Random Safety Auditing, Root Cause Analysis, Failure Mode and Effects Analysis

Robert Ursprung, MD, MMS\textsuperscript{a,\textdagger}, James Gray, MD, MS\textsuperscript{b,c}

Improving quality and safety in health care is a major concern for health care providers, the general public, and policy makers.\textsuperscript{1–4} Errors and quality issues are leading causes of morbidity and mortality across the health care industry.\textsuperscript{5–9} In adult intensive care units, nearly half of all patients suffer at least 1 adverse drug event; 1 in 5 of these patients suffer death or disability from the event.\textsuperscript{10}

Gaps in the quality and safety of health care, however, are not limited to the care provided to adults. There is strong published evidence that patients in the neonatal intensive care unit (NICU) are at high risk for serious medical errors.\textsuperscript{11–14} Kaushal and colleagues\textsuperscript{11} showed that adverse drug events in the NICU occur at a rate that is 8 times those published for hospitalized adults. Anonymous reports of voluntary error from 54 NICUs reveal errors in virtually all domains of care.\textsuperscript{15}

Although these published reports provide a valuable overview of safety issues in health care, the research methods typically do not lend themselves to use by frontline providers. To facilitate compliance with safe practices, many institutions have established quality-assurance monitoring procedures including voluntary incident reporting, chart auditing, and automated data mining of laboratory, pharmacy, and case mix data.\textsuperscript{16–22} Although these methods may improve error detection, they can be time-consuming, costly, and do little to involve frontline providers. To address these concerns, some quality and patient safety programs use safety methods borrowed from other industries that may improve the quality and safety of patient care more efficiently and more effectively.\textsuperscript{23–29}

\textsuperscript{a} Pediatrix Medical Group, Cook Children’s Medical Center, Department of Neonatology, 801 Seventh Avenue, Fort Worth, TX 76104, USA
\textsuperscript{b} Division of Newborn Medicine, Harvard Medical School, USA
\textsuperscript{c} Division of Clinical Informatics, Department of Neonatology, Beth Israel Deaconess Medical Center, Boston, MA, USA
\textdagger} Corresponding author.

\textit{E-mail address:} robert_ursprung@pediatrix.com

doi:10.1016/j.clp.2010.01.008

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Three techniques that have been found useful in the health care setting are failure mode and effects analysis (FMEA), root cause analysis (RCA), and random safety auditing (RSA). When used together, these techniques are effective tools for system analysis and redesign focused on providing safe delivery of care in the complex NICU system (Table 1).

**RANDOM SAFETY AUDITING**

RSA, also known as random auditing, or random process auditing, is an intuitive method that can be applied by frontline clinical staff to enhance quality and safety in a busy work environment. Rather than attempt to monitor all procedures, processes, or process elements in clinical care, this methodology focuses on monitoring a subset of error-prone points in the system. From this subset, items are selected at random for measurement. Immediate feedback can be provided to frontline clinical staff, and subsequent aggregate analysis permits robust coverage of complex systems over time.

Characteristics of RSA that make it attractive to health care include its low cost to implement, minimal requirements for training of staff, the ability to detect errors (many of which are not easily detectable by other means), and perhaps most importantly, the flexibility of the methods. Audit questions can be created, eliminated, or revised as safety/quality priorities change. The auditing methods can be adapted to the culture and workflow of a given work setting.

The Center for Patient Safety in Neonatal Intensive Care (the Center) adapted RSA methodology to the health care setting as a novel approach to improve quality and patient safety. More than just a tool to detect errors, RSA has the potential to reduce future errors through the identification of system failures that contribute to gaps in quality and safety. Further, RSA incorporates features of evidence-based behavior change agents, including audit and feedback, self-efficacy, social norms, and reinforcement.

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Initial Use in the Health Care Setting

The usefulness of RSA in the health care setting was first shown in an NICU in a tertiary care children’s hospital. The 5-week single-unit study detected more than 300 errors, representing such diverse aspects of care as alarm settings, patient identification, hand hygiene, labeling of tubes, syringes, and medications. In addition to identifying and counting errors, the audit tool stimulated productive discussions among clinicians, because the audits identified major remediable gaps in performance. These bedside discussions, in conjunction with feedback of summarized audit data to staff and management, led to rapid changes in policy and practice.

For example, the audits revealed that only 9% of NICU patients wore their patient identification (ID) band as stipulated by unit policy. This finding is especially concerning in light of data showing NICU patients are at high risk for misidentification. An RCA (see next section), prompted by the audit data, identified several barriers to use of the identification system. These barriers included such circumstances as the frequent removal by bedside clinicians of the hard plastic ID band to avoid abrasions and lacerations of fragile infant skin. In addition, even when these bands were not causing skin breakdown, they were often removed to facilitate intravenous (IV) access. Bands were often not replaced because the process to procure a new one was labor intensive for the bedside nurse (Fig. 1). Prompt process changes, including purchase of an ID band that addressed nursing concerns, resulted in sustainable compliance rates greater than 90%.

Although this initial study of RSA was conducted in a research paradigm with a dedicated research nurse, a subsequent follow-up study showed that RSA conducted by frontline providers detected errors at the same rate as a research team auditing concurrently. The authors’ experience has shown that RSAs may reduce future errors in 4 important ways: (1) identifying system failures, (2) increasing provider awareness of issues relevant to quality and safety, (3) involving more staff in improvement efforts, and (4) exploiting advantages of the audit and feedback loop.

![A](image1)

![B](image2)

Fig. 1. (A) The plastic ID bands were felt to damage preterm infant’s skin and when moved to facilitate IV access, the process for procuring a new band was labor intensive for the bedside nurse. (B) A softer ID band that could be moved was substituted, resulting in a sustainable 10-fold increase in compliance with unit policy regarding ID band location.
The ease of adoption of RSA was shown by the Vermont Oxford NIC/Q 2002 Quality Improvement Collaborative. A survey of NICUs participating in this collaborative found 26 of 44 NICUs implemented RSA within 6 months of receiving an RSA toolkit and educational presentation. NICUs documented improvement in diverse aspects of care, including hand hygiene, patient identification, breast milk administration, pain management, appropriate labeling of IV tubing, and preprocedure time-outs. When these units were asked to identify the most valuable aspects of RSA implementation in their unit, the responses included “error detection,” “error detection and subsequent educational opportunity,” “education and feedback to the staff,” “education and reinforcement of practice expectations,” “multidisciplinary collaboration,” “involving more staff in patient safety (increased team spirit),” “showing change over time, both in areas needing improvement and areas performing well.”

Three of the 26 participating NICUs reported an adverse experience. These units reported that some staff felt they were being watched. This barrier can be overcome by improving multidisciplinary participation in auditing and development of a culture of safety, a blame-free environment concerning auditing, and feedback of audit results.

**Implementing RSA in Your Unit**

“No one time” preparation work before implementation of RSA

Successful implementation of RSA requires customization of the audit questions and methods to fit the policies, culture, and workflow of your unit (Fig. 2). Implementation begins with the selection of a multidisciplinary audit team. This team needs a leader and should include participants from any discipline the audit questions will assess (eg, nursing, nurse practitioner, respiratory therapist, pharmacist, attending physician, trainees).

The initial task for the RSA team is to identify the unit’s quality and safety priorities. The team then creates a list of relevant audit questions. The authors suggest starting with 5 to 15 items. Although it may be tempting to focus on a larger number of items, this is not recommended for initial implementation. The authors’ experience has shown that with a large number of audit questions, the staff may lose focus. A list of sample audit questions is contained in Appendix 1; the list is not comprehensive, nor will all questions be applicable to your unit. In addition, some rewording of the questions may be required to address the problems that seem to be of greatest concern in an individual NICU.

After refining a list of audit items, the RSA team must determine the process for selecting 1 question each day at random and documenting the audit results. Most units choose to print a deck of audit cards (Fig. 3). Each card contains 1 question, with multiple copies of each question in the deck (ie, 10 copies of each question). For items of special high priority, the deck may be “weighted,” with a higher proportion of those cards. The deck is shuffled to randomize the order of questions. Many units include a trivia question on the back of the card that can be shared with staff during auditing to add levity to the process and keep staff engaged.

In addition, there needs to be a designated location to store the audit cards before and after their use. Many units have chosen to create an audit card storage box. The more attractive the box, the less likely it will be accidentally thrown away or misplaced. The box can serve as a reminder to staff that quality and safety are priorities in your unit.

**Daily Implementation of RSA**

The specific methods are flexible and should be tailored to fit the dynamics of workflow in the NICU. In general, one card should be chosen daily to audit and every relevant piece of equipment or patient should be assessed for that question. Depending
on the priorities and the areas of concern, you may choose to audit only a certain group of patients. One example of a relevant patient subgroup might be level III patients. If your unit has more than 1 rounding team, these teams may audit different items. Auditing weekend and night shifts should be considered, as differing issues might arise during these compared with day shifts.

Depending on the specific question, the auditor (the person completing the audit card) might be a charge or staff nurse, attending physician, trainee, respiratory therapist, or

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**Fig. 2.** Random safety audit process chart.
another appropriate designee. Some questions may be best served by having a few trained auditors to maximize consistency of the grading of the audit (eg, hand hygiene). Some units have divided the questions up by specialty involved. For example, questions that deal with issues relevant to nursing may best be audited by a nurse.

The optimal time to audit depends in part on the particular audit question, and how rounds are conducted in your unit. Some questions may best be assessed before rounds at a morning sign-in/check-out (eg, “Were all appropriate/intended neonatal personnel at the last 24 hours’ high-risk deliveries in sufficient time?”). Other questions may be best evaluated during multidisciplinary rounds (eg, “Was the attending physician called for all appropriate events?”). Other questions could most efficiently be evaluated after rounds whenever the auditor has time to complete the audit (eg, “Are the pulse oximeter’s alarms set according to unit guidelines or provider order?”). Some items may require covert auditing (eg, hand hygiene), because of the altered behavior that commonly occurs when people believe that they are being evaluated.

For a given patient, each item is scored “No error,” “Error,” “N/A” or “Unknown,” in an all-or-nothing manner, using the checkboxes on the card for rapid documentation. For example, considering the audit question “During the last 48 hours, were orders written using prohibited abbreviations?”, if a particular set of orders has 5 abbreviations (3 approved and 2 prohibited), the patient should be scored “Error” (not “Mostly correct” or “3 correct and 2 errors”).

Some items cannot be completed simply by a yes/no from the team and will require verification by an auditor reviewing the issue at hand (eg, “Is the Ambu bag and mask appropriately set up at the bedside?”). The space under “Notes” is intended to allow brief descriptions of errors detected to assist in differentiating trivial from more significant errors when summarizing data. Neither patient nor provider names should appear on the audit card. For auditing to detect errors effectively, the staff must believe the goal is to improve patient care, not to punish providers. On completion of the audit, the card should be stored in a secure location. Used cards can then be collected every 2 to 4 weeks for analysis, allowing summarized feedback of the audit results to frontline staff and management. The audit card deck can be refreshed with new cards as needed.

Fig. 3. Sample random audit card, with an audit question on alarm settings and result table to record the audit. A sample trivia question is also shown.

What are the four ACOG criteria to define perinatal asphyxia?
• Arterial cord pH < 7.0
• Apgar < 4 for ≥ 5 min.
• Abnormal neuro exam
• Multi organ dysfunction

What are the pulse oximeter alarm settings? Are they set according to unit policy or provider order?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| No Error |
| Error |
| N/A |
| Unknown |

Notes

1   2    3   4    5   6   7   8   9  10  11 12 13 14  15 16 17 18 19

What are the pulse oximeter alarm settings? Are they set according to unit policy or provider order?

Notes

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Many audit questions lend themselves to providing immediate feedback to frontline providers. Timely feedback completes the loop of audit and feedback behavior change, a key strength of RSA. Timely feedback is more likely to modify provider behavior than no feedback, or feedback that is delayed (which is common for incident reports).

The local champion should summarize the audit results periodically (e.g., every other week or monthly) to allow summarized data to be presented to unit staff and management. Audit results can be presented as graphs over time, optimally with a run chart or statistical process control chart. The optimal method to communicate feedback varies from unit to unit, but could include announcements at staff meetings, e-mails, and posters in break rooms.

Some audit items are subjective (e.g., “Was the attending physician called for all ‘appropriate’ events?”). The compliance percentage in such situations may be of limited value, yet the results may still have some importance in the way that overall care is managed in the NICU. These questions can prompt multidisciplinary discussions that can expose weak systems or processes, and reinforce expectations among unit staff.

The list of items audited is not intended to be comprehensive or static. When problems have been addressed and repeat audits show compliance, it may be appropriate to audit these items less frequently or eliminate them from audit altogether. Conversely, as new concerns arise, new audit questions can be added.

RSA facilitates monitoring of a broad range of complex systems for errors and quality deficiencies without the need for significant infrastructure or resource allocation. RSA involves frontline staff in quality and safety efforts, becoming more than just a tool to detect errors. Auditing has the potential to reduce future errors and provide a method for correction of system failures before they become ingrained in daily practice.

**ROOT CAUSE ANALYSIS**

RCA (perhaps more appropriately termed root causes analysis) is a methodology for identifying the basic or causal factors that underlie variation in performance. RCA has been used to investigate industrial accidents for decades and has been common in the health care setting since the 1990s. The Joint Commission (JC), the principle health care accrediting organization in the United States, now requires organizations under its jurisdiction to perform an RCA in response to every sentinel event. The JC views RCAs and the resultant actions plans as confidential.

The JC defines a sentinel event as, *an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.* Some organizations also choose to perform RCA on near-miss events.

Although it is a retrospective approach to error analysis, the goal of RCA is to prevent future adverse events, through correction of the root causes underlying system vulnerabilities that facilitate errors. The sine qua non of RCA is an intense focus on human factors and system vulnerability characteristics that contribute to errors, and away from personal blame. The RCA can be broken down into 5 key steps (Box 1).

1. Identification of sentinel or other important events that require an RCA

The initial phase for the development of an RCA program includes defining criteria for which events require review with RCA. Once these criteria are defined, a mechanism to identify these events and alert relevant staff is needed.
Assemble an RCA team

It is essential to have the RCA team led by a person with training and experience in RCA. Although the composition of the RCA team varies with each event, it should always be multidisciplinary, including frontline staff with intimate knowledge of the event, and personnel with knowledge of the systems and processes that might have played a role in the event. Furthermore, the team should include senior leadership of the organization, who can facilitate implementation and monitoring of the RCA action plan.

For example, the RCA team evaluating a sentinel event in which an enteral medication was given intravenously should include at least a physician, a nurse, a pharmacist, and a senior hospital manager. At least 1 team member should be experienced in leading an RCA. Depending on the circumstances of the error and workflow at the institution, the team might also include a pharmacy technician, a patient care technician, information systems staff, a unit manager, a nurse practitioner, and physician trainees. Not all team members necessarily participate in every aspect of the RCA.

Diagram the event, reconstruct the process: What happened?

A structured framework should be followed during RCA (see Appendix 1 for a sample framework created by the JC). The initial step is to describe what happened in detail through medical record review and interviews with relevant personnel, patients, and family. To facilitate accuracy, this review should occur as quickly as possible after the event. The description of the episode should include who was affected, what area or services were involved, and when the event occurred. As the details of what happened are identified, the steps in the process, as designed, should also be determined.

Why did the event happen? Moving from proximate to root causes

After the initial reconstruction and description of what happened, the focus of the team shifts to understanding why the event occurred. To be thorough and credible, the analysis should progress from the immediately visible (proximate) causes in the clinical processes to the deeper root causes in the systems supporting care. Each proximate cause typically has underlying root causes. To expose root causes, the team should start with a proximate cause and ask “Why did this happen?” The team repeats this question until the underlying root causes are identified (Box 2, Fig. 4). Typically 5 iterations of asking why should be sufficient (“5 Whys”). This process is repeated for each proximate cause. Many find a flow diagram or Ishikawa diagram to be helpful in working through and documenting this discovery process (Fig. 5).

For example, consider an event in which a child receives a 10-fold medication overdose. One potential series of events follows.
A physician ordered 10.0 mg of gentamicin. A dose of 100 mg is mistakenly read by the pharmacist because of the presence of a trailing zero and the use of a fax machine to transmit this order to the pharmacy. The pharmacist filled the order without reviewing the patient’s weight, perhaps because it was not readily available in the pharmacy. The nurse did not double-check the medication dose before administration possibly because appropriate dosing references were not available at the bedside.

(5) Development and implementation of an action plan

Once the sequence of events and the underlying root causes are determined, the RCA team should focus on reengineering the systems or processes that facilitated the error. Not all systems or processes are modifiable. The potentially modifiable root causes can be prioritized for systems reengineering.

Proposed changes may need to be tested before or after large-scale implementation. The action plan should document who is responsible for implementation, the time frame for implementation of change, and how the effectiveness of the interventions in reducing risk will be assessed.

**Barriers to Effective RCA**

Some RCAs do not produce improvement because they are performed incorrectly. Having an experienced and effective leader is therefore essential. Flawed RCAs can also result when the team places undue emphasis on finding the single most important root cause, ignoring lesser possible causes. Uncovering all root causes is important to allow the most effective and efficient systems-based interventions to be implemented. Additional barriers to effective RCA and action plan implementation can include lack of resources, uncooperative colleagues, and unsupportive management. Thus, having support from institutional or units leadership and a team leader with experience or knowledge of the RCA process and potential pitfalls is essential.

**Box 2**

**Framework for an RCA and action plan in response to a sentinel event**

1. What human factors were relevant to the outcome?
   a. Were the staff trained and competent?
   b. Was staffing ideal?
   c. Was communication among participants adequate?
   d. Was the environment appropriate for the task?
   e. Was the culture conducive to risk identification and risk reduction?

2. How did the performance of equipment affect the outcome?

3. What controllable environmental factors contributed to the outcome?

4. What uncontrollable factors contributed to the outcome?

5. Information systems: was all appropriate information
   a. Available?
   b. Accurate?
   c. Complete?
   d. Unambiguous?

6. Other contributing factors
10X overdose of gentamicin results in renal failure

Environment | Equipment | Information systems | Leadership
---|---|---|---

Communication | Personnel | Policy & Procedure | Patient

Fig. 4. Sample RCA of a death related to an unrecognized pericardial effusion (proximate cause). RCA showed multiple root causes that contributed to the death. PICC, peripherally inserted central catheter.

Fig. 5. The Ishikawa diagram can be created during the RCA through open communication among RCA team members. The category headings are flexible and should be adapted to the individual event. The RCA team should identify as many contributory factors as possible, moving from superficial (proximate) causes to deeper root causes.
Adapted from industry, RCA methodology is now well accepted and commonplace in the health care setting. RCA is an important qualitative tool facilitating learning from errors. A multidisciplinary team including an experienced leader and senior leadership from the organization is essential for RCA to lead to a functional action plan that can mitigate future hazards.

**FAILURE MODE AND EFFECTS ANALYSIS**

FMEA (also known as failure mode, effect, and criticality analysis) is a valuable tool for improving patient safety. Unlike RCA, FMEA is a proactive risk reduction technique that attempts to identify the possibility of future system failures that could affect patient care processes and, ultimately, the patient. Properly implemented, inclusion of an FMEA-based approach to risk reduction addresses JC requirements that ensure that “an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented.” Often compared with hazard analysis and critical control points, a method used extensively in food safety programs, FMEA has a long history of successful use in the engineering and software industries. As a nonstatistical method, FMEA can easily be taught to multiple members of the health care team.

Although various approaches to perform FMEA exist, all FMEA implementations share a common conceptual framework.

- **Failures**: Failures are undesirable or unintended deviations, or errors that affect a process or system.
- **Modes**: Modes are the way in which the process or system can fail.
- **Effects**: Effects are the consequences that result from a process or system failure.
- **Analysis**: Analysis is an examination of the way that individual processes or process failures might interact to determine the ultimate outcome seen from the process. In addition, the analysis phase identifies methods to decrease the frequency of or mitigate the consequences of process failure.

*Box 3* lists the steps suggested in the generic FMEA process described by the JC. Other approaches including that outlined in the Veterans Administrations Health Care Failure Mode and Effect Analysis (HFMEA) can be found elsewhere.

### Identifying a High-risk Process

High-risk processes may have a high frequency of failure or may have low failure rates but each failure is likely to lead to significant adverse consequences. High-risk processes that are candidates for FMEA include clinical processes, such as accurately identifying patients during encounters, procedural processes, such as identifying the physician responsible for a patient’s care out of hours, or administrative processes, such as ensuring a suitable supply of equipment within the NICU. The presence of new equipment or systems within a unit, such as smart pumps or computerized provider order entry (CPOE), may introduce new care processes that can be prone to error because of their novelty. Potential topics within an NICU include, but are not limited to, patient identification, medication administration, stabilization before, during, or following transport, blood product use, and timely and complete sharing of information with families.

### Assembling a Team

Teams involved in FMEA should include members from all disciplines involved in the identified process, but generally should be limited to 10 members or less. Team
members might include non-NICU staff such as radiology or ultrasound technicians, consulting services, parents, or even staff from affiliated hospitals (eg, if the process spans institutions). Inclusion of an individual not familiar with the process may also lend a fresh perspective. A successful team includes not only those individuals who can characterize the process, identify failure modes, and understand their effect but also individuals who are needed for the design and implementation of new processes. Consideration should be given to the use of an external facilitator to lead the group through subsequent steps. It is not necessary that the facilitator has domain knowledge of the process, but rather this individual should stimulate the participation of all team members and keep the group moving forward in the FMEA process.

**Diagram the Process**

All the steps that are required in the process should be sequentially identified and placed into a flowchartlike presentation. Use of a large whiteboard with erasable markers or a blank wall covered with sticky notes can facilitate the iterative nature of this endeavor. Planning for more than a single session can provide participants with an opportunity to identify and focus on hidden steps within a complex process. Once complete, or at interim stages, a digital camera can be used to make copies of the process. Two representations may be needed: the way that the process is intended to occur and the way that it actually occurs. Once completed, various preexisting formats exist for final documentation of the process.

**Identify Failure Modes**

Brainstorming is used to identify the potential ways in which failures could occur during each step of the process. Brainstorming need not proceed in the sequential manner outlined in the flowchart, but rather should be a stream-of-consciousness exercise for the participants. Examples of potential failure modes during the use of a CPOE system may be the selection (either by human or computerized action) of an incorrect medication or medication dosage for a patient. While conducting this portion of the exercise, no attempt should be made to narrow the list of potential failure modes.

**Prioritize Failure Modes**

Here the potential critical degree of each failure mode is estimated. Criticality is a complex construct that attempts to measure the relative importance of a failure

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**Box 3**  
**JC generic FMEA**

1. Select a high-risk process and assemble a team  
2. Diagram the process  
3. Brainstorm the potential failure modes and determine the effects  
4. Prioritize failure modes  
5. Identify root causes of failure modes  
6. Redesign the process  
7. Analyze and test the new process  
8. Implement and monitor the redesigned process

mode through consideration of its likelihood, potential for detection, and seriousness (as measured by severity of potential effects). The JC does not require that any particular rating scale be used. Individual institutions often create new or adapt existing scales to suit their own particular circumstances. A review of various approaches is available elsewhere.38,43

An example of 1 approach is seen in the Veterans Administration HFMEA 4-category schema (Fig. 6, HFMEA matrix), which includes frequent (likely to occur several times per year), occasional (probably will occur several times in a 1- to 2-year period), uncommon (possibly may happen in a 5-year period), and remote events (may happen once in a 6- to 30-year period). Similarly, within this framework categorization of seriousness occurs along another 4-point axis that includes catastrophic (ie, could lead to death), major (ie, could lead to permanent loss of body function), moderate (ie, could lead to increased length of stay for 1 or 2 patients), and minor (ie, effect is unlikely to be noticed). For each FMEA, a risk level for immediate action should be determined.

After categorizing the frequency and seriousness of a failure mode, the ability to detect it should be considered. Failures at 1 stage of a process can be mitigated if the failure is readily observed. Even a serious failure that occurs frequently may have little effect on patients if it is noted at once and downstream steps are able to respond to the previous failure. In comparison, tightly coupled processes in which there is little ability to buffer the effects of previous failure are more likely to lead to a cascade of events that result in patient harm.

Identify Root Causes of Failure Modes

The RCA techniques described earlier can be applied to enable system redesign of the identified high-priority processes. Emphasis must be placed on identification of root causes, not just proximate causes of the failure modes.

Redesign the Process

The team should then focus on ways in which to redesign the process by considering the most critical failure modes identified. In general, there are 3 approaches to redesign: the prevention of failure modes; improved detection of failures; and implementation of recovery processes that mitigate the effects of failure (ie, prevent failures that do occur from reaching the patient).

Analyze and Test the New Process

Before implementation of the newly designed process, team members should consider performing another FMEA on the newly created process. Although it is

![Fig. 6. HFMEA matrix. Each failure mode is assigned a criticality index based on the cross product of its probability and severity.](image-url)
tempting to examine only the modified steps, this approach can miss important inter-
actions between new and existing steps that may lead to errors.

**Implement and Monitor the Redesigned Process**

As mentioned earlier, the implementation of newly designed processes can dramati-
cally alter the function of existing clinical care in unforeseen ways. As part of any
system reengineering, an active plan for ongoing monitoring of the new process
should be created and implemented.

**FMEA Summary**

FMEA through its systematic, proactive approach to safety can identify error-prone
systems and prevent the effects of medical error from reaching the patient. Complete
and successful review of a clinical process using FMEA requires the commitment of
significant resources, but is likely to result in a valuable return on investment. If
viewed solely as a mandate that must be completed to ensure compliance with regu-
lations, FMEA is likely to be performed in a manner that will not achieve its full poten-
tial value.

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APPENDIX 1: POTENTIAL RANDOM AUDIT QUESTIONS

Questions focusing on infection control

1. Does this patient’s bedside have an alcohol hand rub dispenser easily accessible, which delivers product properly? Score each bedside independently.
   - Compliance with hand hygiene is directly tied to convenience of use, thus the dispenser should be in close proximity to the bed, without obstacles to reaching the dispenser. Further, the dispenser should not be empty or clogged, such that 1 “pump” or “squirt” delivers sufficient product for hand hygiene.45,46

2. Is this antimicrobial soap dispenser delivering product properly (ie, it is not empty or clogged, such that 1 pump or squirt delivers sufficient product for hand hygiene)? Score each dispenser independently.
   - Compliance with hand hygiene is directly tied to convenience of use.45,46

3. Are there gloves of various sizes (ie, small, medium, and large) easily accessible from this patient’s bedside? Score each bedside independently.

4. Is lotion (provided by the hospital free of charge) easily accessible to this patient’s bedside and is it functioning properly (ie, not empty or clogged)? Score each dispenser independently.
   - Skin irritation is a major deterrent to compliance with hand hygiene; the US Centers for Disease Control and Prevention (CDC) recommend lotions be available free of charge.46

5. Is this sink working properly, with water temperature that is not too hot?
   - Hot water leads to greater skin irritation; skin irritation leads to lower hand hygiene compliance.46

6. Is this paper towel dispenser functioning properly (ie, not empty or malfunctioning)? Score each dispenser independently.
   - Compliance with hand hygiene is directly tied to convenience of use.45,46

7. Are there hand hygiene reminders (ie, posters, flyers, stickers) visible in the NICU?
   - Education is essential for any successful hand hygiene improvement effort.46

8. Was there feedback of the unit’s most recent hand hygiene compliance rates to NICU staff (ie, a poster displayed in a break room, an e-mail, discussion at staff meetings, other)?
   - Education is essential for any successful hand hygiene improvement effort. Feedback to staff of the current hand hygiene compliance rate is recommended.46

9. Does this staff member know the most recent hand hygiene compliance rate specific to their role (ie, nursing, respiratory therapist, neonatal nurse practitioner [NNP], physician) in the NICU? Audit as many staff members as time allows.
   - Education is essential for any successful hand hygiene improvement effort. Feedback to staff of the current hand hygiene compliance rate is recommended.46

10. Are any NICU clinical staff wearing artificial nails? Score each caregiver independently.
    - Those wearing artificial nails are more likely to harbor gram-negative pathogens on their fingertips than those with natural nails before and after hand-washing.46

11. For any patients who had a blood culture obtained in the last 48 hours, is there documentation of site and amount of blood sent for culture and does it meet your local guidelines concerning the volume of blood collected?
    - Follow your laboratory’s recommendations. Most experts recommend 1 mL as the minimum volume of blood for a neonatal blood culture; sensitivity of the
culture increases with increasing blood volume. Some recommend use of 2 blood cultures per evaluation.

12. Are any patients in the unit on vancomycin or aminoglycosides (eg, gentamicin, tobramycin)? If so, were indicated drug-monitoring levels performed at the appropriate times?

13. If any patients are being treated for infections in which there is a positive culture and known antimicrobial sensitivities, has the antibiotic coverage been narrowed appropriately? Examples:
   - Changing from vancomycin and gentamicin to vancomycin alone when treating *Staphylococcus epidermidis* (also known as coag-negative staph).
   - Changing from vancomycin to oxacillin when treating methicillin sensitive *Staph aureus*.

14. If this infant was on antibiotics for a rule-out sepsis evaluation that was initiated 48 to 96 hours ago (2–4 days), were the antibiotics discontinued at less than or equal to 48 hours from the time of the evaluation, or is there justification for the continuation of antibiotics?
   - The goal of this question is to evaluate if nonindicated doses of antibiotics are being administered.

15. If this patient has a central line (eg, umbilical artery catheter, umbilical venous catheter, Broviac catheter, peripherally inserted central catheter [PICC] ) were maximal barrier precautions used during its insertion?
   - Maximal barrier precautions (cap, mask, sterile gloves, sterile gown, and large sterile field) have been shown to reduce catheter-related bloodstream infections when compared with use of minimal barrier precautions (sterile gloves and a smaller sterile field) during central line insertion.
   - As an alternative, you could audit this question during the insertion of a central line.

16. If the history and physical (H&P) examination or accompanying documentation gives the results of the mother’s hepatitis B surface antigen (HbsAg) status as anything but negative, was the infant treated per the *American Academy of Pediatrics (AAP) Red Book* Guidelines?
   - Obtain the result of mother’s HBsAg during the infant’s initial 12 hours of life.
   - If mother’s HBsAg is positive or if the result cannot be obtained during the infant’s initial 12 hours of life, the *AAP Red Book* advocates the following treatment:
     - Term infants: hepatitis B vaccine during the initial 12 hours of life, if mother’s HBsAg is positive, also give HB immune globulin (HBIG) during the initial 7 days of life.
     - Preterm infants more than 2 kg: hepatitis B vaccine and HBIG during the initial 12 hours of life.

17. Concerning infants delivered in the last 24 hours. Was this infant screened for group B streptococcal (GBS) infection risk and if appropriate treated according to the CDC’s guideline (or your hospital’s guideline)?
   - Use of the CDC’s guideline has drastically reduced the incidence of early onset GBS infections.

18. Does the H&P document mother’s GBS status, whether or not the mother received intrapartum antibiotic prophylaxis and for what duration, and any sepsis risk factors (including preterm labor, maternal fever, symptoms of chorioamnionitis)?

19. Is the IV tubing labeled according to unit policy and has not expired?
20. Is the NICU understaffed from a nursing standpoint today? Define understaffed per your local standard.

- Understaffing is a predictor of poor adherence to hand hygiene and is an independent risk factor for blood stream infection.\textsuperscript{46,52}

Hand hygiene (HH) monitoring form.

HH monitoring instructions:

1. Be positioned to observe as many bed spaces as possible simultaneously, while still being able to track and record activities correctly. Generally, this is 2 to 4 bed spaces.

2. HH monitoring should be done as part of routine quality monitoring. Other tasks (eg, checking alarm settings, chart review) should be mixed in so that HH is not perceived as the main focus.

3. Make a tick mark for each HH opportunity observed in the “No. of opportunities” row; record the total number of ticks in the total column.

4. Make a tick mark for each HH opportunity performed correctly (“No. performed correctly” row); record the total number of ticks in the total column.

This section is placed on the back of the HH monitoring form.

These random audit questions were originally developed by the Center for Patient Safety in Neonatal Intensive Care in conjunction with the Vermont Oxford Network’s iNICQ collaborative.

Questions focusing on safety

1. If anyone at the bedside participated in a surgical or invasive procedure at this patient’s bedside during the last 7 days (ie, chest tube, lumbar puncture [LP], PICC/umbilical line placement or adjustment), was there a final verification process, such as a time-out, to confirm the correct:
   - Patient
   - Procedure and
   - Site (when applicable; ie, right or left)
   using active (not passive) communication techniques?

- Patient misidentification is a common source of error in the NICU.\textsuperscript{53,54}

2. If a verbal medication order was given/received during the last 24 hours (by someone currently at the bedside), did verification read-back occur in each instance?\textsuperscript{54}

3. Is there a procedure note written for all procedures done within the last 48 hours?
   - Including:
     - Intubation
     - Umbilical line
     - Peripheral arterial line
     - PICC or other central line
     - LP
     - Chest tube insertion
     - Paracentesis/thoracentesis

4. Were indicated drug-monitoring levels performed during the last 48 hours?
   - Aminoglycoside antibiotics
   - Vancomycin
   - Phenobarbitol/phenytoin
   - Prothrombin time and partial thromboplastin time tests: If on anticoagulation dosing with heparin
Precautions followed: Applies only to patients on isolation precautions (eg, contact, droplet). Give credit only if all components of the specific type of precautions are followed.

HH Before initial patient contact: Give credit only if the caregiver practices HH immediately before patient contact, or has practiced HH on leaving an immediately adjacent bed space (on their way to the current patient’s bed space). If the caregiver has practiced HH at some other intensive care unit location, HH must be repeated, if only to breed good habits and reassure family members.

gloves donned: Per CDC standard precautions policy, gloves are required before contact with: mucous membranes, nonintact skin or wounds, body fluids, excretions/secretions.

HH after glove removal: always required (hands are easily contaminated when removing gloves).

HH before inserting/manipulating invasive devices: HH is required (even if gloves are donned). Invasive devices include any intravascular catheter (including the catheter sites, dressings, and administration set), bladder catheters, chest tubes, endotracheal tubes (including suctioning, manipulating of ventilator tubing connections), any other devices inserted into sterile body sites.

HH when leaving the bedside after contact: Contact refers to: for patients not on precaution, contact with the patient or their bed (incubator/warmer/crib); for patients on precautions, the above plus the patient’s general environment (eg, supporting equipment, dedicated computer keypad).

<table>
<thead>
<tr>
<th>Staff Member</th>
<th>Precautions followed</th>
<th>HH prior to initial patient contact</th>
<th>HH after glove removal</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
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<td>Respiratory team</td>
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<td>Critical Admit</td>
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<td>Non-nursing</td>
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<tr>
<td>Physician</td>
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<tr>
<td>Sitter</td>
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<tr>
<td>Other</td>
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</tbody>
</table>

a Precautions followed: Applies only to patients on isolation precautions (eg, contact, droplet). Give credit only if all components of the specific type of precautions are followed.
b HH Before initial patient contact: Give credit only if the caregiver practices HH immediately before patient contact, or has practiced HH on leaving an immediately adjacent bed space (on their way to the current patient’s bed space). If the caregiver has practiced HH at some other intensive care unit location, HH must be repeated, if only to breed good habits and reassure family members.
c Gloves donned: Per CDC standard precautions policy, gloves are required before contact with: mucous membranes, nonintact skin or wounds, body fluids, excretions/secretions.
d HH after glove removal: always required (hands are easily contaminated when removing gloves).
e HH before inserting/manipulating invasive devices: HH is required (even if gloves are donned). Invasive devices include any intravascular catheter (including the catheter sites, dressings, and administration set), bladder catheters, chest tubes, endotracheal tubes (including suctioning, manipulating of ventilator tubing connections), any other devices inserted into sterile body sites.
f HH when leaving the bedside after contact: Contact refers to: for patients not on precaution, contact with the patient or their bed (incubator/warmer/crib); for patients on precautions, the above plus the patient’s general environment (eg, supporting equipment, dedicated computer keypad).
• Anti-factor Xa: If anticoagulated with enoxaprin (low molecular weight heparin)
5. Have the positions of the current central venous lines (CVLs) and surgical drains/tubes been verified by radiograph and repositioned if necessary?
  • Inappropriate location of a central catheter tip is associated with significant complications
6. Was a diagnostic test (ie, laboratory test, radiograph, other) ordered and not obtained during the last 48 hours (not including test scheduled for the future)?
7. Was a diagnostic test (ie, laboratory test, radiograph, other) repeated because of a technical or procedural problem during the last 48 hours?
  • For example, blood specimen clotted or patient not positioned properly for radiograph
8. Was there a delay in informing parents of a significant clinical event/change in clinical status during the prior 48 hours?
9. In the last 2 days, did suboptimal communication within or to the team adversely affect clinical management?
  • For example:
    • Important information not communicated during rounds or during checkout
    • Delay in reporting of a consult
    • Delay in reporting of a diagnostic test (laboratory test/radiology/echo)
10. Did an endotracheal tube, surgical drain/tube, or CVL migrate out of its appropriate location during the last 48 hours?
11. Are there medications or syringes at the patient’s bedside in violation of or not labeled according to unit policy?
  • Medication errors are exceptionally common in the NICU
12. Was the attending physician called for all appropriate events?
13. Is the patient ID band appropriately located (according to unit policy), and was it verified at the beginning of the shift?
14. If this patient received breast milk for his/her most recent feed, were the breast milk and patient identified according to unit policy and was this documented appropriately?
  • Patient misidentification and administration of breast milk to the wrong infant is common
15. Are the nurse’s safety checks appropriately documented for this shift?
16. Are the respiratory therapist’s safety checks appropriately documented for this shift?
17. Is the inspection sticker from biomedical engineering current for all pumps, isolettes, and ventilators at the patient’s bedside?
18. Is this patient’s bedside area devoid of any charts, order forms, or medications belonging to another patient?
19. Is the bedside suction set up according to unit guidelines or provider order (for nonintubated and intubated patients and repogle, chest tube, surgical drain)?
20. Were all orders written during the previous shift reviewed by the incoming and outgoing nurse at shift change?
21. For nil-by-mouth patients only, do the intravenous fluid/medication drips as currently administered equal the total daily fluids order/goal (within 10 mL/kg/d)?
22. Is the patient’s weight recorded on the most recent medication order sheet?
23. During the last 48 hours, were orders written using abbreviations prohibited by your hospital?
24. What are the cardiac apnea monitor alarm limits? Are they set according to unit guidelines or provider order?
25. What are the pulse oximeter alarm limits? Are they set according to unit guidelines or provider order?
26. Are the Ambu bag and mask set up according to unit guidelines?

27. Does the H&P contain the:
   a. prenatal screens?
   b. estimated gestational age or estimated date of confinement (including method
      of assessment)?
   c. medications mother received during pregnancy and labor?
   d. sepsis risk factors?
   e. reason for maternal presentation?
   f. method of delivery, including reasons for:
      i. spontaneous vaginal delivery?
      ii. induced vaginal delivery (why induced)?
      iii. cesarean section (why cesarean performed)?

28. Were all appropriate neonatal personnel notified of a high-risk delivery in sufficient
   time to respond appropriately?

29. Were all appropriate/intended neonatal personnel at the high-risk delivery on
   time?

30. Is the delivery room (DR) appropriately set up for a delivery, and are all appropriate
    supplies needed for delivery available? If you keep relevant supplies in the DR
    (audit each DR) or in a box/bag you bring with your team (audit each box/bag).
    Include in your assessment items such as:
    a. Functioning laryngoscope with 00, 0, and 1 sized blades
    b. Endotracheal tubes: 2.5, 3.0, 3.5
    c. Stylet
    d. Tape
    e. Appropriate sized masks for various sized infants
    f. Appropriate suctioning equipment: bulb suction, suction tubing, meconium
       aspirator, DeLee suction, other
    g. Other

31. If appropriate, was an antenatal consult done by the neonatology team before
    delivery? If not, please document why.

32. If this patient had an antenatal consult done by the NICU team, was the informa-
    tion available to the team at the time of delivery after delivery?

33. Did a registered nurse sign off on an order that used prohibited abbreviations?

34. Did the pharmacy sign off on an order that used prohibited abbreviations?

35. Are all consents appropriately filled out and signed by the parent and appropriate
    hospital personnel?

36. Was the patient’s pain evaluated during the last 12 hours and documented in the
    medical record?

37. Was pain control used according to unit guidelines?

38. Were all medications/fluids requiring a double check by unit policy done so
    including appropriate documentation?

39. Have the eye examinations been done at the appropriate postconceptual age?

40. Are the arterial line monitor alarms on and set according to unit guidelines or
    a provider order?

41. Is all the breast milk in the refrigerator/freezer labeled and stored according to unit
    policy?

These random audit questions were originally developed by the Center for Patient
Safety in Neonatal Intensive Care in conjunction with the Vermont Oxford Network’s
iNICQ collaborative.
## Appendix 2: A framework for RCA and an action plan

<table>
<thead>
<tr>
<th>Level of Analysis</th>
<th>Questions</th>
<th>Root Cause</th>
<th>Ask “Why?”</th>
<th>Take Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What happened?</strong></td>
<td>Sentinel event</td>
<td>What are the details of the event? (Brief description)</td>
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<td></td>
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<td>When did the event occur? (Date, day of week, time)</td>
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<td>What area/service was affected?</td>
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<tr>
<td><strong>Why did it happen?</strong></td>
<td>The process or activity in which the event occurred</td>
<td>What are the steps in the process, as designed? (A flow diagram may be helpful here)</td>
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<tr>
<td></td>
<td></td>
<td>What steps were involved in (contributed to) the event?</td>
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<tr>
<td><strong>What were the most proximate factors?</strong></td>
<td>Human factors</td>
<td>What human factors were relevant to the outcome?</td>
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<tr>
<td></td>
<td></td>
<td>Equipment factors</td>
<td>How did the equipment performance affect the outcome?</td>
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<tr>
<td></td>
<td></td>
<td>Controllable environmental factors</td>
<td>What factors directly affected the outcome?</td>
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<td></td>
<td></td>
<td>Uncontrollable external factors</td>
<td>Are they truly beyond the organization’s control?</td>
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<td>Other</td>
<td>Are there any other factors that have directly influenced this outcome?</td>
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<td></td>
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<td>What other areas or services are affected?</td>
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</table>

This template is provided as an aid in organizing the steps in an RCA. Not all possibilities and questions will apply in every case, and there may be others that will emerge in the course of the analysis. However, all possibilities and questions should be fully considered in your quest for root cause and risk reduction. As an aid to avoiding loose ends, the 3 columns on the right are provided to be checked off for later reference:

- “Root cause?” should be answered “Yes” or “No” for each finding. A root cause is typically a finding related to a process or system that has a potential for redesign to reduce risk. If a particular finding that is relevant to the event is not a root cause, be sure that it is addressed later in the analysis with a “Why?” question. Each finding that is identified as a root cause should be considered for an action and addressed in the action plan.
- “Ask ‘Why?’” should be checked off whenever it is reasonable to ask why the particular finding occurred (or did not occur when it should have), to drill down further. Each item checked in this column should be addressed later in the analysis with a “Why?” question. It is expected that any significant findings that are not identified as root causes themselves have roots.
- “Take action?” should be checked for any finding that can reasonably be considered for a risk reduction strategy. Each item checked in this column should be addressed later in the action plan. It will be helpful to write the number of the associated action item on page 3 in the “Take action?” column for each of the findings that requires an action.

(continued on next page)
<table>
<thead>
<tr>
<th>Level of Analysis</th>
<th>Questions</th>
<th>Root Cause</th>
<th>Ask “Why?”</th>
<th>Take Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why did that happen? What systems and processes underlie those proximate factors? (Common cause variation here may lead to special cause variation in dependent processes)</td>
<td>Human resources issues</td>
<td>To what degree are staff properly qualified and currently competent for their responsibilities?</td>
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<td>How did actual staffing compare with ideal levels?</td>
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<td>What are the plans for dealing with contingencies that would tend to reduce effective staffing levels?</td>
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<td>To what degree is staff performance in the operant process(es) addressed?</td>
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<td>How can orientation and in-service training be improved?</td>
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<td>Information management issues</td>
<td>To what degree is all necessary information available when needed? Accurate? Complete? Unambiguous?</td>
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<td></td>
<td>Environmental management issues</td>
<td>To what degree is communication among participants adequate?</td>
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<td>Leadership issues:</td>
<td>To what degree was the physical environment appropriate for the processes being performed?</td>
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<td></td>
<td>– Corporate culture</td>
<td>What systems are in place to identify environmental risks?</td>
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<td></td>
<td>– Encouragement of communication</td>
<td>What emergency and failure mode responses have been planned and tested?</td>
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<td></td>
<td>– Clear communication of priorities</td>
<td>To what degree is the culture conducive to risk identification and reduction?</td>
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<td></td>
<td>Uncontrollable factors</td>
<td>What are the barriers to communication of potential risk factors?</td>
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<td>To what degree is the prevention of adverse outcomes communicated as a high priority? How?</td>
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<td></td>
<td>What can be done to protect against the effects of these uncontrollable factors?</td>
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<tr>
<td>Action plan</td>
<td>Risk reduction strategies</td>
<td>Measures of effectiveness</td>
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<tr>
<td>----------------------------------------------------------------------------</td>
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<tr>
<td>For each of the findings identified in the analysis as needing an action, indicate the planned action expected, implementation date and associated measure of effectiveness...</td>
<td>Action item 1:</td>
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<td>OR...</td>
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<td>If after consideration of such a finding, a decision is made not to implement an associated risk reduction strategy, indicate the rationale for not taking action at this time</td>
<td>Action item 2:</td>
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<tr>
<td>Check to be sure that the selected measure will provide data that will permit assessment of the effectiveness of the action</td>
<td>Action item 3:</td>
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<tr>
<td>Consider whether pilot testing of a planned improvement should be conducted</td>
<td>Action item 4:</td>
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<tr>
<td>Improvements to reduce risk should ultimately be implemented in all areas where applicable, not just where the event occurred. Identify where the improvements will be implemented</td>
<td>Action item 5:</td>
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<tr>
<td>Cite any books or journal articles that were considered in developing this analysis and action plan:</td>
<td>Action item 6:</td>
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