Sentinel Event Policy

Purpose.
To identify the procedure for responding to sentinel events or serious adverse events reported in an organization that is actively involved in the Joint Commission International's (JCI) accreditation process.

Definition of Sentinel Event.
A sentinel event is a *patient safety event* (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following:

- Death
- Permanent harm
- Severe temporary harm*

An event is considered a sentinel event and is subject for review, if it is one of the following:

- death that is unrelated to the natural course of the patient's illness or underlying condition (**for example**, death from a postoperative infection or a hospital-acquired pulmonary embolism);
- death of a full-term infant; and
- suicide
- major permanent loss of function unrelated to the patient's natural course of illness or underlying condition
- wrong-site, wrong-procedure, wrong-patient surgery;
- transmission of a chronic or fatal disease or illness as a result of infusing blood or blood products or transplanting contaminated organs or tissues;
- infant abduction or an infant sent home with the wrong parents; and
- rape, workplace violence such as assault (leading to death or permanent loss of function); or homicide (willful killing) of a patient, staff member, practitioner, medical student, trainee, visitor, or vendor while on hospital property. (*Also see* SQE.8.2)

Goals of the Sentinel Event Policy:

1. To have a positive impact in improving patient care, treatment, and services and in preventing unintended harm;
2. To focus the attention of a hospital that has experienced a sentinel event on understanding the factors that contributed to the event (such as underlying causes, latent conditions and active failures in defense systems, or hospital culture), and on changing the hospital's culture, systems, and processes to reduce the probability of such an event in the future;
3. To increase the general knowledge about patient safety events, their contributing factors, and strategies for prevention;

4. To maintain the confidence of the public, clinicians, and hospitals that patient safety is a priority in accredited hospitals;

Policy.

1. JCI Accreditation reviews historical actions taken by the organization in response to sentinel events or serious adverse events in the accreditation process, including during full accreditation surveys (initial and triennial) and, as appropriate, focused surveys.
2. At a minimum, an organization must develop an operational sentinel event definition to include those events that are subject to review as described under the standard that addresses sentinel events from the accreditation program for which they are applying and the JCI Sentinel Event Policy.
3. Accredited organizations are expected to identify and respond appropriately to all sentinel/serious adverse events occurring in the organization or associated with services that the organization provides, regardless whether self-reported or JCI becomes aware of the event, by preparing a thorough and credible comprehensive systematic analysis (i.e. Root Cause Analysis) and action plan within 45 business days of the event or of becoming aware of the event.
4. An organization's appropriate response to a sentinel or serious adverse event includes all the following:
   - A formalized team response that stabilizes the patient, discloses the event to the patient and family, and provides support for the family as well as staff involved in the event
   - Notification of hospital leadership
   - Immediate investigation
   - Completion of a comprehensive systematic analysis for identifying the causal and contributory factors
   - Strong corrective actions derived from the identified causal and contributing factors that eliminate or control system hazards or vulnerabilities and result in sustainable improvement over time
   - Time line for implementation of corrective actions
   - Systemic improvement/monitoring effectiveness of action
5. A reviewable sentinel event is subject to review by JCI Accreditation Office of Quality and Safety Monitoring (OQSM) and includes any occurrence that meets defined JCI sentinel event criteria and as described in the organizations operational sentinel event policy.
6. If an organization wishes to voluntarily self-report an event that is subject to review by JCI Accreditation, the organization can submit the report to JCI OQSM at JCIQuality@jcrinc.com. Self- reporting an event is not required and there is no difference in the expected response, timeframes, or review procedures whether the hospital voluntarily reports the event or Joint Commission International becomes aware of the event by some other means.

7. All comprehensive analysis and action plans will be considered and treated as confidential by JCI Accreditation.

8. An initial on-site review of a sentinel/serious adverse event will usually not be conducted unless it is determined that there is a potential ongoing immediate threat to patient health and safety or potentially significant noncompliance with JCI standards and/or Accreditation Participation Requirements (APRs). (See Threat to Health and Safety Policy, IACP.0004.) All are immediately referred to JCI Vice President (VP) Accreditation, Standards and Measurement for authorization to conduct a For-Cause survey.

9. Disclosable Information: If JCI Accreditation receives an inquiry about the accreditation decision of an organization that has experienced a reviewable sentinel event, the organization's accreditation decision will be reported in the usual manner without referring to the sentinel event. If the inquirer specifically references the specific sentinel event, JCI Accreditation will acknowledge that it is aware of the event and currently working or has worked through the sentinel event with the organization.

Definitions:

Patient Safety Events - Sentinel events are one category of patient safety events. A *patient safety event* is an event, incident, or condition that could have resulted or did result in harm to a patient. A *patient safety event* can be, but is not necessarily, the result of a defective system or process design, a system breakdown, equipment failure, or human error. Patient safety events also include adverse events, no-harm events, close calls, and hazardous conditions, which are defined as follows:

- An *adverse event* is a patient safety event that resulted in harm to a patient.
- A *no-harm event* is a patient safety event that reaches the patient but does not cause harm.
- A *near miss* (or "close call" or "good catch") is a patient safety event that did not reach the patient.
- A *hazardous* (or "unsafe") *condition(s)* is a circumstance (other than a patient's own disease process or condition) that increases the probability of an adverse event.

Comprehensive Systematic Analysis/Root Cause Analysis (RCA) is a process for identifying the basis or causal factors that bring about variation in performance, including the occurrence, or possible occurrence of a sentinel event. An RCA focuses primarily on systems and processes, not on individual performance. The analysis progresses from special causes in clinical processes to common causes in organizational processes & systems and identifies potential improvements in these processes or systems that would tend to decrease the likelihood of such events in the future or determines, after analysis that no such improvement opportunities exist. The identified vulnerabilities can then be mitigated or eliminated preventing future like harm events.

Thorough analysis – To be thorough, the comprehensive systematic analysis must include the following:

- The analysis repeatedly asks a series of "Why" questions, until it identifies the

systemic causal factors associated with each step in the sequence that led to the sentinel event to determine where redesign might reduce risk;
- The analysis focuses on systems and processes, not solely on individual performance
- 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

- An inquiry into all areas appropriate to the specific type of event
- 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;

Credible analysis - To be credible, the comprehensive systematic analysis must do the following:

- Include participation by a process owner who is not a member of the response team; typically, this is a senior leader of the hospital or a designee
- Include individual representation from each of those areas/systems/processes/disciplines associated with the steps that had led up to the event, but that were not directly involved in the event.
- Those with direct involvement in the event should be interviewed separately by leadership and should not be part of the comprehensive analysis team.
- Each action recommended by a review team should be approved or disapproved, preferably by the CEO or alternatively by another relevant member of top management.
    - If an action is disapproved, the reason for its disapproval should be shared with the comprehensive systematic analysis and action team, so that the constraint can be understood and
    - Another action can be developed by the team to replace the disapproved action, if the system vulnerability is not otherwise effectively addressed in the action plan.
- Interview patients, family, or patient representatives directly involved with this event when appropriate to ensure a thorough understanding of the facts
- Include Patient representative not involved in the event
- Be internally consistent (that is, not contradict itself or leave obvious questions unanswered)
- Provide an explanation for all findings of "not applicable" or "no problem"
- Include a bibliography of any relevant literature

Action plan - The product of the RCA in response to the identified system and process contributing factors is an action plan that addresses each factor's corrective action that the organization intends to implement in order to reduce the risk of similar events from occurring in the future.
The action plan should describe the hospital's risk reduction strategies, as well as how the effectiveness of those strategies will be evaluated/monitored.

For-Cause Survey –

For-Cause survey is an on-site survey that is limited in scope, content and length and designed to

gather information on a specific issue(s) related to the applicable JCI Accreditation Standards, International Patient Safety Goals and/or APRs. A For-Cause survey may be conducted after the receipt of information regarding the occurrence of any event or series of events in an accredited/certified organization that creates, but is not limited to the following significant situations:

- Concern of a potential ongoing threat to health and safety and/or immediate threat to patient/public/staff health and safety within the organization.
- To confirm/investigate an applicable condition(s) that resulted in the organization being classified as "*At Risk for Denial of Accreditation*" and was not covered by a focused survey or the threat to health and safety protocol. (See Policy IACP.0004: *Threat to Health and Safety Protocol*).
- Confirm eligibility or accreditation status following sanctions, penalties, limitation in operations imposed by a regulatory, legal or other authoritative body; or voluntary closure of services for a period of time.

Special Cause is a factor that intermittently and unpredictably induces variation over and above what is inherent in the system. It often appears as an extreme point (such as a point beyond the control limits on a control chart) or some specific, identifiable pattern in data.

Common Cause is a factor that results from variation inherent in the process or system. The risk of a common cause can be reduced by redesigning the process or system.