



2009

THE PHYSICAL ENVIRONMENT

MEDICAL EQUIPMENT


George Mills, Senior Engineer
Standard Interpretation Group
The Joint Commission



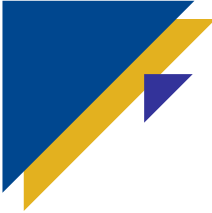
OVERVIEW

STANDARDS IMPROVEMENT INITIATIVE (SII)

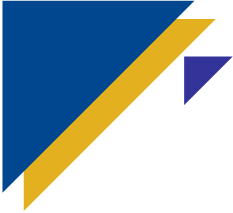
RE-STRUCTURING HIGHLIGHTS

- 
- ▶ SII did not create any new requirements
 - Deeming language added for clarity
 - ▶ Replaced bulleted lists with expanded Elements of Performance
 - ▶ Enhance clarity and objectivity of standards and EPs
 - Removed words like “appropriate”
 - ▶ Three chapters are the Physical Environment
 - Management of the Environment of Care
 - Emergency Management Chapter
 - Life Safety Chapter

RE-STRUCTURING HIGHLIGHTS

- 
- ▶ Environment of Care (EC)
 - ❑ Merging Safety & Security
 - ❑ Training moved from HR to EC
 - ▶ Life Safety Chapter (LS)
 - ❑ Compliance with the Life Safety Code
 - ❑ Moved ILSM from EC
 - ▶ Emergency Management (EM)
 - ❑ Major changes carried over from 2008
 - ❑ Hazard Vulnerability Analysis (HVA)
 - ❑ Emergency Operations Plan (EOP)

CMS DEEMING ISSUE

- 
- ▶ Joint Commission is required to reconcile our Elements of Performance (EP) with CMS Conditions of Participation (COP)
 - ▶ COPs are the expectations of compliance CMS has related to Medicare/Medicaid reimbursements
 - COPs are federal laws
 - ▶ To reconcile the Joint Commission has added ~~5~~ [1] additional ~~EPs~~
 - ▶ None of these are beyond the current expectations of the Joint Commission

CMS DEEMING ISSUE: SPECIFICS

▶ *EC.02.02.01 EP 14*

- ❑ *Testing badges for exposure from radiology*

▶ *EC.02.02.01 EP 15*

- ❑ *Free from ionizing hazards for patients & staff*

▶ *EC.02.04.03 EP 14*

- ❑ *Staff maintain nuclear medicine equipment annually*

▶ *EC.02.06.01 EP 20*

- ❑ *Environment is clean, sanitary and free of odors*

▶ LS.01.01.01 EP 4

- ❑ Maintain documentation of any inspections or approvals by AHJs related to fire safety

SCORING & DECISION PROCESS



Scoring Scale

- ❑ 0 = Insufficient Compliance
- ❑ 1 = Partial Compliance
- ❑ 2 = Full Compliance

Requirement for Improvement (RFI)

- ❑ All findings of less than full compliance will be cited as a RFI
- ❑ All RFIs require resolution through an Evidence of Standards Compliance (ESC)
 - This includes findings scored partial
 - “Supplemental Findings” (2008 term) are eliminated

EP SCORING CATEGORIES



A: Structural requirements

- ❑ EP's scored yes (2) or no (0)
- ❑ May address issues requiring full compliance

C: Based on number of times an EP is not met

- ❑ Score 2: 0-1 instances of non-compliance
- ❑ Score 1: 2 instances of non-compliance
- ❑ Score 0: ≥ 3 instances of non-compliance
 - Above is based on a sample of 10

NOTE: The 'B' Category has been eliminated

EXAMPLE: CATEGORY A



EC.02.04.01 EP 2:

The hospital inspects, tests & maintains all **life support** equipment. These activities are documented.

- Did you do it? Yes or No [100%]
- Is there documentation?

EXAMPLE: CATEGORY C

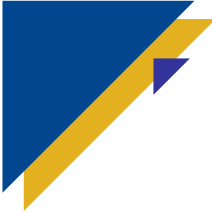


EC.02.04.01 EP 3:

The hospital inspects, tests & maintains all **non-life** support equipment **identified on the medical inventory**. These activities are documented.

- How many times did you **not** do it?
- Is there documentation?

CRITICALITY



Criticality defined as *“the immediacy of risk to patient safety or quality of care as a result of noncompliance with a Joint Commission requirement.”*

4 Levels of Criticality

1. Immediate Threat to Life (ITL)

- PDA until resolved

2. Situational Decision Rules

- Based on specific situations at time of survey

3. Direct Impact Requirements

- Noncompliance may create an immediate risk to patient safety or quality of care

4. Indirect Impact Requirements

- Based on planning and evaluation of care processes

2009 SCORING DECISION MODEL



**Immediacy of risk to patient care
and the organization's
certification status**

**Timeline for resolution of
non-compliant findings**

Higher

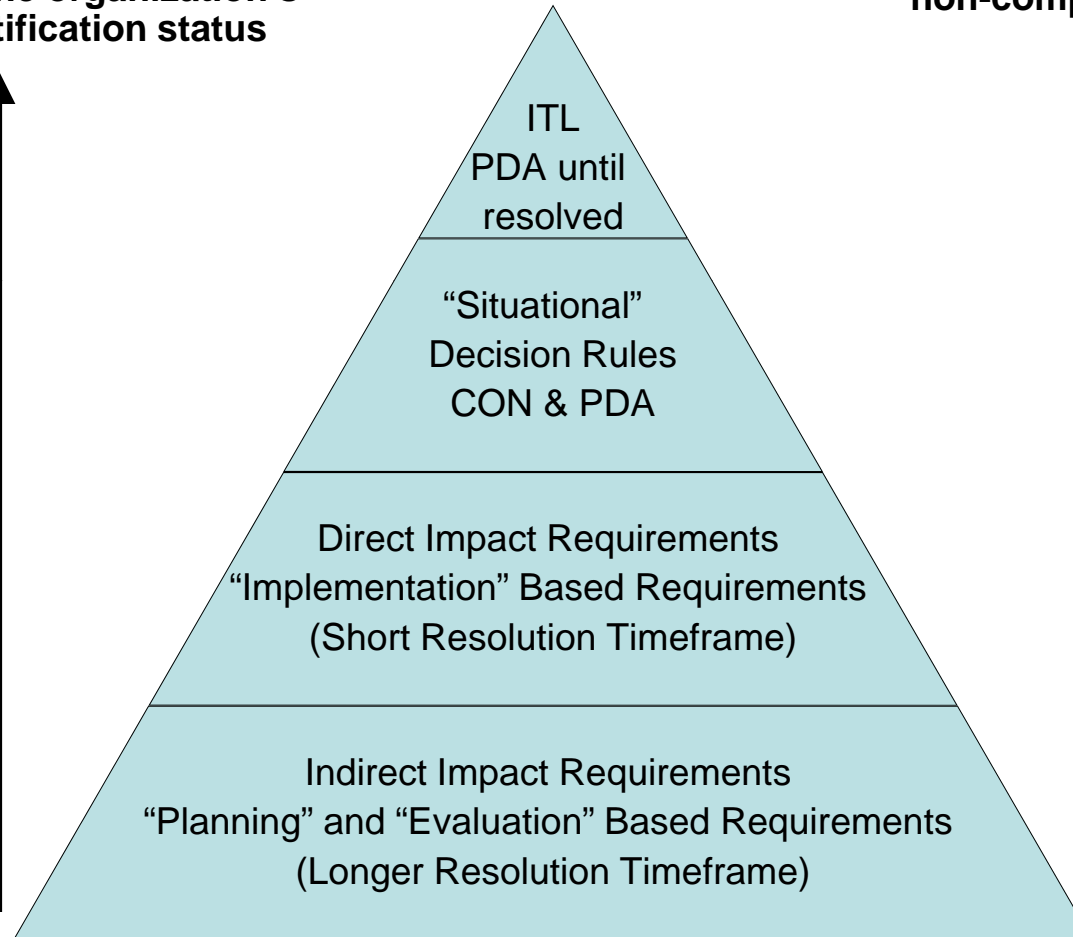


Lower

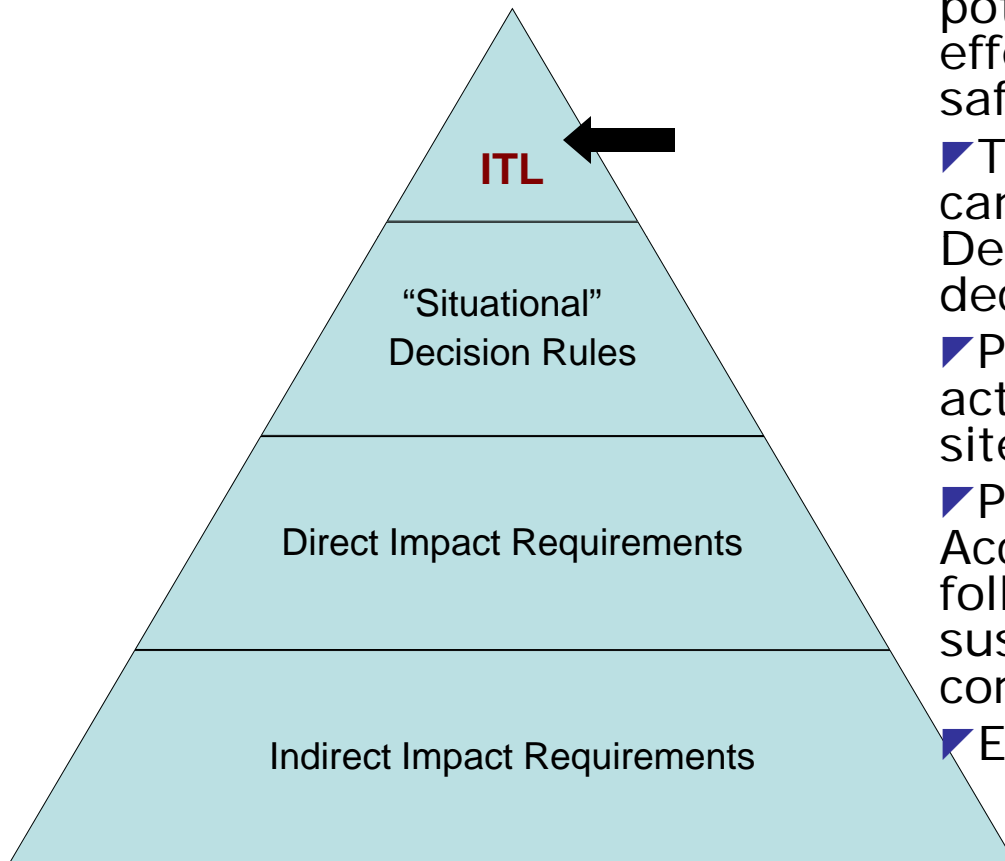
Shorter



Longer



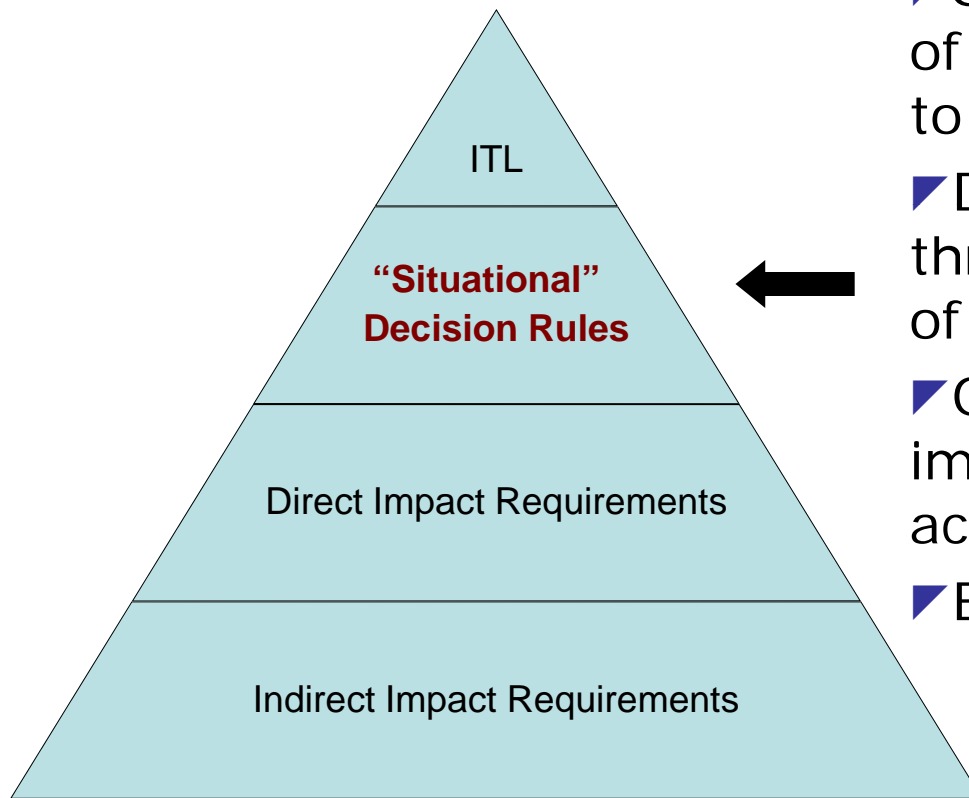
2009 SCORING DECISION MODEL



Immediate Threat to Life

- ▀ Situations, identified during survey, which have or may potentially have a serious adverse effect on patient health and safety.
- ▀ The Joint Commission President can issue an expedited Preliminary Denial of Accreditation (PDA) decision.
- ▀ PDA remains until corrective action is demonstrated, via an on-site validation review.
- ▀ PDA changes to Conditional Accreditation which includes a follow-up review to assess sustained implementation of corrective action.
- ▀ Examples:
 - ❑ Inoperable fire alarm system
 - ❑ Lack of Master Alarms for Medical Gas System

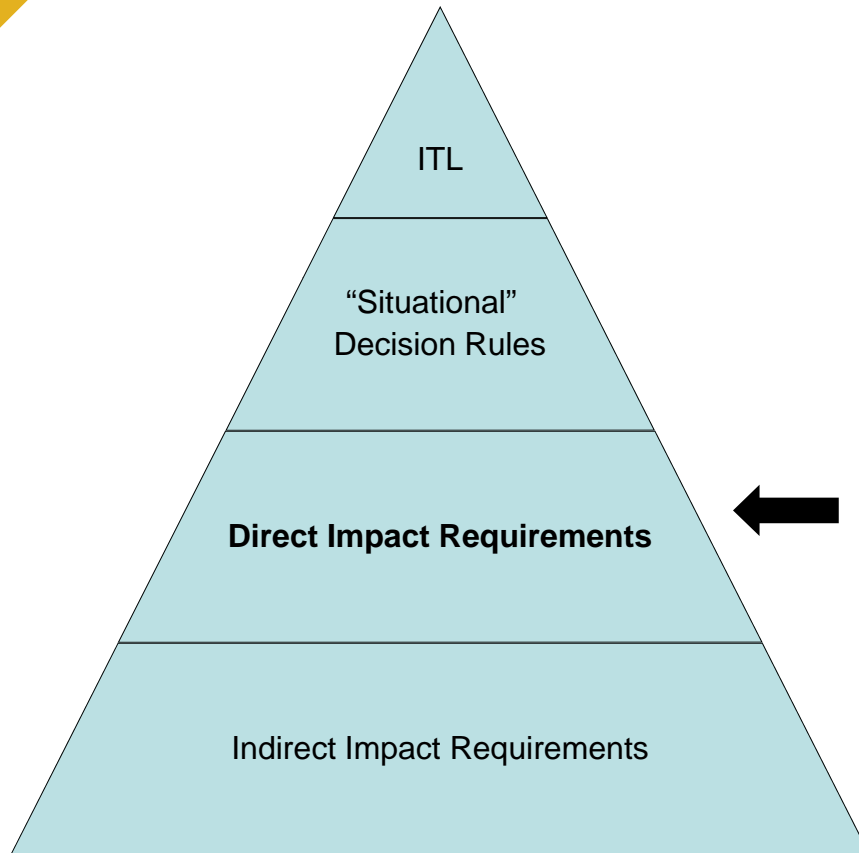
2009 SCORING DECISION MODEL



Situational Decision Rules

- ▶ Situations in which a decision of PDA or CON is recommended to the Accreditation Committee
- ▶ Demonstration of resolution through submission of Evidence of Standards Compliance (ESC).
- ▶ Onsite review to validate implementation of corrective action.
- ▶ Examples:
 - ❑ Failure to implement corrective action in response to accepted PFI
 - ❑ unlicensed facility

2009 SCORING DECISION MODEL



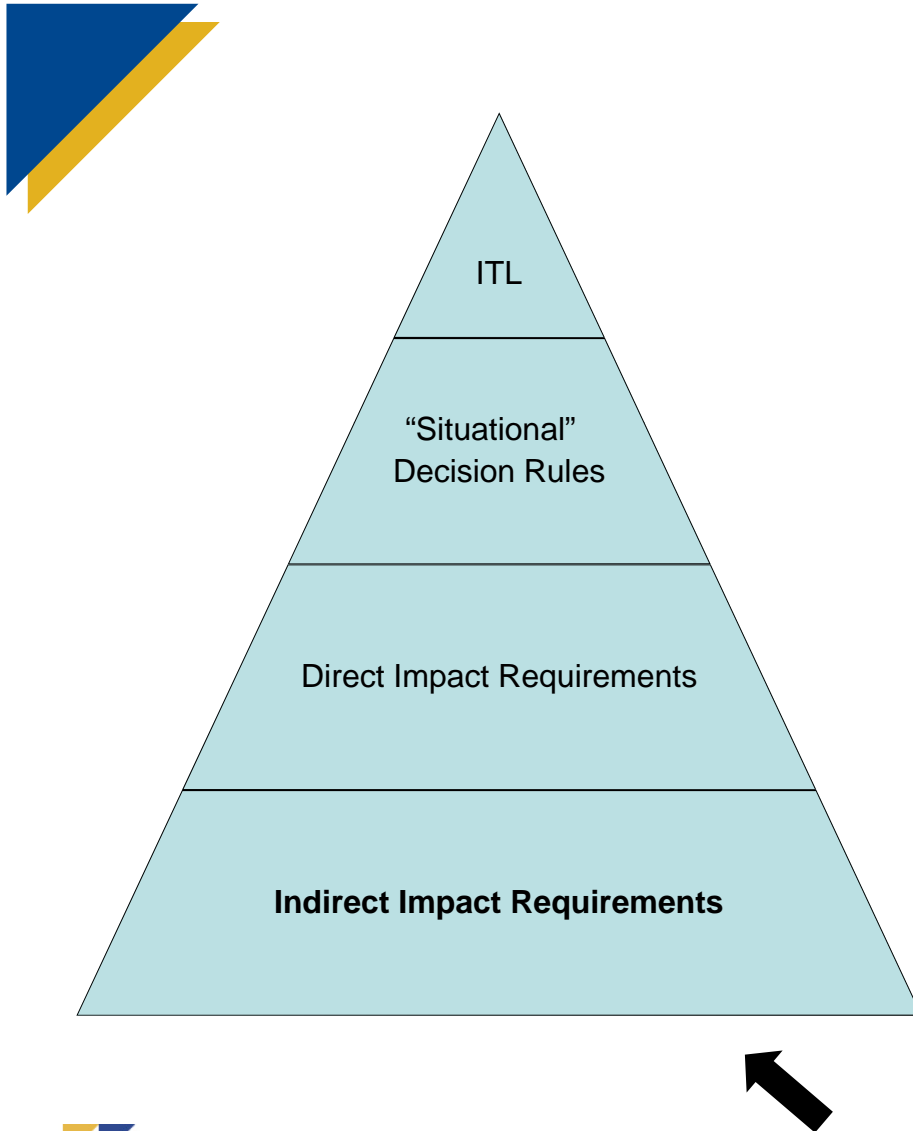
Direct Impact Requirements

- ▶ Non-compliance results in direct impact on quality of care and patient safety
- ▶ "Implementation" based requirements
- ▶ Non-compliant requirements must be addressed via ESC submission process
 - ❑ **Short time-frame (45 days)**
- ▶ Decision is pending submission of ESC within established timeframe
- ▶ Failure to resolve results in progressively more adverse decision (e.g., Provisional, Conditional, PDC)
- ▶ Example:
 - ❑ Inspects, tests & maintains Life Support Systems

2009 SCORING DECISION MODEL

Indirect Impact Requirements

- ▶ Initially less immediacy of risk; failure to resolve non-compliance increases risk
- ▶ “Planning” and “Evaluation” based requirements
- ▶ Non-compliant requirements must be addressed via ESC submission process
 - ❑ **Longer time-frame (60 days)**
- ▶ Decision is pending submission of ESC within established timeframe
- ▶ Failure to resolve = progressively more adverse certification decision (e.g., Provisional, Conditional, PDC)
- ▶ Examples:
 - ❑ Piping used for AASS is not used to support any other item
 - ❑ Hospital provides storage space to meet patient needs



DIRECT IMPACT COUNT



Environment of Care

- 38 Direct Impact


- 5 Direct Impact in EC.02.04

Life Safety Chapter

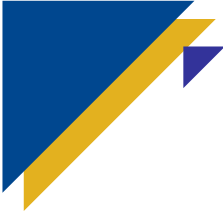
- 56 Direct Impact

Emergency Management

- 3 Direct Impact



INTERNAL INTENSIVE REVIEW



- Quantitative measure for identifying organization whose survey findings should be subject to a more intensive review by Central Office

- Bands of screening points have been established to adjust for differences in size and complexity

- | <u>HAP Screening Points:</u>
Surveyor Days | # Non-compliant
Direct Impact Stds |
|---|---------------------------------------|
| 1 – 4 | 7 |
| 5 – 6 | 8 |
| 7 – 9 | 9 |
| 10 – 13 | 11 |
| ≥ 14 | 13 |



SURVEY PROCESS

SURVEY METHODS




Tracer Methodology

- ❑ An opportunity to deviate from routine survey strategies
- ❑ User & Maintainer Interviews

Document Review

- ❑ 8 of 11 Elements of Performance require documentation
- ❑ Documentation may be reviewed during
 - Touring
 - EC Session

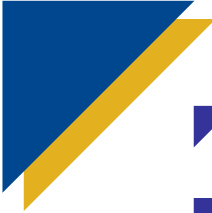
OBSERVED **BUT** CORRECTED ON SITE




Findings that are appropriately documented as "Observed but Corrected On-Site" have the following characteristics:

- ▶ The deficiencies are easily corrected and do not pose a significant threat to patient safety.
- ▶ The correction should not require any organizational planning or forethought
- ▶ The practice is correct but the policy needed amending to coincide with the practice, so the policy was amended
- ▶ Corrections to a form that was missing an element or piece of information and the change would not impact the process

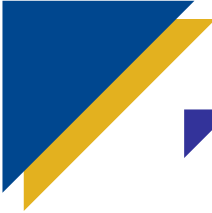
CORRECT USE OF “OBSERVED BUT CORRECTED ON SITE”

- 
- ▶ Gap in ceiling tile that is repositioned
 - ▶ Stretcher or gurney blocking medical gas shut-off valves that could easily be moved
 - ▶ Food cart parked in front of a fire extinguisher but can be easily moved
 - ▶ Partially burned out exit light that is corrected on discovery
 - ▶ Refrigerator logs missing a few dates, but temperatures before and after missing dates are within range—no evidence of any trends (could be applied to other types of logs)

WHEN **NOT** TO ALLOW “CORRECTED ON SITE”

- 
- ▶ Penetrations in a rated barrier
 - ▶ A policy is written or amended during survey that requires change in practice, education of staff and/or implementation
 - ▶ Adding a suicide risk assessment to an assessment form (would require careful consideration of the population served, education of the staff in terms of conducting the assessment, etc)
 - ▶ Multiple fire doors fail to latch

TIME DEFINED

- 
- ▶ For the Physical Environment the Joint Commission has defined time in the **Introduction** of the EC chapter:
 - ▶ Daily, weekly, monthly and quarterly are calendar references
 - ▶ Semi-annual is 6 months from last occurrence +/- 20 days
 - ▶ Annual is 12 months from last occurrence +/- 30 days



MEDICAL EQUIPMENT MANAGEMENT

EC.02.04.01
EC.02.04.03

SII MEDICAL EQUIPMENT



EC.1.01.01

The hospital plans to minimize risks in the environment of care. Note: One or more persons can be assigned to manage risks associated with the management plans described in this standard.

- 7 The hospital has a written plan for: managing medical equipment. (see also EC.04.01.01 EP 1) **A, D**

SII MEDICAL EQUIPMENT



EC.04.01.01 The hospital manages medical equipment risks.

EP 1 The hospital solicits **input from individuals who operate and service equipment** when it selects and acquires equipment. **A**

EP 2 The 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 hospital **evaluates new types of equipment before initial use to determine** whether they should be included in the inventory (see also EC.01.01.01 EP 7) **C, D**


LIFE SUPPORT DEVICES



The following definition appears in the glossary of the Comprehensive Accreditation Manual:

Life Support Equipment: Any device used for the purpose of sustaining life and whose failure to perform its primary function, when used according to manufacturer's instructions and clinical protocol, will lead to patient death in the absence of immediate intervention (examples include ventilators, heart-lung bypass machines).

SII MEDICAL EQUIPMENT (EC.02.04.01)



3 The hospital identifies the activities for maintaining, inspecting and testing for all medical equipment on the inventory.

Note: 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 metered maintenance may be selected to ensure reliable performance. **C, D**

ACTIVITIES FOR MAINTAINING, INSPECTING & TESTING




▶ Strategies *such as*


- ❑ predictive maintenance
- ❑ reliability-centered maintenance
- ❑ interval-based inspections
- ❑ corrective maintenance
- ❑ metered maintenance

*“Analyzing cause and effect
versus documenting work.”*

SII MEDICAL EQUIPMENT (EC.02.04.01)

- 
- 4 The hospital identifies 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 EP 2 & 3) **A, D**

SII MEDICAL EQUIPMENT (EC.02.04.01)



5 The 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. **A**

6 The hospital identifies procedures to follow when medical equipment fails, *including* using emergency clinical interventions, and backup equipment **A, 3, D**

SII MEDICAL EQUIPMENT

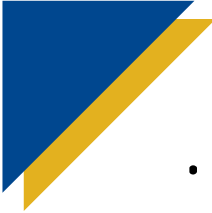


EC.02.04.03


The hospital inspects, tests, and maintains medical equipment.

- 1 Before initial use of medical equipment on the medical equipment inventory, the hospital performs *safety, operational, and functional checks*. (See also EC.02.04.01 EP 2) **C, 3**

SII MEDICAL EQUIPMENT (EC.02.04.03)

- 
- .2 The hospital inspects, tests, and maintains all life support equipment. *These activities are documented.* **A, 3, D**
 - .3 The hospital inspects, tests, and maintains non-life support equipment identified in the medical equipment inventory. These activities are documented **C, D**

SII MEDICAL EQUIPMENT (EC.02.04.03)



.4 The *hospital* conducts performance testing of and maintains all sterilizers. These activities are documented.

A, 3, D

.5 The *hospital* performs equipment maintenance and chemical and biological testing of water used in hemodialysis. These activities are documented.

A, 3, D



QUESTIONS?

DEFIBRILLATORS: FAQ




Q. Are defibrillators considered by The Joint Commission to be life support equipment?

A. YES.

Defibrillation is a response to life-threatening cardiac arrhythmias, ventricular fibrillation and ventricular tachycardia. Defibrillation consists of delivering a therapeutic dose of electricity to the affected heart with a defibrillator. **The dose of electricity restores a normal heart rhythm, allowing the heart to continue to function in the patient.**

Therefore, the Joint Commission considers defibrillators life support equipment.

DEFIBRILLATORS: FAQ




See EC.02.04.1 EP 2

Maintenance activities then must be identified for equipment on the inventory. A maintenance strategy for defibrillators could include a range of activities from a visual inspection of the single-use AED (automatic external defibrillator) to the scheduled maintenance activities.

- ❑ **NOTE:** Daily function or operational checks of a defibrillator in clinical use settings based on organization policy are **not** considered Equipment Maintenance

QUESTIONS

- 
1. Vendor responsibilities:
 - When is the vendor responsible to the Joint Commission?
 - Clarify competency requirements for vendors
 - Clarify vendor access to security sensitive areas
 2. What happens if an organization disagrees with a surveyor during survey?
 3. Is there an opportunity to challenge a finding after the survey?

SIG SUPPORT: 630 792 5900



George Mills, MBA, FASHE, CEM, CHFM, CHSP
Senior Engineer SIG

Jerry Gervais, CHFM
Engineer SIG

John Maurer CHFM, CHSP
Engineer SIG

Michael Chisholm, CHFM
Engineer SIG