National Patient Safety Goal (NPSG) NPSG.06.01.01 Improve the safety of clinical alarm systems.
Effective January 1, 2014 APPLICABLE TO HOSPITALS AND CRITICAL ACCESS HOSPITALS

Element of Performance
EP 1 As of July 1, 2014, leaders establish alarm system safety as a hospital priority.
EP 2 During 2014, identify the most important alarm signals to manage based on the following: ● Input from the medical staff and clinical departments ● Risk to patients if the alarm signal is not attended to or if it malfunctions ● Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue ● Potential for patient harm based on internal incident history ● Published best practices and guidelines
EP 3 As of January 1, 2016, establish policies and procedures for managing the alarms identified in EP 2 above that, at a minimum, address the following: ● Clinically appropriate settings for alarm signals ● When alarm signals can be disabled ● When alarm parameters can be changed ● Who in the organization has the authority to set alarm parameters ● Who in the organization has the authority to change alarm parameters ● Who in the organization has the authority to set alarm parameters to “off” ● Monitoring and responding to alarm signals ● Checking individual alarm signals for accurate settings, proper operation, and detectability (For more information, refer to Standard EC.02.04.03)
EP 4 As of January 1, 2016, educate staff and licensed independent practitioners about the purpose and proper operation of alarm systems for which they are responsible.

Proposed Worksheet A to help in fulfilling NPSF 06.01.01 EP 2

WHEN is this "due"? During 2014: Identify the most important alarm signals to manage based on:

Type of Alarm *(items listed are only examples, list is not exhaustive)*	Risk to patient if alarm signal is not attended to or it malfunctions Describe risk(s) and assign level High Medium Low	Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue	Potential for patient harm based on internal incident history	Published best practices and guidelines	Medical staff support of this type of alarm
CLINICAL					
Respirator					
Cardiac monitor					
Anesthesia machine					
IV smart pump					
Sleep apnea machine					
Bed: fall warning (mattress sensor)					
Fluoroscopy machine					
CT machine					
MR machine					
Ferrous detector (at entrance to Zone 4 of MR suite)					
Linear accelerator					

NON CLINICAL – but impact on patient safety					
Locked door alarm					
Infant security band	Possible unauthorized movement of neonate off the unit or out of the hospital (abduction)				

NPSF 06.01.01 EP 3- when is this "due"? By 1/1/16

Proposed Clinical Alarm Accountability Matrix

Type of Alarm Generic type, vendor, Model number	Location Name unit(s) or depts where installed or used	Clinically appropriate settings for alarm signals	WHEN alarm signals can be disabled	WHEN alarm parameters can be changed	WHO has authority to SET alarm parameters	WHO has authority to CHANGE alarm parameters	WHO has the authority to turn alarm parameters to "OFF"	WHO has responsibility for monitoring and responding to alarms	WHO has responsibility for checking individual alarm signals for accurate settings, proper operation, and detectability	WHO is responsible for educating (all persons with these responsibilities) regarding the purpose and proper operation of alarm systems [under their responsibility] TRACK training date(s) for all such personnel	Do the job descriptions for all responsible parties fully outline these responsibilities?
Implementation		1-1-16	1-1-16	1-1-16	1-1-16	1-1-16	1-1-16	1-1-16	1-1-16	1-1-16	This element is

date of the NPSG EP requirement											not part of the NPSG 06.01.01
Example: Cardiac Monitors in E.D.	All ED treatment rooms										

Notes:

1- There are facility alarms (such as the piped in gas lines) that impact on clinical care (i.e. if piped in O2 line service becomes inoperable or an alarm goes off on the annunciator panel). Accountability for monitoring and responding to alarms of that nature should also be defined in a similar manner to this grid.

2- There are clinical devices/machines that have dosing protocols/parameters embedded within them (ex. CAT Scan, MR machines, Fluoroscopy and other radiation machines). Accountability for verifying the vendor's pre-set parameters, changing these parameters, periodically checking the parameters, performing calibration checks, etc., should also be outlined using a similar type of grid.

Joint Commission source document

R3 Report I Requirement, Rationale, Reference

A complimentary publication of The Joint Commission Issue 5, December 11, 2013 **www.jointcommission.org**

Published for Joint Commission accredited organizations and interested health care professionals, *R3 Report* provides the rationale and references that The Joint Commission employs in the development of new requirements. While the standards manuals also provide a rationale, the rationale provided in *R3 Report* goes into more depth. The references provide the evidence that supports the requirement.

Alarm system safety

Requirements

The requirement addressed in this issue of R3 Report is a National Patient Safety Goal (NPSG) that is effective January 1, 2014 for hospitals and critical access hospitals. As noted in the elements of performance below, the NPSG will be implemented in two phases. The first phase heightens awareness of the potential risks associated with clinical alarms, and the second phase introduces requirements to mitigate those risks.

This NPSG addresses clinical alarms that can compromise patient safety if they are not properly managed. This includes alarms from equipment such as cardiac monitors, IV machines, ventilators, etc. that have visual and/or auditory components. In general, this does not include items such

as nurse call systems, alerts from computerized provider order entry (CPOE), or other information technology (IT) systems. Some psychiatric or rehabilitation hospitals may not use alarms that can present a serious safety issue because there is minimal use of medical devices that measure a patient's physiologic status. In these situations, it is acceptable if the hospital can demonstrate that the issue was considered but a limited number of such devices – or no devices at all – were identified as priorities.

NPSG.06.01.01: Improve the safety of clinical alarm systems.

EP 1: As of July 1, 2014, leaders establish alarm system safety as a hospital priority.

EP 2: During 2014, identify the most important alarm signals to manage based on the following:

- Input from the medical staff and clinical departments
- Risk to patients if the alarm signal is not attended to or if it malfunctions
- Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue
- Potential for patient harm based on internal incident history
- Published best practices and guidelines

(For more information on managing medical equipment risks, refer to Standard EC.02.04.01.)

EP 3: As of January 1, 2016, establish policies and procedures for managing the alarms identified in EP 2 above that, at a minimum, address the following:

- Clinically appropriate settings for alarm signals
- When alarm signals can be disabled
- When alarm parameters can be changed
- Who in the organization has the authority to set alarm parameters
- Who in the organization has the authority to change alarm parameters
- Who in the organization has the authority to set alarm parameters to "off"
- Monitoring and responding to alarm signals
- Checking individual alarm signals for accurate settings, proper operation, and detectability

(For more information, refer to Standard EC.02.04.03)

EP 4: As of January 1, 2016, educate staff and licensed independent practitioners about the purpose and proper operation of alarm systems for which they are responsible.

Rationale

One of the earliest NPSGs, in effect in 2003 and 2004, addressed the effectiveness of clinical alarm systems. The goal addressed preventive maintenance and testing of alarm systems and whether settings were appropriate and sufficiently audible. This goal was retired in 2005 because it was felt that sufficient attention had been brought to the issue.

Several years later, concerns were raised again about alarm safety. Clinical alarms have been at or near the top of the ECRI *Top 10 List of Technology Hazards* for several years.[1] Also, there have been a number of reports in the press of deaths attributed to "alarm fatigue." In some hospital units, alarm signals per patient per day can reach several hundred. Many of the signals do not require clinical intervention, but clinicians become overwhelmed by the volume of alarm signals and become desensitized or immune to the sounds. This is known as "alarm fatigue." In these cases, alarm volume may be turned down, alarms may be turned off inappropriately, or alarm settings may be adjusted outside of safe limits. These situations can have serious consequences.

The Joint Commission Sentinel Event database contains 98 reports of alarm events between January 2009 and June 2012. Eighty of those events resulted in patient death. In addition, a Food and Drug Administration (FDA) database contains 566 alarm-related patient deaths between January 2005 and June 2010.[2]

This situation led to a Summit on Medical Device Alarms in October 2011 that was co-convened by the Association for the Advancement of Medical Instrumentation (AAMI), the ECRI Institute, the American College of Clinical Engineering (ACCE), the Food and Drug Administration (FDA), and The Joint Commission. The Summit identified themes, challenges, and actions that can be taken immediately to improve safe use of clinical alarms. Also identified were priority actions requiring further study or longer timeframes to fully address; further study is in process on these longer-term issues.

Following the Alarms Summit, The Joint Commission conducted an environmental assessment on clinical alarm safety issues. A survey was sent out in March 2012 to assess the status of clinical alarm management in the field. Almost 1,600 responses were received, and 90 percent of hospital respondents agreed that clinical alarm management was a safety issue. Although 70 percent believed alarms were effectively managed, fewer than 50 percent of the respondents had an organization-wide process for alarm management.

Reference

The issues addressed in the elements of performance for the NPSG are consistent with the recommended actions that emerged from the Alarms Summit. These elements are also aligned with suggested practices that have been identified by professional organizations, including the ECRI Institute and AAMI.[3,4,5] During phase I, The Joint Commission will monitor emerging evidence about leading practices, will solicit feedback from hospitals on their experiences with the requirements of the NPSG, and will obtain feedback from surveyors about implementation issues and leading practices observed during surveys. The Joint Commission is aware of efforts currently underway that will support the field in implementing the second phase of the NPSG requirements. This includes an AAMI initiative to identify best practices in setting alarm parameters. It is important to note, therefore, that before they are implemented on January 1, 2016, the proposed phase II requirements may be enhanced based on new knowledge.

Feedback from the field

A field review of the proposed NPSG on safety of clinical alarm systems was conducted in January and February 2013; 2,700 individuals responded to the survey. There was some concern about the lack of agreed-upon solutions for alarm safety issues, but this should be mitigated by the ongoing work noted above and information learned in phase I. Approximately 88 percent of the respondents agreed that clinical alarm safety is an important safety issue and 75 percent agreed it should be a NPSG. The development of a goal on this topic was supported by The Joint Commission's Hospital Professional and

Technical Advisory Committee and the Patient Safety Advisory Group, as well as several professional organizations.

Select bibliography

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