



Advancing Transfusion and
Cellular Therapies Worldwide

AABB Interorganizational Task Force on Quarantine Release Errors

White Paper

BACKGROUND

On June 10-11, 2010, the US Department of Health And Human Services (HHS) Advisory Committee for Blood Safety and Availability (ACBSA) met to reexamine the Food and Drug Administration (FDA) policy that states that a man who has had sex with another man (MSM) at any time since 1977 should be deferred indefinitely from donating blood. Information was presented on the higher prevalence rate of many transfusion-transmitted diseases among men who have sex with other men.¹ A concern was noted that if the MSM deferral is relaxed, the potential risk to the blood supply from inadvertent release of a blood product from a donor who was found to be positive for a transfusion-transmitted infectious disease (TTID) could increase. This type of release of an unsuitable product was referred to at the meeting as a “quarantine release error” (QRE).

One of the recommendations from the ACBSA was that HHS should take action to investigate and reduce the risk of QREs from blood collection establishments.

As a result of the ACBSA discussions, the FDA held a workshop titled *Quarantine Release Errors in Blood Establishments* on September 13, 2011. The purpose of this public workshop was to provide a forum for discussion of QREs and provide the FDA and industry with information necessary to reduce the rates of QREs. The workshop focused on the extent and characteristics of QREs in blood establishments and the specifications of blood establishment computer software (BECS) systems as they relate to inventory control. This public workshop included presentations and panel discussions by industry and government experts knowledgeable in the field.

The workshop announcement referred to QREs as “the inadvertent release of blood or blood components either before completion of testing and determination that all other criteria affecting the safety, purity, or potency of the product have been met, or despite findings that would render the blood or blood components unsuitable for release.”

During the workshop, it became clear that no standard definition of QREs existed and there was a lack of understanding that not all QRE events pose an equal risk. Until a standard definition was established, it would be difficult to discuss what actions are necessary to weigh the risks and

reduce the occurrence of QREs. Therefore, one outcome of the FDA workshop was a decision by AABB to create an interorganizational task force to 1) develop a common vocabulary to use for discussing QREs, 2) develop processes to stratify the risk of QREs, and 3) explore environmental issues and human factors contributing to QREs. The Interorganizational Task Force on Quarantine Release Errors was created with representation from AABB, America's Blood Centers, the Advanced Medical Technology Association, the Agency for Healthcare Research and Quality, the American Red Cross, the Armed Services Blood Program, the College of American Pathologists, the Food and Drug Administration, Health and Human Services and the Plasma Protein Therapeutics Association. This paper is the work of the task force.

The terms hazard assessment and risk assessment, while technically being distinct, are used synonymously both in this paper and the appendices. A hazard is simply something in the environment with the potential to cause harm (eg, oil spill on the floor). However, the risk of someone falling could be either high or low depending upon the amount of traffic on the floor. Risk assessment combines the hazard with the probability or likelihood of encountering it to yield some indicator of risk.

I. ESTABLISH A COMMON VOCABULARY FOR QREs

Definition

The task force consensus definition of a **quarantine release error** - a deviation recognized by a staff member who determined that the event had the potential to affect the safety, purity, or potency of the product and the product was subsequently distributed.

This includes:

1. Events in which the product was identified as potentially unsuitable, not managed appropriately (ie, not quarantined), and distributed before resolution.
2. Events in which the product was identified as unsuitable, quarantined, inappropriately released from quarantine, and subsequently distributed.

Information received after a product is released, resulting in a determination that the product should have been quarantined, is not considered a QRE.

Examples of QREs

The following reports of QREs are provided as examples:

1. Upon arrival in the lab from the collection area, an Apheresis Platelet unit was found to be cold to the touch. The thermometer reading was 19.5 C. All platelet products drawn on that day were quarantined until further investigation could be performed. Two units were found to be acceptable and were made available for release. The unit with a temperature excursion (temperature outside allowable limits) was inadvertently released along with one of the other units. The error was discovered the same day as the release and the unit was recalled and returned to the collection center.

2. During record review, the donation record was discovered to have an unanswered question. The screener failed to complete the donor history before donation, the phlebotomist failed to identify the omission, and the unit was subsequently distributed. Although documentation was present that the discrepancy was identified at lot release and donor follow-up was attempted, the donation was not quarantined.
3. A unit that had a red cell antibody and was reactive for antibody to hepatitis C virus (anti-HCV) was released from quarantine when the antibody identification was completed on 6/17. The unit was shipped to a consignee on 6/23. During a repeat reactive audit on 7/15, the HCV-reactive nature of the unit was noted. Donor center staff failed to follow the standard operating procedure (SOP) by not discarding the HCV-reactive unit after review of the laboratory testing results. They also failed to determine unit suitability from the test results before releasing the unit from quarantine status upon completion of the red cell antibody identification. Also, staff overlooked the reactive anti-HCV result and treated the unit as red cell antibody-positive only, placing it in the quarantine bin for pending antibody identification rather than the bin for viral test-positive units.
4. Forty-five units of frozen plasma were placed on hold on 6/27 for a freezer temperature excursion that occurred on 6/26. The electronic “holds” were removed on 7/7 even though the review board decision to release these units was not completed until 8/4. Nine of the plasma units were shipped to consignees before the final decision for disposition was made.

Categorization of QREs

A QRE must be reported as a deviation to the FDA’s Center for Biologics Evaluation and Research (CBER) because it is related to a distributed product. In an effort to better categorize QREs submitted in Biological Product Deviation (BPD) reports, the FDA posted to its website updated BPD Codes for Fiscal Year 2013 (<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129721.htm#blcd>). Codes related to QREs are listed in the accompanying table. A new code (QC-94-18) was added to capture events associated with failure to quarantine due to a viral testing issue. CBER also included additional directions for using particular BPD codes related to events associated with failure to quarantine.

Facilities should use the QC-94-** BPD codes to report an event that was recognized by a staff member who determined, before distribution, that the event has the potential to affect the safety, purity, or potency of the distributed product and the product was either not quarantined or inappropriately released from quarantine and distributed. The description of the event should include details of the initial event that warranted quarantine of the product. The following are examples of details that should be included: collection time extended by 10 minutes, (QC-94-12); product manufactured 40 minutes past the acceptable time limit (QC-94-13); unit number discrepancy (QC-94-14); donor history question related to malaria risk travel was incomplete (QC-94-15); and storage temperature exceeded acceptable limits by 5 C (QC-94-17). CBER captures this specific information in the database to facilitate trending and analysis at a level of granularity to enhance the categorization of QREs.

Updated BPD Codes for Fiscal Year 2013

BPD Code	Definition
QC-94-**	Distribution of product that did not meet specifications
QC-94-12	Product identified as unsuitable due to a collection deviation or unexpected event <i>{event discovered prior to distribution, but failed to quarantine product; includes collection time extended, discrepant, or not documented; potential air contamination, unit or associated unit was clotted or hemolyzed}</i>
QC-94-13	Product identified as unsuitable due to a component preparation deviation or unexpected event <i>{event discovered prior to distribution, but failed to quarantine product; includes leukoreduction or irradiation not performed within specifications; transport (from collection center) conditions unacceptable, not documented, or discrepant}</i>
QC-94-14	Product identified as unsuitable due to a labeling deviation or unexpected event <i>{event discovered prior to distribution, but failed to quarantine product}</i>
QC-94-15	Product identified as unsuitable due to a donor screening deviation or unexpected event <i>{event discovered prior to distribution, but failed to quarantine product; includes donor history question not answered or incomplete; abbreviated donor history questionnaire used instead of full-length}</i>
QC-94-16	Product identified as unsuitable due to a donor deferral deviation or unexpected event <i>{event discovered prior to distribution, but failed to quarantine product}</i>
QC-94-17	Product identified as unsuitable due to a shipping or storage deviation or unexpected event <i>{event discovered prior to distribution, but failed to quarantine product; includes temperature excursions, shipping time out of specification}</i>
QC-94-18	Product identified as unsuitable due to a viral testing deviation or unexpected event <i>{event discovered prior to distribution, but failed to quarantine product, includes products released with positive or incomplete viral testing}</i>

II. DEVELOPING PROCESSES TO STRATIFY RISKS OF QREs

Identification and stratification of risks is a valuable exercise as both a reaction to an event and a proactive analysis of processes to reduce or minimize the likelihood of a serious deviation occurring. Evaluation and investigation of QREs involves a multi-step process that can occur over time. Risk assessment is utilized at various points of this process.

When a deviation has occurred, the first step is to gain control of the product and to assess the impact of the deviation. Risk assessment can guide the decision to retrieve and quarantine products. It can also be employed when evaluating the level of investigation needed for an event and determining the need for a full root-cause analysis (RCA).

Risk Assessment

Each facility should define its own process for assessing the impact of the deviation on the product and the recipient. Questions facilities should consider in their risk assessment process include the following:

- What is the level of risk to the product?
- What is the level of risk to the recipient?
- Do we need to perform a root-cause analysis or just trend the deviation?

Because each facility has unique processes and procedures with differing risk levels for a deviation occurring or reoccurring, there is no one risk level that can be assigned to a specific deviation or QRE. However, what is key is that not all QREs pose the same risk. Some QREs have great potential to directly affect the recipient. Other QREs do not generally affect the product or the recipient. For example, QREs related to infectious disease testing errors have the potential to significantly affect the recipient, while QREs related to a minor temperature excursion (for example, 1 C) do not generally affect patient safety, but are still a deviation.

When a product has been transfused, a health hazard evaluation (HHE) is beneficial in determining the risk to the recipient. HHEs assess the adverse events that may occur as a consequence of a problem with a product. When making the HHE, it is important to consider the following:

- Whether any disease or injuries have already occurred from the use of the product.
- Varying segments of the population (eg, children, surgical patients, etc) who may be exposed to the product in question.
- The degree of seriousness of the health hazard to which the populations at risk would be exposed.
- The likelihood of occurrence of the hazard.
- Immediate or long-range consequences of occurrence of the hazard.

Before an assessment can be made, it is important to have good background information on the nature of the problem and investigations conducted. Appendix A contains an example of an assessment tool that can be used when performing HHEs.

There are a number of methods of assessing risk of an event, but inherent in risk assessment is determining the severity and frequency of an event occurring. It is this assessment that will drive the level of the investigation. Appendix B provides a sample risk assessment tool that could be used as a model for developing or modifying an existing risk assessment process. It should be noted that not all deviations are QREs; however, all QREs are deviations.

Root-Cause Analysis

Root-cause analysis/investigation is a retrospective approach to get to the true root cause(s) of process problems. A root cause is the fundamental breakdown or failure of a process that, when resolved and preventive actions are put into place, prevents the problem from reoccurring. To learn more about RCA, refer to Chapter 7 of the Veterans Administration National Center for Patient Safety Improvement Handbook which can be found at: http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2389

Not all events are equal nor do they deserve the time and effort required to perform a full RCA. A facility's risk assessment program should include a process for trending deviations and to determine if, and which level of, a RCA is necessary in order to effectively develop corrective actions. The RCA may also be required by regulation, accrediting agency standards, when a sentinel event occurs or as defined in a SOP. Assessment of the risks associated with specific deviations allows the facility to analyze some individual events using RCA while relegating other events to a process for trending and periodic review. Appendix C provides a sample RCA approach to analyzing a failure and determining all of the underlying conditions and factors that could have caused the failure. Additional RCA tools can be found on the American Society of Quality website at <http://asq.org/index.aspx>

III. HUMAN FACTORS AND THE COMPLEX WORK ENVIRONMENT

Many factors can contribute to the occurrence of a QRE. As the use of computer systems has become more widespread in the workplace, the interaction of humans with the tools and technology they use has become increasingly recognized as important. As noted in one of the examples cited earlier, some QREs are caused by a failure of the system or staff to recognize that a product was in quarantine for more than one reason. It is important to establish processes to ensure that each quarantine reason is documented and resolved individually before product release.

Human factors is the discipline that takes into account human strengths and limitations in the design of interactive systems of people, tools, technology, and work systems to ensure safety, effectiveness, and ease of use. Other factors that can influence system performance and thus errors include the design of the physical environment, the organizational environment (eg, group norms, safety culture), the nature of the tasks performed (eg, repetitive vs varied), health worker characteristics, and even changes in the external environment (eg, government initiatives, health-care policy, and political climate). Most adverse events are not the result of any single factor, but occur from the unsuspected alignment of several factors that have been neglected. Appendix D lists additional factors under a similar set of broader categories.²

In recognizing the multiple interacting factors that make for a complex work environment and that lead to error, human factors practices include, among others: 1) avoiding reliance on memory, vigilance, and good intentions, 2) simplifying and standardizing routine practices, 3) examining new technology for new sources of error, unintended consequences, and adverse

impacts on the workflow, 4) precluding error through safe design, and 5) adopting a systems perspective that focuses on the interactions among a system's components. The challenge is to design tools, technology, and work environments as an integrated system, thereby mitigating potential harmful consequences.

IV. PREVENTIVE ACTIONS

Preventive actions to reduce the likelihood of a deviation can be taken as a new process is designed, when an existing process is modified, or after a deviation has occurred. The selection of a preventive action or process revision is based on the reduction of the perceived risk of the new process. Risk assessment can be employed when systems or processes are modified to determine if the potential for failure has been reduced or if new failure modes have been introduced.

The tool frequently cited as useful in identifying risks when designing or modifying a process is the failure modes and effects analysis (FMEA). The FMEA calculates a risk priority number based on severity, frequency, and the ability to detect problems. Appendices E and F provide two examples of FMEAs. Additional information about a health-care FMEA can be found at <http://www.patientsafety.gov/SafetyTopics.html#HFMEA>

The key to error prevention is good process design. For example, the design of processes for releasing products from quarantine should anticipate and protect against the "more than one nonconformance" scenario. Process design considerations for preventing quarantine release errors can be found in Appendix G.

SUMMARY

The single most important fact related to QREs is that not all are equal in risk. The best use of resources is to focus efforts on QREs with the potential to cause the greatest harm to recipients. The key to better tracking, trending, understanding, and analysis of QREs is to improve the description of events when they are reported. This will enable the correct categorization of a deviation and enhance the risk assessment processes so that not all individual deviation events result in market withdrawals or RCAs.

Numerous risk assessment tools can assist in determining if risk prevention actions should be taken. Likewise, error prevention may encompass a number of strategies including computerization and workplace and process redesign. However, attention to the human factors associated with errors is the most likely intervention to further reduce deviations.

References

1. Epstein J. Remarks at the meeting of the Advisory Committee on Blood Safety and Availability, June 10-11, 2010. [Available at <http://www.fda.gov/http://www.hhs.gov/ash/bloodsafety/advisorycommittee/pastmeetings/acbsa2010-june-10-11mtg.pdf> (accessed August 22, 2013).]
2. Henriksen K, Dayton E, Keyes MA, et al. Chapter 5. Understanding adverse events: A human factors framework. In: Hughes RG, ed. Vol. 1. Patient safety and quality: An evidence-based handbook for nurses. AHRQ Publication No. 08-0043. Rockville, MD: Agency for Healthcare Research and Quality, 2008:67-85.

Additional Reading

Books:

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Tillman B, Tillman T, Rose RR, Woodson WP. Human factors design handbook, 3rd ed. New York: McGraw-Hill, 2013.

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Gieras I, Sherman P, Minsent D. Patient safety trilogy: Perspectives from clinical engineering. *Biomed Instrum Technol* 2013;47:137-42.

Karwowski W. A review of human factors challenges of complex adaptive systems: Discovering and understanding chaos in human performance. *Hum Factors* 2012;54:983-95.

Wiseman S, Cox AL, Brumby DP. Designing devices with the task in mind: Which numbers are really used in hospitals? *Hum Factors* 2013;55:61-74.

Appendix A
Sample HHE

Health Hazard Evaluation (HHE) INSTRUCTIONS

What this form is about

This form provides staff with a standard method for performing and documenting a safety assessment for potentially nonconforming blood or blood components.

Who should know how to use this form

This form applies to all facilities that initiate, conduct, resolve, and document problem investigations. The Medical Director will complete the evaluation on this form, as applicable.

Introduction

FDA expects that each manufacturer will conduct its own health hazard evaluation to assess the potential risk of the unsuitable product. Guidance on conducting such an evaluation is located in 21 CFR 7.41. The organization must evaluate nonconforming blood or blood components for disposition. Should the disposition result in a recall, FDA has ultimate responsibility for determining the recall classification. This form provides a method to document the health hazard evaluation.

Instructions

Use the following instructions to complete the form. Unused fields may be left blank.

When instructions are given to record the initials/employee ID in the table, you may record either the initials only, the ID number only, or both initials and ID.

Section 1 – Nonconformance Information (To be completed by QA staff)

In the field....	Record.....
Material Review Board number	MRB number assigned, if facility logging system in use.
Issue Number	Issue number as assigned per Automated Problem Management System. Record the issue number on page 2 in field provided.
Facility	Name of the facility where nonconformance occurred.
Brief description of nonconformance	Brief description of nonconformance, for example what happened, when, etc, indicating if products have been distributed by selecting the appropriate box.
Has the blood center received reports of adverse recipient reactions from hospitals involving the nonconforming components?	Select yes or no and briefly summarize the nature of adverse reaction, if applicable. Check NA, for example, if products are not distributed.
Occurrence: Were all products affected by the nonconformance?	Select yes, no, or unknown. If unknown is checked, explain, for example, unknown explanation for QC failure.
Completed by (Initials/ID)	Name, initials, or employee ID of QA person
Date	Date on which the form is initiated

Appendix A
 Sample HHE (continued)

Section 2 – Health Assessment (To be completed by the medical director)

In the field....		Record.....
A	What is the probability of an adverse event occurring as a result of the nonconformance?	Select the appropriate checkbox
B	What would be the expected severity of harm to the recipient, if the nonconformance caused an adverse reaction, assuming worst case?	Answer question based on medical knowledge and understanding of the nonconformance
C	Is any patient population at greater risk from the nonconformance?	Answer question based on medical knowledge and understanding of the nonconformance
D	Can the nonconformance be easily identified by the consignee before use?	Select the appropriate checkbox

Section 3 – Safety Impact (To be completed by the medical director)

Select the appropriate probability of an adverse event and the type of potential harm the adverse event could cause. The medical director determines the safety impact based on his or her judgment regarding the potential harm and the probability of the nonconformance. (Refer to sections 2A and 2B as directed.)

Section 4 – Recommendation (To be completed by the medical director)

In the field....	Record.....
Specific wording regarding risk to be communicated to the consignee	If specific guidance is required, briefly explain specific guidance on the decision and medical judgment
Medical director	Initials/ID
Date	Date assessment completed

Appendix A
Sample HHE (continued)

Health Hazard Evaluation (HHE) FORM

1. NONCONFORMANCE INFORMATION		To be completed by QA staff:	
MRB #:	Issue Number	Facility:	
Brief description of nonconformance:			
Have products been distributed? <input type="checkbox"/> Yes <input type="checkbox"/> No			
<i>Has the blood center received reports of adverse recipient reactions from hospitals involving the non-conforming components?</i>			
<input type="checkbox"/> Yes ► <i>If yes, briefly summarize</i> <input type="checkbox"/> No <i>nature of adverse reaction,</i> <input type="checkbox"/> NA <i>and include copy of report:</i>			
Occurrence: <i>Were all products affected by the nonconformance?</i>			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown, explain _____			
Completed by (Initials/ID): ►			Date: ►

The following sections (2-4) are to be completed by the medical director

2. HEALTH ASSESSMENT	
A	<i>What is the probability of an adverse event occurring as a result of the nonconformance?</i>
<input type="checkbox"/> Certain <input type="checkbox"/> Possible <input type="checkbox"/> Not likely or none <input type="checkbox"/> Unknown, explain	
B	<i>What would be the expected severity of harm to the recipient, if the nonconformance caused an adverse reaction, assuming worst case?</i>
<input type="checkbox"/> Life-threatening; death has or could occur. Critical; significant injury or permanent impairment <input type="checkbox"/> Moderate; temporary, reversible complications (eg, medical or surgical intervention needed to prevent or reverse significant injury) <input type="checkbox"/> Minor; limited, transient complications <input type="checkbox"/> Negligible; no health consequences	
Issue Number _____	
C	<i>Is any patient population at greater risk from the nonconformance?</i>
<input type="checkbox"/> Yes ► What segment of the population is most at risk? <input type="checkbox"/> No <input type="checkbox"/> Infants <input type="checkbox"/> Children <input type="checkbox"/> Pregnant women <input type="checkbox"/> Elderly <input type="checkbox"/> Immunocompromised <input type="checkbox"/> Other	

Appendix A
 Sample HHE (continued)

D <i>Can the nonconformance be easily identified by the consignee before use?</i>				
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> Unknown, explain				
3. SAFETY IMPACT				
PROBABILITY (see 2A)	POTENTIAL HARM (see 2B)			
	Life-threatening Critical	Temporary/ Reversible	Minor	Negligible
Certain				
Possible				
Not likely / None				
Unknown				
4. RECOMMENDATION				
<i>Specific wording regarding risk to be communicated to the consignee</i>				
MD (Initials/ID): ▶		Date: ▶		

Appendix B
Risk Assessment

Example of a Risk Assessment Process Useful to Determine the Level of Investigation to be Assigned to Operational Deviations

A. Calculate the Safety Rating

The safety rating describes the most severe medical consequence of a particular problem. The higher the rating, the more harmful the problem may be. The most likely consequence is determined by multiple factors, including the inherent ability of the problem to cause harm and the availability of treatment.

Scoring:

- 4-Reasonable probability of death
- 3-Reasonable probability of permanent damage
- 2-Temporary or medically reversible adverse health consequences or where the probability of serious health problems is remote
- 1-Not likely to cause adverse health consequences

B. Calculate the Detectability Rating

The detectability rating defines the probability that the problem would be detected during the process, and would be corrected or intercepted before patient or donor harm is done.

Scoring:

- 3-Difficult to detect
- 2-Easy to detect, but few existing points of detection in process
- 1-Easy to detect by multiple points of detection in the process or computer system

C. Calculate the Risk Rating Score

Risk Rating Score = Safety Rating × Detectability Rating

D. Determine the Risk Level Based on Rating Score

Risk Rating Score	Risk Level
9-12	Major
5-8	Moderate
1-4	Minor

Appendix C Fault Tree

Fault Tree Analysis

Fault tree analysis (FTA) is a root-cause analysis tool that uses a top-down approach to analyzing a failure or potential undesirable event and determining all the conditions and factors that caused the event to happen. It was developed in 1962 for the US Air Force by Bell Telephone Laboratories and was later adopted and used extensively by the Boeing Company. FTA is a diagrammatic representation of the event along with the contributing factors that led to the event. The contributing factors are connected through logic gates. A fault tree may consist of “OR” or “AND” logic gates. An “OR” logic gate is used if the contributing factor can cause the event by itself; an “AND” logic gate is used if all the factors are necessary to cause the event.

FTA has six main steps:

- Definition of the system, undesirable event (TOP) and boundary conditions, ie, which parts of the system are included in the analysis.
- Construction of the fault tree
 - Define the TOP clearly. It should answer “what,” “where,” and “when.”
 - What are the events and conditions causing the TOP event?
 - Connect using “AND” or “OR” gate.
- Identification of the minimal cut sets
 - A cut set in a fault tree is a set of basic events whose (simultaneous) occurrence ensures that the TOP event happens.
 - A cut set is said to be minimal if the set cannot be reduced without losing its status as a cut set.
 - The TOP event will occur if all the basic events in a minimal cut set occur at the same time.
- Qualitative analysis of the fault tree
- Quantitative analysis of the fault tree
- Reporting of results

FTA is best applied to large and complex processes. It is suitable for analyzing multiple failures. It helps improve the understanding of the process and the possible causes of a failure or a potential failure. FTA is used to identify potential actions to reduce the risk of failure. FTA may not be suitable for analyzing systems with dynamic properties and assessing normal operations. FTA is binary (fail-success); therefore, it may not be able to address some problems. The success of FTA depends largely on the skill of the analyst(s).

Reference

Rausand M, HØjland A. System reliability theory, 2nd edition. Hoboken, NJ: John Wiley & Sons, 2004.

Appendix D
Human Factors

Factors that Influence Human Behavior

Social climate or cultural issues

- Group norms and practices
- Communication patterns and barriers
- Climate for self-reporting of errors
- Multidisciplinary/multicultural workforce
- Clarity of role and responsibilities
- Interdepartmental cooperation
- The organization's ability to recover from disruptive incidents

Nature of the work procedures and practices

- Workload
- Job stressors
- Cognitive complexity
- Physical requirements
- Changing requirements
- Competing tasks
- Equipment malfunction
- Individual vs teamwork
- Information transfer

Physical environment

- Workplace layout
- Workplace hazards
- Ergonomics
- Safety features
- Signage and barriers
- Lighting
- Noise
- Temperature and humidity
- Distractions
- Ventilation, contaminants, and pollutants
- Vibration
- Security features

Individual characteristics

- Knowledge, skills, and training
- Physical and cognitive capabilities
- Alertness/fatigue
- Attitude
- Personality factors

Health-Care Failure Modes and Effects Analysis (HFMEA) – Sample 1

The engineering community has used failure modes and effects analysis for a number of years as an interdisciplinary team technique to proactively identify the risks in systems that can potentially harm people, damage expensive equipment, or threaten the environment. Given the recent national focus on patient safety, very similar techniques increasingly have been applied to health care. The five-step HFMEA technique described here has been developed and used extensively by the Department of Veterans Affairs' National Center for Patient Safety.¹

Step 1. Define the high-risk topic or high-vulnerability area that merits the time and resources of the HFMEA team.

Step 2. Assemble a multidisciplinary team that includes subject matter experts knowledgeable about key processes, a risk assessment advisor or risk manager who can help guide the risk assessment methodology, and a team leader skilled in managing the group and keeping it on track.

Step 3. Develop and verify a process flow diagram. Start with key or major processes of an overall process and then identify the sub-processes under each key process. It may be necessary to drill down to sub-process steps under the sub-processes. Given process complexity, it is easy to become overwhelmed by the detail generated. At first, it may be necessary to simply focus on a highly vulnerable sub-process worth the team's attention, because it may yield a number of potential failure modes with contributing causes that merit remediation.

Step 4. Conduct the hazard analysis which involves listing all the potential failure modes along with contributing factors for each of the sub-processes. Failure modes are operationally defined as the different ways a particular sub-process or sub-process step can fail to accomplish its intended purpose. Next, the severity and likelihood of a potential failure mode is determined. A severity score assesses the impact of the failure mode on patient care [ie, catastrophic (4), major (3), moderate (2), and minor (1)], but instead of general descriptors, it is better to use clear operational definitions tailored to the particular application. The likelihood scores might range from frequent (4, several times a year), occasional (3, a few times every year), uncommon (2, once every two to five years), and remote (1, once in 10 years or more). This scheme allows creation of a 4 × 4 matrix with risk scores ranging from 16 to 1, enabling cut-off boundaries for taking further action to be established. Further, a decision tree is used to determine whether the higher-scoring failure modes warrant further action based on criticality (ie, is the step in the process so critical that its failure will result in system failure or a serious adverse event?), existence of effective control measures (ie, does an effective control measure exist for the identified hazard that substantially reduces its likelihood?), and detectability (ie, is the hazard so visible and obvious that it will be discovered before it interferes with completion of a process?).

Step 5. Take action and monitor outcome measures. Describe actions to be taken in eliminating, controlling, or accepting failure mode causes. Identify who owns the process for ensuring compliance of each action. Obtain full leadership commitment. Identify outcome measures to be used as part of the evaluation plan to assess the success of the actions taken in the redesigned process. Ensure the system functions effectively and new vulnerabilities have not been unintentionally introduced.

Helpful Hints

- 1) Despite good intentions, no process, activity, or system can be made completely risk-free. Some level of risk is always present. Risk is a property of dynamic, open systems and it can wax and wane on a daily basis. Proactive risk assessment techniques such as HFMEA enable many, but not all, of the risks to be identified so that a determination can be made as to the level of risk that is acceptable to the organization. Given limited resources, most organizations use risk assessment techniques as a way of managing risk in a prioritized fashion.
- 2) Risk assessment techniques should not be perceived as silver bullets or panaceas to an organization's safety and quality assurance problems. If treated as a stand-alone tool, separate from an organization's ongoing quality improvement efforts, it will likely fail. To be used effectively, it is but one tool that needs to be integrated with other system-based and policy-driven efforts to create a culture of safety and high quality within and across the various levels of the organization.
- 3) Most organizations that become interested in risk assessment techniques start with good intentions, but lose their initial enthusiasm when they realize the amount of effort it takes to become sufficiently proficient so that the benefits outweigh the costs. As with any tool, it takes practice, practice, and more practice to become proficient in its use.
- 4) A frequent criticism of many off-the-shelf risk assessment techniques that are adopted by organizations is the level of effort in terms of time and human resources to conduct the assessment. "Do the benefits outweigh the costs?" is a legitimate question. The benefits are difficult to measure because many of the risks that are eventually removed or mitigated are low probability events (but have high severity scores) to begin with. As a consequence, many organizations find themselves tweaking or simplifying the off-the-shelf package so it is better tailored to their needs.
- 5) Too many organizations get bogged down in the mechanics of the risk assessment procedure – thinking that strict adherence yields the golden nuggets – and are glad that they may be expected to do it just once a year. Doing it just once a year is like taking a region's temperature once a year at random and thinking that one has an accurate reflection of the region's climate. To be useful, risk assessment techniques need to be easier to use, less time-consuming to conduct, and more frequently executed.
- 6) It is important to understand that the assessment of risk is just the start of an overall safety and quality improvement process. Have the contributing factors to the prioritized risk been fully identified? Have alternative strategies and solutions to the risk been generated? Has the impact (both the positive and negative consequences) of these strategies and solutions on other components of the overall system been considered? Is there an evaluation plan in place to assess the effectiveness of the changes? Does the organization fully support the extended effort? If not, one can question the wisdom of performing a risk assessment in the first place.

Appendix E
FMEA (continued)

- 7) These other considerations and contextual factors have led many organizations to the realization that it's not all about the risk assessment tool or the score it generates. Most safety problems are multifactorial in nature, taking more than a singular tool to address. It would be short-sighted indeed to consider the risk-assessment tool as a hammer and QREs simply as nails that require pounding. The contributing factors to QREs for which risk assessment techniques are being considered are more than nails. Like other deeply rooted safety problems, they very likely will require the appropriate alignment of work-related and organizational cultural factors if risk assessment is to be used successfully.

Example of an HFMEA as Applied to Quarantine Release Errors

The VA National Center for Patient Safety² defined 5 steps in the FMEA process:

- Step 1-Define the Topic
- Step 2 -Assemble the Team
- Step 3 -Graphically Describe the Process
- Step 4 -Conduct the Analysis
 - A. List Failure Modes
 - B. Determine Severity and Probability
 - C. Use the Decision Tree
 - D. List all Failure Mode Causes
- Step 5 -Identify Actions and Outcome Measures

This chart would be completed in Step 4 of the VA process for a single process step such as releasing a quarantined unit. All factors that could lead to the failure should be listed.

FMEA Process Step Name: Computer Release from Quarantine													
Hazard Analysis									Identify Actions and Outcomes				
Failure Mode (define before defining causes)	Potential Causes	Scoring			Decision Tree Analysis				Action type (Eliminate, Control, Accept)	Actions or Rationale for stopping	Outcome Measures	Person Responsible	Management Concurrence
		Severity	Probability	Hazard Score	Single Point Weakness	Existing Control	Detectability	Proceed?					
Computer Not Used	System down	Moderate	Occasional	6	Y	N	N	Y	Control	Two person release during down	Reduction in Improper Release Events	Department Manager	Y
	Failure to follow SOP	High	Frequent	10	N	Y	N	Y	Control	Progressive Discipline	Reduction in Improper Release Events	Section Supervisor	Y

Appendix E
FMEA (continued)

References

1. DeRosier J, Stalhandske E, Bagian JP, Nudell, T. Using health care failure mode and effect analysis: TheVA National Center for Patient Safety's prospective risk analysis system. *The Joint Commission Journal on Quality Improvement* 2002;28:248-67.
2. Stalhandske E, DeRosier J, Wilson R, Murphy J. Healthcare FMEA in the Veterans Health Administration. *Patient Safety & Quality Healthcare*, September/October, 2009:30-3.

Failure Modes and Effects Analysis – Sample 2

Initiate and Document Risk Assessment

A. Identify failure modes

"Failure modes" refers to the ways a process or device could fail.

B. Assess the potential risk impact of each failure mode

A process or device failure could adversely affect a company or consumer in a number of ways. For example, a failure could affect the health and safety of a user or consumer, the productivity of the business, or functionality of a critical system (eg, software). The potential impact of each failure mode can be rated as high, medium, or low.

Example of impact valuation:

Impact Value	Impact Definition
High	Will cause significant business loss, major disruption in operations, and/or significant health risk to operator or consumer.
Medium	Will cause business loss, minor disruptions in operations, or disruption for which there is a sustainable alternative process.
Low	Will cause a minor impact in operations or some very small but acceptable business losses.

C. Assess likelihood of each failure mode

- High Likelihood
 - Risks with high likelihood are those that can be estimated as the risk occurring one or more times per thousand operations, transactions, or use.
- Medium Likelihood
 - Risks with medium likelihood are those that can be estimated as the risk occurring between one and nine times per ten thousand operations, transactions, or use.

Appendix F
FMEA (continued)

- Low Likelihood
 - Risks with low likelihood are those that can be estimated as the risk occurring less than once per ten thousand operations, transactions, or use. Note that this figure is provided for guidance only and it is not intended that statistical calculations will be used to determine risk likelihood.

D. Assess probability of detection

Evaluate the probability of detecting the occurrence of the failure based on a relative scale:

- High or Probable
 - The product is 100% reviewed (ie, every unit is checked automatically by a validated system, or there are at least two downstream automatic sample checks [performed on a statistically significant sample]).
 - The system performs 100% error checking, including all critical inputs and output parameters (format, range, etc).
- Medium or Likely
 - There is one automatic downstream sample check of the product (performed on a statistically significant sample), or at least one proceduralized (in accordance with a current approved standard operating procedure [SOP]) manual check.
 - The system performs limited error checking.
- Low or Not Likely
 - There are no automated downstream checks and manual checks are not required by existing procedures.
 - The system does not perform any error checking.

E. Determine risk classification

- The “Risk Classification” is derived by considering both the impact value of the failure and the likelihood of the failure. This is used as an interim step in the final determination of risk priority, with risk being classified as one of the following: High (H), Medium (M), or Low (L). The relevant risk classification can be determined by finding the cell where the risk impact and risk likelihood intersect.

Appendix F
FMEA (continued)

Risk Classification Matrix

Risk Impact	High	Medium	High	High
	Medium	Low	Medium	High
	Low	Low	Low	Medium
		Low	Medium	High
		Risk Likelihood		

F. Derive Risk Priority

- Risk priority is determined based upon the risk classification determined above and the probability of detection. The risk priority provides a final categorization that can be used to guide the following:
 - Whether or not active risk control measures need to be undertaken
 - Whether the monitoring of risks is sufficient
- Risk priority is derived from a combination of risk classification and probability of detection (and is therefore also a function of risk impact and risk likelihood). Risk priority can be determined by referencing the table below:

Risk Priority

Risk Classification	High	High	High	Medium
	Medium	High	Medium	Low
	Low	Medium	Low	Low
		Low	Medium	High
		Probability of Detection		

G. Evaluate Final Risk

- The purpose of this review is to determine whether any high- or medium-priority risks are unacceptable and to determine an appropriate course of action. Potential courses of action include either of the the following:
 - Implementation of further risk control measures, to reduce the risk to an acceptable level.
 - Agreeing that the risk is unacceptable, that no further practical risk control measures are available, and that the system/process must be discontinued.
- In determining whether final risks are unacceptable, prime consideration should be given to whether the medical or business benefits outweigh the residual risk to product quality, patient and donor safety, or business operations.

Process Design to Prevent Quarantine Release Errors

The design of processes for placing products into quarantine and subsequently releasing them should anticipate and protect against the "more than one nonconformance" scenario. This is especially important during periods of computer downtime. Establishments should be aware of times when staffing levels or temporary workflow changes will also increase the opportunity for QREs and plan for suitable reviews to mitigate the risks.

Product quarantine should be both physical and electronic

Physical quarantine

- Location should be physically separate from released inventory and incompletely processed products.
- Area must be sufficient in size to prevent overflow or mixing with other products.
- Area should be clearly labeled so that staff working in the area will understand products in the space are unsuitable (and not just waiting to be processed).
- Access to quarantine space should be controlled
 - When possible, limit access to staff who are authorized to release products from quarantine, recognizing that other staff may need access in order to place products in quarantine.
- Visual cues on units eg, special tags:
 - Tags can be helpful for steering products into quarantine, eg, hospitals identifying returned products as "problems" can help prevent them from inadvertently being placed into available inventory.
 - Tags that list each problem with the unit may also help with the "two nonconformance" challenge.

Electronic quarantine

- Staff training is key to successful use of electronic quarantine controls.
 - Understand which electronic control prevents product distribution/shipping.
 - Use the available control(s).
 - Be aware of potential workarounds required by the system, eg, if the product is in a particular location or status, will the electronic control take effect?

Appendix G Process Design (continued)

- The system must be robust enough to handle a product with two nonconformances
 - Ideally, the electronic system would generate a separate electronic control for each nonconformance so that deactivation/removal of one control would not release a unit that has another problem.
 - If this is not possible, another system/workaround must be developed to communicate each nonconformance and ensure each is addressed before product release.

Communicating “release” decisions

- SOPs should define release review criteria including the number of reviews and responsible staff at each step.
- Communication of decisions should be specific as to which components are cleared and which specific problem is resolved.
- SOPs should describe how to use the reports that are generated.
 - Does the computer system automatically generate a report that is used?
 - Will a report be manually generated?

Releasing products from quarantine

- SOPs should define the process to release products from quarantine including staff authorized to do so.
- Staff attention to detail is critical: deal with one unit at a time and minimize distractions.
- High-risk conditions include:
 - Urgency of task
 - Distractions
 - Batch release (Note: even in a situation where a batch of units was quarantined, the release process must treat each unit separately because there may be a unit that has more than one nonconformance).

Computer downtime

- Consider whether it is necessary to release products when the computer system will not be available.
 - SOPs should address placing products in quarantine during downtime.
 - SOPs should address review of all reasons for quarantine and ensure all problems are resolved before release.

- Recovery from downtime:
 - Ensure that SOPs address entry of all work that occurred during downtime.
 - Ensure that any problems encountered are addressed before additional product release.