

Prepublication Requirements

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Standards Revisions Related to Medical Equipment and Utility System Maintenance

APPLICABLE TO CRITICAL ACCESS HOSPITALS

Effective January 1, 2015

Environment of Care (EC)

Standard EC.02.04.01

The critical access hospital manages medical equipment risks.

Elements of Performance for EC.02.04.01

A 2. [Ⓧ] The critical access hospital maintains either a written inventory of all medical equipment or a written inventory of selected equipment categorized by physical risk associated with use (including all life-support equipment) and equipment incident history. The critical access hospital evaluates new types of equipment before initial use to determine whether they should be included in the inventory. (See also EC.02.04.03, EPs 1 and 3). [Ⓡ]

C 3. [Ⓧ] The critical access hospital identifies high-risk medical equipment on the inventory for which there is a risk of serious injury or death to a patient or staff member should the equipment fail. (See also EC.02.04.03, EP 2)

Note: *High-risk medical equipment includes life-support equipment.*

The concepts of previous EPs 3 and 4 were merged in the revised EP 4.

C 3. [Ⓧ] The critical access hospital identifies, in writing, the activities for maintaining, inspecting, and testing for all medical equipment on the inventory. (See also EC.02.04.03, EPs 2 and 3; PC.02.01.09, EP 3)

Note: *Critical access hospitals may use different strategies for different items as appropriate. For example, strategies such as predictive maintenance, reliability-centered maintenance, interval-based inspections, corrective maintenance, or motorized maintenance may be selected to ensure reliable performance.* [Ⓡ]

A 4. [Ⓧ] The critical access hospital identifies, in writing, frequencies for inspecting, testing, and maintaining medical equipment on the inventory based on criteria such as manufacturers' recommendations, risk levels, or current hospital experience. (See also EC.02.04.03, EPs 2 and 3) [Ⓡ]

A 4. [Ⓧ] The critical access hospital identifies the activities and associated frequencies, in writing, for maintaining, inspecting, and testing all medical equipment on the inventory. These activities and associated frequencies are in accordance with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program. (See also EC.02.04.03, EP 2)

Note: *The strategies of an AEM program must not reduce the safety of equipment and must be based on accepted standards of practice.* * [Ⓡ]

* An example of standards for a medical equipment program is the American National Standards Institute/Association for the Advancement of Medical Instrumentation handbook ANSI/AAMI EQ56: 2013, Recommended Practice for a Medical Equipment Management Program.

Key: **A** indicates scoring category A; **C** indicates scoring category C; [Ⓧ] indicates that documentation is required; [Ⓜ] indicates Measure of Success is needed; [⚠] indicates an Immediate Threat to Health or Safety; [⚡] indicates situational decision rules apply; [⚡] indicates direct impact requirements apply; [Ⓡ] indicates an identified risk area

A 5. Ⓓ The critical access hospital's activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers' recommendations:

- Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining be in accordance with the manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements
- Medical laser devices
- Imaging and radiologic equipment (whether used for diagnostic or therapeutic purposes)
- New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies

Note: Maintenance history includes any of the following documented evidence:

- Records provided by the hospital's contractors
- Information made public by nationally recognized sources
- Records of the critical access hospital's experience over time

A 6. Ⓓ A qualified individual(s) uses written criteria to support the determination whether it is safe to permit medical equipment to be maintained in an alternate manner that includes the following:

- How the equipment is used, including the seriousness and prevalence of harm during normal use
- Likely consequences of equipment failure or malfunction, including seriousness of and prevalence of harm
- Availability of alternative or backup equipment in the event the equipment fails or malfunctions
- Incident history of identical or similar equipment
- Maintenance requirements of the equipment

(For more information on defining staff qualifications, refer to Standard HR.01.02.01)

C 7. Ⓓ The critical access hospital identifies medical equipment on its inventory that is included in an alternative equipment maintenance program.

A 5 8. The critical access hospital monitors and reports all incidents in which medical equipment is suspected in or attributed to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990. **R**

A 6 9. Ⓓ The critical access hospital has written procedures to follow when medical equipment fails, including using emergency clinical interventions and backup equipment. **⚠ R**

Standard EC.02.04.03

The critical access hospital inspects, tests, and maintains medical equipment.

Elements of Performance for EC.02.04.03

C 1. Before initial use and after major repairs or upgrades of medical equipment on the medical equipment inventory, the critical access hospital performs safety, operational, and functional checks. (See also EC.02.04.01, EP 2) **⚠ R**

A 2. Ⓓ The critical access hospital inspects, tests, and maintains all ~~life-support~~ high-risk equipment. These activities are documented. (See also EC.02.04.01, EPs 3 and 4; PC.02.01.09, EP 8; PC.02.01.11, EP 2)

Note: High-risk medical equipment includes life-support equipment. **⚠ R**

C 3. Ⓓ The critical access hospital inspects, tests, and maintains non-~~life-support~~ high-risk equipment identified on the medical equipment inventory. These activities are documented. (See also EC.02.04.01, ~~EPs 2-4;~~ PC.02.01.09, EP 8; PC.02.01.11, EP 2) **Ⓜ R**

Standard EC.02.05.01

The critical access hospital manages risks associated with its utility systems.

Elements of Performance for EC.02.05.01

A 2. Ⓓ The critical access hospital maintains a written inventory of all operating components of utility systems or maintains a written inventory of selected operating components of utility systems based on risks for infection, occupant needs, and systems critical to patient care (including all life-support systems). The critical access hospital evaluates new types of utility components before initial use to determine whether they should be included in the inventory. (See also EC.02.05.05, EPs 1, 3-5)

C 3. Ⓓ The critical access hospital identifies high-risk operating components of utility systems on the inventory for which there is a risk of serious harm or death to a patient or staff member should the component fail.

Note: High-risk utility system components include life-support equipment.

The concepts of previous EPs 3 and 4 were merged in the revised EP 4.

C 3. Ⓓ The critical access hospital identifies, in writing, inspection and maintenance activities for all operating components of utility systems on the inventory. (See also EC.02.05.05, EPs 3-6; EC.02.05.09, EP 1)

Note 1: Critical access hospitals may use different approaches to maintenance. For example, activities such as predictive maintenance, reliability-centered maintenance, interval-based maintenance, corrective maintenance, or motorized maintenance may be selected to ensure dependable performance.

Note 2: For guidance on maintenance and testing activities for Essential Electric Systems (Type I), see NFPA 99, 1999 edition (Section 3-4.4).

A 4. Ⓓ The critical access hospital identifies, in writing, the intervals for inspecting, testing, and maintaining all operating components of the utility systems on the inventory, based on criteria such as manufacturers' recommendations, risk levels, or hospital experience. (See also EC.02.05.05, EPs 3-6)

A 4. Ⓓ The critical access hospital identifies the activities and associated frequencies, in writing, for inspecting, testing, and maintaining all operating components of utility systems on the inventory. These activities and associated frequencies are in accordance with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program.

Note 1: The strategies of an AEM program must not reduce the safety of equipment and must be based on accepted standards of practice. *

Note 2: For guidance on maintenance and testing activities for Essential Electric Systems (Type I), see NFPA 99, 1999 edition (Section 3-4.4).

** An example of guidelines for physical plant equipment maintenance is the American Society for Healthcare Engineering (ASHE) book Maintenance Management for Health Care Facilities.*

A 5. Ⓓ The critical access hospital's activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers' recommendations:

- Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining be in accordance with the manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements
- New operating components with insufficient maintenance history to support the use of alternative maintenance strategies

Note: Maintenance history includes any of the following documented evidence:

- Records provided by the critical access hospital's contractors
- Information made public by nationally recognized sources
- Records of the hospital's experience over time

A 6. Ⓓ A qualified individual(s) uses written criteria to support the determination whether it is safe to permit operating components of utility systems to be maintained in an alternate manner that includes the following:

- How the equipment is used, including the seriousness and prevalence of harm during normal use
- Likely consequences of equipment failure or malfunction, including seriousness of and prevalence of harm
- Availability of alternative or backup equipment in the event the equipment fails or malfunctions
- Incident history of identical or similar equipment
- Maintenance requirements of the equipment

(For more information on defining staff qualifications, refer to Standard HR.01.02.01)

C 7. Ⓓ The critical access hospital identifies operating components of utility systems on its inventory that is included in an alternative equipment maintenance program.

A 5 14. The critical access hospital minimizes pathogenic biological agents in cooling towers, domestic hot- and cold-water systems, and other aerosolizing water systems. ^A

A 6 15. In areas designed to control airborne contaminants (such as biological agents, gases, fumes, dust), the ventilation system provides appropriate pressure relationships, air-exchange rates, and filtration efficiencies.

Note: *Areas designed for control of airborne contaminants include spaces such as operating rooms, special procedure rooms, delivery rooms for patients diagnosed with or suspected of having airborne communicable diseases (for example, pulmonary or laryngeal tuberculosis), patients in “protective environment” rooms (for example, those receiving bone marrow transplants), laboratories, pharmacies, and sterile supply rooms. For further information, see Guidelines for Design and Construction of Health Care Facilities, 2010 edition, administered by the Facility Guidelines Institute and published by the American Society for Healthcare Engineering (ASHE).* ^A **R**

A 7 16. ^D The critical access hospital maps the distribution of its utility systems.

Standard EC.02.05.05

The critical access hospital inspects, tests, and maintains utility systems.

Note: *At times, maintenance is performed by an external service. In these cases, critical access hospitals are not required to possess maintenance documentation but must have access to such documentation during survey and as needed.*

Elements of Performance for EC.02.05.05

C 1. ^D The critical access hospital tests utility system components on the inventory before initial use and after major repairs or upgrades. The completion date of the tests is documented. (See also EC.02.05.01, EP 2)

A 3. ^D **The critical access hospital inspects, tests, and maintains the following:** ~~Life-support~~High-risk utility system components on the inventory. These activities are documented. (See also EC.02.05.01, EPs 2-4)

Note: *High-risk utility system components include life-support utility system components.* ^A **R**

A 4. ^D **The critical access hospital inspects, tests, and maintains the following:** Infection control utility system components on the inventory. These activities are documented. (See also EC.02.05.01, EPs ~~2-4~~ 2 and 4) ^A **R**

C 5. ^D **The critical access hospital inspects, tests, and maintains the following:** ~~Non-life-support~~high-risk utility system components on the inventory. These activities are documented. (See also EC.02.05.01, EPs ~~2-4~~ 2 and 4) ^M