technology advances and new data are brought forward, the recommended practice will be reviewed and, if necessary, revised. Within the context of this recommended practice, “shall” indicates requirements strictly to be followed in order to conform to the recommended practice; “should” indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; “may” is used to indicate that a course of action is permissible within the limits of the recommended practice; and “can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—This foreword does not contain provisions of the AAMI Recommended Practice*, Recommended practices for an equipment management program* (AAMI EQ56:1999), but it does provide important information about the development and intended use of the document.

Introduction

Medical equipment is an essential part of health care. Appropriate management of equipment maintenance is vital for ensuring that medical equipment remains safe for its intended use, that equipment life is maximized, and that total lifetime costs are minimized. In addition, an equipment management program is required by accrediting and licensing agencies. Accrediting agencies include the Joint Commission on Accreditation of Healthcare Organizations and the American Osteopathic Association. Licensing agencies include the Federal Health Care Financing Agency, as well as state departments of health and other licensing bodies.

This recommended practice has been developed by experts in the field of health care equipment management: clinical engineers, biomedical engineers, biomedical equipment technicians, and medical equipment manufacturing engineers. This recommended practice defines the minimal components of an equipment management program. Many existing programs exceed these standards by very wide margins. It is hoped that this recommended practice will help provide a clear understanding of the minimal expectations for an equipment management program and the resources necessary to achieve those expectations.

It is our intention that this recommended practice be used as a baseline to inspire other programs to exceed these standards.

Recommended practice for a medical equipment management program

1 Scope

1.1 General

This AAMI Recommended Practice applies to any entity responsible for the management of medical equipment used as part of the routine care of patients, including health care organizations as a whole, divisions and departments within health care organizations, and outside vendors such as medical equipment manufacturers, shared service providers, and independent service organizations.

1.2 Inclusions

This AAMI Recommended Practice specifies required characteristics for a management program designed to minimize certain risks associated with equipment that is used in a health care organization during routine care of patients. The document addresses the structure of such a program, the documentation that must be produced by the program, program staffing, and resources that should be allocated to those responsible for maintaining medical equipment. Definitions of terms and normative references are also included, as are notes and rationale that expand the provisions of the document.

1.3 Exclusions

This AAMI Recommended Practice does not cover training needs of equipment users, nor does it cover competency assessment of the users of equipment included in the equipment management program.

Rationale: This recommended practice focuses on medical equipment acquisition and maintenance, but consideration of other aspects of equipment management is also a requisite for a complete program. In most health care organizations, however, clinical engineers and biomedical equipment technicians are directly involved in equipment acquisition and maintenance, while the responsibility for other activities, such as training in the use of equipment, is delegated to others within the health care organization.

The expertise of the members of the AAMI Equipment Management Committee was primarily in the acquisition and maintenance of medical equipment. While some members had much broader experience, the Committee as a whole did not feel comfortable identifying requirements for other aspects of a complete equipment management program.

2 Normative reference

The following document contains provisions that, through reference in the text, constitute provisions of this recommended practice. At the time of publication, the edition indicated was valid.

Safe Medical Devices Act of 1990, implementing regulations

Medical Device User Facility and Manufacturer Reporting, Certification and Registration; Delegations of Authority; Medical Device Reporting Procedures: Final Rules; Department of Health and Human Services, Food and Drug Administration, 21 CFR Parts 803 and 807, as published in the Federal Register: December 11, 1995 (Volume 60, Number 237), pages 63577-63606.[1]

[1] At the time of the publication of this American National Standard, the pamphlet, Medical Device Reporting for User Facilities, was available from the FDA's website at http://www.fda.gov.

3 Definitions

For the purpose of this recommended practice, the following definitions apply:

3.1 abnormal use: Use of equipment in a manner that is inconsistent with the operating instructions provided by the equipment manufacturer.

3.2 acceptance date: Date on which a piece of equipment is placed into service for its intended use by the health care organization.

3.3 acceptance testing: Interaction with medical equipment designed to determine whether or not newly received equipment is in good operating condition, prior to being placed into service for its intended use.

3.4 health care organization: Organization that provides medical, dental, psychiatric, nursing, obstetrical, or surgical care.

NOTE—Health care organizations include, but are not limited to, hospitals, nursing homes, limited care facilities, clinics, medical and dental offices, and ambulatory care centers, whether permanent or movable.

3.5 inspection: Interaction with medical equipment designed to detect unsuspected equipment problems, or to perform preventive maintenance.

NOTE—In general, an inspection is initiated on a scheduled basis and not in response to a reported failure.

3.6 maintenance: Interaction with medical equipment designed to identify and correct suspected equipment problems, or to perform activities designed to prevent the future occurrence of problems (preventive maintenance).

NOTE—Maintenance may be initiated on either an unscheduled basis (usually repairs) or on a scheduled basis (usually preventive maintenance).

3.7 medical equipment: Device that is intended to be used for diagnostic, therapeutic, or monitoring care provided to a patient by a health care organization.

NOTE—Medical equipment includes devices such as monitoring equipment, life support equipment, imaging equipment, laboratory equipment, mechanical equipment, transport equipment, as well as any other equipment supporting the care of a patient, whether or not it is in the immediate vicinity of a patient. In addition, this category includes other devices, such as computers, that support the care of a patient when in a health care organization, but are generally not specifically manufactured for use in a health care organization. As used in this recommended practice, the term “equipment” refers to medical equipment.

3.8 normal use: Use of equipment in a manner consistent with the operating instructions provided by the manufacturer of the equipment.

3.9 service agent: Individual, generally an employee, providing inspection and/or other maintenance services on equipment on behalf of a service provider.

3.10 service provider: Group with the responsibility to provide inspection and/or other maintenance services on a specific piece of equipment.

NOTE—A service provider may be a department within the health care organization, an equipment manufacturer, an independent service organization operated by a third party, a shared service, or other similar organizations.

3.11 training: Interaction with medical equipment designed to provide education to an equipment user or a service agent about the proper method for operating or maintaining the equipment.

3.12 use: Operation of the equipment in conjunction with the medical treatment provided to a patient.

NOTE—Use does not include operation of the equipment during acceptance testing, inspection, maintenance, or training activities.

4 Requirements

4.1 Program design

4.1.1 Equipment inventory inclusion criteria

The health care organization shall develop a document that describes the equipment to be included in the equipment management program. In identifying whether or not to include equipment in the program, the document shall describe criteria that take into account:

a) the equipment function, such as whether equipment is used for life support, routine treatment, diagnosis, monitoring, or as a convenience item;

b) the physical risks associated with the equipment during both normal use and reasonably anticipated abnormal use;

NOTE—The use of the term “abnormal use” is not intended to sanction any use of equipment in a manner that is contrary to the specific operating instructions provided by the manufacturer.

c) the maintenance requirements of the equipment; and

d) the incident history of the equipment, both within the health care organization and as reported by generally available sources outside the health care organization.

Any additional criteria that the organization believes may be useful for proper management of the equipment may be used.

NOTE—The specification of criteria for inclusion in the equipment inventory is designed to permit the health care organization to concentrate its resources on equipment representing the greatest risk. Additional criteria over and above those specified in 4.1.1 a) to d) may also be helpful. For example, location (such as intensive care unit versus clinic) may help determine frequency of use, and thus the likelihood of an equipment problem that could cause an injury.

Rationale: Not all equipment used in a health care organization will become part of the equipment management program. A method of clearly differentiating equipment included in the program from equipment not included in the program is essential. This clause is designed to ensure that the organization has developed its criteria in a rational manner. While other aspects of the equipment and its use can be helpful in determining whether to include a particular device, a minimal set of criteria that should be considered include equipment function, physical risks associated with the equipment during use, maintenance requirements, and known equipment incident history. The reference to additional criteria at the end of clause 4.1.1 is included to ensure that the health care organization clearly understands that the list of criteria presented in 4.1.1 is considered a minimal list, and that, if helpful, extra criteria may be included.

In developing the equipment inventory list, the health care organization may find the U.S. FDA’s classification of medical devices useful[2]. Most health care organizations will want to include devices falling into class II or class III within their equipment inventory list. Each organization, however, should consider information from a variety of sources, such as its own experience, the general criteria listed in section 4.1.1, and the FDA classifications when developing its final equipment inventory list.

a) Equipment function helps to identify the potential risks associated with equipment. For example, equipment used to sustain patient life generally poses a much greater risk to patients than office equipment used in an organization’s administrative areas and probably should be given higher priority for inclusion in the equipment management program.

b) Some equipment poses a physical risk to patients or users during use. For example, proper use of a piece of equipment may require that a patient or user be exposed to sharp surfaces. Other equipment may pose an electrical shock hazard. As equipment wears, parts may loosen or guards may be broken. Such events can result in an injury. It is also important to recognize that equipment

[2] At the time of the publication of this American National Standard, information on U.S. FDA classifications was available from the FDA’s website at http://www.fda.gov.

is sometimes used improperly. The organization should consider how a device might be used incorrectly and determine whether such use could pose an additional risk to a patient or user.

Including “reasonably anticipated abnormal use” in the criteria is intended to remind each health care organization to consider whether any procedures that might be employed by an equipment user (whether or not those procedures are part of the manufacturer’s instructions) could justify a change in the decision to include or exclude a device from the equipment inventory.

c) Many devices have maintenance requirements. For example, mechanical devices, such as wheelchairs, often require periodic adjustment. As parts wear or loosen, significant hazards can be created. An equipment management program should work to ensure that these kinds of hazards are detected and corrected before an injury occurs.

d) Most health care organizations require that incidents involving actual or potential injuries be reported. In addition, alerts and recalls related to identified or potential hazards are published by both government agencies (e.g., the Food and Drug Administration) and private organizations (e.g., ECRI, Quest Publishing). Because a particular health care organization’s experience with a device may be limited, the organization should take positive steps to ensure that its decisions benefit from the experience of those outside the organization.

4.1.2 Evaluation of the need for inclusion

4.1.2.1 Evaluation of equipment prior to initial use

All new equipment shall be evaluated against the criteria in 4.1.1 a) to d) before initial use to determine whether or not it should be included in the program. This evaluation shall be documented.

Rationale: When the health care organization receives a device that obviously is not excluded by the criteria, there should be documentation that the device has been evaluated for inclusion. The existence of this documentation will affirm that the device has been appropriately inspected and evaluated. The “obvious exclusion” clause included in this rationale is intended to make clear that, if an organization’s established criteria clearly excludes small devices—such as stethoscopes, thermometers, or blood pressure cuffs—there is no need to maintain documentation that demonstrates that such devices have been individually evaluated for inclusion.

4.1.2.2 Required documentation when equipment inclusion criteria change

If the equipment inventory inclusion criteria described in section 4.1.1 are changed:

a) documentation shall reflect the change;

b) the documentation shall record items deleted from the equipment inventory by the change; and

c) the documentation shall record the types of items to be added to the inventory by the change, steps taken by the health care organization to locate these items for inventory inclusion, and, if known, the specific items added to the inventory as a result of the change.

Rationale: The criteria for inclusion of equipment in the equipment management program should be dynamic. The health care organization should change its criteria if experience indicates that equipment either possesses more or less of a risk than was assumed when the criteria were originally developed. This will help the organization get the most value out of the resources it devotes to this program.

As the criteria change, the equipment included in or excluded from the program will change. The requirements in this section are intended to help organizations identify the consequences of such changes.

a) The organization should maintain a history of its criteria over time. This will help identify what criteria were used at any point in time and could provide some of the information needed to determine the value of any changes made in the inclusion criteria.

b) Any items that are deleted from the inventory should be identified to enable a health care organization to demonstrate the actual effect of modifying its criteria.

c) If the criteria will cause more items to be added to the inventory, the organization must be able to show that it is actually taking the steps necessary to add the newly identified items into the inventory.

4.2 Program implementation

4.2.1 Equipment inventory

4.2.1.1 Equipment inventory list

All equipment used in patient-care activities that meets the criteria of 4.1.1, regardless of ownership, shall be listed in the equipment inventory, including the following:

a) health care organization-owned equipment;

b) equipment owned by other organizations, such as leased equipment, rented equipment, loaned equipment, or evaluation equipment;

c) employee-owned equipment;

> NOTE—The category of "employee-owned" equipment is intended to include equipment owned by health care organization employees, as well as others who normally work in the health care organization but may not be employees, such as physicians.

d) research equipment; and

e) patient-owned equipment.

> NOTE—The requirement for inclusion of patient-owned equipment in the inventory applies only to patient-owned medical equipment used as part of the organization's treatment of the patient and meeting the other criteria [see 4.1.1 a) to d)] for inclusion within the program.

Rationale: Any equipment used as part of a patient's treatment can pose a risk to the patient or user. Therefore, the inventory of equipment included in the equipment management program must include all equipment meeting the organization's criteria, regardless of ownership. Various categories of equipment are delineated in 4.2.1.1 a)–e) to provide a checklist that will assist the organization as it considers the types of equipment that might be in use in their facility.

Equipment expected to be in the health care organization for a short time (two weeks or less), such as equipment on short-term loan, does not need to be included in this inventory, because it would not meet the requirement imposed in 4.2.1.3 a). All equipment meeting the inclusion requirements of the program and expected to be in the organization for longer than 15 days must be included in the inventory. The organization is encouraged, but not required, to develop a mechanism for tracking all pieces of equipment used in the care of patients, regardless of the amount of time the item will be in the organization.

a) Equipment owned by the heath care organization generally constitutes the bulk of items included in the inventory of most organizations. It is very likely that many items falling into this category will be used to provide patient care.

b) It is common for health care organizations to provide patient care services with equipment owned by other entities. For example, equipment shortages may cause a hospital to rent equipment. In other cases, an organization may find it financially advantageous to lease equipment for periods ranging from one month to several years. In an effort to demonstrate the benefits of a device, a sales representative may allow a health care organization to borrow an item for a few weeks. All of these examples would place equipment into service while its ownership remained with another party.

c) In some cases, employees find it advantageous to purchase their own equipment to provide patient-care activities. Whether these individuals are direct employees of the health care organization or function as independent practitioners using the organization's facilities and services to provide patient treatment, their equipment could potentially harm a patient.

d) It is common in a teaching hospital for a research device to be brought in as part of a study. These types of devices may be owned by a researcher, or a research-oriented department at a university, medical school, or perhaps a company. Again, regardless of the source of ownership, a patient may face a risk from the device.

e) Occasionally (primarily in some long-term care situations), a patient-owned device may be used as part of the organization's treatment procedures. If a device is used in this way and meets the criteria for inclusion, then it should be included. The note following 4.2.1.1 e) clarifies the requirements for patient-owned equipment. This Committee recognizes that the use of patient-owned medical equipment for treatment within a health care organization is a rare event.

4.2.1.2 Information to be included

The inventory should include at least the following information for each piece of equipment:

a) a unique identification number;

b) the equipment manufacturer;

c) the equipment model number;

d) the equipment serial number;

e) a description of the equipment;

f) the location of the equipment (for equipment generally kept in a fixed location or moved infrequently);

g) the identity of the department considered to own the equipment;

> NOTE—A smaller organization, such as a clinic, may not have multiple departments. Therefore, this requirement would not apply. Typically, larger health care organizations, such as a hospital, will have many departments that are considered to own individual pieces of equipment. If this is the case, the "owner" department should be identified in the inventory.

h) identification of the service provider responsible for the equipment; and

i) the acceptance date (month and year) of the equipment.

Any additional information that the organization believes could be useful for proper management of the equipment may be kept in the inventory.

Rationale: The Committee carefully weighed the minimal pieces of information necessary to ensure that any device in the inventory is identified. The list presented in Clause 4.2.1.2 represents the Committee's view of such a minimal set. The objective of requiring this information is to allow devices to be identified for both maintenance and recall purposes.

a) The unique identification number is an identifier that provides a key to accessing other information about the device. While equipment can be identified by its manufacturer, model number, and serial number, some devices do not have serial numbers. Having a unique number assigned to the equipment facilitates the identification of the equipment.

   During discussion about the inclusion of this item on the equipment inventory list, there was some sentiment to require that this number be clearly marked on the item. While this is probably a good idea in most cases, some health care organizations believe they can adequately track equipment by serial number rather than requiring the assignment and/or the attachment of an additional number. In addition, where equipment is included in the list but is not owned by the organization—such as loaner equipment, employee-owned equipment, or patient-owned equipment—the actual owner of the equipment may not allow it to be marked with an identification number.

b) The manufacturer of the equipment must be identified to provide access to service information, parts information, and device recall information.

c) The equipment model number must be identified to provide access to service information, parts information, and device recall information.

d) The equipment serial number must be identified to provide access to service information, parts information, and device recall information. Some pieces of equipment included in the equipment management program will not have serial numbers.

e) The description of the equipment, while generally supplementary to the manufacturer and model number combination, provides the information necessary for most equipment service agents and users to quickly identify the device. The health care organization or the service provider might consider using the standard nomenclature found in the ECRI's Health Devices Sourcebook or the Medical Device Register to provide an "industry standard" description, or alternately might use its own "common" description.

   Some organizations have found it helpful to maintain two fields providing descriptive information. For example, an organization might use a standard nomenclature field corresponding to the "standard" terminology used by ECRI or the MDR in order to aid in comparisons against standard publications, such as FDA recall notices or comparisons against inventory lists in other hospitals. Concurrently, the organization might also use a common description field that identifies the colloquial terminology used by equipment operators in the health care organization.

f) The location of the equipment provides guidance to service agents on locating a device that is due for inspection. Many health care organizations utilize portable equipment that typically is used for only a short time (a few days) in a particular location. (For example, infusion pumps are used in many health care organizations and often are not kept in a single location.) In cases where equipment is expected to be moved frequently, it is generally impractical to track its location in the inventory list.

g) Knowing the owner of the equipment facilitates interaction between service agents and equipment users. This information is also used by facilities that allocate the costs associated with equipment over its lifetime.

h) Providing the identity of the service provider for a device assures that primary responsibility for the maintenance of a device is known to equipment users and other service providers.

i) The month and year a device is put into service is used to initiate a schedule for the maintenance of the equipment and to provide the information necessary to determine how long a device has been in service.

The statement regarding additional information at the end of clause 4.2.1.2 is intended to emphasize that the list in 4.2.1.2 is a minimal list. Many health care organizations track additional information, such as software revision information and/or financial information (such as acquisition cost, replacement cost, estimated useful life, etc.), which allows the organization's management process to make informed decisions about equipment and the equipment management program. The inclusion of any additional information the organization believes to be useful is encouraged.

4.2.1.3 Inventory accuracy

The inventory's accuracy shall be maintained so that all equipment included in the program can be tracked after its acquisition by the health care organization. To facilitate this:

a) all additions to the inventory shall be made within 15 calendar days after the equipment is put into service; and

   NOTE—The 15 day requirement is intended to minimize the likelihood that the health care organization is unaware it is using a device that has been recalled. For further clarification on the issue of the inventory listing, please see the first note under subclause 4.2.1.5.

b) all changes to existing inventory records shall be made within 60 calendar days of the date of change.

Rationale: An equipment inventory is valuable only to the extent that the inventory is accurate. If an inventory does not contain items expected to be in the inventory, if items that have been removed from the organization are still part of the inventory, or if the inventory does not correctly identify the equipment (e.g., incorrect manufacturers or descriptions), then the information needed to identify the existence within the organization of a recalled device (for example) may not be available. Accurate estimates for staffing requirements also cannot be made unless the inventory is accurate.

a) The requirement that additions to the inventory be made within 15 calendar days was controversial. Some members of the AAMI Equipment Management Committee felt that their organizations, as then operating, could not meet this requirement. However, the majority of committee members believed that meeting this time frame was an important objective and should be required. The concern focused on tracking devices that might be recalled. If a recalled device is not included in the inventory listing, then there is a significant possibility that the device might remain in service, leading to a potentially dangerous situation. The 15-day window was considered a reasonable compromise that minimized this possibility, while still being within the capability of the vast majority of health care organizations. In addition, the Committee was not persuaded that significant resources would be required for those organizations performing less frequent additions (typically, once per month) to develop procedures to meet this shorter time frame.

b) The AAMI Equipment Management Committee believed that changes to the inventory records should be made as soon as possible. However, the Committee did not view changes in the inventory (such as corrections to a manufacturer's name or revised location information) to have the same urgency as the addition of new equipment. In the case of a recalled device, it is better to have the device listed in the inventory, even if some of the information about the device is incorrect. The 60-day window cited in clause 4.2.1.3 b) allows organizations that update inventories on a monthly basis to continue their current method of operation.

4.2.1.4 Auditing inventory accuracy

The inventory's accuracy shall be audited by verifying at least the existence, identification number, manufacturer, and description of a statistically significant sample of the equipment each year. Audit procedures should verify the accuracy of the information recorded in the inventory, as well as the inclusion of all equipment used in the health care organization that meets the criteria for inclusion.

The health care organization shall establish its own standards for the accuracy of the inventory, and document those standards. If this audit determines that those standards have not been met, the organization shall take action to correct any identified deficiencies.

NOTE—The values chosen below reflect the minimum sample quantities necessary to ensure that the inventory is at least 85% accurate. A more accurate inventory would require less sampling. The numbers are derived from the equation:

$$s = \sqrt{\left[\frac{(p)(1-p)}{n}\right] \times \left[1 - \frac{n}{N}\right]}$$

where s is the standard error of the sample, p is the mean accuracy of the inventory, n is the sample size, and N is the population size.

To derive the numbers used here, a mean accuracy for the inventory was assumed to be 90%, with a standard error of 5%. In this way, the following statement can be made with 95% confidence: Based upon the sample, if the accuracy of the selected sample is 90% or greater, then the mean accuracy of the entire population is the same as the accuracy of the sample +/- 5%. This assumes that the selected samples are truly randomly selected.

For example, to find the sample size required, this equation can be rewritten as:

$$n = \frac{Np(1-p)}{Ns^2 + p(1-p)}$$

If the total number of items in the inventory is 100 items, then:

$$n = \frac{(100)(0.9)(1-0.9)}{(100)(0.5)^2 + (0.9)(1-0.9)}$$

$$n = \frac{9}{(100)(0.0025) + (0.9)(1-0.9)}$$

$$n = \frac{9}{0.25 + 0.09}$$

$$n = \frac{9}{0.34}$$

$$n = 26.5$$

This number is then rounded up to the next highest integer. Therefore, for an inventory of 100 items, 27 items must be tested to demonstrate the accuracy of the inventory.

If the inventory were actually 95% accurate, then the sample size required by this equation would be 16 items. Therefore, the more accurate the inventory, the lower the sample size required to verify the accuracy of the inventory.

For an inventory consisting of less than 100 items, the audit shall consist of at least 27 randomly selected pieces of equipment.

For an inventory of between 100 and 500 items, the audit shall consist of at least 34 randomly selected pieces of equipment.

For an inventory of between 501 and 1000 items, the audit shall consist of at least 35 randomly selected pieces of equipment.

For an inventory of more than 1000 items, the audit shall consist of at least 36 randomly selected pieces of equipment.

Rationale: The sample sizes selected in this clause were chosen to permit verification of at least 85% accuracy with a 95% confidence interval. Experience shows that most inventories will be far more than 85% accurate. However, to verify a less accurate inventory would have required very large sample sizes, especially for smaller inventories, so the numbers presented here were selected.

4.2.1.5 Inventory listing

The capability to readily compile the inventory into a paper document that can be kept in a single location shall exist.

NOTE—An organization should be able to determine quickly whether or not it is using a device (e.g., in response to a recall notification). While most health care organizations will choose to have an actual inventory listing reproduced periodically, some organizations may choose to keep their inventory in an electronic form. Whether or not an electronic or other non-paper format is used as the primary means of listing inventory, 4.2.1.5 requires the capability to produce such a written listing upon demand.

It is acceptable to maintain multiple inventories (for example, if multiple service providers each maintain their own inventory). Some health care organizations maintain a separate inventory list or file for equipment the organization expects to hold or use for a short time (such as a few days to a few months), but that may be held

for more than 15 days. This is also acceptable, provided that the equipment on this separate list is inspected when due, as is similar equipment held or used by the organization on a permanent basis.

For all cases in which multiple inventories exist, regardless of reason, it is required that the health care organization be able to assemble all of the inventories in a single location upon demand.

Only items meeting the inclusion criteria of 4.1.1 shall be included in this document.

NOTE—It is acceptable to include more than the equipment in the equipment management program in the inventory, if there are other items that the health care organization desires to track and maintain. If the inventory includes items that are excluded from the formal equipment management program, there must be a way to clearly identify and separate the equipment in the program from other equipment listed in the inventory.

Rationale: These requirements are intended to ensure that the inventory for the equipment management program is complete and can be used to determine whether a specific piece of equipment exists.

The requirement that only items meeting the inclusion criteria be included serves to ensure that the inventory document accurately reflects the equipment management program inventory. While other inventories may exist within the organization, such as a capital assets inventory, the organization should be able to clearly identify whether a particular device is or is not part of the equipment management program inventory and thus subject to the requirements of this recommended practice. Some organizations, as a convenience, maintain a “master” inventory that includes inventories of devices that may not be part of the program. This is acceptable as long as the equipment management program inventory is readily separable. The requirement for clear identification is intended to facilitate auditing of the inventory by an outside agency.

4.2.2 Procedures

4.2.2.1 Equipment testing and inspection procedures

The health care organization shall develop or adopt, and implement written equipment testing and inspection procedures that:

a) accurately describe the activities that will be performed during the inspection of a device;

NOTE—This recommended practice is not intended to require that any specific test be included in any inspection procedure. It is, however, the intention of this standard that all requirements for performance testing and preventive maintenance be considered when scheduled inspection procedures are developed, rather than just considering electrical leakage current and grounding resistance testing requirements.

b) include documentation to verify completion of the inspection; and

NOTE—This clause is not intended to require any specific documentation. Documentation of specific results, pass/fail results, or results outside specified limits would all be acceptable.

c) include an estimate of the time required to perform an inspection.

NOTE—It is expected that this estimate will be used to determine the staffing requirements in subclause 4.6.

Rationale: This requirement is intended to allow each health care organization to identify its own needs for the scheduled testing or inspection of equipment, while later requirements build on this requirement by asking that the organization demonstrate it is actually implementing its written procedures. Accurate identification of the procedures to be followed when testing or inspecting equipment is one step in ensuring that service agents know what is expected of them and that procedures will be uniformly followed as different service agents work on the same device.

a) The intention of this paragraph is to ensure that any activities that are part of the scheduled testing or inspection program conducted by the health care organization represent an appropriate expenditure of resources and effort. These procedures should take into account the actual risks posed by the equipment as it is used and as it ages. The perception of the AAMI Equipment Management Committee is that evidence does not support aggressive testing of electrical leakage current and grounding while excluding other inspection procedures such as examination for

mechanical damage. It is up to each health care organization, however, to identify the steps it will take as part of its testing or inspection procedures and it is that organization's responsibility to justify the need for those steps as part of the equipment management program.

b) When a testing or inspection procedure is completed, some type of documentation will be completed. The organization's requirements for that documentation should be contained in its procedures so that service agents know what is expected of them and to ensure uniformity of reporting.

c) The requirement to include an estimate of the time required to perform an inspection is intended to ensure that appropriate resources are available to the service provider to carry out the documented procedures on all the equipment in the inventory. There is an implicit assumption that the health care organization will undertake a management process, from time to time, to guarantee that the estimates given for these procedures are grounded in reality.

4.2.2.2 Equipment repair procedures

The health care organization shall develop or adopt written procedures that:

a) describe the general activities that a service agent should perform when repairing a device, including any guidelines to be used in the selection of replacement parts;

b) describe the documentation used to record all information that the health care organization considers relevant about a repair, who within the organization will receive copies of this documentation, and where this documentation will be filed;

c) describe for equipment users how to obtain equipment repair services, and the hours during which such services are available. These repair request procedures should be readily available to those within the health care organization who are responsible for obtaining repair services; and

d) describe what operators should do to care for patients during an emergency or scheduled downtime of critical equipment.

Rationale: The health care organization should develop standard procedures that delineate its expectations when repairs are made to its equipment.

a) The repair procedures should describe the activities that a service agent will undertake when repairing equipment. For example, the procedures might describe who should be notified that the equipment will be out of service, the methods that might be used to test equipment to identify the cause of a problem, how the agent can assure that all parts are properly tracked as equipment is disassembled and reassembled, how tests should be conducted to verify proper completion of the repair, etc.

   On some occasions, a repair will involve the replacement of defective parts. It is important that the service provider select replacement parts that will function properly. In some cases, some parts used in medical devices are considered critical to its proper and safe operation. The selection of inappropriate replacement parts might void any certification the equipment has received (such as certification by Underwriters' Laboratories or the Canadian Standards Association). (Equipment manufacturers can often provide information on which parts might be critical to performance or safety.) For this reason, the organization should establish guidelines to verify that any replacement parts will not diminish the performance or safety of the equipment.

b) Documentation related to a repair is essential for identifying what actions have been performed during the repair. Typically, this documentation will include the date of the repair; the identity of the person performing the repair; the identification of the problem; and a description of the actions taken to remedy the problem, such as adjustments or replacement of any parts. This information is important both for legal reasons and to provide the information needed by quality improvement activities. The procedures required in this section would identify what information must be included in the documentation. In addition, if the health care organization requires that copies of the documentation be given to certain individuals in the organization, such as department managers or

equipment users, these should be identified. Finally, by identifying where this documentation will be kept, it can be found if needed at a later time.

c) Equipment users need to know how to obtain repairs on the equipment they are using. This minimizes the probability of equipment being used that is not in good repair and which may be potentially dangerous to either the user or a patient.

d) Equipment operators need to know how to care for patients when specific equipment is unavailable (e.g., the availability and location of spare equipment or procedures to be followed to compensate for the lack of equipment).

4.2.2.3 Records retention

The health care organization shall establish and implement a policy for the retention of inspection and repair records generated under clauses 4.2.2.1 b) and 4.2.2.2 b).

Rationale: Equipment inspection and repair records lose their value over time. The retention of active records and disposal of records that are old and no longer needed should be guided by policies established by the health care organization.

4.3 Service agent training

4.3.1 Training documentation

The health care organization shall develop written documentation that:

a) describes the training received by each service agent; and

b) includes a method for evaluating the training needs of each person performing equipment maintenance activities.

> NOTE—As with all other parts of this recommended practice, this particular clause applies both to employees and outside contractors of the health care organization. If maintenance activities are assigned to an outside service organization, it is still the health care organization's responsibility to ensure that the training needs of the service provider's agents are met by their employer so that they can competently perform the jobs expected of them within that health care organization.

Rationale: The purpose of service agent training is to ensure that each service agent is capable of performing assigned work. This clause requires that documentation be developed to demonstrate that each agent has received appropriate training. As with all other portions of this document, the ultimate responsibility for meeting the requirements imposed by this recommended practice falls upon the management of the health care organization. It is important that the health care organization verify that any service provider working on its behalf ensures the competence of its service agents.

a) Documentation helps guarantee that identified training has been received.

b) Training should focus on identified weaknesses or deficiencies. This requirement is intended to assure that training needs are assessed when a training curriculum is developed.

4.3.2 Training responsibilities

Each service provider with maintenance responsibilities described in this recommended practice shall provide the training necessary to ensure that each service agent is competent to perform his or her job.

Each service provider shall provide each service agent with at least 72 hours of formal training over three years. This time may include attendance at factory schools, seminars, conferences, other training courses, health care organization in-service training, reading of professional publications, or similar activities.

The service provider should consider all of the following when providing training:

a) the need of current service agents to learn the procedures used for the inspection of equipment;

b) any safety training required by governmental or other regulatory bodies;

c) the unique needs of new service agents (at least 36 hours should be allowed during the agent's first year for orientation activities and other training);

d) the skills needed by present service agents to prepare them for other related career positions for which they have demonstrated an interest; and

e) the experience and knowledge needed by service agents to achieve certification as clinical engineers or biomedical equipment technicians, as appropriate.

Rationale: The responsibility for meeting this recommended practice falls upon all service providers, not just those that are direct employees of a health care organization. Training should be planned in a manner that helps assure its usefulness is maximized.

The AAMI Equipment Management Committee wanted to develop requirements that specified employee competence, rather than a specific quantity of training. However, the difficulty of measuring competence in an objective way prevented this. There was concern that some service providers had been reducing training for financial reasons, without necessarily ensuring that service agents remained competent. As a compromise, the Committee specified the minimum requirement of 72 hours of training over a three year period, based on its belief that all service agents should receive an average of at least two hours of training per month and to take into account financial and time constraints imposed upon some service providers, making compliance with an annual training requirement difficult.

The selection of specific training activities is left to the discretion of the service provider (in consultation with the health care organization), based upon its needs and the needs of its service agents.

a) The written procedures identified in clause 4.2.2.1 define a set of procedures that a service agent is expected to follow. Training should help ensure that each service agent performing those procedures has the skills necessary to properly follow and complete the procedure.

b) Safety training required by law or regulation must be provided to employees.

c) New employees hired by a service provider must be integrated into the organization to successfully perform the jobs expected of them. The Committee arrived at the 36-hour requirement by increasing the minimum average annual training requirement for all service agents by fifty percent to reflect its opinion that this group of employees requires more intensive training. The training described in this clause is expected to take place during the first year of the service agent's service to guarantee that the employee understands from the start the health care organization's and the service provider's expectations for performance.

d) Employees perform best when motivated by the possibility of advancement. In addition, service providers benefit when they can take advantage of an employee's experience. Therefore, the service provider should take into account the skills that a service agent might need to prepare for the possibility of moving into another position closely related to the present position.

e) Peer recognition of competence provides unique value to both the service provider and the employee. When planning for training, it is appropriate that service providers at least consider how training activities can help move an employee forward to achieving that recognition through a certification program.

4.4 Acceptance testing

The health care organization shall develop and implement a system to ensure that all equipment included in the equipment management program is inspected by the assigned service agent for acceptance testing prior to its initial use.

NOTE—The service agents for the same type of equipment may be different depending upon the ownership of the equipment. For example, in a hospital, equipment owned by the hospital might be inspected by the hospital's own clinical engineering department. If the same type of equipment is rented, the hospital might choose to have the rental agent perform this inspection. If this inspection is performed by the rental agent, then the health care organization would be required to ensure the competence of the rental agent's employees.

Procedures shall be established and implemented to prevent the use of equipment that has not been acceptance tested.

NOTE—Procedures to implement this clause might include physical separation of the new equipment from the area in which it will be used, impounding the equipment in a special area, non-destructive temporary disabling of the equipment, or appropriate labeling.

Acceptance testing shall follow procedures established by the health care organization, include activities sufficient to provide reasonable assurance that the equipment functions appropriately prior to its initial use, and be documented.

NOTE—It is the intention of this recommended practice to broaden the scope of acceptance testing beyond electrical leakage current and grounding resistance testing.

The health care organization shall develop and implement procedures to ensure communication between the assigned service agent and any other departments and individuals that the health care organization decides should be informed about the status of an acceptance test. In developing this procedure, the organization should consider notification of:

a) the department using the equipment and equipment users;

b) the department responsible for approving payment for the equipment;

c) the department responsible for tracking capital assets; and

d) the department responsible for training equipment users.

Rationale: The intention of acceptance testing is to ensure that all equipment is verified to be in good operating condition prior to its initial use. Occasionally, new equipment is not manufactured properly or may be damaged in transit. Often, users are anxious to install and use new equipment but are not competent to determine whether hidden damage exists that could create a threat to the patient or the user. The requirements in this section are designed to ensure that all equipment is acceptance tested before it is placed into use and to prevent the use of equipment that has not been checked by a person competent to verify that it is in good operating condition.

The requirement to establish and implement procedures to prevent the use of equipment that has not been acceptance tested is intended to ensure that the health care organization follows a uniform set of procedures when acceptance testing is done. Acceptance testing can be very different from the scheduled testing or inspection done after the equipment is in service. The acceptance test should include enough activities to verify that the equipment is in good working condition and is safe for its intended purpose, not just that its electrical leakage current and grounding resistance fall within certain specifications.

Good communication between the service agent responsible for acceptance testing a piece of equipment and various other departments and individuals in the health care organization helps smooth the acceptance testing process, and helps guarantee that the organization is capable of properly reacting to the existence of new equipment.

a) The department using the equipment and the equipment users are often concerned about the status of their equipment. Often, equipment users must make appropriate plans to prepare for the use of new equipment. For example, plans may need to be made for removing old equipment and/or installing new equipment, or user training may be required before the new equipment can be safely used. Good communication can ensure that this transition takes place as smoothly as possible.

b) Most health care organizations do not pay for equipment before they have positive notification that it has been received. Communication between the service agent performing the acceptance test and the department responsible for payment can help ensure that a vendor receives payment in a timely manner. If equipment is not received in good working condition, some organizations choose to withhold payment until any defects are corrected.

c) Many of the items included in the equipment management program will be considered capital assets by the health care organization. As such, they often will be tracked in a financial asset inventory and will be depreciated over their useful life. The notification described in this section is

intended to allow those responsible for tracking capital assets to become aware of the arrival of a new item when appropriate.

d) User training in many health care organizations is often handled by a dedicated department (e.g., Nursing Education). If this is the case, the responsible department needs to be aware of the arrival of a new piece of equipment so the steps necessary to initiate training activities can be taken.

4.5 Scheduled inspection

The health care organization shall develop and implement a procedure for assigning inspection intervals to all equipment included in the program. The procedure should document the goals of the equipment inspection and demonstrate how the intervals selected are consistent with those goals.

Scheduled inspections shall follow the procedures described in clause 4.2.2.1.

a) The results of inspection shall be documented in accordance with clause 4.2.2.1 b).

b) Identification of failed inspections shall be tracked by equipment type to provide information necessary to modify intervals.

NOTE—The intention is to provide the information necessary to consider modification of the inspection intervals if justified by a pattern of multiple failures. This subclause does not require a change in intervals in response to one or multiple failures.

Rationale: The intention of the scheduled inspection program is to identify potential hazards caused by equipment wear and aging that are not apparent or have not been reported by the equipment operator. Establishing an appropriate inspection interval provides a mechanism for initiation of that inspection process. It is expected that the intervals assigned to equipment inspections can be justified by the needs identified by the health care organization.

This subclause requires that the inspections follow the procedures established by the organization.

a) Documentation of the results of an inspection is needed to allow verification that an inspection has taken place.

b) This subclause assumes that incidents can be prevented by identifying problems at an early stage. The more frequently inspections are performed, the more resources are utilized. The information gathered by this requirement can be used by the organization to identify an acceptable failure rate and then modify inspection intervals to achieve that rate, while controlling utilization of the health care organization's resources.

4.6 Staffing

The health care organization shall review the staffing plan of each service provider to determine whether the service provider is able to provide sufficient staff to handle anticipated activities within that organization.

Sufficient staff shall be available to perform scheduled inspections, based upon the equipment inventory and the average inspection times indicated in the procedures. Sufficient staff shall be available to perform repairs (unscheduled maintenance). Documentation will demonstrate the expected requirement for repairs based upon the health care organization's experience or other health care organization-specified criteria. The need for other activities such as documentation, training, and other program support time is taken into account when developing the staffing plan.

The requirements of this clause shall apply to all service providers, whether or not they are direct employees of the health care organization. The health care organization shall obtain documentation from any outside service providers to demonstrate that the service provider can provide sufficient staff to meet its service obligations.

NOTE—The documentation provided by the service provider need not be detailed but should be sufficient to allow the health care organization to reasonably conclude that the service provider has the staff to meet its obligations to the health care organization. At a minimum, the documentation should describe the estimated amount of labor the service provider expects to provide, and show that the available staff is capable of

providing that labor. If it provides service to more than one health care organization, the service provider should be able to demonstrate that it is capable of meeting all of its customers' expected needs.

Each service agent shall be appropriately educated, trained, experienced, licensed, and/or certified to perform the jobs assigned to that service agent.

NOTE—Minimum education requirements for a clinical engineer are generally considered to be a bachelor's degree (or equivalent qualifications in terms of education and/or experience) in an engineering or scientific area, and, for a biomedical equipment technician, an associate's degree (or equivalent qualifications in terms of education and/or experience) in an engineering or scientific area. The value of experience and certification as a clinical engineer or biomedical equipment technician should be recognized by the service provider. Job assignments should reflect the education, experience, and demonstrated capabilities of employees.

Rationale: Each service provider has committed itself to perform certain functions for the health care organization. The intention of this clause is to require demonstration that the service provider actually has the capability to meet its commitments.

The procedures and equipment inventory discussed in previous clauses of this recommended practice identify requirements for staffing. This clause requires the service provider to show that it has the labor capability to meet the requirements that the organization's inspection procedures define. In addition to scheduled inspections, unscheduled maintenance will also be required from time to time. This requirement stipulates that the labor to meet that anticipated need is also available. This clause is also intended to demonstrate that the health care organization is able to show how it developed the estimate it is using for the time needed to perform repairs.

While scheduled inspections and repairs often represent the bulk of the time commitments imposed on a service provider, other activities will also take place. This subclause is also intended to ensure that those other activities are taken into account when staffing requirements are identified.

This subclause is also intended to clarify that all service providers are expected to demonstrate that they have sufficient staff available to meet commitments. The AAMI Equipment Management Committee believes that the health care organization should know the capabilities of any contractors that it uses as part of its equipment management program, just as it should know the capabilities of its in-house employees.

The subclause also specifies that use of an outside service provider obligates the health care organization to audit the service provider's ability to comply with the staffing requirements stipulated by this recommended practice and required to provide the contracted services.

Additionally, all service agents are expected to be qualified for the work they are expected to perform. This subclause allows the service provider to establish its own qualifications, with the expectation that the qualifications of a service agent are demonstrated by a combination of appropriate education, training, experience, and certification.

4.7 Space

Sufficient space should be available to perform the work assigned to the service provider, including space for:

a) work areas;

b) equipment awaiting repair;

c) replacement parts inventory; and

d) documentation.

NOTE—In general, about 120 square feet per service agent is a reasonable minimum amount of space needed to perform the activities described. However, each health care organization may approach the issue of space differently. For example, some organizations will incorporate documentation storage and parts storage into the immediate work area, while others will have such storage in a remote location.

An adequate area shall be available for any necessary sequestration of equipment that should not be used, such as equipment awaiting acceptance testing or equipment under investigation in response to an incident.

NOTE—As indicated in the second note under subclause 4.4, Acceptance testing, several methods are allowed for preventing equipment that has not been accepted from being used. If physical sequestration of the equipment is not used by the health care organization, then space need not be allocated for this function. However, in other cases (see 4.15, for example), equipment does need to be physically removed from its normal environment (e.g., equipment involved in an incident). For such cases, policies need to be developed that clearly provide a location for the required sequestration.

Hand washing facilities shall be provided to service agents working with equipment that may expose them to potential infectious agents or other contact hazards.

Appropriate provisions shall be made to provide facilities for proper disinfection and cleaning of equipment.

NOTE—The cleaning and disinfection of equipment may or may not be the responsibility of the service provider. Regardless of how this responsibility is delegated within the health care organization, facilities must be provided for this service that are adequate to prevent unnecessary exposure of service agents to potential hazards.

Ventilation in the work area shall meet all regulatory requirements related to the adequate dissipation of vapors associated with chemicals (fluids, agents, substances, compounds, etc.) that are used in the work area.

Rationale: Space is required for the people and equipment performing the work identified in this recommended practice. While it is left to the health care organization and the service provider to identify the specific amount of space needed, the work aspects identified in 4.7 specify the major functions commonly associated with equipment maintenance that require space.

When equipment is not in service, precautions need to be taken to assure that equipment users are aware that the equipment cannot be used. In some cases, removal of equipment from its normal working environment is the best way to guarantee this. In cases where an incident has occurred, it may be imperative that equipment be placed in a secured area until an investigation can be undertaken, so that the potential for contamination of important evidence is minimized. This requirement is intended to ensure that such segregation of equipment can take place.

Hand washing has been demonstrated to be an effective means of controlling the spread of infectious agents. These infectious agents may be present on equipment serviced within the work area. Chemicals are often used for the cleaning and lubrication of equipment. Service agents should have ready access to a sink where they can properly clean their hands if exposed to such chemicals or other contact hazards.

Medical equipment can contribute to the spread of infectious agents if not properly cleaned. The health care organization should ensure that the equipment can be properly cleaned before maintenance activities start.[3]

Chemicals used for the cleaning and lubrication of equipment often produce potentially hazardous vapors. Adequate ventilation helps reduce the risk posed by these vapors.

4.8 Financial resources

The health care organization shall know the costs associated with the provision of the services necessary under the equipment management program.

The organization shall establish a budget that provides sufficient funding to meet these anticipated costs.

Rationale: A preliminary step in assessing the adequacy of funding for the equipment management function is knowing what funds are required. To accomplish this, the health care organization must know what its costs are for the equipment management program. An equipment management program can only meet its goals if allocated financial resources are sufficient to meet the identified costs.

[3] For more information, see ANSI/AAMI ST35–1996, Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings.

4.9 Tools available

Each service provider shall ensure that tools are readily available to its service agents to perform the activities described in the inspection procedures. When identifying the tools required, the service provider should consider the need for:

a) basic hand tools, such as screwdrivers and pliers;

b) larger tools, such as power drills, hammers, and wrenches;

c) basic test equipment, such as a voltmeter and an electrical leakage current analyzer;

d) specialized test equipment, such as an electrosurgical unit analyzer or a laser power output meter; and

e) any personal protective equipment required by government regulations or the service provider's safety program.

Procedures should be established and implemented to ensure the calibration of test equipment that might require periodic recalibration.

Rationale: Equipment maintenance activities generally require that certain tools are readily available. The inspection procedures identified by the organization should serve as the basis for identifying the tools required to successfully perform the inspections. Additional tools may be required to perform certain repairs. The categories of tools listed in 4.9 a) to e) are general classifications of the tools used as part of maintenance activities.

Measurements made as the basis of maintenance and calibration activities often rely on test equipment. It is generally accepted within the service industry that test equipment must be within its specified accuracy to ensure that measurements made using the test equipment are reliable. If the test equipment is determined not to be accurate, then it should be recalibrated against suitably traceable standards to bring it back to its specified accuracy.

4.10 Assessment and planning

The health care organization shall receive reports of indicators that allow the organization to determine compliance with the equipment management program. Each service provider shall develop an indicator that reflects its performance of scheduled inspections. Each service provider shall also develop an indicator that reflects its performance of repairs.

The health care organization shall have a plan to address deficiencies identified by changes in these indicators and be able to show that it uses the performance improvement process to identify and correct deficiencies.

NOTE—Performance improvement is intended to be a generic term that reflects the health care organization's efforts to improve the quality of outcomes. Other terms may be used to describe this, including total quality management, continuous quality improvement, etc.

Each service provider shall implement a performance improvement process that:

a) is designed to assess the organization's performance annually; and

b) is used to plan for any changes that are reasonably anticipated based upon the information gathered by the assessment.

Rationale: Performance improvement activities require that indicators be monitored to help determine the current quality of actions performed as part of the equipment management program. A fundamental part of the equipment management program is the performance of scheduled inspections. Therefore, each service provider is expected to develop an indicator that reflects its performance of those inspections.

Equipment repairs (unscheduled maintenance) are another fundamental part of the equipment management program. Therefore, each service provider is expected to develop an indicator that reflects its performance of repairs.

As indicators are monitored, their values will vary. If the indicators show a deficiency, the health care organization should have a plan to react to that deficiency. Those plans should be consistent with the health care organization's overall approach to the performance improvement process.

In addition, performance improvement programs provide a formal method for ensuring that an organization can respond positively to the changes it encounters.

a) Annual assessment of the service provider's performance provides a basis for future improvements. Designing a process provides a way to formalize that assessment.

b) The assessment process should include anticipation of changes that may be required to continue providing the health care organization with the services that it expects.

4.11 Equipment selection

The health care organization's experience with equipment and equipment vendors shall be considered as part of the health care organization's program for the purchase of new equipment. The program shall document the equipment selection process and demonstrate that the health care organization's experience is utilized as part of the equipment selection process.

Rationale: Decisions about equipment selection should receive input based on the experience gained as part of the equipment management program. The program should be expected to provide, at a minimum, experience related to equipment types and equipment vendors. The equipment selection process should be documented to assure that the health care organization can follow its process. Documentation should also demonstrate that the experience gathered through the equipment management program is actually used when new equipment is purchased.

4.12 Removal from service

The health care organization shall establish and implement a policy for the removal from service of equipment determined to be unsafe or no longer suitable for its intended application.

The health care organization may include other criteria when deciding whether to replace or retire equipment, such as the dependability of the equipment or the cost of ownership.

Rationale: A particular concern in some health care organizations is the tendency to continue using old equipment even after it has been determined that the equipment is no longer safe or no longer working appropriately. This provision requires that the health care organization have appropriate policies in place to remove equipment that should not be used.

Sometimes, even if equipment of this type is not actively used, it might be placed in storage for use as back-up equipment, due to the cost of purchasing new equipment. This can create problems if the equipment is used. Equipment placed in storage will often deteriorate simply because of the effects of time on components. Once in storage, the regular program of equipment inspections may be suspended. This saves inspection time on equipment that is unlikely to be used, but if the equipment is eventually used without an appropriate inspection, there is a higher likelihood of a problem that could endanger the user or the patient. If stored equipment is kept in the equipment management program, then resources will be devoted to its inspection on a regular basis, even if the equipment is unlikely to be used.

While the primary objective of this section is to ensure that equipment that is no longer safe for its intended use is removed from service, other appropriate criteria, such as dependability and cost, will be used by an organization to determine when equipment should be replaced.

4.13 Communication between service agents and service providers

NOTE—Requirements in this subclause concern the relationship between a service provider, its employees, and the health care organization. As such, it applies to those employees of the service provider who can be expected to perform work on behalf of the health care organization on a regular basis (at least once per

calendar quarter). It is not intended to be a requirement for communication between the service provider and all of its employees.

The service provider shall communicate with its employees who provide service in the health care organization about the following:

a) service provider operations, especially changes in those operations; and

b) health care organization operations, especially changes that can be expected to have an impact on the service provider.

These service provider employees shall communicate with the service provider management about any changes in the health care organizations in which they work that impact on the service provider.

The service provider should hold at least one staff meeting per month with these employees to exchange the information described in 4.13 a) and b).

NOTE—The format of this meeting (gathering in a central location, telephone conference call, video conference, etc.) may be selected by the service provider to best meet its needs. This meeting need not be a meeting of the service provider's entire staff; however, the meeting must be structured in a way that encourages two-way communication between the service provider and such employees.

Rationale: The actual services furnished by a service provider are performed by its service agents. Adequate communication between the service provider and its employees helps guarantee that the service provider is capable of delivering the services expected in an environment that is subject to frequent change.

Service agents should be knowledgeable about the service provider that employs them, particularly concerning any changes taking place within the service provider. Also, as service agents work on behalf of a health care organization, they should be knowledgeable about changes in the operation of that health care organization, especially those changes that may affect their own service provider.

Because service agents are in frequent contact with the health care organizations in which they are working, they will often receive information that could have an impact on their service provider. These service agents have an obligation to pass that information to the management of the service provider so that it can respond effectively and appropriately to those changes.

At least one formal mechanism should exist to promote the information exchange described in 4.13 a) and b). A monthly staff meeting was considered to be the minimum necessary to ensure that appropriate communication will take place.

4.14 Communication between the service provider and the health care organization

The health care organization's administration shall provide to the service provider timely information on an ongoing basis that can affect the equipment management program.

The service provider shall provide timely information on an ongoing basis regarding:

a) the inspection status of the health care organization's equipment; and

b) conditions that indicate a need for additional user training.

The health care organization and the service provider shall establish a procedure for the method and frequency of these reports. The service provider shall communicate relevant information about equipment failures and user errors to the health care organization's safety officer, safety committee, quality improvement committee, or risk management committee, as appropriate. As an alternative, the appropriate committee may assign a designated representative to receive these reports who will analyze the reports and then communicate significant information to the committee.

Rationale: In order to respond effectively to changes that may take place within the health care organization and the service provider, good communication must exist between the two groups. This requirement is intended to ensure that any needed communication takes place.

As part of its routine activities, the service provider gathers certain information about equipment. Ultimately, it is the obligation of the health care organization to guarantee that any needed information is distributed to the people who require it. The service provider is expected to facilitate this information distribution by working with equipment users to confirm that they know the inspection status of their equipment and are familiar with any problems that may indicate a need for additional user training.

a) Knowledge about the inspection status of equipment is important for users so that they can assist in making equipment available for inspection when those inspections are due.

b) Many equipment problems are the result of improper operation of the equipment. As the service provider determines that problems could be the result of user errors, it should provide that information to the equipment users so that they can make arrangements to obtain additional user training.

The responsibility for the investigation of equipment failures and user errors rests with the health care organization's safety officer, safety committee, quality improvement committee, or risk management committee. Therefore, to ensure that the appropriate committee is kept aware of significant equipment management issues, the service provider should report information to the safety officer or appropriate committee.

4.15 Incident investigation and failure analysis

The health care organization shall assign an appropriately qualified person to participate in the investigation of incidents related to the malfunction or misuse of equipment.

Information about these failures shall be shared with appropriate health care organization personnel (such as the safety officer, safety committee, quality improvement committee, or risk management committee, along with those within the organization responsible for determining the equipment inventory inclusion criteria, and those responsible for selecting new equipment).

When not constrained by legal requirements or patient confidentiality requirements, the health care organization and the service provider should consider reporting relevant information to private organizations that compile, investigate, and publish information about equipment failures.

The health care organization shall develop and implement policies for the removal of equipment from service until an incident in which the equipment has been involved is appropriately investigated. Equipment involved in an incident, along with any accessories (including disposables) in use at the time of the incident, shall be appropriately secured against tampering until the incident has been investigated. The health care organization's legal counsel must review and provide consent for the following:

a) release to the manufacturer for repair of the equipment;

b) release to any party for investigation of the incident;

c) release for normal use.

When appropriate, changes shall be made to prevent the reoccurrence of incidents.

Rationale: When incidents related to equipment occur, it is important that they be investigated by a qualified individual to verify that a proper analysis is performed and to protect the health care organization's legal rights. Information about equipment incidents must be reported to the appropriate health care organization committee so that the committee can provide the oversight necessary for appropriate actions to be taken to prevent a repetition of the incident.

If an equipment-related incident occurs, the equipment involved and any accessories (including disposables) in use at the time of the incident should be collected, marked, and removed from service.

Often, an equipment-related incident involves misuse or malfunction of the equipment accessories and/or disposables, rather than just the equipment itself. A reconstruction of the event or a thorough investigation may not be possible without proper identification and secure storage of the associated accessories and

disposables. All such equipment and associated accessories must be safely secured until the incident has been properly investigated and until potential legal aspects of the incident are identified.

Policies that address the impounding of the equipment involved in an incident facilitate this process. A storage location within the health care organization must be identified to permit equipment to be impounded while an investigation is ongoing. A health care organization's ability to defend itself in legal proceedings could be impaired if repairs are made. Review by legal counsel will help assure that the health care organization's legal rights are properly protected and that its responsibilities are properly exercised.

Any equipment involved in an incident should not be used until an appropriate investigation has been completed. Review by legal counsel helps confirm that the investigation has been concluded in a way that takes the health care organization's legal rights and responsibilities into consideration.

Equipment-related incidents may indicate a deficiency in the operation of the health care organization or service provider. If a deficiency is identified, appropriate steps should be taken to correct that deficiency, and so protect others who may be affected by the operation of the equipment.

Depending upon the severity of the incident, reporting may be required under the Safe Medical Devices Act of 1990 (see also 4.1.1 d). Voluntary mechanisms also exist for collecting and widely disseminating information about defects in medical equipment. Voluntary programs include ECRI's Health Devices Alerts program and the Food and Drug Administration's Medwatch program. Distributing appropriate information about incidents through programs such as these can alert other health care organizations to the need for corrective actions or caution in relation to certain equipment.

Section 4.1.1 d) requires that a health care organization consider the experience of other organizations in deciding what to include in its equipment management program. The requirement in 4.15 is intended to complement that requirement by encouraging a health care organization to provide feedback into a mechanism that organizations can use to benefit from the experience of others.

4.16 Safe Medical Devices Act

Each service provider shall participate, as appropriate, in the health care organization's program of compliance with the Safe Medical Devices Act of 1990, as implemented through appropriate regulations issued by the Food and Drug Administration.

Rationale: Compliance with the Safe Medical Devices Act of 1990, which identifies reporting responsibilities when an equipment failure leads to a death or serious injury, is required by federal law. Each service provider should be prepared to work with the health care organization's program of compliance with this act.

Annex A
(informative)

Bibliography

1. AOA Accreditation Requirements: Acute Care Hospitals; Division of Hospital Accreditation, Department of Education, American Osteopathic Association, Chicago, Illinois, 1992.

2. Comprehensive Accreditation Manual for Hospitals—The Official Handbook; 1998 edition; Joint Commission on Accreditation of Health care Organizations, Oakbrook Terrace, Illinois, 1997.

3. Health Devices Sourcebook, 1998: Health care Planning and Purchasing Directory with Official International Nomenclature, ECRI, Plymouth Meeting, PA, 1997.

4. Medical Device Register 1998: The Official Directory of Medical Suppliers, Medical Economics Data, Montvale, New Jersey, 1998.

5. Medical Device User Facility and Manufacturer Reporting, Certification and Registration; Delegations of Authority; Medical Device Reporting Procedures; Final Rules; Department of Health and Human Services, Food and Drug Administration, 21 CFR Parts 803 and 807, as published in the Federal Register: December 11, 1995 (Volume 60, Number 237), pages 63577–63606 (these are the implementing regulations for the SMDA of 1990 and MDA of 1992).[4]

6. The Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992, U.S. Dept. of Health and Human Services, Public Health Service/Food and Drug Administration, Center for Devices and Radiological Health, Washington, D.C., 1993 (this is a pamphlet explaining this legislation).

[4] At the time of the publication of this American National Standard, the pamphlet, Medical Device Reporting for User Facilities, was available from the FDA's website at http://www.fda.gov.