APPROVED BY:	RESPONSIBILITY:	EFFECTIVE DATE:	POLICY NO.	PAGE
Rey M. Vega Hospital Administrator/CEO	Patient Safety Officer Patient Safety Committee	December 14, 2011	A-PS700	1 of 27
TITLE: ROOT CAUSE ANALYSIS FOR SENTINEL EVENTS				
LAST REVIEWED/REVISED: 10/2011				
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PURPOSE:

The purpose of the Sentinel Event Policy is to define the process for identification, reporting, investigation and management of sentinel events that occur in the Guam Memorial Hospital Authority.

DEFINITION:

Sentinel Event: Sentinel events are rare events that lead to catastrophic patient outcomes.

- A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.
- Such events are called "sentinel" because they signal the need for immediate investigation and response.
- The terms "sentinel event" and "error" are not synonymous; not all sentinel events occur because of an error, and not all errors result in sentinel events.

REPORTABLE SENTINEL EVENTS:

Reporting of any and all sentinel events is mandated by the Leadership (Board of Trustees, Medical Executive Committee, and the Hospital Administration) of Guam Memorial Hospital Authority. Reporting of sentinel events is mandatory for all hospital staff. This includes both salaried and non-salaried visiting medical practitioners.

Sentinel Events are to be reported to the Hospital Administrator/CEO via the appropriate chain of command, the Patient Safety Officer, and the Associate Administrator of Medical Services immediately. A Patient Safety Form (blue form) must be completed and submitted to the Patient Safety Officer.

Refer to GMHA Administrative Policy No. 6180-6, Patient Safety Program for more information.

INVESTIGATION OF SENTINEL EVENTS:

Sentinel events often signal serious breakdowns in healthcare systems and require thorough investigation and response. The investigation of a sentinel event should involve a comprehensive and systematic analysis of the facts to identify contributing factors. Recommendations and strategies should be developed and implemented to minimize the occurrence of similar events in the future. The following standards for investigating sentinel events shall be followed:

1. Where there has been an incident that requires investigation, the initial primary responsibility is to ensure safety and care of patients and staff.
2. The investigation should at all times respect the dignity of all persons involved.
3. An investigation into an incident will involve a comprehensive and systematic analysis of facts to identify root causes or contributing factors.

4. There should not be any blame or fault apportioned to individuals involved.
5. A senior staff member who was not directly involved in the incident and who can maintain objectivity should facilitate the investigation process.
6. A hospital will, consistent with its obligation to take reasonable care, advise patients of any serious adverse event which has caused harm or in which there is a potential for harm to arise.
7. The investigation considers all relevant disciplines;
8. The investigative team should be fully composed of independent members who were not involved in the incident;
9. The investigation considers all interpretations of the factors which may have led to the incident and is focused on system issues;
10. The investigation involves interviews or input from staff involved in the incident;
11. The patient and/or their support person are interviewed if it is believed that their input can add to the information;
12. That all major contributing factors are discovered/identified and relevant literature or other internal/ external evidence has been considered;
13. Recommendations are based on contributing factors;
14. Recommendations are achievable and measurable;
15. Where possible, the recommendations should consider the opportunities to eliminate, minimize or treat the risks;
16. Ongoing monitoring to ensure the recommendations are implemented and evaluated to determine whether the contributing factors have been addressed by the recommended action;
17. Where possible the recommendations and action are fed back to the patient and, with their permission, to their support person or relative (please note, this information cannot be disclosed if the case is under legal review) and after the investigation is completed all relevant staff and service providers should be informed of the investigation outcome and key lessons are learned.

Note: If during the course of the investigation of a sentinel event it is suspected that the event may contain elements of blameworthy behavior or a purposeful unsafe act, the investigation team should immediately cease the investigation and refer it to the Risk Manager and Senior Management so that it can be managed using the appropriate management and governance processes. Such behavior or acts include:

- Physical altercation or sexual misconduct by staff or other individuals involving a patient; or
- Non-compliance with a hospital or health service policy or practice concerning work safety.

In some cases it is possible that an event will be a sentinel event and involve some incidental blameworthy behavior or purposeful unsafe act that is perhaps secondary to the adverse outcome pertaining to the patient. In such cases, the investigation of the sentinel event can continue alongside parallel processes of performance management into the alleged or suspected behavior or acts of staff members involved. Any incident of the nature contemplated in this note should be reported to the hospital's Legal Counsel or other relevant bodies in order to deal with the potential liability claims.

RESPONSIBILITY:

Guam Memorial Hospital is expected to identify and respond appropriately to all sentinel events occurring in the hospital or associated with services that the hospital provides, or provides for. Appropriate response includes conducting a timely, thorough, and credible root cause analysis; developing an action plan designed to implement improvements to reduce risk; implementing the improvements; and monitoring the effectiveness of those improvements.

The hospital will prepare a thorough and credible root cause analysis and action plan within 30 calendar days of the event or of becoming aware of the event.

ROOT CAUSE ANALYSIS:

Root cause analysis (RCA) is a process for identifying the factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis 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 and 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.

- 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.

A root cause analysis will be considered **acceptable** if it has the following characteristics:

- The analysis 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;
- The analysis repeatedly digs deeper by asking "Why?"; then, when answered, "Why?" again, and so on;
- The analysis identifies changes that could be made in systems and processes (either through redesign or development of new systems or processes) that would reduce the risk of such events occurring in the future;
- The analysis is thorough and credible.

To be **thorough**, the root cause analysis must include the following:

- 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 analysis of the underlying systems and processes through a series of "Why?" questions to determine where redesign might reduce risk;
- An inquiry into all areas appropriate to the specific type of event;
- An identification of risk points and their potential contributions to this 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.

To be **credible**, the root cause analysis must do the following:

- Include participation by the leadership of the hospital and by individuals most closely involved in the processes and systems under review;
- 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 consideration of any relevant literature.

Basic steps to a three meeting RCA include:

A. Step One:
   1. Construct a simple flowchart of the event.
   2. Work out what the team knows and what the team does not not—ask "what, how, and why?" Any unanswered questions will form the basis of the questions that will need to be asked and the information that team members need to collect. Gathers as much information as possible about the event from a variety of sources (e.g., interview those involved and witnesses, review documentation) to determine the facts.

3. Who/what was involved?
4. Where/when did the incident happen?
5. What was the incident?
6. How did it happen?

B. Step Two :

1. Construct a detailed flowchart of events and identify where processes broke down (i.e. if an intervention was made at that point the sentinel event may not have occurred).
2. Construct a cause and effect diagram to identify the root causes. Analyze the factual information to determine the contributing factors and causes. There will always be a number of issues contributing to any event. Investigators should consider the following factors:
    a. Patient factors Root Cause Analysis (RCA) Guidelines
    b. Communication factors
    c. Knowledge, skills and competence
    d. Work environment and scheduling
    e. Equipment factors
    f. Policies, procedures and guidelines
    g. Safety mechanisms

C. Step Three:

1. Make recommendations based on the contributing factors aimed at minimizing the occurrence of similar incidents in the future. Recommendations must be feasible and within management's control to fix. Investigators should ensure that each recommendation identifies the individual(s) who will be accountable for the implementation and ongoing monitoring of recommendations. Hospital Administrator/CEO has ultimate responsibility for ensuring the recommendations are implementation.
2. Develop a report containing the contributing factors and the recommendations.

See Attachment II for the Root Cause Analysis Worksheet.

See Attachment III for the Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events. A detailed inquiry into the specific areas listed is expected when conducting a root cause analysis for the specific type of sentinel event identified in the table.

ACTION PLAN:

The product of the root cause analysis is an action plan that identifies the strategies that the hospital intends to implement in order to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.

An action plan will be considered acceptable if it does the following:

- Identifies changes that can be implemented to reduce risk or formulates a rationale for not undertaking such changes;
- Identifies, in situations where improvement actions are planned, who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated.

REVIEWABLE SENTINEL EVENTS

The subset of sentinel events that is subject to review by The Joint Commission includes any occurrence that meets any of the following criteria:

- The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition; or
  Note 1: A distinction is made between an adverse outcome that is primarily related to the natural course of the patient's illness or underlying condition (not reviewable) and a death or major permanent loss of function that is associated with the treatment (including "recognized complications") or lack of treatment of that condition, or otherwise not clearly and primarily related to the natural course of the patient's illness or underlying condition (reviewable). In indeterminate cases, the event will be presumed reviewable and the hospital's response will be reviewed under the Joint Commission's Sentinel Event Policy according to the prescribed procedures and time frames without delay for additional information such as autopsy results.

  Note 2: Major permanent loss of function" means sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or lifestyle change. When "major permanent loss of function" cannot be immediately determined, applicability of the Joint Commission's Sentinel Event Policy is not established until either the patient is discharged with continued major loss of function, or two weeks have elapsed with persistent major loss of function, whichever occurs first.

- The event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition):
  - Suicide of any patient receiving care, treatment and services in a staffed around-the-clock care setting or within 72 hours of discharge;
  - Unanticipated death of a full-term infant;
  - Abduction of any patient receiving care, treatment, and services;
  - Discharge of an infant to the wrong family;
  - Rape (Rape, as a reviewable sentinel event, is defined as unconsented sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the hospital, including oral, vaginal or anal penetration or fondling of the patient's sex organ(s) by another individual's hand, sex organ, or object. One or more of the following must be present to determine reviewability:
    - Any staff-witnessed sexual contact as described above;
    - Admission by the perpetrator that sexual contact, as described above, occurred on the premises;
    - Sufficient clinical evidence obtained by the hospital to support allegations of unconsented sexual contact.
  - Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups);
  - Surgical and nonsurgical invasive procedure on the wrong patient, wrong site, or wrong procedure;
  - Unintended retention of a foreign object in a patient after surgery or other procedure;
  - Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter);
  - Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose.

See also Attachment III for Examples of Reviewable and Nonreviewable Sentinel Events.

REQUIRED HOSPITAL RESPONSE TO A REVIEWABLE SENTINEL EVENT

If The Joint Commission becomes aware (either through voluntary self-reporting or otherwise) of a sentinel event that meets the preceding criteria and the event has occurred in an accredited hospital, the hospital is expected to do the following:

- Prepare a thorough and credible root cause analysis and action plan within 45 calendar days of the event or of becoming aware of the event; and

- Submit to The Joint Commission its root cause analysis and action plan, or otherwise provide for Joint Commission evaluation of its response to the sentinel event under an approved protocol (see Section VI), within 45 calendar days of the known occurrence of the event.

The Joint Commission will then determine whether the root cause analysis and action plan are acceptable. If the determination that an event is reviewable under the Joint Commission's Sentinel Event Policy occurs more than 45 calendar days following the known occurrence of the event, the hospital will be allowed 15 calendar days for its response. If the hospital fails to submit an acceptable root cause analysis within the 45 calendar days (or within 15 calendar days, if the 45 calendar days have already elapsed), the following consequence will result (depending on the length of time the hospital fails to submit a root cause analysis):

- If the hospital has failed to submit a root cause analysis within an additional 45 days following its due date, its accreditation decision may be impacted.

Please note that a hospital that experiences a sentinel event as defined by the hospital, but that does not meet the criteria for review under the Sentinel Event Policy, is still expected to complete a root cause analysis (as required by Standard LD.04.04.05) but does not need to submit it to The Joint Commission.

For more information refer Attachment IV for the Joint Commission's Sentinel Event Policy.

ATTACHMENTS:

I: **ROOT CAUSE ANALYSIS WORKSHEET**
II: **MINIMUM SCOPE OF ROOT CAUSE ANALYSIS FOR SPECIFIC TYPES OF SENTINEL EVENTS**
III: **EXAMPLES OF REVIEWABLE AND NONREVIEWABLE SENTINEL EVENTS**
IV: **THE JOINT COMMISSION'S SENTINEL EVENT POLICY**

ATTACHMENT I

Root Cause Analysis (RCA) Form

Note 1: These documents or records or information contained herein, which resulted from a focused review, are confidential and privileged. This material shall not be disclosed to anyone without authorization as provided for by law or its regulations. (RCAs and Aggregated Reviews are considered to be focused reviews).

Note 2: The Risk Management Program Officer (or designee) is responsible for providing information for items 1 – 7, and for ensuring that there is Senior Management consideration and sign off on items 18 and 21 of this form. The RCA Team is responsible for providing information for the remainder of this form.

Note 3: Questions or items below marked with an "*" (asterisk) are not applicable for Aggregated Reviews.

DEMOGRAPHIC INFORMATION

1. Case Number _____
If individual case, use patient's two initials and last four digits of Social Security number. If aggregated review, use the initial of the type (E = elopements, F = falls, M = medication errors); then the year and the quarter of the review (e.g., F – 10 – Q4)

2. RCA Type (check one): Individual Case _____ Aggregated Review _____

3. Date of Event or Close Call (for individual cases only)
_____

4. Describe the actual event(s) or close call(s):
_____
_____
_____
_____

5. Has this type of adverse event or close call occurred before?* Yes _____ No _____

If "Yes", note most recent prior date ___/___/_____

If "Yes", were corrective actions developed and implemented then? Yes _____ No _____

If "Yes", describe previous interventions:
_____
_____
_____
_____

6. **Immediate Actions***. There are a variety of actions that may need to be taken immediately following an adverse event or close call. Review the list of actions noted below and provide additional information, as indicated. If an action is not relevant or not appropriate for this adverse event or close call, just check the "N/A" option and move on to the next item.

A. Provided immediate care/treatment to individuals involved in the event (this includes patients, staff, or visitors)
Yes _____ (if "Yes", provide date) Date _____ No _____ N/A ____
Briefly describe the type of care/treatment that was provided:
_____

_____

_____

B. Made the situation safe and immediately prevented recurrence
Yes _____ (if "Yes", provide date) Date _____ No _____ N/A ____
Describe actions taken to make the situation safe and prevent recurrence:

_____

_____

_____

C. Physically removed specific equipment or supplies that malfunctioned
Yes _____ (if "Yes", provide date) Date _____ No _____ N/A ____
Describe which items were removed and what interventions were taken (e.g., sotred with other evidence related to the event, sent to CSR or Biomed for evaluation, contacted manufacturer, etc.):

_____

_____

_____

D. Established and maintained the chair of evidence (refer to the "Chain of Evidence Checklist")
Yes _____ (if "Yes", provide date) Date _____ No _____ N/A ____
Describe what evidence was collected (e.g., supplies, biological samples, equipment, photographs, etc.) and note where the evidence was stored and/or referred:

_____

_____

_____

E. Notified GMHA Security and Police
Yes _____ (if "Yes", provide date) Date _____ No _____ N/A ____
Note when GMHA Security and Police were notified, and who was notified:
Time: _____ Who was notified: _____

F. Notified Facilities Maintenance
Yes _____ (if "Yes", provide date) Date _____ No _____ N/A ____
Who was notified: _____

G. Other Immediate Action taken by the hospital. (This option is provided for use in describing any action not covered in items A-G)
Date _____
Action: _____

_____

_____

7. **RCA Structure.** Provide key information about the overall structure of this RCA (please see introductory comments regarding team charters).

a. Date RCA Team chartered ___/___/_____

b. The RCA team's final report is due to the Risk Management Program Officer on: ___/___/_____

c. Date RCA actually completed: ___/___/_____

RCA PROCESS

8. **Initial Understanding of Event.** Sketch the RCA Team's **initial flow chart** below (i.e., what does the team think happened?). For Aggregated Reviews, flow chart any suspected common themes or elements. This flow chart will map out what the team understands to be the sequence of what happened and when it happened.

9. (Continued) **Description of Event.** In addition to the initial flow sheet, please provide brief highlights of the sequence of events, mapped out, above.

_____

_____

_____

_____

10. **Resources.** List the involved services/departments, information needed by the team (e.g., policies, procedures, reports, regulations, medical records, committee minutes, etc.).

Information Needed	Source Department or Individual	Responsible Team Member	Due Date

11. **Personnel Needed.** List those providing information to the team (e.g., interviewees).

Name	Title	Date

12. **References.** List the literature/references reviewed by the team.

13. **Final Understanding of Events.*** What is the team's final interpretation of what actually happened—what was the sequence of events/factors—that ultimately resulted in the adverse event or close call?
*(Provide a written description, below, and also **attach a flow chart** that illustrates this sequence of events/factors to the RCA Form.)*

14. **Root Cause/Contributing Factor Table.** Now that the RCA Team has pulled all the findings together (# 14), it is time to display and describe the root cause/contributing factors in the "Root Cause/Contributing Factors Table" on the next page.

***Note:** Each root cause/contributing factor displayed in the "Root Cause/Contributing Factor Table" must be addressed again in item #18, the "RCA Team Action Plan".*

14. **Root Cause/Contributing Factors Table (Page 1)**

Instructions: Item #--Assign a number to each root cause/contributing factor. Description—Briefly describe the root cause/contributing factor. Category—Categorize each root cause/contributing factor by putting an X under as many letter codes that apply.

TEX	Technical failures beyond the control & responsibility of the investigating organization	**TD**	Failures due to poor design of equipment, software, labels, or forms	**TC**	Construction failures despite correct design	**TM**	Material defects not classified under TD or TC
OEX	Failures at an organizational level beyond the control & responsibility of the investigating organization.	**OK**	Failures resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to all new or inexperienced staff	**OP**	Failures related to the quality and availability of the protocols within the department (too complicated, inaccurate, unrealistic, absent, or poorly presented)	**OM**	Internal management decisions in which safety is relegated to an inferior position in the face of conflicting demands or objectives; this is a conflict between production needs and safety (e.g., decisions about safety levels.
OC	Failures resulting from the collective approach to risk and attendant modes of behavior in the investigating organization.	**HEX**	Human failures originating beyond the control and responsibility of the investigating organization.	**HKK**	The inability of an individual to apply existing knowledge to a novel situation.	**HRQ**	Incorrect fit between an individual's qualifications, training, or education and a particular task.
HRC	Lack of task coordination within a healthcare team in an organization.	**HRV**	Failures in the correct and complete assessment of a situation, including relevant conditions of the patient and materials to be used, before starting the intervention.	**HRI**	Failures that result from faulty task planning (selecting the wrong protocol) and/or execution (selecting the right protocol but carrying it out incorrectly)	**HRM**	Failures during monitoring of the process or patient status during or after the intervention.
HSS	Failures in performance of the fine motor skills	**HST**	Failures in whole-body movements	**PRF**	Failures related to patient characteristics or conditions that influence treatment and are beyond the control of staff	**X**	Failures that cannot be classified in any other category

		Category																			
Item #	**Description**	**TEX**	**TD**	**TC**	**TM**	**OEX**	**OK**	**OP**	**OM**	**OC**	**HEX**	**HKK**	**HRQ**	**HRC**	**HRV**	**HRI**	**HRM**	**HSS**	**HST**	**PRF**	**X**

14. **Root Cause/Contributing Factors Table (Page ____)**

		Category																				
Item #	**Description**	**TEX**	**TD**	**TC**	**TM**	**OEX**	**OK**	**OP**	**OM**	**OC**	**HEX**	**HKK**	**HRQ**	**HRC**	**HRV**	**HRI**	**HRM**	**HSS**	**HST**	**PRF**	**X**

15. **Effectiveness of Previous Solution.** If this kind of adverse event or close call occurred before (please refer back to item # 7, did the preventive actions minimize the severity or extent of this adverse or close call?

Yes _____ No _____

(If "Yes", describe how the adverse event or close call was minimized)

_____
_____
_____
_____
_____
_____

16. **Feedback to the Reporter.*** Once the RCA is nearly completed, it is important for the team leader to arrange a final opportunity to talk with the original reporter (i.e., the individual or group that initially reported the adverse event or close call) to verify that the RCA team has fully understood what happened from the reporter's perspective. It is also appropriate and desirable for the team leader to discuss the team's recommendations and to ask the reporter for any additional suggestions about how to eliminate or correct root cause/ contributing factors during this conversation. (This does not mean that the reporter will read or be provided with a copy of the RCA or that individual specific findings will be discussed with them…those things would be a breach of the confidential/protected nature of the RCA process.)

17-A. In the opinion of the original reporter, are the root cause/contributing factors, and the actions proposed by the RCA Team to remedy these factors, on target?

Yes _____ No _____ Original Reporter Not Known _____

If "No", please describe additional suggestions by the reporter.

_____
_____
_____
_____
_____

17-B. Will the reporter's additional suggestions be incorporated by the RCA Team?

Yes _____ No _____ Original Reporter Not Known _____

If "no", please explain why not.

_____
_____
_____
_____
_____

17. **RCA Outcomes.** Who needs to know (or could benefit from knowing) the findings and recommendations of the RCA team? (This may include only a small number of individuals or it may have relevance for all staff.)

What was learned?	Who needs to know?	How to share it?

18. **RCA Team Plan Table.** Display and describe recommended actions resulting from this RCA in the table on the following pages. All "Root Cause/Contributing Factors" previously identified in question #15 must be reflected in the RCA Team Plan table. Please use the same item numbers developed for root cause/contributing factors in question # 15 so it is easy to compare information).

As experts, the RCA Team may recommend three possible options for dealing with each root cause/contributing factor (i.e., to eliminate, control, or accept the factor). In addition, the team is expected to make recommendations about: What the most effective remedial action is, Designating responsibility for implementing the action, Defining a reasonable outcome measure for the action (i.e., to measure whether or not the action was effective), and Setting a realistic target date for measurement.

It is anticipated that the RCA Advisor will be involved with the RCA Team and senior management, in determining final close-out for each root cause/contributing factor. In the event that senior management does not concur with a proposed action developed by the RCA Team, an alternate solution will be developed and documented on the "Revised RCA Plan".

Example. An example of the differences between eliminating, controlling, or accepting a root cause or contributing factor follows:

Let's say that a piece of equipment was temperamental to use, but most staff knew how to get it to work and no one was ever injured. One day a new staff member tried to use the equipment and was injured because they followed the written procedure for use, but did not know about the dangerous temperamental features.

To eliminate the problem, the piece of equipment would need to be removed and fixed or replaced. (There would also need to be targeted staff discussion and education to ensure that people no longer tolerated equipment that did not work correctly, and that policies and procedures for notifying relevant support services for timely repairs were followed. Some measures of whether or not the corrective actions actually eliminate the problem might be: equipment spot checks; analysis of repair referrals/turnaround times, and; analysis of equipment related staff injuries.).

To control the problem, an additional procedural step warning notice might be added to the procedure list for that piece of equipment, and all new employees would be oriented more specifically.

To accept the problem would mean that although there would formal or informal discussion along the lines of "don't let this happen again/pay attention next time" essentially nothing would change, and the associated risk would be accepted.

RCA Team Action Plan Table Instructions. On the following pages are tables to gather and process information about your action plan. Here are explanations and definitions for each column to be filled out:

- **Item # and Description of Item**—Use the exact same item number that identified factors in item # 14, and descriptions (the Root Cause/Contributing Factors Table).
  Note: each "Item" may have more than one "Action", and each "Action" may address more than one "Item"

- **Description of Action**—Describe action in enough detail for management action.

- **Action**—Describe recommended action for each factor by entering **one** letter code:

E = eliminate; **C** = control; **A** = accept

- **Personnel Responsible**—Note name and title of person in charge of implementation.
- **Outcome Measure**—Describe data to be collected that will measure effectiveness.
- **Measure Data**—Realistic target date for first outcome measurement (MM/DD/YYYY).
- **Management Concurrence**—Management sign-off on each individual section.

RCA Team Action Plan Table.

Revisions: If there are revisions to the Action Plan after non-concurrence, then label item # with an "R" next to it (e.g., 4R, 11R).

Item #	Description of Item	Description of Action	Action (E=eliminate, C=control, A=accept	Personnel Responsibilities	Outcome Measure	Measure Date (MM/DD/YYYY	Senior Mgmt Concurrence (Yes/No)	Mgmt. Notes (if "No")

19. **RCA Costs.** The purpose of this item is to get a ballpark idea of the financial expense associated with conducting this particular RCA.

Person-hours that were directly spent on this RCA: _____

Consultant Costs: _____

Material Costs (e.g., transcription, duplications, etc.): _____

Other (describe): _____

_____

20. **Methods and Tools Used.** List the analytical methods/tools used during this RCA, and attach any documents generated by the team as a supplement to this report when you submit it to the Risk Management Program Officer. Examples include Cause and Effect Diagrams, flow charting, multi-voting, and checklists.
Note: The RCA Team should also update Item 13 ("References") as needed.

_____

_____

_____

_____

_____

21. **RCA Concurrence.** Note the names of the approving officials, and obtain signatures and dates of occurrence with the RCA Team Plans.

Final sign-off will include, at a minimum, the RCA Advisor, the entire RCA Team, and the Hospital Administrator/CEO.

Name/Signature	Title	Date

ATTACHMENT II

Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events

Detailed inquiry into these areas is expected when conducting a root cause analysis for the specified type of sentinel event. Inquiry into areas not checked (or listed) should be conducted as appropriate to the specific event under review.

	Suicide (24-Hour Care)	Medication Error	Procedural Complication	Wrong-Site Surgery	Treatment Delay	Restraint Death	Elopement Death	Assault/Rape/Homicide	Transfusion Death	Patient Abduction	Unanticipated Death of Full-Term Infant	Unintended Retention of Foreign Body	Fall Related
Behavioral assessment process*	X					X	X	X					
Physical assessment process†	X	X	X	X	X	X	X				X		X
Individual identification process		X		X					X				
Individual observation procedures	X				X	X	X	X	X		X		X
Care planning process	X		X			X	X				X		X
Continuum of care	X	X			X	X							X
Staffing levels	X	X	X	X	X	X	X	X	X	X		X	X
Orientation and training of staff	X	X	X	X	X	X	X	X	X	X	X	X	X
Competency assessment/credentialing	X	X	X	X	X	X	X	X	X	X	X	X	X
Supervision of staff‡	X	X	X		X	X			X			X	
Communication with individual/family	X	X		X	X	X	X			X			X
Communication among staff members	X	X	X	X	X	X	X	X	X	X	X	X	X
Availability of information	X	X	X	X	X	X			X		X		X
Adequacy of technological support		X	X										
Equipment maintenance/management		X	X		X	X					X		X
Physical environment§	X	X	X	X		X	X	X	X	X			X
Security systems and processes	X						X	X		X			
Medication management‖		X	X		X				X		X		X

*Includes the process for assessing individual's risk to self (and to others, in cases of assault, rape, or homicide where an individual is the assailant).

†Includes the search for contraband.

‡Includes supervision of physicians-in-training.

§Includes furnishings; hardware (for example, bars, hooks, rods); lightening; distractions.

‖Includes selection and procurement; storage; ordering and transcribing; preparing and dispensing; administration; and monitoring.

ATTACHMENT III

Examples of Sentinel Events that Are Reviewable and Not Reviewable Under the Joint Commission's Sentinel Event Policy

I. Examples of Sentinel Events that Are Reviewable Sentinel Events

- Any patient death, paralysis, coma, or other major permanent loss of function associated with a medical error.
- A patient commits suicide within 72-hours of being discharge from a hospital setting that provides staffed around-the-clock care.
- Any elopement, that is unauthorized departure, of a patient from an around-the-clock care setting resulting in a temporally related death (suicide, accidental death, or homicide) or major permanent loss of function.
- A hospital operates on the wrong side of the patient's body.
- Any intrapartum (related to the birth process) maternal death.
- Any perinatal death unrelated to a congenital condition in an infant having a birth weight greater than 2,500 grams.
- A patient is abducted from the hospital where he or she receives care, treatment, or services.
- Assault, homicide, or other crime resulting in patient death or major permanent loss of function.
- A patient fall that results in death or major permanent loss of function as a direct result of the injuries sustained in the fall.
- Hemolytic transfusion reaction involving major blood group incompatibilities.
- A foreign body, such as a sponge or forceps, that was left in a patient after surgery.

Note: *An adverse outcomes that is directly related to the natural course of the patient's illness or underlying condition; for example, terminal illness present at the time of presentation, is* ***not*** *reportable* ***except*** *for suicide in, or following elopement from, a 24-hour care setting (see above).*

II. Examples of Sentinel Events that Are NOT Reviewable Sentinel Events

- Any "near miss".
- Full or expected return of limb or bodily function to the same level as prior to the adverse event by discharge or within two weeks of the initial loss of said function.
- Any sentinel event that has not affected a recipient of care (patient, client, resident).
- Medication errors that do not result in death or major permanent loss of function.
- Suicide other than in an around-the-clock care setting or following elopement from such a setting.
- A death or loss of function following a discharge "against medical advice (AMA)"
- Unsuccessful suicide attempts unless resulting in major permanent loss of function.
- Minor degrees of hemolysis not caused by a major blood group incompatibility and with no clinical sequelae.

Note: *In the context of its performance improvement activities, an organization may choose to conduct intensive assessment, for example, root cause analysis, for some not reviewable events.*

ATTACHMENT IV

The Joint Commission's Sentinel Event Policy

I. Sentinel Events

In support of its mission to continuously improve the safety and quality of health care provided to the public, The Joint Commission reviews hospitals' activities in response to sentinel events in its accreditation process, including all full accreditation surveys and, as appropriate, for-cause surveys, and random validation surveys specific to Evidence of Standards Compliance (ESC).

- A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.
- Such events are called "sentinel" because they signal the need for immediate investigation and response.
- The terms "sentinel event" and "error" are not synonymous; not all sentinel events occur because of an error, and not all errors result in sentinel events.

II. Goals of the Sentinel Event Policy

The policy has four goals:

1. To have a positive impact in improving patient care, treatment, and services and preventing sentinel events
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 organizational 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 sentinel events, their contributing factors, and strategies for prevention
4. To maintain the confidence of the public and accredited hospitals in the accreditation process

III. Standards Relating to Sentinel Events Standards

Each Joint Commission accreditation manual contains standards in the "Leadership" (LD) chapter that relate specifically to the management of sentinel events.

Hospital-Specific Definition of Sentinel Event

LD.04.04.05, EPs 7 and 8, requires each accredited hospital to define "sentinel event" for its own purposes in establishing mechanisms to identify, report, and manage these events. While this definition must be consistent with the general definition of sentinel event as published by The Joint Commission, accredited hospitals have some latitude in setting more specific parameters to define "unexpected," "serious," and "the risk thereof." At a minimum, a hospital's definition must include those applicable events that are subject to review under the Sentinel Event Policy as defined in Section IV of this chapter.

Expectations Under the Standards for a Hospital's Response to a Sentinel Event

Accredited hospitals are expected to identify and respond appropriately to all sentinel events (as defined by the hospital in accordance with the preceding paragraph) occurring in the hospital or associated with services that the hospital provides, or provides for. Appropriate response includes conducting a timely, thorough, and credible root cause analysis; developing an action plan designed to implement improvements to reduce risk; implementing the improvements; and monitoring the effectiveness of those improvements.

Sentinel Events

Root Cause Analysis

Root cause analysis is a process for identifying the factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis 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 and 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.

Action Plan

The product of the root cause analysis is an action plan that identifies the strategies that the hospital intends to implement in order to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.

Survey Process

When conducting an accreditation survey, the Joint Commission seeks to evaluate the hospital's compliance with the applicable standards, National Patient Safety Goals, and Accreditation Participation Requirements, and to score those requirements based on performance throughout the hospital over time. Surveyors are instructed not to search for sentinel events during a usual survey or to inquire about sentinel events that have been reported to The Joint Commission. Surveyors may conduct an assessment of a hospital's performance improvement practices and procedures, such as root cause analyses and proactive risk assessment.

If, in the course of conducting the usual survey activities, a sentinel event is (newly) identified, the surveyor will take the following steps:

- Inform the CEO that the event has been identified
- Inform the CEO the event will be reported to The Joint Commission for further review and follow-up under the provisions of the Sentinel Event Policy. The surveyor makes no determination of whether or not the event is a reviewable sentinel event, but rather will hand off further discussion to Joint Commission Central Office staff in the Sentinel Event Unit of the Office of Quality Monitoring. Staff in the Sentinel Event Unit will contact the hospital after all survey activity is entirely completed to explore the event and determine whether or not submission of a root cause analysis is required. If so, the hospital will proceed with the steps described after an event is determined to be reviewable. (See the "Required Response to a Reviewable Sentinel Event" section below.)

During the on-site survey, the surveyor(s) will assess the hospital's compliance with sentinel event–related standards in the following ways:

- Review the hospital's process for responding to a sentinel event
- Interview the hospital's leaders and staff about their expectations and responsibilities for identifying, reporting on, and responding to sentinel events
- Ask for an example of a root cause analysis that has been conducted in the past year to assess the adequacy of the hospital's process for responding to a sentinel event. Additional examples may be reviewed if needed to more fully assess the hospital's understanding of, and ability to conduct, root cause analyses. In selecting an example, the hospital may choose a "closed case" or a "near miss"‡ to demonstrate its process for responding to a sentinel event.

IV. Reviewable Sentinel Events

Definition of Occurrences That Are Subject to Review by The Joint Commission Under the Sentinel Event Policy

The definition of a reviewable sentinel event takes into account a wide array of occurrences applicable to a wide variety of health care organizations. Any or all occurrences may apply to a particular type of hospital. Thus, not all of the following occurrences may apply to your particular hospital. The subset of sentinel events that is subject to review by The Joint Commission includes any occurrence that meets any of the following criteria:

- The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition§ ||

or

- The event is one of the follo ing (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition):
  - Suicide of any patient receiving care, treatment and services in a staffed around-the-clock care setting or within 72 hours of discharge
  - Unanticipated death of a full-term infant
  - Abduction of any patient receiving care, treatment, and services
  - Discharge of an infant to the wrong family
  - Rape#
  - Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
  - Surgical and nonsurgical invasive procedure on the wrong patient, wrong site, or wrong procedure**
  - Unintended retention of a foreign object in a patient after surgery or other procedure
  - Severe neonatal hyperbilirubinemia (bilir bin >30 milligrams/deciliter)
  - Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose

Examples of reviewable sentinel events are provided in Table 1 and not reviewable sentinel events are provided in Table 2.

Table 1. Examples of Sentinel Events That Are Reviewable Under The Joint Commission's Sentinel Event Policy††
Any patient death, paralysis, coma, or other major permanent loss of function associated with a medication error
A patient commits suicide within 72 hours of being discharged from a hospital setting that provides staffed around-the-clock care
Any elopement, that is, unauthorized departure, of a patient from an around-the-clock care setting resulting in a temporally related death (suicide, accidental death, or homicide) or major permanent loss of function
A hospital operates on the wrong side of the patient's body
Any intrapartum (related to the birth process) maternal death
Any perinatal death unrelated to a congenital condition in an infant having a birth weight greater than 2,500 grams
A patient is abducted from the hospital where he or she receives care, treatment, or services
Assault, homicide, or other crime resulting in patient death or major permanent loss of function
A patient fall that results in death or major permanent loss of function as a direct result of the injuries sustained in the fall

Hemolytic transfusion reaction involving major blood group incompatibilities A foreign body, such as a sponge or forceps, that was left in a patient after surgery Note: An adverse outcome that is directly related to the natural course of the patient's illness or underlying condition; for example, terminal illness present at the time of presentation, is not reportable except for suicide in, or following elopement from, a 24-hour care setting (see above).

Table 2. Examples of Sentinel Events That Are Not Reviewable Under The Joint Commission's Sentinel Event Policy††
Any close call ("near miss") Full or expected return of limb or bodily function to the same level as prior to the adverse event by discharge or within two weeks of the initial loss of said function Any sentinel event that has not affected a recipient of care (patient, individual, resident) Medication errors that do not result in death or major permanent loss of function Suicide other than in an around-the-clock care setting or following elopement from such a setting A death or loss of function following a discharge against medical advice (AMA) Unsuccessful suicide attempts unless resulting in major permanent loss of function Minor degrees of hemolysis not caused by a major blood group incompatibility and with no clinical sequelae Note: In the context of its performance improvement activities, a hospital may choose to conduct intensive assessment, for example, root cause analysis, for some not reviewable events. Please refer to the "Performance Improvement" (PI) chapter of this Joint Commission accreditation manual.

How The Joint Commission Becomes Aware of a Sentinel Event

Each hospital is encouraged, but not required, to report to The Joint Commission any sentinel event meeting the above criteria for reviewable sentinel events. Alternatively, The Joint Commission may become aware of a sentinel event by some other means such as communication from a patient, a family member, an employee of the hospital, a surveyor, or through the media.

Reasons for Reporting a Sentinel Event to The Joint Commission

Although self-reporting a sentinel event is not required and there is no difference in the expected response, time frames, or review procedures, whether the hospital voluntarily reports the event or The Joint Commission becomes aware of the event by some other means, there are several advantages to the hospital that self-reports a sentinel event:

- Reporting the event enables the addition of the "lessons learned" from the event to be added to The Joint Commission's Sentinel Event Database, thereby contributing to the general knowledge about sentinel events and to the reduction of risk for such events in many other hospitals
- Early reporting provides an opportunity for consultation with Joint Commission staff during the development of the root cause analysis and action plan
- The hospital's message to the public that it is doing everything possible to ensure that such an event will not happen again is strengthened by its acknowledged collaboration with The Joint Commission to understand how the event happened and what can be done to reduce the risk of such an event in the future

Required Response to a Reviewable Sentinel Event

If The Joint Commission becomes aware (either through voluntary self-reporting or otherwise) of a sentinel event that meets the preceding criteria (see Table 1) and the event has occurred in an accredited hospital, the hospital is expected to do the following:

- Prepare a thorough and credible root cause analysis and action plan within 45 calendar days of the event or of becoming aware of the event
- Submit to The Joint Commission its root cause analysis and action plan, or otherwise provide for Joint Commission evaluation of its response to the sentinel event under an approved protocol (see Section VI), within 45 calendar days of the known occurrence of the event

The Joint Commission will then determine whether the root cause analysis and action plan are acceptable. If the determination that an event is reviewable under the Sentinel Event Policy occurs more than 45 calendar days following the known occurrence of the event, the hospital will be allowed 15 calendar days for its response. If the hospital fails to submit an acceptable root cause analysis within the 45 calendar days (or within 15 calendar days, if the 45 calendar days have already elapsed), the following consequence will result (depending on the length of time the hospital fails to submit a root cause analysis):

- If the hospital has failed to submit a root cause analysis within an additional 45 days following its due date, its accreditation decision may be impacted.

Please note that a hospital that experiences a sentinel event as defined by the hospital, but that does not meet the criteria for

review under the Sentinel Event Policy, is still expected to complete a root cause analysis (as required by Standard LD.04.04.05) but does not need to submit it to The Joint Commission.

Review of Root Cause Analyses and Action Plans

A root cause analysis will be considered acceptable if it has the following characteristics:

- The analysis 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
- The analysis repeatedly digs deeper by asking "Why?"; then, when answered, "Why?" again, and so on
- The analysis identifies changes that could be made in systems and processes (either through redesign or development of new systems or processes) that would reduce the risk of such events occurring in the future
- The analysis is thorough and credible

To be thorough, the root cause analysis must include the following:

- 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 analysis of the underlying systems and processes through a series of "Why?" questions to determine where redesign might reduce risk
- An inquiry into all areas appropriate to the specific type of event as described in Table 3
- An identification of risk points and their potential contributions to this 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

To be credible, the root cause analysis must do the following:

- Include participation by the leadership of the hospital and by individuals most closely involved in the processes and systems under review
- 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 consideration of any relevant literature

An action plan will be considered acceptable if it does the following:

- Identifies changes that can be implemented to reduce risk or formulates a rationale for not undertaking such changes
- Identifies, in situations where improvement actions are planned, who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated

All root cause analyses and action plans will be considered and treated as confidential by the Joint Commission. A detailed listing of the minimum scope of root cause analysis for specific types of sentinel events is included in Table 3.

Table 3. Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events

Detailed inquiry into these areas is expected when conducting a root cause analysis for the specified type of sentinel event. Inquiry into areas not checked (or listed) should be conducted as appropriate to the specific event under review.

	TYPES OF SENTINEL EVENTS											
Areas of Potential Root Causes												
Behavioral assessment process‡‡	X				X	X	X					
Physical assessment process§§	X	X	X	X	X	X	X			X		X
Individual identification process		X		X				X				
Individual observation procedures	X				X	X	X	X	X		X		X
Care planning process	X		X			X	X				X		X
Continuum of care	X	X			X	X							X
Staffing levels	X	X	X	X	X	X	X	X	X	X		X	X
Orientation and training of staff	X	X	X	X	X	X	X	X	X	X	X	X	X
Competency assessment/credentialing	X	X	X	X	X	X	X	X	X	X	X	X	X
Supervision of staff‖‖	X	X	X		X	X			X			X	
Communication with individual/family	X	X		X	X	X	X			X			X
Communication among staff members	X	X	X	X	X	X	X	X	X	X	X	X	X
Availability of information	X	X	X	X	X	X			X		X		X
Adequacy of technological support		X	X										
Equipment maintenance/management		X	X		X	X					X		X
Physical environment##	X	X	X	X		X	X	X	X	X			X
Security systems and processes	X					X	X	X		X			

Medication management***		X	X		X			X		X		X

Follow-up Activities

After the Joint Commission has determined that a hospital has conducted an acceptable root cause analysis and developed an acceptable action plan, The Joint Commission will notify it that the root cause analysis and action plan are acceptable and will assign an appropriate follow-up activity, typically one or more Sentinel Event Measures of Success (SE MOS) due in four months (see the "Sentinel Event Measures of Success" section below).

V. The Sentinel Event Database

To achieve the third goal of the Sentinel Event Policy, "to increase the general knowledge about sentinel events, their contributing factors, and strategies for prevention," The Joint Commission collects and analyzes data from the review of sentinel events, root cause analyses, action plans, and follow-up activities. These data and information form the content of the Joint Commission's Sentinel Event Database.

The Joint Commission is committed to developing and maintaining this Sentinel Event Database in a fashion that will protect the confidentiality of the hospital, the caregiver, and the patient. Included in this database are three major categories of data elements:

1.Sentinel event data
2.Root cause data
3.Risk reduction data

De-identified aggregate data relating to root causes and risk-reduction strategies for sentinel events that occur with significant frequency will form the basis for future error-prevention advice to hospitals through Sentinel Event Alert and other media. The Sentinel Event Database is also a major component of the evidence base for the National Patient Safety Goals.

VI. Procedures for Implementing the Sentinel Event Policy

Voluntary Self Reporting of Reviewable Sentinel Events to the Joint Commission

If a hospital wishes to report an occurrence in the subset of sentinel events that are subject to review by The Joint Commission, the hospital will be asked to complete a form accessible through its Joint Commission Connect™ extranet site. From this site, select "Self Report Sentinel Event" from the "Continuous Compliance Tools" section.

Reviewable Sentinel Events that Are Not Reported by the Hospital

If The Joint Commission becomes aware of a sentinel event subject to review under the Sentinel Event Policy which was not reported to The Joint Commission by the hospital, the CEO of the hospital is contacted, and a preliminary assessment of the sentinel event is made. An event that occurred more than one year before the date The Joint Commission became aware of the event will not, in most cases, be reviewed under the Sentinel Event Policy. In such a case, a written response will be requested from the hospital, including a summary of processes in place to prevent similar occurrences.

Determination that a Sentinel Event Is Reviewable Under the Sentinel Event Policy

Based on available factual information received about the event, Joint Commission staff will apply the above definition to determine whether the event is reviewable under the Sentinel Event Policy. Challenges to a determination that an event is reviewable will be resolved through consultation with senior Joint Commission staff.

Initial On-Site Review of a Sentinel Event

An initial on-site review of a sentinel event will usually not be conducted unless it is determined that there is a potential ongoing immediate threat to patient health or safety or potentially significant noncompliance with Joint Commission standards. Immediate Threat to Health or Safety incidents include situations in which the hospital's noncompliance with one or more standards has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient and is likely to continue. Complaints are assigned this priority if the information indicates immediate corrective action is necessary. All are immediately referred to Joint Commission Executive Leadership for authorization to conduct an unannounced for-cause survey. If an on-site ("for-cause") review is conducted, the hospital will be billed an appropriate amount based on the established fee schedule to cover the costs of conducting such a survey.

Disclosable Information

If The Joint Commission receives an inquiry about the accreditation decision of a hospital that has experienced a reviewable sentinel event, the hospital's accreditation decision will be reported in the usual manner without making reference to the sentinel event. If the inquirer specifically references the specific sentinel event, The Joint Commission will acknowledge that it is aware of the event and currently is working or has worked with the hospital through the sentinel event review process.

Submission of Root Cause Analysis and Action Plan

The hospital that experiences a sentinel event subject to the Sentinel Event Policy is asked to submit two documents: (1) the complete root cause analysis, including its findings; and (2) the resulting action plan that describes the hospital's risk reduction strategies and measures for evaluating their effectiveness. This information will be submitted to The Joint Commission Central Office using an online root cause analysis collection tool, also accessible from the "Continuous Compliance Tools" section of the Joint Commission Connect extranet site, under the "Sentinel Event Activities" link.

The root cause analysis and action plan are not to include the name(s) of caregivers and patients involved in the sentinel event.

Alternatively, if the hospital has concerns about waivers of confidentiality protections as a result of sending the root cause analysis documents to The Joint Commission, the following alternative approaches to a review of the hospital's response to the sentinel event are acceptable:

1. A review of the root cause analysis and action plan documents brought to Joint Commission headquarters by hospital staff, then taken back to the hospital on the same day
2. An on-site visit by a specially trained surveyor to review the root cause analysis and action plan
3. An on-site visit by a specially trained surveyor to review the root cause analysis and findings without directly viewing the root cause analysis documents through a series of interviews and a review of relevant documentation. For purposes of this review activity, "relevant documentation" includes, at a minimum, any documentation relevant to the hospital's process for responding to sentinel events, the patient's medical record, and the action plan resulting from the analysis of the subject sentinel event. The latter serves as the basis for appropriate follow-up activity.
4. When the hospital affirms that it meets specified criteria respecting the risk of waiving confidentiality protections for root cause analysis information shared with The Joint Commission, an on-site visit by a specially trained surveyor is arranged to conduct the following:

a. Interviews and reviews relevant documentation, including the patient's medical record, to obtain information about the following:
- The process the hospital uses in responding to sentinel events
- The relevant policies and procedures preceding and following the hospital's review of the specific event, and the implementation thereof, sufficient to permit inferences about the adequacy of the hospital's response to the sentinel event

b. A standards-based survey that traces a patient's care, treatment, and services and the hospital management functions relevant to the sentinel event under review.††

Any one of the four alternatives will result in a sufficient charge to the hospital to cover the average direct costs of the visit. Inquiries about the fee should be directed to The Joint Commission's Pricing Unit at 630/792-5115.

The Joint Commission must receive a request for review of a hospital's response to a sentinel event using any of these alternative approaches within at least five business days of the self-report of a reviewable event or of the initial communication by The Joint Commission to the hospital that it has become aware of a reviewable sentinel event.

The Joint Commission's Response

Joint Commission staff assess the acceptability of the hospital's response to the reviewable sentinel event, including the thoroughness and credibility of any root cause analysis information reviewed and the hospital's action plan. If the root cause analysis and action plan are found to be thorough and credible, the response will be accepted and one or more SE MOS will be assigned (see below for more details).

If the response is unacceptable, staff will provide consultation to the hospital on the criteria that have not yet been met and will allow an additional 15 calendar days beyond the original submission period for the hospital to resubmit its response.

If the response does not meet established criteria, the hospital's accreditation decision may be impacted if The Joint Commission determines the hospital has not undertaken serious improvement efforts.

When the hospital's response (initial or revised) is found to be acceptable, The Joint Commission issues a letter that does the following:

- Reflects the Joint Commission's determination to continue or modify the hospital's current accreditation decision
- Assigns an appropriate follow-up activity, typically one or more SE MOS due in four months

Sentinel Event Measures of Success

The hospital's follow-up activity will be conducted through the Measure of Success (MOS) process. An MOS is a numerical or quantifiable measure usually related to an audit that determines if a planned action was effective and sustained. The SE MOS are due four months after the root cause analysis and action plan are determined acceptable. If the planned action can be associated with a standard or National Patient Safety Goal requirement, it will have a level of compliance expectation based on the type of element of performance (EP) for the associated standard or National Patient Safety Goal requirement. That is, if the action is equivalent to an EP that is identified as an "A" EP, the level of compliance expectation for the SE MOS for that action will be 100%. If the action is equivalent to an EP that is identified as a "C" EP, the minimum required level of compliance for the SE MOS for that action will be 90%. If the action cannot be associated with an existing standard or National Patient Safety Goal requirement, the hospital will identify the level of compliance expectation, which must be at least 85%, subject to approval by The Joint Commission. The following information further outlines the SE MOS requirement:

- If an SE MOS is 90 or more days late, the hospital's accreditation status may be impacted if The Joint Commission determines the hospital has not undertaken serious improvement efforts.
- If an SE MOS is submitted on time but does not meet established levels of compliance, the Joint Commission staff will request an additional four months of data.
- If the second set of data does not meet established levels of compliance, the hospital's accreditation decision may be impacted.

A decision to maintain or change the hospital's accreditation decision as a result of the follow-up activity or to assign additional follow-up requirements will be based on existing decision rules and the determination of staff in the Sentinel Event Unit, unless otherwise determined by the Accreditation Committee.

Handling Sentinel Event–Related Documents

Handling of any submitted root cause analysis and action plan is restricted to specially trained staff in accordance with procedures designed to protect the confidentiality of the documents.

Upon completion of The Joint Commission review of any submitted root cause analysis and action plan and the abstraction of the required data elements for The Joint Commission's Sentinel Event Database, the original root cause analysis documents and any copies will be destroyed. Upon request, the original documents will be returned to the hospital. With the new electronic process, the

information contained in the electronically submitted RCA tool will be de-identified once the review is completed.
The action plan resulting from the analysis of the sentinel event will initially be retained to serve as the basis for the SE MOS. Once the action plan has been implemented and meets the established levels of compliance as determined through the SE MOS, The Joint Commission will destroy the action plan. If the SE MOS was submitted electronically, the information will likewise be de-identified upon completion of the review.

Oversight of the Sentinel Event Policy

The Accreditation Committee of The Joint Commission's Board of Commissioners is responsible for overseeing the implementation of this policy and procedure. In addition to reviewing and deciding individual cases involving changes in a hospital's accreditation decision, the senior staff in Accreditation and Certification Operations will periodically audit the root cause analyses and SE MOS and report these findings to the Accreditation Committee. For the purposes of these audits, The Joint Commission temporarily retains random samples of these documents. Upon completion of the audit, these documents are also destroyed.
For more information about The Joint Commission's Sentinel Event Policy and Procedures, visit The Joint Commission's Web site at http://www.jointcommission.org or call the Sentinel Event Hotline at 630/792-3700.

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* 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.
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† 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.
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‡ Near miss Used to describe any process variation that did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome. Such a "near miss" falls within the scope of the definition of a sentinel event but outside the scope of those sentinel events that are subject to review by The Joint Commission under its Sentinel Event Policy.
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§ A distinction is made between an adverse outcome that is primarily related to the natural course of the patient's illness or underlying condition (not reviewed under the Sentinel Event Policy) and a death or major permanent loss of function that is associated with the treatment (including "recognized complications") or lack of treatment of that condition, or otherwise not clearly and primarily related to the natural course of the patient's illness or underlying condition (reviewable). In indeterminate cases, the event will be presumed reviewable and the hospital's response will be reviewed under the Sentinel Event Policy according to the prescribed procedures and time frames without delay for additional information such as autopsy results.
Back
|| Major permanent loss of function" means sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or lifestyle change. When "major permanent loss of function" cannot be immediately determined, applicability of the policy is not established until either the patient is discharged with continued major loss of function, or two weeks have elapsed with persistent major loss of function, whichever occurs first.
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Rape, as a reviewable sentinel event, is defined as unconsented sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the hospital, including oral, vaginal or anal penetration or fondling of the patient's sex organ(s) by another individual's hand, sex organ, or object. One or more of the following must be present to determine reviewability:
- Any staff-witnessed sexual contact as described above
- Admission by the perpetrator that sexual contact, as described above, occurred on the premises
- Sufficient clinical evidence obtained by the hospital to support allegations of unconsented sexual contact

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‡‡ Includes the process for assessing individual's risk to self (and to others, in cases of assault, rape, or homicide where an individual is the assailant).
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§§ Includes search for contraband.
Back
|||| Includes supervision of physicians-in-training.
Back
Includes furnishings; hardware (for example, bars, hooks, rods); lighting; distractions.
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*** Includes selection and procurement; storage; ordering and transcribing; preparing and dispensing; administration; and monitoring.
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†† For more information about the tracer methodology, see "The Accreditation Process" (ACC) chapter.
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GUAM MEMORIAL HOSPITAL AUTHORITY

REVIEW AND ENDORSEMENT CERTIFICATION

The signatories on this document acknowledge that they have reviewed and approved the following:

□ Bylaws Submitted by: Danielle Manglona, Compliance Officer

□ Rules & Regulations Policy No./Title: No. Pending; Root Cause Analysis for Sentinel Events.

☑ Policies & Procedures

	Date	Signature
Reviewed	10/12/2011	
Endorsed	10/12/2011	
Title	Danielle Manglona, RN Compliance Officer	

	Date	Signature
Reviewed	10/28/11	
Endorsed	10/28/11	
Title	Steven Baacke, RN Chairperson, Patient Safety Committee	

	Date	Signature
Reviewed	10/28/11	
Endorsed	10/28/11	
Title	Rey M. Vega Chairperson, Executive Management Council	

	Date	Signature
Reviewed	10-26-2011	
Endorsed	10-26-2011	
Title	Jonathan P. Sidell, MD Chairperson, Medical Executive Committee	

	Date	Signature
Reviewed	12/13/11	
Endorsed	12/13/11	
Title	Edna Santos, MD Chairperson, Board of Trustees' Quality and Safety Subcommittee	

***Use more forms if necessary. All participating departments/committees in developing the policy should provide signature for certification prior to submitting to the Compliance Officer.**