

# Patient Safety Systems (PS)

## Introduction

The quality of care and the safety of patients are core values of The Joint Commission accreditation process. This is a commitment The Joint Commission has made to patients, families, health care practitioners, staff, and laboratory leaders. This chapter exemplifies that commitment.

The intent of this “Patient Safety Systems” (PS) chapter is to provide laboratories with a proactive approach to designing or redesigning a patient-centered system that aims to improve quality of care and patient safety, an approach that aligns with the Joint Commission’s mission and its standards.

The Joint Commission partners with accredited laboratories to improve health care systems to protect patients. The first obligation of health care is to “do no harm.”

Therefore, this chapter is focused on the following three guiding principles:

1. Aligning existing Joint Commission standards with daily work in order to engage patients and staff throughout the health care system, at all times, on reducing harm.
2. Assisting laboratories with advancing knowledge, skills, and competence of staff and patients by recommending methods that will improve quality and safety processes.
3. Encouraging and recommending proactive quality and patient safety methods that will increase accountability, trust, and knowledge while reducing the impact of fear and blame.

Quality\* and safety are inextricably linked. *Quality* in health care is the degree to which its processes and results meet or exceed the needs and desires of the people it serves.<sup>1,2</sup> Those needs and desires include safety.

The components of a quality management system should include the following:

- Ensuring reliable processes
- Decreasing variation and defects (waste)

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\* The Institute of Medicine defines quality as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. **Source:** Committee to Design a Strategy for Quality Review and Assurance in Medicare, Institute of Medicine. *Medicare: A Strategy for Quality Assurance*, vol. 1. Lohr KN, editor. Washington, DC: The National Academies Press, 1990.

- Focusing on achieving better outcomes
- Using evidence to ensure that a service is satisfactory

Patient safety emerges as a central aim of quality. *Patient safety*, as defined by the World Health Organization, is the prevention of errors and adverse effects to patients that are associated with health care. Safety is what patients, families, staff, and the public expect from Joint Commission–accredited laboratories. While patient safety events may not be completely eliminated, harm to patients can be reduced, and the goal is always zero harm. This chapter describes and provides approaches and methods that may be adapted by a laboratory that aims to increase the reliability of its complex systems while making visible and removing the risk of patient harm. Joint Commission–accredited laboratories should be continually focused on eliminating systems failures and human errors that may cause harm to patients, families, and staff.<sup>1,2</sup>

The ultimate purpose of The Joint Commission’s accreditation process is to enhance quality of care and patient safety. Each requirement or standard, the survey process, the Sentinel Event Policy, and other Joint Commission initiatives are designed to help laboratories reduce variation, reduce risk, and improve quality. Laboratories should have an integrated approach to patient safety so that high levels of safe patient care can be provided for every patient in every care setting and service.

Laboratories are complex environments that depend on strong leadership to support an integrated patient safety system that includes the following:

- Safety culture
- Validated methods to improve processes and systems
- Standardized ways for interdisciplinary teams to communicate and collaborate
- Safely integrated technologies

In an integrated patient safety system, staff and leaders work together to eliminate complacency, promote collective mindfulness, treat each other with respect and compassion, and learn from their patient safety events, including close calls and other system failures that have not yet led to patient harm.

## What Does This Chapter Contain?

The “Patient Safety Systems” (PS) chapter is intended to help inform and educate laboratories about the importance and structure of an integrated patient safety system.

**This chapter describes how existing requirements can be applied to achieve improved**

**patient safety; it does not contain any new requirements.** It is also intended to help all health care workers understand the relationship between Joint Commission accreditation and patient safety.

This chapter does the following:

- Describes an integrated patient safety system
- Discusses how laboratories can develop into learning organizations
- Explains how laboratories can continually evaluate the status and progress of their patient safety systems
- Describes how laboratories can work to prevent or respond to patient safety events (Sidebar 1, below, defines key terminology)
- Serves as a framework to guide laboratory leaders as they work to improve patient safety in their laboratories
- Contains a list of standards and requirements related to patient safety systems (which will be scored as usual in their original chapters)
- Contains references that were used in the development of this chapter

This chapter refers to a number of Joint Commission standards. Standards cited in this chapter are formatted with the standard number in boldface type and are accompanied by language that summarizes the standard. For the full text of a standard and its element(s) of performance (EP), please *see* the Appendix.

## Sidebar 1. Key Terms to Understand

- *Patient safety event*: An event, incident, or condition that could have resulted or did result in harm to a patient.
- *Adverse event*: A patient safety event that resulted in harm to a patient.
- *Sentinel event*<sup>†</sup>: A subcategory of Adverse Events, 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

*continued on next page*

<sup>†</sup>For a list of specific patient safety events that are also considered sentinel events, *see* page SE-1 in the “Sentinel Events” (SE) chapter of this manual.

## Sidebar 1 (continued)

- *Close call* or “near miss,” “no harm,” or “good catch”: A patient safety event that did not cause harm as defined by the term *sentinel event*.
- *Hazardous* (or “unsafe”) *condition(s)*: A circumstance (other than a patient’s own disease process or condition) that increases the probability of an adverse event.

**Note:** *It is impossible to determine if there are practical prevention or mitigation countermeasures available without first doing an event analysis. An event analysis will identify systems-level vulnerabilities and weaknesses and the possible remedial or corrective actions that can be implemented.*

## Becoming a Learning Organization

The need for sustainable improvement in patient safety and the quality of care has never been greater. One of the fundamental steps to achieving and sustaining this improvement is to become a learning organization. A *learning organization* is one in which people learn continuously, thereby enhancing their capabilities to create and innovate.<sup>3</sup> Learning organizations uphold five principles: team learning, shared visions and goals, a shared mental model (that is, similar ways of thinking), individual commitment to lifelong learning, and systems thinking.<sup>3</sup> In a learning organization, patient safety events are seen as opportunities for learning and improvement.<sup>4</sup> Therefore, leaders in learning organizations adopt a transparent, nonpunitive approach to reporting so that the organization can *report to learn* and can collectively learn from patient safety events. In order to become a learning organization, a laboratory must have a fair and just safety culture, a strong reporting system, and a commitment to put that data to work by driving improvement. Each of these require the support and encouragement of laboratory leaders.

Leaders, staff, licensed independent practitioners, and patients in a learning organization realize that *every* patient safety event (from close calls to events that cause major harm to patients) must be reported.<sup>4-8</sup> When patient safety events are continuously reported, experts within the laboratory can define the problem, identify solutions, achieve sustainable results, and disseminate the changes or lessons learned to the rest of the

laboratory.<sup>4,8</sup> In a learning organization, the laboratory provides staff with information regarding improvements based on reported concerns. This helps foster trust that encourages further reporting.

## The Role of Laboratory Leaders in Patient Safety

Laboratory leaders provide the foundation for an effective patient safety system by doing the following:<sup>9</sup>

- Promoting learning
- Motivating staff to uphold a fair and just safety culture
- Providing a transparent environment in which quality measures and patient harms are freely shared with staff
- Modeling professional behavior
- Removing intimidating behavior that might prevent safe behaviors
- Providing the resources and training necessary to take on improvement initiatives

For these reasons, many of the standards that are focused on the laboratory's patient safety system appear in the Joint Commission's Leadership (LD) standards, including Standard **LD.04.04.05** (which focuses on having a laboratorywide, integrated patient safety program within performance improvement activities).

Without the support of laboratory leaders, laboratorywide changes and improvement initiatives are difficult to achieve. Leadership engagement in patient safety and quality initiatives is imperative because 75% to 80% of all initiatives that require people to change their behaviors fail in the absence of leadership managing the change.<sup>4</sup> Thus, leadership should take on a long-term commitment to transform the laboratory.<sup>10</sup>

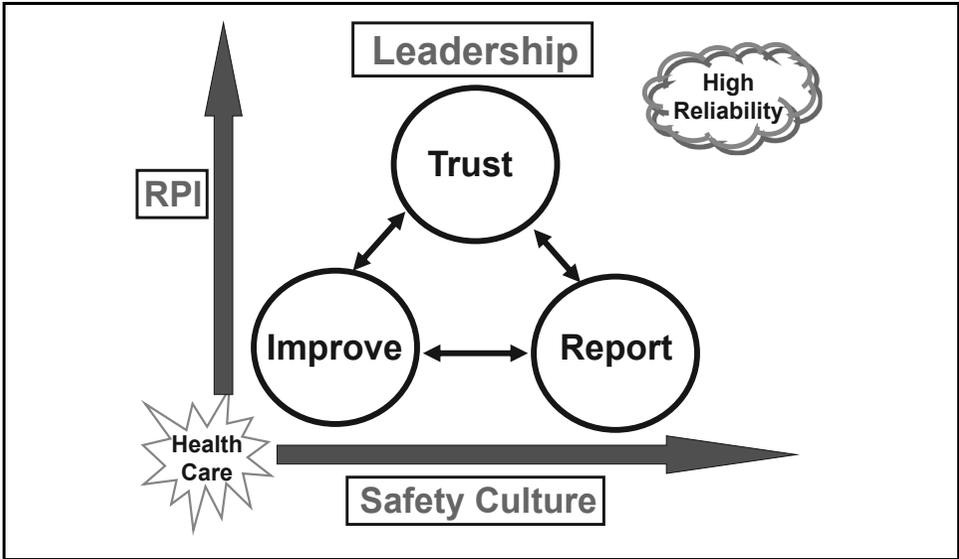
### Safety Culture

A strong safety culture is an essential component of a successful patient safety system and is a crucial starting point for laboratories striving to become learning organizations. In a strong safety culture, the laboratory has an unrelenting commitment to safety and to do no harm. Among the most critical responsibilities of laboratory leaders is to establish and maintain a strong safety culture within their laboratory. The Joint Commission's standards address safety culture in Standard **LD.03.01.01**, which requires leaders to create and maintain a culture of safety and quality throughout the laboratory.

The *safety culture* of a laboratory is the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the laboratory's commitment to quality and patient safety. Laboratories that have a robust safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.<sup>11</sup> Laboratories will have varying levels of safety culture, but all should be working toward a safety culture that has the following qualities:

- Staff and leaders that value transparency, accountability, and mutual respect.<sup>4</sup>
- Safety as everyone's first priority.<sup>4</sup>
- Behaviors that undermine a culture of safety are not acceptable, and thus should be reported to laboratory leadership by staff, patients, and families for the purpose of fostering risk reduction.<sup>4,10,12</sup>
- Collective mindfulness is present, wherein staff realize that systems always have the potential to fail and staff are focused on finding hazardous conditions or close calls at early stages before a patient may be harmed.<sup>10</sup> Staff do not view close calls as evidence that the system prevented an error but rather as evidence that the system needs to be further improved to prevent any defects.<sup>10,13</sup>
- Staff who do not deny or cover up errors but rather want to report errors to learn from mistakes and improve the system flaws that contribute to or enable patient safety events.<sup>6</sup> Staff know that their leaders will focus not on blaming providers involved in errors but on the systems issues that contributed to or enabled the patient safety event.<sup>6,14</sup>
- By reporting and learning from patient safety events, staff create a learning organization.

A safety culture operates effectively when the laboratory fosters a cycle of trust, reporting, and improvement.<sup>10,15</sup> In laboratories that have a strong safety culture, health care providers trust their coworkers and leaders to support them when they identify and report a patient safety event.<sup>10</sup> When trust is established, staff are more likely to report patient safety events, and laboratories can use these reports to inform their improvement efforts. In the trust-report-improve cycle, leaders foster trust, which enables staff to report, which enables the laboratory to improve.<sup>10</sup> In turn, staff see that their reporting contributes to actual improvement, which bolsters their trust. Thus, the trust-report-improve cycle reinforces itself.<sup>10</sup> (*See Figure 1.*)



**Figure 1.** *The Trust-Report-Improve Cycle with Robust Process Improvement® (RPI®)*

In the trust-report-improve cycle, trust promotes reporting, which leads to improvement, which in turn fosters trust.

Leaders need to ensure that intimidating or unprofessional behaviors within the laboratory are addressed, so as not to inhibit others from reporting safety concerns.<sup>16</sup> Leaders should both educate staff and hold them accountable for professional behavior. This includes the adoption and promotion of a code of conduct that defines acceptable behavior as well as behaviors that undermine a culture of safety. The Joint Commission's Standard **LD.03.01.01**, EP 4, requires that leaders develop such a code.

Intimidating and disrespectful behaviors disrupt the culture of safety and prevent collaboration, communication, and teamwork, which is required for safe and highly reliable patient care.<sup>17</sup> Disrespect is not limited to outbursts of anger that humiliate a member of the health care team; it can manifest in many forms, including the following:<sup>4,12,17</sup>

- Inappropriate words (profane, insulting, intimidating, demeaning, humiliating, or abusive language)
- Shaming others for negative outcomes
- Unjustified negative comments or complaints about another provider's care
- Refusal to comply with known and generally accepted practice standards, the refusal of which may prevent other providers from delivering quality care

- Not working collaboratively or cooperatively with other members of the interdisciplinary team
- Creating rigid or inflexible barriers to requests for assistance or cooperation
- Not returning pages or calls promptly

These issues are still occurring in laboratories nationwide. Of 4,884 respondents to a 2013 survey by the Institute for Safe Medication Practices (ISMP), 73% reported encountering negative comments about colleagues or leaders during the previous year. In addition, 68% reported condescending language or demeaning comments or insults; while 77% of respondents said they had encountered reluctance or refusal to answer questions or return calls.<sup>18</sup> Further, 69% report that they had encountered impatience with questions or the hanging up of the phone.

Nearly 50% of the respondents indicated that intimidating behaviors had affected the way they handle medication order clarifications or questions, including assuming that an order was correct in order to avoid interaction with an intimidating coworker.<sup>18</sup> Moreover, 11% said they were aware of a medication error during the previous year in which behavior that undermines a culture of safety was a contributing factor. The respondents included nurses, physicians, pharmacists, and quality/risk management personnel.

Only 50% of respondents indicated that their organizations had clearly defined an effective process for handling disagreements with the safety of an order. This is down from 60% of respondents to a similar ISMP survey conducted in 2003, which suggests that this problem is worsening.<sup>18</sup> While these data are specific to medication safety, their lessons are broadly applicable: Behaviors that undermine a culture of safety have an adverse effect on quality and patient safety.

## **A Fair and Just Safety Culture**

A fair and just safety culture is needed for staff to trust that they can report patient safety events without being treated punitively.<sup>2,8</sup> In order to accomplish this, laboratories should provide and encourage the use of a standardized reporting process for staff to report patient safety events. This is also built into the Joint Commission's standards at Standard **LD.04.04.05**, EP 6, which requires leaders to provide and encourage the use of systems for blame-free reporting of a system or process failure or the results of proactive risk assessments. Reporting enables both proactive and reactive risk reduction. *Proactive risk reduction* solves problems before patients are harmed, and *reactive risk reduction* attempts to prevent the recurrence of problems that have already caused patient harm.<sup>10,15</sup>

A fair and just culture takes into account that individuals are human, fallible, and capable of mistakes, and that they work in systems that are often flawed. In the most basic terms, a fair and just culture holds individuals accountable for their actions but does not punish individuals for issues attributed to flawed systems or processes.<sup>14,18,19</sup> Refer to Standard **LD.04.04.05**, EP 6, which requires that staff are held accountable for their responsibilities.

It is important to note that for some actions for which an individual is accountable, the individual should be held culpable and some disciplinary action may then be necessary. (See Sidebar 2, below, for a discussion of tools that can help leaders determine a fair and just response to a patient safety event.) However, staff should never be punished or ostracized for **reporting** the event, close call, hazardous condition, or concern.

## Sidebar 2. Assessing Staff Accountability

The aim of a safety culture is not a “blame-free” culture but one that balances learning with accountability. To achieve this, it is essential that leaders assess errors and patterns of behavior in a manner that is applied consistently, with the goal of eliminating behaviors that undermine a culture of safety. There has to exist within the laboratory a clear, equitable, and transparent process for recognizing and separating the blameless errors that fallible humans make daily from the unsafe or reckless acts that are blameworthy.<sup>1-10</sup>

There are a number of sources for information (some of which are listed immediately below) that provide rationales, tools, and techniques that will assist a laboratory in creating a formal decision process to determine what events should be considered blameworthy and require individually directed action in addition to systems-level corrective actions. The use of a formal process will reinforce the culture of safety and demonstrate the laboratory’s commitment to transparency and fairness.

Reaching answers to these questions requires an initial investigation into the patient safety event to identify contributing factors. The use of the Incident Decision Tree (adapted by the United Kingdom’s National Patient Safety Agency from James Reason’s culpability matrix) or other formal decision process can help make determinations of culpability more transparent and fair.<sup>5</sup>

### References

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## Data Use and Reporting Systems

An effective culture of safety is evidenced by a robust reporting system and use of measurement to improve. When laboratories adopt a transparent, nonpunitive approach to reports of patient safety events or other concerns, the laboratory begins reporting to learn—and to learn collectively from adverse events, close calls, and hazardous conditions. This section focuses on data from reported patient safety events.

Laboratories should note that this is but one type of data among many that should be collected and used to drive improvement.

When there is continuous reporting for adverse events, close calls, and hazardous conditions, the laboratory can analyze the patient safety events, change the process or system to improve safety, and disseminate the changes or lessons learned to the rest of the laboratory.<sup>20–24</sup>

In addition to those mentioned earlier in this chapter, a number of standards relate to the reporting of safety information, including Performance Improvement (PI) Standard **PI.01.01.01**, which requires laboratories to collect data to monitor their performance,

and Standard **LD.03.02.01**, which requires laboratories to use data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

Laboratories can engage frontline staff in internal reporting in a number of ways, including the following:

- Create a nonpunitive approach to patient safety event reporting
- Educate staff on identifying patient safety events that should be reported
- Provide timely feedback regarding actions taken on patient safety events

## Effective Use of Data

### Collecting Data

When laboratories collect data or measure staff compliance with evidence-based care processes or patient outcomes, they can manage and improve those processes or outcomes and, ultimately, improve patient safety.<sup>25</sup> The effective use of data enables laboratories to identify problems, prioritize issues, develop solutions, and track to determine success.<sup>9</sup> Objective data can be used to support decisions, influence people to change their behaviors, and to comply with evidence-based care guidelines.<sup>9,26</sup>

The Joint Commission and the Centers for Medicare & Medicaid Services (CMS) both require laboratories to collect and use data related to certain patient care outcomes and patient harms. Some key Joint Commission standards related to data collection and use require laboratories to do the following:

- Collect information to monitor conditions in the environment (Standard **EC.04.01.01**)
- Identify risks for acquiring and transmitting infections (Standard **IC.01.03.01**)
- Use data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality (Standard **LD.03.02.01**)
- Have a laboratorywide, integrated patient safety program within their performance improvement activities (Standard **LD.04.04.05**)
- Collect data to monitor their performance (Standard **PI.01.01.01**)
- Improve performance on an ongoing basis (Standard **PI.03.01.01**)

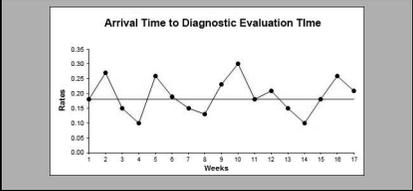
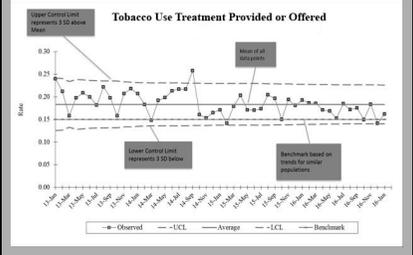
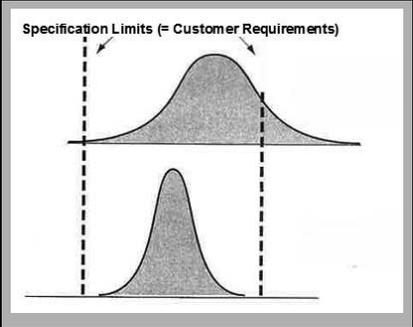
### Analyzing Data

Effective data analysis can enable a laboratory to “diagnose” problems within its system similar to the way one would diagnose a patient’s illness based on symptoms, health history, and other factors. Turning data into information is a critical competency of a

learning organization and of effective management of change. When the right data are collected and appropriate analytic techniques are applied, it enables the laboratory to monitor the performance of a system, detect variation, and identify opportunities to improve. This can help the laboratory not only understand the current performance of laboratory systems but also can help it predict its performance going forward.<sup>23</sup>

Analyzing data with tools such as run charts, statistical process control (SPC) charts, and capability charts helps a laboratory determine what has occurred in a system and provides clues as to why the system responded as it did.<sup>23</sup> Table 1, following, describes and compares examples of these tools. Please note that several types of SPC charts exist; this discussion focuses on the XmR chart, which is the most commonly used.

**Table 1. Defining and Comparing Analytical Tools**

| Tool                              | When to Use  | Example  |
|-----------------------------------|--|--|
| Run Chart <sup>1</sup>            | <ul style="list-style-type: none"> <li>■ When the laboratory needs to identify variation within a system</li> <li>■ When the laboratory needs a simple and straightforward analysis of a system</li> <li>■ As a precursor to an SPC chart</li> </ul>         |    |
| Statistical Process Control Chart | <ul style="list-style-type: none"> <li>■ When the laboratory needs to identify variation within a system and find indicators of why the variation occurred</li> <li>■ When the laboratory needs a more detailed and in-depth analysis of a system</li> </ul> |    |
| Capability Chart <sup>2</sup>     | <ul style="list-style-type: none"> <li>■ When the laboratory needs to determine whether a process will function as expected, according to requirements or specifications</li> </ul>  |  <p data-bbox="660 1204 1073 1337">In the example above, the curve at the top of the chart indicates a process that is only partly capable of meeting requirements. The curve at the bottom of the chart shows a process that is fully capable.</p> |

**Sources:**

1. Agency for Healthcare Research and Quality. Advanced Methods in Delivery System Research—Planning, Executing, Analyzing, and Reporting Research on Delivery System Improvement. Webinar #2: Statistical Process Control. Jul 2013. Accessed Aug 21, 2015. <http://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/webinar02/index.html>. (Example 2, above).
2. George ML, et al. *The Lean Six Sigma Pocket Toolbook: A Quick Reference Guide to Nearly 100 Tools for Improving Process Quality, Speed, and Complexity*. New York: McGraw-Hill, 2005. Used with permission.

## Using Data to Drive Improvement

After data has been turned into information, leadership should ensure the following (per the requirements shown):<sup>27–29</sup>

- Information is presented in a clear manner (Standard **LD.03.04.01**, EP 3)
- Information is shared with the appropriate groups throughout the laboratory (from the front line to the board) (Standards **LD.03.04.01**, **LD.04.04.05**)
- Opportunities for improvement and actions to be taken are clearly articulated (Standards **LD.03.05.01**, EP 4; **LD.04.04.01**)
- Improvements are celebrated or recognized

## A Proactive Approach to Preventing Harm

Proactive risk reduction prevents harm before it reaches the patient. By engaging in proactive risk reduction, a laboratory can correct process problems in order to reduce the likelihood of experiencing adverse events.

In a proactive risk assessment the laboratory evaluates a process to see how it could potentially fail, to understand the consequences of such a failure, and to identify parts of the process that need improvement. A proactive risk assessment increases understanding within the laboratory about the complexities of process design and management—and what could happen if the process fails.

When conducting a proactive risk assessment, laboratories should prioritize high-risk, high-frequency areas. Areas of risk are identified from internal sources such as ongoing monitoring of the environment, results of previous proactive risk assessments, from results of data collection activities. Risk assessment tools should be accessed from credible external sources such as a *Sentinel Event Alert*, nationally recognized risk assessment tools, and peer review literature. Benefits of a proactive approach to patient safety includes increased likelihood of the following:

- Identification of actionable common causes
- Avoidance of unintended consequences

- Identification of commonalities across departments/services/units
- Identification of system solutions

Hazardous (or unsafe) conditions provide an opportunity for a laboratory to take a proactive approach to reduce harm. Laboratories also benefit from identifying hazardous conditions while designing any new process that could impact patient safety. A hazardous condition is defined as any circumstance that increases the probability of a patient safety event. A hazardous condition may be the result of a human error or violation, may be a design flaw in a system or process, or may arise in a system or process in changing circumstances.<sup>‡</sup> A proactive approach to such conditions should include an analysis of the systems and processes in which the hazardous condition is found, with a focus on conditions that preceded the hazardous condition. (See Sidebar 3.)

A proactive approach to hazardous conditions should include an analysis of the related systems and processes, including the following aspects:<sup>30</sup>

- **Preconditions.** Examples include hazardous (or unsafe) conditions in the environment of care (such as noise, clutter, wet floors and so forth), inadequate staffing levels, an operator who is impaired or inadequately trained.
- **Supervisory influences.** Examples include inadequate supervision, planned inappropriate operations, failure to address a known problem, authorization of activities that are known to be hazardous.
- **Organizational influences.** Examples include inadequate staffing, inadequate policies, lack of strategic risk assessment.

The Joint Commission addresses proactive risk assessments at Standard **LD.04.04.05**, EP 10, which requires laboratories to select one high-risk process and conduct a proactive risk assessment at least every 18 months.

Laboratories should recognize that this standard represents a minimum requirement. Laboratories working to become learning organizations are encouraged to exceed this requirement by constantly working to proactively identify risk.

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<sup>‡</sup>Human errors are typically skills based, decision based, or knowledge based; whereas violations could be either routine or exceptional (intentional or negligent). *Routine violations* tend to include habitual “bending of the rules,” often enabled by management. A routine violation may break established rules or policies, and yet be a common practice within an organization. An *exceptional violation* is a willful behavior outside the norm that is not condoned by management, engaged in by others, and not part of the individual’s usual behavior. **Source:** Diller T, et al. The human factors analysis classification system (HFACS) applied to health care. *Am J Med Qual.* 2014 May–Jun;29(3)181–190.

### Sidebar 3. Strategies for an Effective Risk Assessment

Although several methods could be used to conduct a proactive risk assessment, the following steps comprise one approach:

- Describe the chosen process (for example, through the use of a flowchart).
- Identify ways in which the process could break down or fail to perform its desired function, which are often referred to as “failure modes.”
- Identify the possible effects that a breakdown or failure of the process could have on patients and the seriousness of the possible effects.
- Prioritize the potential process breakdowns or failures.
- Determine why the prioritized breakdowns or failures could occur, which may involve performing a hypothetical root cause analysis.
- Design or redesign the process and/or underlying systems to minimize the risk of the effects on patients.
- Test and implement the newly designed or redesigned process.
- Monitor the effectiveness of the newly designed or redesigned process.

### Tools for Conducting a Proactive Risk Assessment

A number of tools are available to help laboratories conduct a proactive risk assessment. One of the best known of these tools is the Failure Modes and Effects Analysis (FMEA). An FMEA is used to prospectively examine how failures could occur during high-risk processes and, ultimately, how to prevent them. The FMEA asks “What if?” to explore what could happen if a failure occurs at particular steps in a process.<sup>31</sup>

Laboratories have other tools they can consider using in their proactive risk assessment. Some examples include the following:

- Institute for Safe Medication Practices Medication Safety Risk Assessment: This tool is designed to help reduce medication errors. Visit <https://www.ismp.org/selfassessments/default.asp> for more information.
- Contingency diagram: The contingency diagram uses brainstorming to generate a list of problems that could arise from a process. Visit <https://healthit.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/contingency-diagram> for more information.

- Potential problem analysis (PPA) is a systematic method for determining what could go wrong in a plan under development. The problem causes are rated according to their likelihood of occurrence and the severity of their consequences. Visit <https://healthit.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/all-workflow-tools> for more information.
- Process decision program chart (PDPC) provides a systematic means of finding errors with a plan while it is being created. After potential issues are found, preventive measures are developed, allowing the problems to either be avoided or a contingency plan to be in place should the error occur. Visit <http://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/process-decision-program-chart>.

## Encouraging Patient Activation

To achieve the best outcomes, patients and families must be more actively engaged in decisions about their health care and must have broader access to information and support. Patient activation is inextricably intertwined with patient safety. Activated patients are less likely to experience harm and unnecessary hospital readmissions. Patients who are less activated suffer poorer health outcomes and are less likely to follow their provider's advice.<sup>32,33</sup>

A patient-centered approach to care can help laboratories assess and enhance patient activation. Achieving this requires leadership engagement in the effort to establish patient-centered care as a top priority throughout the laboratory. This includes adopting the following principles:<sup>34</sup>

- Patient safety guides all decision making.
- Patients and families are partners at every level of care.
- Patient- and family-centered care is verifiable, rewarded, and celebrated.
- The licensed independent practitioner responsible for the patient's care, or his or her designee, discloses to the patient and family any unanticipated outcomes of care, treatment, and services.
- Though Joint Commission standards do not require apology, evidence suggests that patients benefit—and are less likely to pursue litigation—when physicians disclose harm, express sympathy, and apologize.
- Staffing levels are sufficient, and staff has the necessary tools and skills.
- The laboratory has a focus on measurement, learning, and improvement.

- Staff and licensed independent practitioners must be fully engaged in patient- and family-centered care as demonstrated by their skills, knowledge, and competence in compassionate communication.

Laboratories can adopt a number of strategies to support and improve patient activation, including promoting culture change, adopting transitional care models, and leveraging health information technology capabilities.<sup>34</sup>

## **Beyond Accreditation: The Joint Commission Is Your Patient Safety Partner**

To assist laboratories on their journey toward creating highly reliable patient safety systems, The Joint Commission provides many resources, including the following:

- *Office of Quality and Patient Safety*: An internal Joint Commission department that offers laboratories guidance and support when they experience a sentinel event. Laboratories can call the Sentinel Event Hotline (630-792-3700) to clarify whether a patient safety event is considered to be a sentinel event (and therefore reviewable) or to discuss any aspect of the Sentinel Event Policy. The Office of Quality and Patient Safety assesses the thoroughness and credibility of a laboratory's comprehensive systematic analysis as well as the action plan to help the laboratory prevent the hazardous or unsafe conditions from occurring again.
- *Joint Commission Center for Transforming Healthcare*: A Joint Commission not-for-profit affiliate that offers highly effective, durable solutions to health care's most critical safety and quality problems to help laboratories transform into high reliability organizations. For specific quality and patient problems, the Center's Targeted Solutions Tool® (TST®) guides laboratories through a step-by-step process to measure their laboratory's performance, identify barriers to excellence, and direct them to proven solutions. To date, a TST has been developed for each of the following: hand hygiene, hand-off communications, and wrong-site surgery. For more information, visit <http://www.centerfortransforminghealthcare.org>.
- *Standards Interpretation Group*: An internal Joint Commission department that helps laboratories with their questions about Joint Commission standards. First, laboratories can see if other laboratories have asked the same question by accessing the Standards FAQs at [http://www.jointcommission.org/standards\\_information/jcfaq.aspx](http://www.jointcommission.org/standards_information/jcfaq.aspx). Thereafter, laboratories can submit questions about standards to the Standards Interpretation Group by completing an online form at <https://web.jointcommission.org/sigsubmission/sigonlineform.aspx>.

- *National Patient Safety Goals*: The Joint Commission's yearly patient safety requirements based on data obtained from the Joint Commission's Sentinel Event Database and recommended by a panel of patient safety experts. (For a list of the current National Patient Safety Goals, go to [http://www.jointcommission.org/standards\\_information/npsgs](http://www.jointcommission.org/standards_information/npsgs).)
- *Sentinel Event Alert*: The Joint Commission's periodic alerts with timely information about similar, frequently reported sentinel events, including root causes, applicable Joint Commission requirements, and suggested actions to prevent a particular sentinel event. (For archives of previously published *Sentinel Event Alerts*, go to [http://www.jointcommission.org/sentinel\\_event.aspx](http://www.jointcommission.org/sentinel_event.aspx).)
- *Quick Safety*: Quick Safety is a monthly newsletter that outlines an incident, topic, or trend in health care that could compromise patient safety. [http://www.jointcommission.org/quick\\_safety.aspx?archieve=y](http://www.jointcommission.org/quick_safety.aspx?archieve=y)
- *Core Measure Solution Exchange*<sup>®</sup>: Available for accredited or certified laboratories through the *Joint Commission Connect*<sup>™</sup> extranet, laboratories can search a database of over two hundred success stories from accredited health care organizations that have attained excellent performance on core measures, including accountability measures.
- *Joint Commission Resources*: A Joint Commission not-for-profit affiliate that produces books and periodicals, holds conferences, provides consulting services, and develops software products (including AMP<sup>®</sup>, Tracers with AMP<sup>®</sup>, E-dition<sup>®</sup>, ECM Plus<sup>®</sup>, and CMSAccess<sup>®</sup>) for accreditation and survey readiness. (For more information, visit <http://www.jcrinc.com>.)
- *Webinars and podcasts*: The Joint Commission and its affiliate, Joint Commission Resources, offer free webinars and podcasts on various accreditation and patient safety topics.
- *Speak Up*<sup>™</sup> *program*: The Joint Commission's campaign to educate patients about health care processes and potential safety issues and encourage them to speak up whenever they have questions or concerns about their safety. (For more information and patient education resources, go to <http://www.jointcommission.org/speakup>.)
- *Standards BoosterPaks*<sup>™</sup>: Available for accredited or certified laboratories through *Joint Commission Connect*, laboratories can access BoosterPaks that provide detailed information about a single standard or topic area that has been associated with a high volume of inquiries or noncompliance scores. Recent standards BoosterPak topics have included credentialing and privileging in nonlaboratory settings, waived

testing, restraint and seclusion, management of hazardous waste, environment of care (including Standards **EC.04.01.01**, **EC.04.01.03**, and **EC.04.01.05**), and sample collection.

- *Leading Practice Library*: Available for accredited or certified laboratories through *Joint Commission Connect*, laboratories can access an online library of solutions to help improve safety. The searchable documents in the library are actual solutions that have been successfully implemented by laboratories and reviewed by Joint Commission standards experts.
- *Joint Commission web portals*: Through The Joint Commission website, laboratories can access web portals with a repository of resources from The Joint Commission, the Joint Commission Center for Transforming Healthcare, Joint Commission Resources, and Joint Commission International on the following topics:
  - Transitions of care: <http://www.jointcommission.org/toc.aspx>
  - High reliability: <http://www.jointcommission.org/highreliability.aspx>
  - Infection prevention and health care–associated infections (HAI): <http://www.jointcommission.org/hai.aspx>
  - Emergency management: [http://www.jointcommission.org/emergency\\_management.aspx](http://www.jointcommission.org/emergency_management.aspx)
  - Workplace violence prevention resources: [https://www.jointcommission.org/workplace\\_violence.aspx](https://www.jointcommission.org/workplace_violence.aspx)

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## Appendix. Key Patient Safety Requirements

A number of Joint Commission standards have been discussed in the “Patient Safety Systems” (PS) chapter. However, many Joint Commission requirements address issues related to the design and management of patient safety systems, including the following examples.

### Environment of Care (EC)

#### Standard EC.04.01.01

The laboratory collects information to monitor conditions in the environment.

#### Elements of Performance for EC.04.01.01

1. The laboratory establishes a process(es) for continually monitoring, internally reporting, and investigating the following:
  - Injuries to patients or others within the laboratory
  - Occupational illnesses and staff injuries
  - Incidents of damage to its property or the property of others in locations it controls
  - Security incidents involving patients, staff, or others in locations it controls
  - Hazardous materials and waste spills and exposures
  - Fire safety management problems, deficiencies, and failures
  - Laboratory equipment management problems, failures, and use errors
  - Utility systems management problems, failures, or use errors

**Note 1:** *All the incidents and issues listed above may be reported to staff in quality assessment, improvement, or other functions. A summary of such incidents may also be shared with the person designated to coordinate safety management activities.*

**Note 2:** *Review of incident reports often requires that legal processes be followed to preserve confidentiality. Opportunities to improve laboratory services, or to prevent similar incidents, are not lost as a result of following the legal process.*

The laboratory reports and investigates the following:

3. Injuries occurring in the laboratory.

4. Occupational illnesses and staff injuries.
  5. Incidents of damage to its property or the property of others in locations it controls.
  6. Security incidents involving patients, staff, or others in locations it controls.
  8. Hazardous materials and waste spills and exposures.
  9. Fire safety management problems, deficiencies, and failures.
  10. Laboratory equipment management problems, failures, and use errors.
  11. Utility systems management problems, failures, or use errors.
15. Every 12 months, the laboratory evaluates each environment of care management plan, including a review of the plan's objectives, scope, performance, and effectiveness.

### **Standard EC.04.01.03** \_\_\_\_\_

The laboratory analyzes identified environment of care issues.

### **Element of Performance for EC.04.01.03**

2. The laboratory uses the results of data analysis to identify opportunities to resolve environmental safety issues.

### **Standard EC.04.01.05** \_\_\_\_\_

The laboratory improves its environment of care.

### **Element of Performance for EC.04.01.05**

1. The laboratory takes action on the identified opportunities to resolve environmental safety issues.

## **Infection Prevention and Control (IC)**

### **Standard IC.01.03.01** \_\_\_\_\_

The laboratory identifies its risks for acquiring and transmitting infections.

## Elements of Performance for IC.01.03.01

1. The laboratory identifies its infection risks based on the laboratory services it provides. **R**
3. **Ⓢ** The laboratory prioritizes its identified risks for acquiring and transmitting infections. These prioritized risks are documented. **R**

## Leadership (LD)

### Standard LD.03.01.01

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Leaders create and maintain a culture of safety and quality throughout the laboratory.

### Elements of Performance for LD.03.01.01

1. Leaders regularly evaluate the culture of safety and quality.
2. Leaders prioritize and implement changes identified by the evaluation.
4. **Ⓢ** Leaders develop a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.
5. Leaders create and implement a process for managing behaviors that undermine a culture of safety.

### Standard LD.03.02.01

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The laboratory uses data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

### Elements of Performance for LD.03.02.01

1. Leaders set expectations for using data and information to improve the safety and quality of laboratory services. **R**
2. Leaders are able to describe how data and information are used to create a culture of safety and quality. **R**
3. The laboratory uses processes to support systematic data and information use. **R**
4. Leaders provide the resources needed for data and information use, including staff, equipment, and information systems. **R**

5. The laboratory uses data and information in decision making that supports the safety and quality of laboratory services. (*See also* PI.02.01.01, EP 8) **R**
6. The laboratory uses data and information to identify and respond to internal and external changes in the environment. **R**
7. Leaders evaluate how effectively data and information are used throughout the laboratory. **R**

### **Standard LD.03.04.01**

The laboratory communicates information related to safety and quality to those who need it, including staff, licensed independent practitioners, patients, families, and external interested parties.

#### **Elements of Performance for LD.03.04.01**

1. Communication processes foster the safety of the patient and the quality of care.
2. Leaders are able to describe how communication supports a culture of safety and quality.
3. Communication is designed to meet the needs of internal and external users.
4. Leaders provide the resources required for communication, based on the needs of patients, staff, and management.
5. Communication supports safety and quality throughout the laboratory. (*See also* LD.04.04.05, EP 6)
6. When changes in the environment occur, the laboratory communicates those changes effectively.
7. Leaders evaluate the effectiveness of communication methods.

### **Standard LD.03.05.01**

Leaders implement changes in existing processes to improve the performance of the laboratory.

#### **Elements of Performance for LD.03.05.01**

4. Leaders provide the resources required for performance improvement and change management, including sufficient staff, access to information, and training.

## Standard LD.04.04.01

Leaders establish priorities for performance improvement. (Refer to the “Performance Improvement” [PI] chapter.)

### Elements of Performance for LD.04.04.01

1. Leaders set priorities for performance improvement activities and patient health outcomes. (*See also* PI.01.01.01, EPs 1 and 3)
2. Leaders give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities. (*See also* PI.01.01.01, EPs 7, 8, and 23)
3. Leaders reprioritize performance improvement activities in response to changes in the internal or external environment.
4. Performance improvement occurs laboratorywide.

## Standard LD.04.04.05

The laboratory manages safety issues.

### Elements of Performance for LD.04.04.05

6. 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.03.04.01, EP 5; LD.04.04.03, EP 5)

**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.*

7. 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 in the “Sentinel Events” (SE) chapter of this manual. The definition may include any process variation that does not affect the outcome or result in an adverse event, but for which a recurrence carries significant chance of a serious adverse outcome or result in an adverse event, often referred to as a close call or near miss.*

8. 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.

11. 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.04.04.03, EP 5)

## Quality System Assessment for Nonwaived Testing (QSA)

### Standard QSA.01.01.01

The laboratory participates in Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing programs for all regulated analytes.

**Note:** *This participation in the proficiency testing program includes the specialty of Microbiology, and subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; the specialty of Diagnostic Immunology, and subspecialties of Syphilis Serology and general Immunology; the specialty of Chemistry, and subspecialties of routine Chemistry, Endocrinology, and Toxicology; the specialty of Hematology (including routine Hematology and Coagulation); the subspecialty of Cytology (limited to gynecologic examinations); and the specialty of Immunohematology (ABO group and Rho(D) typing, unexpected antibody detection, compatibility testing, and antibody identification).*

### Elements of Performance for QSA.01.01.01

1. © The laboratory participates in a Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing program<sup>§</sup> that meets regulatory requirements for variety and frequency of testing.<sup>||</sup> (See also LD.04.05.07, EP 4) **R**
2. The laboratory authorizes the proficiency testing program to release all data required to determine the laboratory’s compliance for proficiency testing and makes proficiency testing results available to the public as required in the Public Health Service Act, Section 353(f)(3)(F). **R**
3. The laboratory uses a proficiency testing program for each regulated analyte performed. **R**

<sup>§</sup> For information on current proficiency testing providers, see [http://www.cms.hhs.gov/CLIA/14\\_Proficiency\\_Testing\\_Providers.asp](http://www.cms.hhs.gov/CLIA/14_Proficiency_Testing_Providers.asp).

<sup>||</sup> For more information on proficiency testing, see [http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency\\_Testing\\_Providers.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html).

4. The laboratory participates in the same approved proficiency testing program(s) for a full calendar year before designating a different proficiency testing program. If the laboratory designates a different proficiency testing program before the conclusion of a full calendar year, it notifies the Centers for Medicare & Medicaid Services (CMS) or The Joint Commission before this change is made. **R**
5. For each specialty, subspecialty, analyte, or test, the laboratory's proficiency testing results meet satisfactory performance criteria in accordance with law and regulation.

**Note 1:** *Satisfactory performance criteria in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart H, include the following:* **R**

- *Participating in a proficiency testing event. Failure to participate in a proficiency testing event results in a score of 0 for the testing event.*
- *Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and Rho(D) typing and compatibility testing*
- *Attaining a score of 100% for ABO group and Rho(D) typing or compatibility testing*
- *Returning proficiency testing results to the proficiency testing provider within the time frame specified by that provider. Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider results in a score of 0 for the testing event.*
- *Submitting all results on the proficiency testing form. Omission of results could lead to a failure of attaining the score necessary for satisfactory performance.*

**Note 2:** *Most proficiency testing events with fewer than 10 participants automatically result in a score of 100% for the event. These challenges are not sufficient for demonstrating that the laboratory has met satisfactory performance criteria. If this occurs, laboratories must supplement with either interlaboratory comparisons as specified under QSA.01.05.01 or non–Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing provided by the instrument manufacturer.*

*(For proficiency testing events in which the laboratory achieves satisfactory performance but has unacceptable proficiency testing results, see also QSA.01.02.01, EP 2)*

6. The laboratory's proficiency test performance is successful for each specialty, subspecialty, analyte, or test, as required by law and regulation. **R**

**Note:** *Unsuccessful performance is defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart H, as a failure to achieve satisfactory performance for two consecutive testing events or two out of three consecutive testing events.*

7. Individuals who examine gynecologic preparations participate in a Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing program that meets regulatory requirements for variety and frequency of testing and satisfactory performance criteria. **R**

**Note 1:** *For an individual who fails an annual proficiency testing event (less than 90% on a 10-slide proficiency test), the laboratory schedules a retesting event that takes place not more than 45 days after the receipt of the notification of failure. Steps of retesting include the following:*

- *A 10-slide retest (event #2), performed within 2 hours, in which a score of 90% is acceptable*
- *For an individual who fails the 10-slide retest (event #2), the laboratory provides remedial training and education in the area of failure and has evidence that all patient gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide proficiency test (event #3), performed within 4 hours, in which a score of 90% is acceptable.*
- *An individual who fails the last 20-slide proficiency test (event #3) ceases examining gynecologic slide preparations immediately upon notification of test failures and may not resume examining gynecologic slides until the laboratory has evidence that the individual obtained at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until the individual is retested with another 20-slide proficiency test and scores at least 90%.*
- *This final cycle continues until the individual successfully participates in another 20-slide proficiency test.*

**Note 2:** *Unexcused absence by an individual for a retest will result in a test failure.*

(See also QSA.01.02.01, EP 5)