

Joint Commission Updates 2018: Medical Equipment Standards

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Objectives:

- ❑ Discuss The Joint Commission Mission and Deemed status
- ❑ Understand the Survey Process
- ❑ Understand Survey Focus
- ❑ SAFER Matrix
- ❑ Survey Process Changes
- ❑ Survey Preparation and Documentation
- ❑ New / Revised Elements of Performance
- ❑ Questions

Mission:

1. To continuously improve health care
2. By evaluating health care organizations - meaningful assessment
3. To provide safe and effective care
4. Inspiring them to excel

The Joint Commission Deemed Status

1965

1. Congress: SS Amendments
2. IF accredited by JCAH, “deemed” to be in compliance with Medicare Conditions of Participation (CoP’s)

Loss of Deemed Status:

1. Approx. 2/3 to 3/4 of revenue from CMS
2. Spigot turned off

Not all HCO’s deemed by TJC

1. State AHJ’s
2. Competitors
3. Not deemed at all

Deemed Programs:

1. Hospitals
2. Behavior Hospitals
3. Home Care, Hospice
4. Ambulatory Healthcare, including
Surgery Centers
5. Critical Access Hospitals
6. Labs

Survey: Every 3 years (Labs: every 2 years) _____



Leading the Way to **Zero**TM

TJC – Standards and Elements of Performance (EP's)

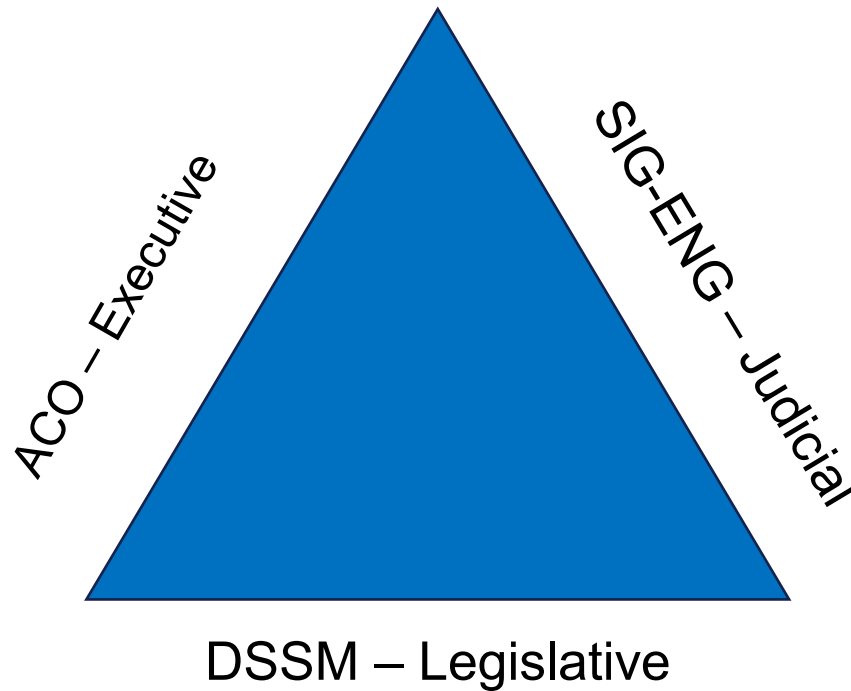
Tell us what you are going to do

Tell us how you did it.

Survey to 2012 editions of:

- NFPA 101 – Life Safety Code
- NFPA 99 – Healthcare Facilities Code

ACO-DSSM-SIG – Like the Government



Survey Types

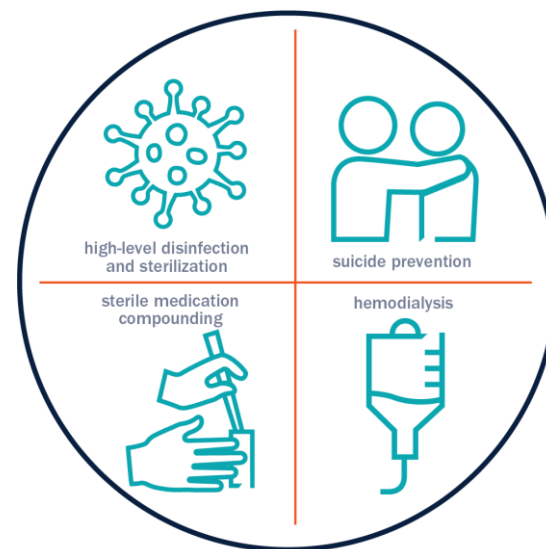
- Full U (Full Unannounced\Triennial)
- Med Def (Medicare Deficiency)
- SSU/OQPS (Special Survey Unit & Office of Quality and Patient Safety)
- ICM 2 or 3 (Intracycle Monitoring)
- Extension Survey (New building/services)
- Medicare Survey (CLD on Initial)

Current and Emerging Patient Safety

Risks—

An Onsite Survey Focus

- High-Level Disinfection/Sterilization
- Suicide Prevention
- Sterile Compounding
- Hemodialysis



4-1-1 on Survey Enhancements

High-Level Disinfection/Sterilization

- Failure to comply with HLD and sterilization guidelines have led to numerous outbreaks across the country.
- Organizations should have adequate facilities and implement consistent processes regardless of the setting where instruments or equipment are being used or reprocessed.
- Surveyors also will evaluate these processes in remote ambulatory settings.

Programs: Hospitals, Critical Access Hospitals, Ambulatory Surgery Centers, Office-Based Surgery

Suicide Prevention

- Will provide guidance on what constitutes adequate safeguards to prevent suicide, an expert panel has been assembled with representatives from provider organizations, experts in suicide prevention and the design of behavioral health care facilities, Joint Commission surveyors and staff, and representatives from the Centers for Medicare & Medicaid Services (CMS).
- Organizations should become familiar with the panel's recommendations, which now distinguish the requirements for different types of health care facilities and areas within psychiatric units.

Settings: Psychiatric hospitals, psychiatric units within general hospitals, general medical/surgical wards, emergency departments

Sterile Compounding

- As seen in recent media reports, despite increased regulations, incidents of contamination continue to occur.
- Expect the survey team to spend additional time in evaluating compounding services within your organization, including in remote ambulatory settings.
- For home care organizations, the new “Medication Compounding” standards chapter will be utilized to evaluate compliance.

Programs: Hospitals, Critical Access Hospitals, Home Care

Hemodialysis

- A very technical, high-risk area, care teams must be capable and competent to protect themselves from the risk of needle sticks, blood exposure and other complications of treatment while caring for hemodialysis patients.

Programs: Hospitals, Critical Access Hospitals, Ambulatory

Survey Analysis For Evaluating Risk (SAFER)

		Immediate Threat to Life <i>(follows current ITL processes)</i>		
		LIMITED	PATTERN	WIDESPREAD
Likelihood to Harm a Patient/Visitor/Staff	HIGH			
	MODERATE			
	LOW			
		Scope		

Customer Impact

- No more Direct and Indirect EP designations
- Consolidated Evidence of Standards Compliance (ESC) into one time frame, 60 days
- No more Opportunities for Improvement (OFIs), no more 'A' and 'C' categories
- See it/Cite it Survey Methodology

Survey Analysis For Evaluating Risk (SAFER)

		Immediate Threat to Life All Standards 0.37% EC 0.22% LS 0.00%		
Likelihood to Harm a Patient/Staff/Visitor	HIGH	All 1.54% EC 1.04% LS 0.21%	All 1.65% EC 1.57% LS 0.23%	All 1.56% EC 2.49% LS 0.13%
	MODERATE	All 16.53% EC 14.10% LS 7.87%	All 12.88% EC 12.32% LS 5.78%	All 4.37% EC 3.89% LS 1.10%
	LOW	All 42.05% EC 40.94% LS 65.72%	All 15.17% EC 18.42% LS 16.83%	All 3.87% EC 5.00% LS 2.14%
		LIMITED	PATTERN	WIDESPREAD

Percent of Hospitals With At Least One Condition Level Deficiency

- 2016
38.7%
- 2017
49.45%

Top Medical Equipment Findings

EC.02.04.03 EP3	Non-high risk equipment PM 100%	414
EC.02.04.03 EP27	Hospital meets NFPA 99-2012: Health Care Facilities Code requirements related to electrical equipment in the patient care vicinity.	232
EC.02.04.03 EP2	High risk equipment PM 100%	112
EC.02.04.01 EP2	Written inventory of all medical equipment	51
EC.02.04.03 EP1	Before initial use and after major repairs or upgrades of medical equipment on the medical equipment inventory, the hospital performs safety, operational, and functional checks.	28
EC.02.04.03 EP4	The hospital conducts performance testing of and maintains all sterilizers. These activities are documented.	21
EC.02.04.01 EP4	Activities and associated frequencies, in writing, for maintaining, inspecting, and testing all medical equipment	9
EC.02.04.01 EP3	Hospital identifies high-risk medical equipment on the inventory	4

HAI's – Hospital Acquired Infections

- Approximately 700,000 cases per year
- Approximately 60,000 deaths per year from HAI's
- Equivalent to one 747-400 every 2.5 days

Surgical Site Fires

- ~65 million hospital & ASC surgeries¹
- Estimated 200 – 240 surgery fires per year
 - Varying severity
 - 30 Serious
- Fire sites²:
- On patient
 - 44% head/neck/upper chest
 - 26 % elsewhere
- In patient
 - 21% airway
 - 8% other



Surgical Site Fires

- 70% - 84% occurred in oxygen-enriched environment²
- Ignition Source²:
 - 70% electrosurgical equipment
 - 10% lasers
 - Fuel
- ABHR 4%

1. Clarke JR, Bruley ME. Surgical fires: Trends associated with prevention efforts. Pennsylvania Patient Safety Advisory 2012 Dec; 9(2): 130-5. [cited 2012 Dec 12].

[http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec;9\(4\)/Pages/130.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec;9(4)/Pages/130.aspx)

2. Health Devices Oct 2009 www.ecri.org/surgical_fires

Life Safety Code Surveyor Days - 2018

Hospitals – Each Physical Address = Min. 2 LSCS days (new)

Gross Building Square Footage

0 – 1,000,000	2 LSCS Days
1,000,000 – 1,500,000	3 LSCS Days
>1,500,000	LSC FD Review

Non Hospital Life Safety Code Surveyor Days - 2018

Gross Building Square Footage

AHC / ASC	1 LSCS Day
Med Def	1 LSCS Day
SSU / OQPS	1 LSCS Day

The Hospital Survey Team

- Team Leader
- Physician or Nurse
- Life Safety Code Surveyor (LSCS)
- Other clinical team members
- Based on physical size of the organization and the amount and types of programs (HAP, OME, AHC, BHC)

Survey Agenda: LSCS Arrives with Team

	Day 1		Day 2
0800 - 0900	Facility Orientation	0800 - 0815	Day #1 Morning Briefing
0900 – 0930	Opening Conference/Introductions Only	0815 – 1200	Building Tour Cont'd
0930 – 1045ish	Document Review	1200 – 1230	Lunch
1045 – 1200	Pressure Relationships (OR's/SPD)	1230 – 1430	EC/EM Sessions (Separate)
1200 – 1230	Lunch	1430 – 1530	Enter day #2 Findings into report
1230 – 1600	Building Tour (End of day Findings)	1530 – 1600	Interim LSCS Exit/Team Exit

Survey Process Changes

Document Review Changes

<u>EC.02.04.01</u>	<u>Management of Medical Equipment Risks</u>
<p><u>EP 2</u></p>	<p><u>Non-deemed status requirement: 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.</u></p> <p><u>Evaluates new types of equipment before initial use to determine whether they should be included in the inventory.</u></p> <p><u>OR</u></p> <p><u>Deemed status requirement: Maintains a written inventory of all medical equipment.</u></p>
<p><u>EP 3</u></p>	<p><u>High-risk medical equipment identified on the inventory</u></p>
<p><u>EP4</u></p>	<p><u>Inventory includes activities and associated frequencies for maintaining, inspecting, and testing all medical equipment on the inventory.</u></p> <p><u>Activities and associated frequencies are in accordance with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program.</u></p>

Survey Process Changes (Cont.)

<u>EC.02.04.03</u>	<u>Medical equipment inspection, testing and maintenance</u>
<u>EP 2</u>	<p><u>All high-risk equipment.</u> Note 1: High-risk equipment includes medical equipment for which there is a risk of serious injury or even death to a patient or staff member should it fail, which includes life-support equipment. Note 2: Required activities and associated frequencies for maintaining, inspecting, and testing of medical equipment completed in accordance with manufacturers' recommendations must have a 100% completion rate. Note 3: Scheduled maintenance activities for high-risk medical equipment in an alternative equipment maintenance (AEM) program inventory must have a 100% completion rate. AEM frequency is determined by the hospital's AEM program.</p>
<u>EP 3</u>	<p><u>Non-high-risk equipment identified on the medical equipment inventory</u> Note: Scheduled maintenance activities for non-high-risk medical equipment in an alternative equipment maintenance (AEM) program inventory must have a 100% completion rate. AEM frequency is determined by the hospital's AEM program.</p>
<u>EP 4</u>	<u>Conducts performance testing of and maintains all sterilizers</u>
<u>EP 10</u>	<u>All occupancies containing hyperbaric facilities comply with construction, equipment, administration, and maintenance requirements of NFPA 99-2012: Chapter 14.</u>

Survey Preparation and Documentation

- Get Organized!
- Ligature Risks
- Complete Documentation, don't give a surveyor a reason to ask a question!
- Don't Provide More Than Requested

High Risk Medical Equipment

- Heart Lung Machine
- Ventilators
- Defibrillators
- Robotic assistive devices

Sentinel Event Alerts

- 18 out of 58 impact the environment of care, including:
 - #9: Infant Abductions
 - #15: Infusion Pumps
 - #22: Preventing needle stick and sharps injuries
 - #37: Emergency electrical power system failures
 - #39: Preventing surgical fires
 - #45: Violence in the health care setting, updated February 2017
 - #47: Radiation risks of diagnostic imaging
 - #50: Medical device alarm safety
 - #55: Preventing falls and fall-related injuries in health care facilities
 - #56: Detecting and treating suicide ideation in all settings

Risk Assessment

- Conducting a Risk Assessment takes a proactive approach to problem resolution, evaluating issues before an event happens
- A proactive risk assessment evaluates a process to identify the “weak link” and adjust to improve reliability
- Complete Documentation, don’t give a surveyor a reason to ask a question!
- Don’t Provide More Than Requested

When to Conduct a Risk Assessment

- Use to evaluate any issue that lacks a clear decision
- Educated guess that drives your assumptions
- Clearly document the process
- Determine when to re-assess the issue
- Problem solving approach to determine appropriate response
- Preventive strategies to address potential issues

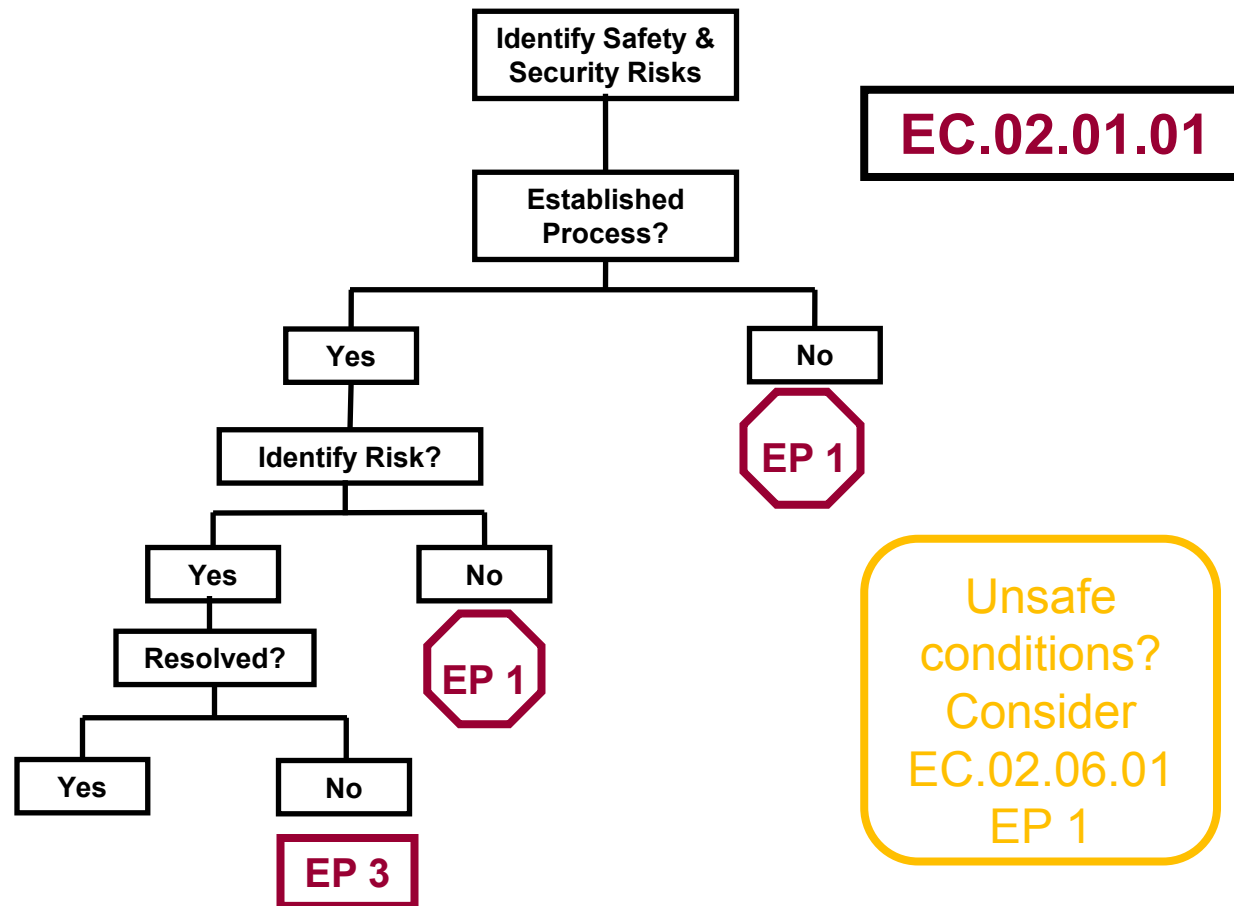
Risk Assessment – 7 Steps

1. Identify the issue
2. Develop arguments in support of the issue
3. Develop arguments against the issue
4. Objectively evaluate both arguments
5. Reach a conclusion
6. Document the process
7. Monitor and reassess the conclusion to ensure it is right conclusion

Risk Assessment Cycle



RISK ASSESSMENT



Evidence of Standards Compliance (ESC)



When responding to a finding the ESC must:

- **Indicate the issue** that is being corrected is in accordance with the finding
- Indicate that this issue has been **corrected**
- Demonstrate **how compliance will be maintained**
- If the finding was about a **periodic task** that has not been completed, show that the task has been completed

Evidence of Standards Compliance (ESC)

- **For example**, if a medical device(s) were found not inspected the month prior to survey. Show that the inspection period has been restarted since survey with 100 compliance. Many orgs state that they “will” ensure that the inspections are completed but not that they have occurred.

Elements of Performance

EC 02.04.03 EP21(Current)

For diagnostic computed tomography (CT) services: At least annually, a diagnostic medical physicist conducts a performance evaluation of all CT imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented.

The evaluation includes the use of phantoms to assess the following imaging metrics:

- Image uniformity
- ~~Slice thickness accuracy~~
- ~~Slice position accuracy (when prescribed from a scout image)~~
- Alignment light accuracy
- Table travel accuracy
- Radiation beam width
- High-contrast resolution
- ~~Low-contrast resolution~~
- Geometric or distance accuracy
- CT number accuracy and uniformity
- Artifact evaluation

Elements of Performance

EC 02.04.03 EP21 (Current)

Note 1: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

Note 2: Medical physicists are accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the physicist. (For more information, refer to HR.01.02.01, EP 1; HR.01.02.05, EP 20; HR.01.02.07, EPs 1 and 2; HR.01.06.01, EP 1; LD.03.06.01, EP 4.)

Elements of Performance

EC 20.04.03 EP 21 (Jan 2019)

For diagnostic computed tomography (CT) services: At least annually, a diagnostic medical physicist conducts a performance evaluation of all CT imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluation includes the use of phantoms to assess the following imaging metrics:

- Image uniformity
- Scout prescription accuracy
- Alignment light accuracy
- Table travel accuracy
- Radiation beam width
- High-contrast resolution
- Low-contrast detectability
- Geometric or distance accuracy
- CT number accuracy and uniformity
- Artifact evaluation

Elements of Performance

EC 20.04.03 EP 21 (Jan 2019)

Note 1: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

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Elements of Performance

EC 02.04.03 EP 34 (Jan 2019)

For hospitals that provide fluoroscopic services: At least annually, a diagnostic medical physicist conducts a performance evaluation of fluoroscopic imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluation includes an assessment of the following:

- Beam alignment and collimation
- Tube potential/kilovolt peak (kV/kVp) accuracy
- Beam filtration (half-value layer)
- High-contrast resolution
- Low-contrast detectability
- Maximum exposure rate in all imaging modes
- Displayed air-kerma rate and cumulative-air kerma accuracy (when applicable)

Elements of Performance

EC 02.04.03 EP 34 (Jan 2019)

Note 1: Medical physicists conducting performance evaluations may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the physicist.

Note 2: This element of performance does not apply to fluoroscopy equipment used for therapeutic radiation treatment planning or delivery.



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