I. Sentinel Events

In support of its mission to continuously improve the safety and quality of laboratory services provided to the public, The Joint Commission reviews laboratories’ 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 an individual’s care, treatment, or services and preventing sentinel events
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 organizational 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 sentinel events, their contributing factors, and strategies for prevention
4. To maintain the confidence of the public and accredited laboratories 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.

Laboratory-Specific Definition of Sentinel Event
LD.04.04.05, EPs 7 and 8, requires each accredited laboratory 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 laboratories have some latitude in setting more specific parameters to define “unexpected,” “serious,” and “the risk thereof.” At a minimum, an laboratory’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 an Laboratory’s Response to a Sentinel Event
Accredited laboratories are expected to identify and respond appropriately to all sentinel events (as defined by the laboratory in accordance with the preceding paragraph) occurring in the laboratory or associated with services that the laboratory 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.

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

*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.
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 laboratory 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 laboratory’s compliance with the applicable standards, National Patient Safety Goals, and Accreditation Participation Requirements, and to score those requirements based on performance throughout the laboratory 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 an laboratory’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 chief executive officer (CEO) that the event has been identified
- Inform the CEO that 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 laboratory after all survey activity is entirely completed to explore the event and determine whether or not submission of

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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.
a root cause analysis is required. If so, the laboratory will proceed with the steps described after an event is determined to be reviewable. (See the “Required Response to a Reviewable Sentinel Event” section)

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

- 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
- Ask for an example of a root cause analysis that has been conducted in the past year to assess the adequacy of the laboratory’s process for responding to a sentinel event. Additional examples may be reviewed if needed to more fully assess the laboratory’s understanding of, and ability to conduct, root cause analyses. In selecting an example, the laboratory 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 laboratory. Thus, not all of the following occurrences may apply to your particular laboratory. The subset of sentinel events that is subject to review by The Joint Commission includes any occurrence that meets any of the following criteria:

‡Near miss Used to describe any process variation that did not affect an outcome but for which a recurrence carries a significant change 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.
The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the individual’s illness or underlying condition§

or

The event is 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):

- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)

How The Joint Commission Becomes Aware of a Sentinel Event

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

§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 laboratory’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.

*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.
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 laboratory voluntarily reports the event or The Joint Commission becomes aware of the event by some other means, there are several advantages to the laboratory 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 laboratories.
- Early reporting provides an opportunity for consultation with Joint Commission staff during the development of the root cause analysis and action plan.
- The laboratory’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 and the event has occurred in an accredited laboratory, the laboratory 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 laboratory will be allowed 15 calendar days for its response. If the laboratory 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 laboratory fails to submit a root cause analysis):

- If the laboratory 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 an laboratory that experiences a sentinel event as defined by the laboratory, 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 1 (page SE-8)
- 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 laboratory 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 1 (page SE-8).

### Table 1. 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.

<table>
<thead>
<tr>
<th></th>
<th>Transfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral assessment process</td>
<td></td>
</tr>
<tr>
<td>Physical assessment process</td>
<td>**</td>
</tr>
<tr>
<td>Individual identification process</td>
<td>X</td>
</tr>
<tr>
<td>Individual observation procedures</td>
<td>X</td>
</tr>
<tr>
<td>Care planning process</td>
<td></td>
</tr>
<tr>
<td>Continuum of care</td>
<td></td>
</tr>
<tr>
<td>Staffing levels</td>
<td>X</td>
</tr>
<tr>
<td>Orientation and training of staff</td>
<td>X</td>
</tr>
<tr>
<td>Competency assessment/credentialing</td>
<td>X</td>
</tr>
</tbody>
</table>

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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).

**Includes search for contraband.**
Table 1. (continued)

<table>
<thead>
<tr>
<th></th>
<th>Transfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supervision of staff††</td>
<td>X</td>
</tr>
<tr>
<td>Communication with individual/family</td>
<td></td>
</tr>
<tr>
<td>Communication among staff members</td>
<td>X</td>
</tr>
<tr>
<td>Availability of information</td>
<td>X</td>
</tr>
<tr>
<td>Adequacy of technological support</td>
<td>X</td>
</tr>
<tr>
<td>Equipment maintenance/management</td>
<td>X</td>
</tr>
<tr>
<td>Physical environment‡‡</td>
<td>X</td>
</tr>
<tr>
<td>Security systems and processes</td>
<td></td>
</tr>
<tr>
<td>Medication management§§</td>
<td>X</td>
</tr>
</tbody>
</table>

Follow-up Activities

After The Joint Commission has determined that an laboratory 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 for more details).

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.

††Includes supervision of physicians-in-training.
‡‡Includes furnishings; hardware (for example, bars, hooks, rods); lighting; distractions.
§§Includes selection and procurement; storage; ordering and transcribing; preparing and dispensing; administration; and monitoring.
The Joint Commission is committed to developing, maintaining, and using this Sentinel Event Database in a fashion that will protect the confidentiality of the laboratory, 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 laboratories 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 an laboratory wishes to report an occurrence in the subset of sentinel events that are subject to review by The Joint Commission, the laboratory 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 Laboratory
If The Joint Commission becomes aware of a sentinel event subject to review under the Sentinel Event Policy that was not reported to The Joint Commission by the laboratory, the CEO 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 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 previous 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 laboratory’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 laboratory 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 laboratory that has experienced a reviewable sentinel event, the laboratory’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 laboratory through the sentinel event review process.

Submission of Root Cause Analysis and Action Plan
The laboratory that experiences a sentinel event subject to the Sentinel Event Policy is asked to submit two documents (in addition to the sentinel event reporting form discussed above): (1) the complete root cause analysis, including its findings, and (2) the resulting action plan that describes the laboratory’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 laboratory has concerns about waivers of confidentiality protections as a result of sending the root cause analysis documents to The Joint Commission, any one of the following four alternative approaches to a review of the laboratory’s response to the sentinel event is acceptable:

1. A review of the root cause analysis and action plan documents brought to Joint Commission headquarters by laboratory staff, then taken back to the laboratory 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 laboratory’s process for responding to sentinel events, the patient’s clinical 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 laboratory 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 a review of relevant documentation, including the patient’s clinical record, to obtain information about 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 services and the laboratory management functions relevant to the sentinel event under review.\[III\]

Any one of the four alternatives will result in a charge to the laboratory sufficient 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 an laboratory’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 laboratory that it has become aware of a reviewable sentinel event.

**The Joint Commission’s Response**

Joint Commission staff assess the acceptability of the laboratory’s response to the reviewable sentinel event, including the thoroughness and credibility of any root cause analysis information reviewed and the laboratory’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 the Sentinel Event Measures of Success section for more details).

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

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

When the laboratory’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 laboratory’s current accreditation decision
- Assigns an appropriate follow-up activity, typically one or more SE MOS due in four months

\[III\] For more information about the tracer methodology, see “The Accreditation Process” (ACC) chapter.
Sentinel Event Measures of Success

The laboratory’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 laboratory 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 laboratory’s accreditation status may be impacted if The Joint Commission determines the laboratory 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 measures of compliance, the laboratory’s accreditation decision may be impacted.

A decision to maintain or change the laboratory’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 laboratory. 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 follow-up activities, 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 an laboratory’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.