



NATIONAL COMMISSION ON FORENSIC SCIENCE



Directive Recommendation: Root Cause Analysis (RCA) in Forensic Science

RECOMMENDATION: The US Attorney General should direct the adoption of appropriate root cause analysis protocols for all forensic science service providers (FSSPs) or forensic science medical providers (FSMPs) that are part of the federal government or are receiving federal funds, and to establish policy for restoration procedures that comply with the recommended root cause analysis process.

BACKGROUND

Forensic laboratories accredited under programs that adhere to the ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, are required to “establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.” A problem or nonconformity may be identified through a number of different techniques, including internal and external audits, reviews of the management system, customer feedback, or staff observations.

Corrective Actions are potential solutions that address a nonconformity and eliminate or minimize the risk of repeating the nonconforming work or departure from policies and procedures. A Corrective Action is a requirement when any error or nonconformity is identified. ISO 17025 (4.9.1) states that “The laboratory **shall** have a policy and procedures that shall be implemented when **any aspect** of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer.” (Emphasis added.) ISO 17025 (4.9.2) states that “Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed”. In addition, “The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.” ISO 17025 (4.11.1). To establish the best corrective actions, and as required by ISO 17025 (4.11.2), an investigation is initiated to determine the root cause(s) of the situation or condition: “The procedure for corrective action shall start with an investigation to determine the root cause(s)

of the problem.” Root Cause Analysis (RCA) is a critical step of determining corrective actions for substantive errors, and may be the most important part of establishing *proper* corrective actions.

IMPLEMENTATION RECOMMENDATIONS

Understanding that all human systems are fallible, and that risks in a system can be minimized, the Department of Justice should encourage federal Forensic Science Service Providers (FSSPs) and Forensic Science Medical Providers (FSMPs) to consistently strive to be “high reliability organizations” and ensure a culture of constant self-monitoring and self-improvement by incorporating established practices of “just culture”¹ and learning from error. To this end, the Department of Justice shall require its FSSPs and FSMPs to create and maintain protocols around the conduct of Root Cause Analysis (RCA) to address nonconforming work or departures from policies or procedures.² The Department or its designee will periodically review those RCA policies to ensure they include the following:

- Objective guidance as to when a RCA should be conducted;
- The regular provision of appropriate training to key personnel on how a RCA should be conducted;
- Training to all employees within the FSSP and FSMP on RCA principles and processes, to enhance the quality of the RCA and its acceptance within the laboratory environment;
- Proper construction of the investigative team conducting a RCA;
- Definition of and procedures for an investigation that identifies the extent of nonconforming work and its causal factor(s) in a blame-free environment, prioritizing continuous improvement of laboratory quality, safety and reliability by learning from nonconformities;
- Recommendations that identify corrective actions to minimize the chance of future recurrence of nonconformities identified in the RCA;
- Guidelines that define when and how to identify other cases that may have also been affected by an identical or similar nonconformity, and the obligation to conduct a retrospective re-analysis of and address such cases;
- Communication of the existence of the nonconformity to internal and external individuals

¹ A “just culture” can be defined as “a culture that recognizes that competent professionals make mistakes and acknowledges that even competent professionals will develop unhealthy norms (shortcuts, “routine rule violations”), but has zero tolerance for reckless behavior.” Agency for Healthcare Research & Quality Glossary, available at http://psnet.ahrq.gov/popup_glossary.aspx?name=justculture.

² Different terms may be used for unplanned and/or unintended occurrences in human systems, including adverse events, errors/omissions, mistakes, nonconformities, etc. We have selected the terms “nonconforming work” or “nonconformity” to include each of these various unplanned and/or unintended occurrences as well as departures from policies or procedures, and note that any of the above may include good faith or malfeasant behavior. Furthermore, “nonconformity” is broadly defined herein to include “near misses,” or unplanned occurrences or events that had the potential to result in a nonconformity but did not do so due to a fortunate turn of events, as opposed to a deliberate system design. Near misses should be addressed with the same diligence and vigor as actual nonconformities.

impacted by the nonconformity;

- Provision of Safe Harbor to employees who report nonconformities or near misses, including use immunity for participation in an RCA and limitations on the disclosure of materials generated in the course of an RCA;
- Implementation of actions designed to minimize the chance of future similar nonconformities and to appropriately redress injury caused by the nonconformity; and
- Documentation of each nonconformity as well as the proposed corrective action in a manner that does not publicly identify confidential information regarding specific individuals or cases, but that makes the learnings from the RCA publicly available for the review and benefit of other FSSPs and FSMPs.

IMPLEMENTATION STRATEGY

The US Attorney General should collaborate with FSSPs and FSMPs as well as experts in the field of RCA to establish guidelines in compliance with the above for the design, implementation, and review of RCAs, and for the periodic review of protocols and procedures regarding RCAs that may be updated over time. In addition, the Organization of Scientific Area Committees (OSAC) should be tasked with further exploration and periodic definition of best practices in RCA as applied to FSSPs and FSMPs.

Appendix A:

Supporting Information and Examples of Root Cause Analysis

Despite the best intentions and best efforts of forensic science professionals, supervisors, and managers, nonconformities will occur in forensic laboratories, as in any complex organization. It is the position of the National Commission on Forensic Science that all responsible forensic science providers should embrace and implement a just culture³ of “learning from error” and continuous improvement to minimize the occurrence of nonconformities and/or misconduct in the performance of forensic science services over time. This is true regardless of an organization’s history of error, since “[a]dverse events, like the number of adverse events, are poor indicators of the general safety of a system. . . . Safe organizations can still have bad adverse events, whereas unsafe systems can escape them for long periods. Furthermore, progress creates new risk that is difficult to anticipate but is a feature of new procedures and technologies.”⁴

Forensic laboratories accredited under programs that adhere to the ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories are required to “establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.” A problem may be identified through a number of different techniques, including internal and external audits, reviews of the management system, customer feedback, or staff observations.

“Corrective actions” are potential solutions that eliminate or minimize the risk of repeating the nonconforming work or departure from policies and procedures. Corrective action is a requirement when any error or nonconformity is identified. To identify the best corrective actions, and as required by ISO 17025,⁵ an investigation is initiated to determine the root cause(s) of the situation or condition. Root Cause Analysis (RCA) is a critical step and may be the most important part of identifying and implementing appropriate corrective actions.

³ A “just culture” can be defined as “a culture that recognizes that competent professionals make mistakes and acknowledges that even competent professionals will develop unhealthy norms (shortcuts, “routine rule violations”), but has zero tolerance for reckless behavior.” Agency for Healthcare Research & Quality Glossary, available at http://psnet.ahrq.gov/popup_glossary.aspx?name=justculture.

⁴ Barach P, Berwick DM. Patient Safety and the reliability of health care systems. *Ann Intern Med* 2003, 138(12):997-8. Barach uses the health care term “adverse event” to define an unintended outcome; in the forensic science context we use the ISO 9000-defined term “nonconformity,” which encompasses any deviation from a policy or procedure regardless of its impact.

⁵ ISO/IEC 17025:2005(E) (hereafter, ISO 17025), General requirements for the competence of testing and calibration laboratories, Section 4.11.2 Cause Analysis. “The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.”

ISO/IEC 17025 also requires laboratories to establish procedures to identify needed improvements and potential sources of nonconformities.⁶ This proactive process is termed “preventative action” and follows a similar process of Root Cause Analysis to identify the best solutions to prevent or minimize the chance of nonconformity from occurring.

RCA has been used productively not only throughout the healthcare industry but also in aviation, manufacturing and other quality-minded industries to conduct event reviews that lead to actionable change of policies and procedures to reduce the occurrence of nonconformities. The goal of RCA is to learn from nonconformities and to implement corrective actions in order to reduce further similar events that might compromise lab report or opinion integrity. An important feature of the RCA is that it is a blame-free analysis: “[b]laming and punishing for adverse events that are made by well-intentioned people . . . drives the problem of iatrogenic harm underground and alienates people who are best placed to prevent such problems from recurring.”⁷

A subset of nonconformity is the “near miss,” a nonconformity or unplanned event that had the potential to affect the accuracy or reliability of the laboratory results or work product, but did not do so through a fortuitous intervention. Only a fortunate break in the chain of events prevented a potentially systemic nonconformity.. Near misses are nonconformities and must be evaluated as such. Further, they should be evaluated in the same way they would be if the nonconformity had actually occurred. To do otherwise would suggest that because this near miss did not result in a nonconformity, the contributing factors that caused the near miss have been resolved.

This document sets forth recommendations for the standardized use of RCA to identify why an error has occurred in a forensic laboratory setting and make recommendations for the prevention of the future occurrence of similar nonconformities.

Types of Nonconformities Suitable for Root Cause Analysis and A Structure for Analyzing Causes.

It is common for a RCA to identify multiple factors that combined to cause the nonconformity. Indeed, the purpose of the RCA is to identify any and all contributing factors. While no framework can specifically identify and catalog all factors that could contribute to a nonconformity, one framework for evaluating nonconformities has been provided by British researcher Dr. James Reasons. Dr. Reasons describes three different types of error:

1. *Decision error*: One made because information, knowledge, or experience is lacking
2. *Skill-based error*: One made while engaged in a familiar task

⁶ ISO 17025, Section 4.12.” 4.12.1 Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

⁷ Rinciman WB, Merry AF, *Error, blame, and the law in health care – an antipodean perspective*. Ann Intern Med. 2003 Jun 17; 138(12):974-9.

3. *Perceptual error*: One made because input to one of the five senses is degraded or incomplete.

These errors typically fall into one of four categories:

1. *Unsafe Acts*: those performed by the operator
2. *Preconditions for Unsafe Acts*: environmental factors contributing to the error
3. *Supervision*: management actions affecting the operator
4. *Organizational Influences*: culture, policies, or procedures of the organization that affect the operator.

Dr. Reasons describes some nonconformities as “errors” and others as “violations,” distinct from errors in that they are “intentional departure[s] from accepted practice.” Violations may be:

1. Routine violation: habitual, repeat departures, enabled by “bending of the rules.”
2. Exceptional violation: a willful departure outside norms, not condoned by management.

A structure for categorizing different causes of many common unintentional or intentional nonconformities follows.

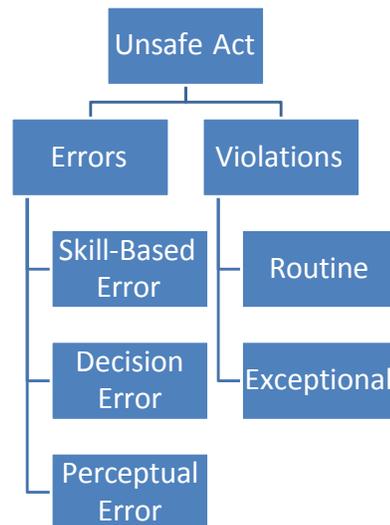


Figure 1: Types of Unsafe Acts.

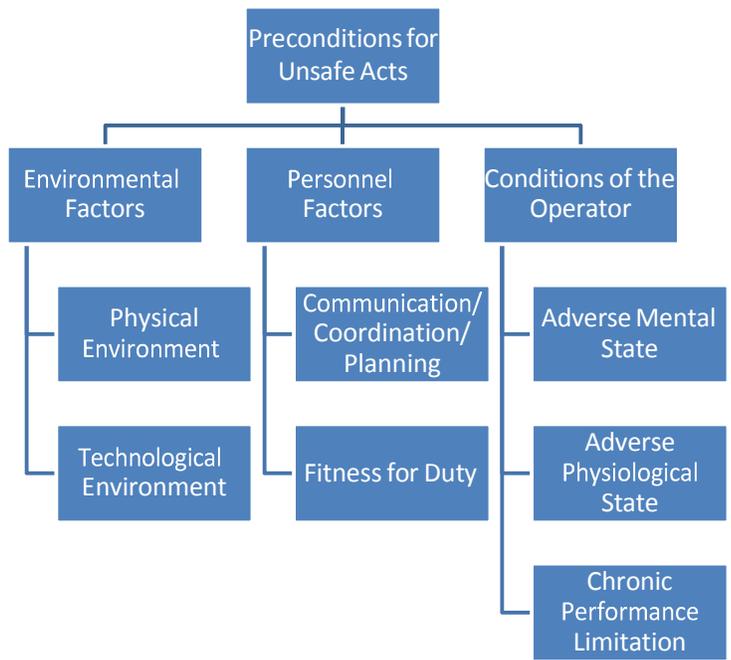


Figure 2. Causes of Preconditions for Unsafe Acts.

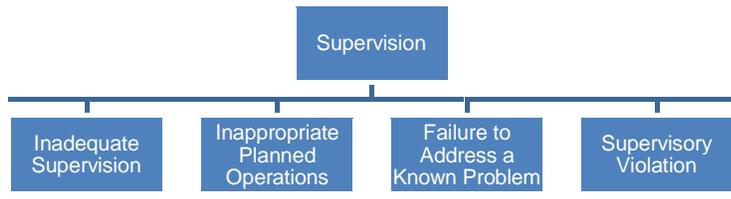


Figure 3. Causes for Nonconformities of Supervision.

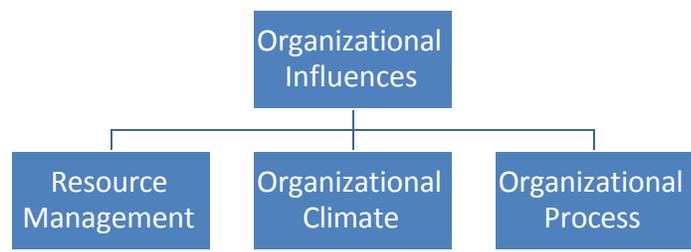


Figure 4. Causes of Undue Organizations Influences.

How should an RCA be conducted?

It cannot be emphasized enough that **RCAs are not performance evaluations, and their purpose is learning, not punishment.** Accordingly, personnel and discipline issues should be handled through a separate process from RCA. In many contexts, including transportation and healthcare, the activities and output of an RCA are inadmissible as evidence and excluded from discovery in litigation to ensure this purity of purpose. The “just culture” focus of the RCA creates shared accountability: the system is responsible for providing an environment that is optimally designed for safe care and staff is responsible for their choices of behavior and for reporting system vulnerabilities.⁸

While specific recommendations for the conduct of RCAs may differ, a few themes emerge from review of RCAs across industries:

- Construction. RCAs should be performed by a team. There is a benefit to engaging multiple perspectives and multidisciplinary personnel whose backgrounds encompass the various parts of the technical analysis and management systems, and reporting process to ensure a holistic review of factors that contributed to the nonconformity that might otherwise be overlooked.
 - The number of participants conducting the RCA can vary depending on the nature of the nonconformity. For more substantial nonconformities, RCAs often work best when performed by multidisciplinary teams, from all levels of staff, with fundamental knowledge of the specific area involved.
 - The team should have people who were not involved with the specific incident to ensure objectivity in the review.
 - A facilitator should be appointed who was not directly implicated in the incident.
- Investigation. The nonconformity should be analyzed for its causal factors.
 - Detailed review of the event by the team
 - Identify problems – *what* went wrong. Is this a one-time event or a recurring error?
 - Identify Root Causes/Contributing Factors – *why* it went wrong. Focus on objective causes and minimize causation conclusions that focus solely on blaming an individual or individuals, rather than evaluating environmental, organizational, supervisory, and other factors where possible
 - Prioritize the factors that contributed to the nonconformity, evaluating both their severity and the probability that these factors will cause harm in the future
 - Develop interventions that conform with the prioritization and likelihood of repetition of the various factors

⁸ Agrawal, A. *Patient Safety: A Case-based Comprehensive Guide*. 2014

- Recommendation. The team should make specific, prioritized recommendations for corrective actions that are intended to prevent occurrences of similar events. The recommendations may incorporate input from primary operators who will be affected by the recommendations to enhance their ability to be implemented efficiently. These recommendations should be made in writing and stored for future review as needed.
- Implementation. Implement those corrective actions, considering the quality of analysis, the cost of the suggested interventions, and their likely real-world impact on safety and reliability.
- Evaluation. Evaluate the corrective actions and take subsequent additional action as needed.
- Professional Standards and a “Just Culture.” A “Just Culture” is one that balances blame-free event reviews with the need for professionals, including FSSP/FSMPs, to be personally accountable for adherence to reasonable standards of professional conduct. Typically, this involves the creation of a separate disciplinary process, managed outside the RCA process, in the event that the RCA uncovers evidence of intentional wrongdoing by any individual. A sample tool to assess the necessity of such a parallel disciplinary process used in a hospital setting is attached.

To preserve the integrity of the RCA as a blame-free event review, it is important that any disciplinary process be additional to, and separate from, the RCA, and that the individual in charge of making determinations about disciplinary action be informed by, but not reporting to or involved in, the RCA itself.

Documentation/Implementation of Improvement.

ISO/IEC 17025 4.11.3 and 4.11.4 requires all selected changes resulting from corrective action investigations be documented and implemented. In addition, laboratories are required to monitor the results of the corrective actions to ensure the effectiveness of the solutions; this monitoring should similarly be documented.

In the criminal justice context, documentation and implementation of corrective action should include the obligation on the part of the panel conducting the RCA to communicate the nonconformity to individuals or agencies involved in casework that may have been affected by the nonconformity.⁹ This duty extends to other individuals who may be similarly situated to those directly affected by the nonconformity that has been discovered. For example, an RCA could be performed on a nonconformity regarding the miscalibration of an instrument used to assess blood tests in a single DUI case. If an error is discovered, it would lead to an obligation to identify all others who might be affected by the miscalibration and inform them about the re-

⁹ Note that corrective action may correct errors from which inferences of guilt or innocence may be drawn

evaluation of their cases. Not all nonconformities affect casework, but when they do, it is important to note that the life and liberty of a human being may be (or may not be) affected.

For this reason, forensic science service providers have a duty to inform others of the nonconformity, which should include a new, amended, or supplemental report with the correct results and an explanation of the initiating nonconformity distributed to the various parties in a case. The FSSP/FSMP must work with the proper legal authority to identify and notify all individuals whose cases were affected by the nonconformity/error, and should participate in the suitable remedy as appropriate.

Training of Personnel to Conduct RCAs.

Root cause analysis may be the most difficult part of establishing proper corrective actions following a nonconformity. By becoming proficient at investigating and solving problems of nonconformity in their work, a laboratory will ultimately need to conduct fewer investigations. But if done inappropriately, a root cause analysis investigation may lead to the inadvertent blame of individuals instead of identifying where a work process has broken down. Such blame will be detrimental to encouraging participation in the root cause analysis process.

A study that evaluated an aggregated group of RCAs in the healthcare setting identified lack of time (55%), unwilling colleagues (34%) and inter-professional differences (31%) as the top three barriers to RCAs.¹⁰ Each of these barriers can be addressed, at least in part, by experienced facilitation and support from senior management within the organization.

Accordingly, a recommendation is made to establish key individuals within a forensic laboratory to serve as facilitators of root cause panels. Characteristics of successful RCA facilitators will likely include, but may not be limited to:

- Interested in facilitating and documenting problems
- Excellent listening skills
- Naturally inquisitive
- Comfortable speaking in front of a group
- Detail-oriented
- Relatively calm disposition
- Good rapport with front-line personnel and management

Once selected, these individuals should be required to receive annual specialized training on the topic of root cause analysis to include practice in running group facilitations.

¹⁰ Bowie, Paul, Skinner, J. and de Wet, C. *Training health care professionals in root cause analysis: a cross-sectional study of post-training experiences, benefits, and attitudes.* BMC Health Services Research 2013, 13:50.

When Should an RCA Be Conducted?

ISO 17025 (4.9.2) states, “Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.” ISO 17025 (4.11.2) continues, “The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.” Properly done, RCAs include: *investigation* of facts and circumstances that caused or contributed to the nonconformity; *development* of interventions that should minimize the chance of future similar nonconformities, *implementation* of those interventions, and *evaluation* of the impact of the interventions. As such, they should be deployed with an eye towards the severity and risk of the problem.

Some laboratories, including the FBI Laboratory, categorize nonconformities in their work product as Level 1 or Level 2. Level 1 nonconformities are situations or conditions that directly affect and have a fundamental impact on the quality of the work product or the integrity of evidence. Level 2 nonconformities are situations or conditions that may affect the quality of the work, but does not, to any significant degree, affect the fundamental reliability of the work product or the integrity of the evidence.

Another approach, modeled after that of the Veterans’ Health Administration (VHA), evaluates whether a full RCA is needed based on the severity of the nonconformity and the likelihood of its reoccurrence.¹¹

		Severity			
		Catastrophic Systemic errors in procedure that affect several outcomes or reported results; intentional misconduct or recklessness in execution of role	Major Casework or proficiency test error that affects outcome or reported result. Potential problems that may affect the reliability, accuracy or performance of a test procedure or policy; serious negligence in execution of role	Moderate Clerical nonconformity affecting result but corrected during the review process prior to reporting; nonconformity that does not affect outcome or reported result	Minor Clerical nonconformity that does not affect outcome or reported result
Probability	Frequent Likely to occur multiple times in 1 year	3	3	2	1
	Occasional May occur several times in 1-2 years	3	3	2	1
	Uncommon May happen once in 2-5 years	3	2	1	1
	Remote May happen once in 5+ years	3	2	1	1

RCA Required for 3, Recommended for 2, Optional for 1

Table 1. Potential RCA Initiation Matrix.

¹¹ A “near miss” should be included for RCA review if its score qualifies when viewed as if the event had actually occurred

When an RCA is required or recommended, it should be conducted both on actual nonconformities and on nonconformities that *could* have occurred but for a fortuitous intervention or timely discovery. Such interventions are called “near misses,” and they should be scored in the SAC Matrix as if they were an event that actually occurred. Such reviews of near misses or “close calls” are valuable “because they occur much more frequently than adverse or reviewable sentinel events and do not require harm to a patient before learning can occur.”¹² Indeed, “the absence of safety, like poor health, is clearly signaled by near misses, injuries, and fatalities, which lend themselves to close analysis and quantification.”¹³

It is also important that the RCA process include steps designed to understand whether or not the error has been repeated, and if so, the extent of the nonconformities. An example would be the use of an improper reagent in a chemical test – appropriate auditing should be conducted to ensure what other tests, if any, might have been similarly compromised by the improper reagent. Another example might be the calibration of lab equipment, which would likely require a review of all tests conducted between the dates of the last calibration and the discovery of the error.

Creating a “Safe Harbor” to Encourage Transparency and Reporting of Error

It has been shown in numerous settings that providing a “safe” environment – that is, an environment that encourages and prevents negative use of important quality and/or reliability information – enhances participation in RCAs, and thus improves both their frequency and their substance.

The key characteristics of such a Safe Harbor include:

1. Qualified Immunity for Participants.
 - a. An individual should not be disciplined in any way for participating in a RCA, or offering a candid and good faith assessment of the role of others in an incident under review.
 - b. In addition, an individual who reports an error should receive positive consideration from any disciplinary body if the individual self-reports an error within a reasonable time after the incident (e.g., 10 days). Note that this does not protect the individual from any liability that may accrue for the individual’s role in the error, though the FSSP/FSMPs should consider the positive impact of the self-reported information in its assessment of any necessary punishment.

¹² Bagian, James et al., *The Veterans Affairs Root Cause Analysis System in Action*. Journal on Quality Improvement, 2002, Vol. 28 No. 10, 531 – 545, at 531.

¹³ *Making Sense of Root Cause Analysis Investigations of Surgery-Related Adverse Events*, Cassin, Bryce R., Barach, Paul R., Surg Clin N Am. 92 (2012) 101-115.

2. Protection from discovery for Notes, Minutes, Correspondence, and/or Reports generated as part of an RCA. In order to ensure that the RCA is an event review only, designed to learn from error and improve upstream processes, materials generated as part of an RCA should not, generally speaking, be discoverable in civil or criminal litigation related to the incident. This is in keeping with Peer Review Protection Acts that hold healthcare event reviews as undiscoverable in 46 states throughout the United States.¹⁴

3. Nothing in this safe harbor should be viewed as limiting the discovery rights of individuals to information about the underlying facts related to a nonconformity (i.e., facts or documents pertaining to the actual nonconformity, as opposed to documents generated by the RCA process). The purpose of the safe harbor is merely to ensure that no one is penalized as a result of his or her participation in a valuable event review designed to improve the technical and management system process, the quality of the laboratory work product, and the fair administration of justice.

¹⁴ To the extent an error justifying a RCA occurs in a criminal case, the defendant may have enhanced rights to learn about the results of the RCA as part of his/her criminal defense. Such an issue can be managed by the court of relevant jurisdiction on a case-by-case basis, with the information that the Attorney General views the protection of RCA work product to be an important public interest that does not preclude any discovery sought by the defendant on the underlying facts at issue.