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	Title: CONDUCTING A ROOT CAUSE ANALYSIS (RCA POLICY)	Origination Date:
		Effective Date: 11-26-08
		Retires Policy Dated: N/A
		Previous Versions Dated: N/A
		Hospital Governing Board Approval Date:

I. SCOPE:

This policy applies to _____ (“Hospital/Facility”), its employees, medical staff, contractors, patients, and visitors regardless of service location or category of patient.

II. PURPOSE:

The purpose of this policy is to ensure proper management, trending, analysis and evaluation of actual or potential Sentinel Events via performance of a thorough and credible Root Cause Analysis¹ (RCA).

III. POLICY:

A Sentinel Event is defined by Joint Commission (JC) as an unexpected death or permanent loss of function not related to the natural course of the patient’s illness or underlying condition, or the risk thereof (refer to Sentinel Event Policy).

- The expectation is that an RCA be conducted on any reviewable event as defined by JC as well as those events that are established as reportable per state regulations.
- RCAs will be completed within 14 days for those events meeting the definition of a Sentinel Event.
- Near Misses may also be included as a reviewable event to proactively examine processes and create interventions before harm to patients, staff or visitors occur.

IV. PROCEDURE:

A. Identification of a Sentinel Event/Critical Incident

1. A Sentinel Event is defined as an unexpected occurrence involving unanticipated death or major permanent loss of function not related to the natural course of the patient’s illness or underlying condition.

¹“Root cause analysis” means a process for identifying the base or contributing causal factors that underlie variations in performance associated with adverse events, Sentinel Events or near misses.

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2. A Sentinel Event may also include an unexpected event which could potentially lead to a serious adverse patient outcome.
3. Incidents involving serious threat or injury to staff and/or visitors may also be considered critical incidents, and the same process is to be followed.
4. Incidents where suspected or known confidentiality or security breaches are evident may also be considered a critical incident necessitating review.

Note: Confidentiality or security breaches will be referred to the Hospital Compliance Officer/Security Officer for review and investigation.

It is expected that an RCA be conducted on any incident meeting the definition stated above.

B. Reporting of a Sentinel Event/Critical Incident

1. When a Sentinel Event occurs within the facility, an incident report should be filed in the eSRM system as soon as possible but not more than 24 hours after the event or discovery of the event. The author filing the report should also immediately notify their supervisor.
2. The Risk Manager or designee shall also notify all appropriate personnel within the facility as well as the Corporate Clinical Risk Management and/or Quality Management Department through the use of the corporate notification button contained within the eSRM system.

C. Process for Completing the Root Cause Analysis and Action Plan (also refer to: Sentinel Event Response & Reporting Policy)

1. Any potential or actual event must have a thorough and credible RCA completed within 14 days from the date of the event.
2. Occasionally, some events will become known well after the event occurred (such as, a retained sponge is found a month after the original surgical procedure). In these cases, the RCA will be due 14 days from the date of discovery.

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3. The RCA shall be prepared using the Joint Commission Framework for Root Cause Analysis (see Attachment A).
4. The RCA shall be a confidential and privileged document prepared and maintained in accordance with state peer review, quality assurance, performance improvement or other statute.

D. Confirm that the Root Cause Analysis Framework Meets JC Standards

The RCA shall have the following characteristics:

1. The analysis shall focus primarily on systems and processes, not on individual performance;
2. The analysis should progress from special causes in clinical processes to common causes in organizational processes;
3. The analysis should repeatedly dig deeper by asking “Why?;” then, when answered, ask “Why?” again, and so on;
4. The analysis should identify changes that could be made in systems and processes (either through redesign or development of new systems or processes) which would reduce the risk of such events occurring in the future;
5. For confidentiality purposes, the RCA shall not include the patient’s name, medical record number, the name of the care providers or RCA participants;
6. The analysis of the RCA must be *thorough* and *credible*. The facility shall completely address/answer all components of the JC Framework (see Attachment A for a template) and include all of the tools in Attachments B-D to this policy.
 - a. The Risk Manager shall reference the VA National Center for Patient Safety questions to drill down on each question.

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- b. A thorough and credible RCA includes all of the following components:
- (1) A timeline of the event
 - (2) A completed JC Framework (Attachment A)
 - (3) An Action Plan with measurable action items (Attachment B)
 - (4) A Cause and Effect Diagram (Fishbone) (Attachment C)
 - (5) Three Process Flow Charts (Attachment D)
 - (a) One depicting the process which occurred
 - (b) One depicting how the process should have occurred
 - (c) One depicting what will be done to address the issues (how it will occur in the future)
 - (6) A Bibliography consisting minimally of 5-7 cited references
- c. To be thorough, the analysis must include the following:
- (1) A determination of the human and other factors most directly associated with the Sentinel Event and the process(es) and systems related to its occurrence.
 - (2) An analysis of the underlying systems and processes through a series of “Why?” questions to determine where redesign might reduce risk;
 - (3) An identification of risk points and their potential contributions to this type of event;
 - (4) A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination after analysis, that no such improvement opportunities exist;

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(5) Inquiry into all appropriate areas specific to the type of the Sentinel Event.

d. To be *credible*, the RCA must do the following:

- (1) Include participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review;
- (2) Be internally consistent (that is, not contradict itself or leave obvious questions unanswered);
- (3) Provide an explanation for all findings of “not applicable” or “no problem;”
- (4) Include consideration of any relevant literature.

E. Confirm that the Action Plan Meets Joint Commission Standards

1. The hospital’s action plan **shall**:

- a. Identify changes that can be implemented to reduce risk or formulate a rationale for not undertaking such changes
- b. Identify, in situations where improvement actions are planned, who is responsible for implementation (by title and not by name), when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated.
- c. For confidentiality purposes, the action plan shall not include the patient’s name, the name of the care providers or RCA participants.
- d. Include actions that are definitive in nature.
- e. Include measurements that are quantifiable.
- f. Be written in a manner that identifies the new process rather than focusing on past deficiencies that may have existed in the prior process

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2. The hospital's action plan **shall not** refer to the Sentinel Event or its causation.

F. Measure the Effectiveness of the Action Plan

1. The hospital shall identify and follow a process for measuring the effectiveness of its action plan for a period of six (6) months.
2. The hospital Risk Manager shall maintain documentation of the effectiveness measurements pursuant to the document retention requirements of this policy.
3. The hospital's measurements shall not reference the Sentinel Event or its causation. The hospital's measurements shall be made available for JC review if requested.

G. Maintain Confidentiality and Privileged Status of Root Cause Analysis

1. The RCA and its contents are confidential and privileged and shall not be copied, sent to or verbally discussed with JC or any other third party including state surveyors. The hospital may provide a surveyor a timeline or synopsis of the event, the action plan, performance measures and data.
2. The RCA shall be maintained by the Risk Manager. In circumstances that may require reporting information to an outside agency a copy of the RCA may be requested by corporate Clinical Risk Management and/or Quality Management Departments, the Assistant General Counsel or Regulatory Counsel or the Chief Compliance Officer.
3. The RCA and its contents shall not be attached to or described in the minutes of hospital committees unless the committee is acting within the scope of **[reference to state peer review, quality assurance, performance improvement or other state statute]**.

H. Joint Commission Survey and Mock Root Cause Analysis

1. During the JC survey, the JC will be evaluating compliance with JC's Sentinel Event Policy and Procedure and compliance with JC Standards.

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2. In order to meet these standards, the hospital shall annually conduct a “mock” RCA so that the hospital can demonstrate its understanding, ability and implementation of the requirements of the JC’s Sentinel Event policies and procedures without disclosing an actual RCA. The mock RCA shall be based on a topic covered in the JC’s Sentinel Event Alert and shall not be based on an actual Sentinel Event or near miss at the hospital.

I. Responding to the Joint Commission’s Sentinel Event Inquiries

1. In the event JC contacts the hospital to inquire about a Sentinel Event, the hospital’s Risk Manager shall immediately consult with the Tenet Clinical Quality/Quality Management Department for guidance on how to respond to the JC.
2. The JC offers four different alternatives for a hospital to respond when they learn of a Reviewable Sentinel Event through either the hospital’s voluntary report or otherwise.
3. Alternative 3 would ordinarily be the most appropriate alternative for reporting, absent a determination by the Assistant General Counsel that another alternative is legally acceptable under the circumstances:

Alternative 3: The hospital will request an on-site visit by a JC surveyor to conduct interviews and review relevant documentation to obtain information about the process and findings of the RCA and resulting action plan, without actually reviewing the RCA.

J. Media or External Inquiries Related to a Sentinel Event

1. Staff are not to discuss any Sentinel Event with the media and/or the press.
2. Staff shall contact their immediate supervisor who will notify the Risk Manager and/ or the Administrator on-call if they are approached by the media or any external agency.
3. The hospital representative shall notify the Corporate or Regional Communications representative to receive guidance on how to respond to such inquiries.

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K. Intense Analysis

There are situations when the event/critical incident may not be due to underlying issues with processes or systems but are based solely on individual performance or technique and, therefore, the completion of a full RCA may not be necessary. In these cases, only after approval from Corporate Clinical Risk Management or Quality Management, will an Intense Analysis (Attachment E) be approved for use. If process issues surface while completing the Intense Analysis, the Risk Manager will convert the review to a full RCA.

J. Document Retention

The hospital's Risk Manager shall retain the RCA, action plan and other documentation generated pursuant to this policy according to the requirements of Administrative Policy AD 1.1., Records Management.

L. Enforcement

All employees whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this policy. Failure to comply with this policy will be subject to appropriate disciplinary action pursuant to all applicable policies and procedures, up to and including termination. Such disciplinary action may also include modification of compensation, including any merit or discretionary compensation awards.

V. REFERENCES:

- The Joint Commission Comprehensive Accreditation Manual for Hospitals, 2008.
- Root Cause Analysis in Healthcare: Tools and Techniques; Third edition (2005). Joint Commission Resources
- [VA National Center for Patient Safety](#)
- Hospital Patient Safety Plan
- Sentinel Event & Reporting Policy
- Hospital Occurrence Reporting Policy

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VI. ATTACHMENTS:

- Attachment A: Joint Commission Framework for Root Cause Analysis
- Attachment B: Corrective Action Plan
- Attachment C: Cause and Effect Diagram
- Attachment D: Process Flow Diagram
- Attachment E: Intense Analysis Form