

Sentinel Events (SE)

I. Sentinel Events

The Joint Commission adopted a formal Sentinel Event Policy in 1996 to help laboratories that experience serious adverse events improve safety and learn from those sentinel events. Careful investigation and analysis of patient safety events, as well as strong corrective actions that provide effective and sustained system improvement, is essential to reduce risk and prevent patient harm. The Sentinel Event Policy explains how The Joint Commission partners with laboratories that have experienced a serious patient safety event to protect the patient, improve systems, and prevent further harm.

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 also considered sentinel if it is one of the following:

- Suicide of any patient receiving care, treatment, or services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the emergency department (ED)
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment, or services

**Severe temporary harm* is critical, potentially life-threatening harm lasting for a limited time with no permanent residual; requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition. Adapted from: Healthcare Performance Improvement. *The HPI SEC & SSER Patient Safety Measurement System for Healthcare, rev. 2*. Throop C, Stockmeier C. May 2011. Accessed Jan 16, 2020. <https://www.pressganey.com/docs/default-source/default-document-library/hpi-white-paper---sec-amp-sser-measurement-system-rev-2-may-2011.pdf?sfvrsn=0>.

- Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED) leading to the death, permanent harm, or severe temporary harm of the patient
- Administration of blood or blood products having unintended ABO and non-ABO (Rh, Duffy, Kell, Lewis, and other clinically important blood groups) incompatibilities,[†] hemolytic transfusion reactions, or transfusions resulting in severe temporary harm, permanent harm, or death[‡]
- Sexual abuse/assault of any patient while receiving care, treatment, and services while on site at the organization/facility or while under the supervision/care of the organization[§]
- Sexual abuse/assault of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization/facility or while providing care/supervision to patients/clients
- Physical assault of any patient (leading to death, permanent harm, or severe temporary harm) while receiving care, treatment, and services while on site at the organization/facility or while under the supervision/care of the organization
- Physical assault (leading to death, permanent harm, or severe temporary harm) of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization/facility or while providing care/supervision to patients/clients
- Homicide of any patient while receiving care, treatment, and services while on site at the organization/facility or while under the supervision/care of the organization
- Homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization/facility or while providing care/supervision to patients/clients

[†]If a clinical determination warrants the use of Rho(D) positive blood to a Rho(D) negative recipient or uncrossmatched blood in emergent or lifesaving interventions, this would not be considered a sentinel event to be reviewed.

[‡]Administration of blood or blood products where the safety, potency, or purity has been compromised while the blood product in question was in the laboratory's control. Source: Food and Drug Administration, Center for Biologics Evaluation and Research. *21 CFR 606.171*.

[§]Sexual abuse/assault (including rape) as a sentinel event, is defined as nonconsensual sexual contact including oral, vaginal, or anal penetration or fondling of the individual's sex organ(s) by another individual. One or more of the following must be present to determine that it is a sentinel event:

- 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 organization to support allegations of unconsented sexual contact

- Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong (unintended) procedure for a patient^{||}
- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery[#]
- 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
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the hospital. To be considered a sentinel event, equipment must be in use at the time of the event; staff do not need to be present.**
- Any intrapartum (related to the birth process) maternal death

^{||}Surgeries or other invasive procedures performed at the wrong site, on the wrong patient, or that are the wrong (unintended) procedure for a patient are reviewable under the policy, regardless of the type of procedure or the magnitude of the outcome. *Invasive procedure* is defined as a procedure in which skin or mucous membranes and/or connective tissue are incised or punctured, an instrument is introduced through a natural body orifice, or foreign material is inserted into the body for diagnostic or treatment-related purposes. Examples of invasive procedures include central line and chest tube insertions, biopsies and excisions, and all percutaneous procedures (e.g., cardiac, electrophysiology, interventional radiology). Exclusions include venipuncture, which is defined as a collection of blood from a vein. **Note:** *These exclusions are still considered patient safety events and should be reviewed by the appropriate local quality and safety teams.*

[#]“After surgery” is defined as any time after the completion of final skin closure, even if the patient is still in the procedural area or in the operating room under anesthesia. This definition is based on the premise that a failure to identify and correct an unintended retention of a foreign object prior to that point in the procedure represents a system failure, which requires analysis and redesign. It also places the patient at additional risk by extending the surgical procedure and time under anesthesia. If a foreign object (for example, a needle tip or screw) is left in the patient because of a clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a sentinel event to be reviewed. However, in such cases, the organization shall (1) disclose to the patient the unintended retention, and (2) keep a record of the retentions to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may identify opportunities for improvement.

^{**}*Fire* is defined as a rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities. Source: National Fire Protection Association. *NFPA 901: Standard Classifications for Incident Reporting and Fire Protection Data*. Quincy, MA: NFPA, 2016.

- Severe maternal morbidity (not primarily related to the natural course of the patient's illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm^{††}
- Fall resulting in any of the following: any fracture; surgery, casting, or traction; required consult/management or comfort care for a neurological (e.g., skull fracture, subdural or intracranial hemorrhage) or internal (e.g., rib fracture, small liver laceration) injury; a patient with coagulopathy who receives blood products as a result of the fall; or death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall)^{††}

The above list is consistent across all Joint Commission accreditation programs, though some of these events may be unlikely to occur in certain settings. In cases in which the laboratory is uncertain that a patient safety event is a sentinel event as defined by The Joint Commission, the event will be presumed to be a patient safety event and not a sentinel event unless determined otherwise through further investigation or the presentation of relevant information. Patient safety events require analysis and should be shared with the Office of Quality and Patient Safety through an organization response (*see* the “Patient Safety Systems” [PS] chapter).

All sentinel events must be reviewed by the laboratory, and are subject to review by The Joint Commission. Accredited laboratories are expected to identify and respond appropriately to all sentinel events (as defined by The Joint Commission) occurring in the laboratory or associated with services that the laboratory provides. An appropriate response includes all of 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

^{††}*Severe maternal morbidity* is defined, by the American College of Obstetrics and Gynecology, the US Centers for Disease Control and Prevention, and the Society of Maternal and Fetal Medicine, as a patient safety event that occurs from the intrapartum through the immediate postpartum period (24 hours), requiring the transfusion of 4 or more units of packed red blood cells (PRBC) and/or admission to the intensive care unit (ICU). *Admission to the ICU* is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support. Ongoing vigilance to better identify patients at risk and timely implementation of clinical interventions consistent with evidence-based guidelines are important steps in the ongoing provision of safe and reliable care. Appropriate systems improvements can be informed by identifying occurrences of maternal morbidity, reviewing the cases, and analyzing the findings.

^{††}This definition applies to all staffed-around-the-clock care settings. For care settings not staffed around the clock, the fall must occur during a time when staff are present in the setting for the definition to apply.

- Notification of laboratory 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 with measurable outcomes

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

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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 *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.

The laboratory determines how it will respond to patient safety events that do not meet the Joint Commission’s definition of sentinel event. Adverse events shall prompt notification of laboratory leaders, investigation, and corrective actions, in accordance with the laboratory’s process for responding to patient safety events that do not meet the definition of sentinel event. An adverse event may or may not result from an error.

No harm events, close calls (“near misses”), and hazardous conditions are tracked and used as opportunities to prevent harm, in accordance with the laboratory’s process for responding to patient safety events that do not meet the definition of sentinel event. Such opportunities could include comprehensive analysis, risk identification, and corrective action implementation and sustainment.

II. Goals of the Sentinel Event Policy

The policy has the following four goals:

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 laboratory 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 laboratory culture) and on changing the laboratory’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 laboratories that patient safety is a priority in accredited laboratories.

III. Responding to Sentinel Events

Standards

Each Joint Commission accreditation manual contains standards that relate specifically to the management of sentinel events. (See the Appendix to this chapter for related standards.)

Standard **LD.03.09.01**, element of performance (EP) 4, requires each accredited laboratory to define *patient safety event* and to communicate this definition throughout the laboratory. This definition must encompass sentinel events as defined by The Joint Commission. An accredited laboratory is encouraged to include in its definition events, incidents, and conditions in which no or only minor harm occurred to a patient. The laboratory determines how it will respond to patient safety events that do not meet the definition of sentinel event.

Comprehensive Systematic Analysis

As indicated above, appropriate response to a sentinel event includes the completion of a comprehensive systematic analysis for identifying the causal and contributory factors. Root cause analysis, which focuses on systems and processes, is the most commonly used form of comprehensive systematic analysis used to identify the factors that underlie a sentinel event.

A laboratory may use other tools and methodologies to conduct its comprehensive systematic analysis. The Joint Commission encourages the laboratory to contact the patient safety specialist assigned to the laboratory's event or to call the Office of Quality and Patient Safety at 630-792-3700 if it has questions regarding using the tools discussed above or other tools it is considering. (See the "Review of Comprehensive Systematic Analyses and Corrective Action Plans" section for further discussion of acceptability.)

Corrective Action Plan

The product of the comprehensive systematic analysis is a corrective action plan. The corrective action plan identifies the strategies that the laboratory intends to implement in order to reduce the risk of similar events occurring in the future. The identified actions should eliminate or control system hazards or vulnerabilities that have been identified by the comprehensive systematic analysis. Analysis teams should identify at

least one stronger or intermediate strength action when possible (see Figure 3 on page 17 of the National Patient Safety Foundation [NPSF] *RCA2: Improving Root Cause Analyses and Actions to Prevent Harm* report at https://c.ymcdn.com/sites/www.npsf.org/resource/resmgr/PDF/RCA2_v2-online-pub_010816.pdf for more information on strength of action). The plan must address the following:

- Identification of corrective actions to eliminate or control system hazards or vulnerabilities directly related to causal and contributory factors
- Responsibility for implementation
- Time lines for completion
- Strategies for evaluating the effectiveness of the actions
- Strategies for sustaining the change

Reporting a Sentinel Event to The Joint Commission

Each laboratory is strongly encouraged, but not required, to report to The Joint Commission any patient safety event that meets the Joint Commission definition of sentinel event. A laboratory benefits from self-reporting in the following ways:

- The Joint Commission can provide support and expertise to the laboratory during the review of a sentinel event.
- A review with the Office of Quality and Patient Safety provides the opportunity for the laboratory to collaborate with a patient safety specialist who is educated as a Master's prepared clinician or human factors engineer, is a certified professional in patient safety (CPPS), is trained in Robust Process Improvement® (RPI), and is likely to have reviewed similar events.
- Reporting raises the level of transparency in the laboratory and helps promote a culture of safety.
- Reporting conveys the laboratory's message to the public that it is doing everything possible, proactively, to prevent similar patient safety events in the future.

Further, 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 laboratories.

The value of this review is reflected by the fact that a vast majority of sentinel events reported to The Joint Commission are self-reported by the organizations that experienced the 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 laboratory, a surveyor, or through the media.

Self-reporting a sentinel event is not required and there is no difference in the expected response, time frames, or review procedures, whether the laboratory voluntarily reports the event or The Joint Commission becomes aware of the event by some other means. If a laboratory wishes to report to The Joint Commission an occurrence of a sentinel event or clarify whether an event meets the sentinel event definition, the laboratory will be asked to complete a form accessible through its *Joint Commission Connect*[®] extranet site. From this site, place the cursor over “Continuous Compliance Tools.” A drop-down list will appear. From this list, select “Self Report Sentinel Event.”

If The Joint Commission becomes aware of a sentinel event that was not reported by the laboratory to The Joint Commission, the CEO (or designee) of the laboratory 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 laboratory, including a summary of the processes that were designed to prevent similar occurrences.

Required Response to a Sentinel Event

All sentinel events must be reviewed by the laboratory, whether or not they are reported to The Joint Commission. In addition, if The Joint Commission becomes aware (either through voluntary self-reporting or otherwise) of a sentinel event that meets the criteria of this policy and the event has occurred in an accredited laboratory, the laboratory is expected to do the following:

- Prepare a thorough and credible comprehensive systematic analysis and corrective action plan within 45 business days of the event or of becoming aware of the event.
- Submit to The Joint Commission its comprehensive systematic analysis and corrective action plan, or otherwise provide for Joint Commission evaluation its response to the sentinel event using an approved methodology within 45 business days of the known occurrence of the event. The Joint Commission Office of Quality and Patient Safety will conduct a collaborative review with the organization

leadership or designee to determine whether the comprehensive systematic analysis and corrective action plan are acceptable. The optional alternative approaches to this review appear on the following pages.

The fact that a laboratory has experienced a sentinel event will not impact its accreditation decision. However, willful failure to respond appropriately to the sentinel event could have such an impact. For instance, if the laboratory fails to submit a comprehensive systematic analysis within an additional 45 days following its due date, its accreditation decision may be impacted. In these instances, patient safety specialists in the Office of Quality and Patient Safety, along with the medical director and patient safety officer, would recommend to the chief medical officer and the executive leadership of The Joint Commission to change the laboratory's accreditation status.

Submission of Comprehensive Systematic Analyses and Corrective Action Plans

A laboratory that reports sentinel event must submit the comprehensive systematic analysis, including the resulting corrective action plan with measurement that describes the laboratory's risk reduction strategies as well as how the effectiveness of those strategies will be evaluated. This information is submitted electronically and will be reviewed in a conference call involving Joint Commission staff and laboratory staff (Alternative–0). Documents shall not include the names of caregivers and patients involved in the sentinel event.

If the laboratory has concerns about sending the comprehensive systematic analysis documents to The Joint Commission, the following four optional alternative approaches to a review of the laboratory's response to the sentinel event are acceptable:

1. A review of the comprehensive systematic analysis and corrective action plan documents brought to Joint Commission headquarters by laboratory staff, then taken back to the laboratory on the same day (Alternative–1). This can also be performed via web-based video conferencing with a patient safety specialist who is located at The Joint Commission (Web-Alternative). When the web-based video conference is used, the laboratory's participants remain at the laboratory.
2. An on-site meeting at the laboratory with a Joint Commission patient safety specialist to review the comprehensive systematic analysis and corrective action plan documents (Alternative–2). This can also be performed via web-based video conferencing with a patient safety specialist who is located at The Joint Commission (Web-Alternative).

3. An on-site review with a Joint Commission patient safety specialist to review the corrective action plan and relevant documentation (Alternative–3). The patient safety specialist may ask questions regarding the comprehensive systematic analysis, but will not review that document itself. For purposes of this review activity, *relevant documentation* includes, at a minimum, any documentation relevant to the laboratory’s process for responding to sentinel events and the corrective action plan resulting from the analysis of the sentinel event. The corrective action plan serves as the basis for determining appropriate follow-up activity. This can also be performed via web-based video conferencing with a patient safety specialist who is located at The Joint Commission (Web-Alternative).
4. An on-site visit by a specially trained surveyor arranged to conduct the following (Alternative–4):
 - a. Interview and review of relevant documentation, including, if applicable, the patient’s medical record, to evaluate the following:
 - The process the laboratory uses in responding to sentinel events
 - The relevant policies and procedures preceding and following the laboratory’s review of the specific event, and the implementation thereof, sufficient to permit inferences about the adequacy of the laboratory’s response to the sentinel event
 - b. A standards-based survey that traces a patient’s care, treatment, and services and the laboratory management functions relevant to the sentinel event under review

Each of these options will result in a fee to the laboratory to cover the average direct costs of the option. 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 laboratory’s response to a sentinel event using any of these options within five business days of the self-report of a sentinel event or of the initial communication by The Joint Commission to the laboratory that it has become aware of a sentinel event.

Review of Comprehensive Systematic Analyses and Corrective Action Plans

A comprehensive systematic analysis will be reviewed for thoroughness, credibility, and acceptability. A laboratory’s comprehensive systematic analysis should identify system vulnerabilities so that they can be eliminated or mitigated. The analysis should not focus on individual health care worker performance, but should seek out underlying systems-

level causations that were manifested in personnel-related performance issues.^{§§} To help adhere to these characteristics it is recommended but not required that the following guidelines be considered when developing causative factor statements:^{|||}

- Clearly show the cause-and-effect relationship.
- Use specific and accurate descriptors for what occurred, rather than negative and vague words.
- Human errors must have a preceding cause.
- Violations of procedure are not root causes, but must have a preceding cause.
- Failure to act is only causal when there is a preexisting duty to act.

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
- 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
- The analysis of the underlying systems and processes through the series of “Why” questions determines 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 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 laboratory or a designee^{##}

^{§§}National Patient Safety Foundation. *RCA2: Improving Root Cause Analyses and Actions to Prevent Harm*. Boston: National Patient Safety Foundation, 2015.

^{|||}Department of Veterans Affairs. *Veterans Health Administration Patient Safety Handbook 1050.01*. Mar 4, 2011. Accessed Jan 16, 2020. http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2389.

^{##}A senior leader is not necessarily required to be actively involved in the day-to-day work of the comprehensive systematic analysis team. However, the team should report to the senior leader or designee, and he or she should be involved in deciding or approving the actions the laboratory will take as a result of the comprehensive systematic analysis.

- 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 developed by the team to replace it if the system vulnerability is not otherwise effectively addressed in the corrective action plan.^{***}
- Include patients, family, or patient representatives when appropriate to ensure a thorough understanding of the facts.
- Include 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 a bibliography of any relevant evidence-based literature

A corrective action plan will be considered **acceptable** if it does the following:

- Identifies and implements actions to eliminate or control systems hazards or vulnerabilities
 - It is recommended but not required that review teams should attempt to identify actions that are likely to reduce the risk or prevent the event from recurring and if that is not possible, reduce the severity or consequences if it should recur.
 - It is recommended that the review team use a tool that will assist in identifying stronger actions that provide effective and sustained system improvement. A tool such as the Action Hierarchy can help organizations evaluate the strength of the corrective actions identified in their comprehensive systematic analysis. The US Department of Veterans Affairs National Center for Patient Safety developed this tool in 2001.^{††}
- Identifies, in situations in which improvement actions are planned, who is responsible for implementation, when the action will be implemented, how the effectiveness of the actions will be evaluated, and how the actions will be sustained
- Identifies at least one stronger or intermediate strength action for each comprehensive systematic analysis

^{***}National Patient Safety Foundation. *RCA2: Improving Root Cause Analyses and Actions to Prevent Harm*. Boston: National Patient Safety Foundation, 2015.

^{††}An example of the Action Hierarchy tool is available at https://www.patientsafety.va.gov/docs/joe/rca_tools_2_15.pdf, page 28.

All comprehensive systematic analyses and corrective action plans will be considered and treated as confidential by The Joint Commission.

Follow-up Activities

After The Joint Commission has determined that a laboratory has conducted an acceptable comprehensive systematic analysis (for example, root cause analysis) and developed an acceptable corrective action plan, The Joint Commission will notify the laboratory that the comprehensive systematic analysis and corrective action plan are acceptable and will assign an appropriate follow-up activity. This will be a mutually agreed upon documentation of sustained improvement and reduction of risk, which may include one or more sentinel event Measure(s) of Success (SE MOS).

IV. The Sentinel Event Database

The third goal of the Sentinel Event Policy is to increase the general knowledge about patient safety events, their contributing factors, and strategies for prevention. To achieve this, The Joint Commission collects and analyzes data from the review of sentinel events and their comprehensive systematic analyses, corrective action plans, and follow-up activities. These data and information comprise the content of the Joint Commission's Sentinel Event Database.

The Sentinel Event Database is a major component of the evidence base for developing and maintaining the Joint Commission's National Patient Safety Goals. The database also informs the development prevention advice to laboratories through *Sentinel Event Alert* or other media. For these purposes, The Joint Commission uses de-identified aggregate data relating to root causes, contributing factors, and risk-reduction strategies. The Joint Commission is committed to developing and maintaining this Sentinel Event Database in a fashion that will protect the confidentiality of the laboratory, the caregiver, and the patient.

V. Determination That a Sentinel Event Is Subject to Review

In order to determine if an event is sentinel, it must be submitted as a self report (*see* "Reporting a Sentinel Event to The Joint Commission" for a review of the self-report process). Based on available information received about the event, a patient safety specialist from the Office of Quality and Patient Safety (OQPS) will determine whether

an event meets the definition in Section I, and is therefore a sentinel event. Challenges to a determination that an event is a sentinel event will be resolved through discussions between senior Joint Commission staff and senior laboratory leaders.

VI. Optional 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 a potential ongoing Immediate Threat to Health or Safety exists. An *Immediate Threat to Health or Safety* is a threat that represents the most immediate risk and has or may potentially have serious adverse effects on the health or safety of patients. All potential Immediate Threats to Health or Safety are referred to Joint Commission executive leadership for authorization to conduct an unannounced on-site for-cause survey. If an on-site survey is conducted, the laboratory will be billed a sufficient charge, based on an established fee schedule, to cover the costs of conducting such a survey.

VII. Disclosable Information

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

VIII. The Joint Commission's Response

Patient safety specialists from The Joint Commission assess the acceptability of the laboratory's response to the sentinel event, including the thoroughness and credibility of any comprehensive systematic analysis information reviewed and the laboratory's corrective action plan. (Root cause analysis is the most commonly used method of comprehensive systematic analysis.) If the comprehensive systematic analysis and corrective action plan are found to be thorough and credible, patient safety specialists from The Joint Commission will notify the laboratory and assign one or more or other mutually agreed upon documentation of sustained improvement and reduction of risk, such as SE MOS. (See the "Sentinel Event Measures of Success [SE MOS]" section below for more details.)

A patient safety specialist, who is educated as a Master's prepared clinician or human factors engineer, is a certified professional in patient safety (CPPS), and is trained in RPI will provide consultation to the laboratory if the response is unacceptable and will allow an additional 15 business days beyond the original submission period for the laboratory to resubmit its response. If the response is still unacceptable, the laboratory's accreditation decision may be impacted.

IX. Sentinel Event Measures of Success (SE MOS)

The laboratory's follow-up activity may be conducted through the SE MOS process. SE MOS is a numerical or quantifiable measure, ideally with a numerator and denominator, that indicates whether a planned action was effective and sustained. The SE MOS is due on a mutually agreed upon date.

If an SE MOS is used, then the following information would apply:

- If an SE MOS is submitted on time but does not meet pre-established levels of compliance, the patient safety specialist from The Joint Commission will request an additional four months of data. If the second set of data does not meet pre-established levels of compliance, the laboratory's accreditation decision may be impacted.
- If submission of an SE MOS is 90 or more days late, the laboratory's accreditation status may be impacted.

X. Handling Sentinel Event–Related Documents

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

At the time the review of the de-identified comprehensive systematic analysis is entered into the Sentinel Events Database, the original documents will be destroyed, as well as any copies. However, upon request the original documents may be returned to the laboratory. The information contained in any electronically submitted comprehensive systematic analysis tool will be de-identified after the review is completed.

The corrective action plan resulting from the analysis of the sentinel event will initially be retained long enough to serve as the basis for appropriate follow-up activities, such as the SE MOS or other mutually agreed upon documentation of sustained improvement. After the corrective action plan has been implemented and meets the established levels of compliance, The Joint Commission will destroy and delete the corrective action plan. If the SE MOS was submitted electronically, the information will likewise be de-identified upon completion of the review.

XI. Oversight of the Sentinel Event Policy

The executive leadership of The Joint Commission is responsible for approval of this policy and overseeing its implementation. In addition to reviewing and deciding individual cases involving changes in a laboratory's accreditation decision, Joint Commission staff will periodically audit the comprehensive systematic analysis and documentation of follow-up activities. For the purposes of these audits, The Joint Commission temporarily retains random de-identified 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, visit the Joint Commission's website at <https://www.jointcommission.org/resources/patient-safety-topics/sentinel-event/sentinel-event-policy-and-procedures/> or call the Office of Quality and Patient Safety at 630-792-3700.

XII. Survey Process

When conducting an accreditation survey, The Joint Commission seeks to evaluate the laboratory's compliance with the applicable standards, National Patient Safety Goals, and Accreditation Participation Requirements, and to assess the laboratory's performance based on those requirements. Surveyors are instructed not to search for or investigate sentinel events during an accreditation survey or to inquire about sentinel events that have been reported to The Joint Commission. However, surveyors may assess a laboratory's performance improvement practices, such as its processes for responding to a sentinel event.

If, in the course of conducting any survey activities, a potential serious patient safety event is newly identified, the surveyor will take the following steps:

- Inform the laboratory 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

Surveyors are not authorized to review the comprehensive systematic analysis documents and determine credibility, thoroughness, or acceptability because they are limited to applying the related standards and elements of performance to assess performance improvement practices, such as processes for responding to safety events, adverse events, hazardous unsafe conditions, close calls, and sentinel events.

The surveyor makes no determination of whether or not the event is a sentinel event and does not focus on or explore the event further, but rather will hand off further discussion to a patient safety specialist in the Office of Quality and Patient Safety. Surveyors are not authorized to investigate sentinel events. The patient safety specialist will contact the laboratory after all survey activity is entirely completed to explore the event and determine whether or not submission of a comprehensive systematic analysis is required. If so, the laboratory will proceed with the steps described after an event is determined to be a sentinel event. (*See* the “Required Response to a Sentinel Event” section in this chapter.)

During the on-site survey, the surveyor(s) will assess the laboratory’s compliance with sentinel event–related standards in the following ways (*see* Standard LD.03.09.01 in the Appendix):

- Review the laboratory’s process for responding to a sentinel event
- Interview the laboratory’s leaders and staff about their expectations and responsibilities for identifying, reporting on, and responding to sentinel events

Appendix. Accreditation Requirements Related to Sentinel Events

The following standard and associated elements of performance (EPs) are related to sentinel events:

Leadership (LD)

Standard **LD.03.09.01**

The laboratory manages safety issues.

Elements of Performance for LD.03.09.01

3. The leaders provide and encourage the use of systems for blame-free internal reporting of a system or process failure, or the results of a proactive risk assessment. (See also LD.03.08.01, EP 1)

Note: *This EP is intended to minimize staff reluctance to report errors in order to help an organization understand the source and results of system and process failures. The EP does not conflict with holding individuals accountable for their blameworthy errors.*

4. The leaders define patient safety event and communicate this definition throughout the organization.

Note: *At a minimum, the organization's definition includes those events subject to review as described in the "Sentinel Events" (SE) chapter of this manual*

5. The laboratory conducts thorough and credible comprehensive systematic analyses (for example, root cause analyses) in response to sentinel events as described in the "Sentinel Events" (SE) chapter of this manual.
8. To improve safety, the laboratory analyzes and uses information about system or process failures and, when conducted, the results of proactive risk assessments. (See also LD.03.08.01, EP 1)