VHA NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook provides guidance for minimizing the chance of the occurrence of untoward outcomes consequent to medical care.

2. SUMMARY OF MAJOR CHANGES: This is a new handbook that incorporates Root Cause Analysis, a widely understood methodology for dealing with patient safety-related issues allowing for clear and more rapid communication of information up and down the organization, thus speeding the process of safety improvement.

3. RELATED DIRECTIVE: VHA Directive 1051/1.

4. RESPONSIBLE OFFICE: The National Center for Patient Safety (10X) is responsible for the contents of this VHA Handbook. Questions may be referred to 734-930-5890.

5. RESCISSION: VHA Handbook 1051/1 dated January 13, 1998, is rescinded.

6. RECERTIFICATION: This document is scheduled for recertification on or before the last working date of January 2007.

S/Thomas L. Garthwaite, M.D.
Under Secretary for Health

DISTRIBUTION CO: E-mailed 1/31/2002
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 1/31/2002

CONTENTS

VHA NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK

PARAGRAPH **PAGE**

APPENDIXES

VHA NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK

1. PURPOSE

This Veterans Health Administration (VHA) Patient Safety Improvement Handbook provides a roadmap that can be used to guide the VHA in the accomplishment of its goal of minimizing the chance of the occurrence of untoward outcomes consequent to medical care.

2. BACKGROUND

a. It has been reported in the medical literature that as many as 180,000 deaths occur in the United States each year due to errors in medical care, many of which are preventable. In order to take actions that will improve this situation, it is necessary to have a clear picture as to what is actually happening so that appropriate steps can be taken to prevent such occurrences. For this prevention effort to be effective, it is necessary to establish methods of gathering and analyzing data from the field that allows the formation of the most accurate picture possible. It is believed that only by viewing the health care continuum as a 'system' can truly meaningful improvements be made. A systems approach that emphasizes prevention, not punishment, as the preferred method to accomplish this goal will be used. Armed with this type of information, the most appropriate conclusions can be drawn from which prudent solutions can be formulated, tested, and implemented. ***NOTE:*** *Ultimately, this effort can be successful only if emphasis on safety and responsibility for improving it resides at all levels of the organization. This activity requires a true team effort.*

b. Through the use of procedures, methods, clarifying examples, and appropriate feedback loops at all levels of the organization (with accompanying rationale), it is hoped that this overall goal can be achieved. Incorporation of a widely understood methodology for dealing with these safety-related issues allows for a clear and a more rapid communication of information up and down the organization, thus speeding the process of safety improvement. ***NOTE:*** *For this to occur training must take place to complement the contents of this handbook; reading it alone is not sufficient.*

3. SCOPE

This handbook:

a. Delineates what types of events are to be considered within the Patient Safety Program and how they should be dealt with, as well as defining the disposition of other Adverse Events resulting from a criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse by an impaired provider and/or staff; or events involving alleged or suspected patient abuse of any kind.

b. Specifies the method by which the need for conducting a Root Cause Analysis (RCA) will be determined and the procedure for communicating related findings throughout the organization. These procedures address the management component as well as the frontline needs. ***NOTE:*** *Directions in this handbook for reporting Adverse Events and Close Calls do*

not eliminate the need for the provider to document or report events related to a patient as applicable by other requirements.

4. DEFINITIONS

a. **Adverse Events.** Adverse Events that may be candidates for an RCA are untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other VHA facility.

(1) Adverse Events may result from acts of commission or omission (e.g., administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment).

(2) Some examples of more common Adverse Events include: patient falls, adverse drug events, procedural errors and/or complications, completed suicides, parasuicidal behaviors (attempts, gestures, and/or threats), and missing patient events. ***NOTE:*** *All Adverse Events require reporting and documentation in the Patient Safety Information System. However, the type of review required is determined through the Safety Assessment Code (SAC) Matrix scoring process, as outlined in Appendix D.*

b. **Sentinel Events.** Sentinel Events are a type of Adverse Event. Sentinel Events, as defined by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), are unexpected occurrences involving death, serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. The phrase "risk thereof" includes any process variation for which a recurrence would carry a significant chance of serious adverse outcomes.

(1) Sentinel Events signal the need for immediate investigation and response. Immediate investigations may be an RCA, or, in the case of an intentionally unsafe act, administrative action.

(2) Some examples of reviewable Sentinel Events include:

(a) Death resulting from a medication error or other treatment related error;

(b) Suicide of a patient in a setting where they receive around-the-clock care;

(c) Surgery on the wrong patient or body part regardless of the magnitude of the operation; and

(d) Hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities.

NOTE: *Events considered to be JCAHO reviewable "Sentinel Events" are included in the catastrophic severity category of the SAC Matrix; also see Appendix D.*

c. **Close Calls.** A Close Call is an event or situation that could have resulted in an Adverse Event but did not, either by chance or through timely intervention (see App. A). Such events have also been referred to as "near miss" incidents.

(1) An example of a Close Call would be a surgical or other procedure almost performed on the wrong patient due to lapses in verification of patient identification, but caught at the last minute by chance.

(2) Close Calls are opportunities for learning and afford the chance to develop preventive strategies and actions: they receive the same level of scrutiny as Adverse Events that result in actual injury; and they require reporting and documentation in the Patient Safety Information System. ***NOTE:*** *However, the same as for Adverse Events, the SAC Matrix scoring process and score determines the type of review.*

d. **Intentionally Unsafe Acts**

(1) Intentionally unsafe acts, as they pertain to patients, are any events that result from: a criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse by an impaired provider and/or staff; or events involving alleged or suspected patient abuse of any kind.

(2) Intentionally unsafe acts are to be dealt with through avenues other than those defined in this handbook (i.e., Administrative Investigation (AI) or other administrative methods as determined by the facility Director and by applicable directives and regulations). The goal of these investigations, as it is with RCAs, needs to focus on answering the questions of what happened, why did it happen, and what do we do to prevent it from happening again. ***NOTE:*** *Guidance on what to do when criminal or intentionally unsafe acts are suspected is described in paragraph 6.*

(3) Facilities must maintain a log of all such events, including the disposition of all these cases.

e. **RCA.** RCA is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with Adverse Events or Close Calls. An RCA is a specific type of focused review that is used for all Adverse Events or Close Calls requiring analysis. Consistent use of RCAs further refines the implementation and increases the quality and consistency of focused reviews. To avoid confusion, the term RCA is used to denote this type of focused review and will adhere to the guidelines provided in this Handbook. Root Cause Analyses need to be initiated with a specific charter memo, and the term "Root Cause Analysis" needs to be used in documents so that they will be protected and confidential under Title 38 United States Code (U.S.C.) 5705 and its implementing regulations.

(1) RCAs have the following characteristics:

(a) The review is interdisciplinary in nature with involvement of those knowledgeable about the processes involved in the event.

(b) The analysis focuses primarily on systems and processes rather than individual performance.

(c) The analysis digs deeper by asking "what" and "why" until all aspects of the process are reviewed and contributing factors are considered.

(d) The analysis identifies changes that could be made in systems and processes through either redesign or development of new processes, or systems that would improve performance and reduce the risk of the Adverse Event or Close Call recurrence.

(2) To help adhere to these characteristics, the following five guidelines need to be considered when developing root cause statements:

(a) Root cause statements need to include the cause and effect.

(b) Negative descriptions are not to be used in root cause statements.

(c) Each human error has a preceding cause.

(d) Violations of procedure are not root causes, but must have a preceding cause.

(e) Failure to act is only a root cause when there is a pre-existing duty to act.

(3) To be thorough, an RCA must include:

(a) A determination of the human and other factors most directly associated with the event or Close Call and the processes and systems related to its occurrence (there is rarely only one underlying cause).

(b) Analysis of the underlying systems through a series of "why" questions to determine where redesigns might reduce risk.

(c) Identification of risks and their potential contributions to the Adverse Event or Close Call.

(d) Determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.

(4) To be credible, an RCA must:

(a) Include participation by the leadership of the organization (this can range from chartering the RCA team, to direct participation on the RCA team, to participation in the determination of the corrective action plan) and by individuals most closely involved in the processes and systems under review. In cases where the facility Director serves on the RCA team, final concurrence is to come from the Veterans Integrated Service Network (VISN) Director, or designee.

(b) Be internally consistent (i.e., not contradict itself or leave obvious questions unanswered).

(c) Include consideration of relevant literature.

(d) Include corrective actions, outcome measures, and top management approval.

(e) Meet the National Center for Patient Safety (NCPS) and JCAHO requirements. NCPS provides a computer-assisted tool that must be used to guide RCA teams, document the RCA, and communicate to NCPS and VISNs. It is referred to in this Handbook as the Patient Safety Information System.

f. **Employee Rights.** RCAs do not involve sworn testimony. They can generate written confidential quality assurance documents if this is appropriately indicated in writing at the outset of the review (as in the RCA charter memo). Facility staff represented by an exclusive representative must be afforded all rights in accordance with their collective bargaining agreement.

5. GOALS

The goal of the Patient Safety Program is to prevent injuries to patients, visitors, and personnel. This is accomplished by taking small steps in the way things are done so that the level of faith and trust in the VHA patient safety system is established and these behaviors become a part of all employee behavior. This is a never-ending process. In this way a "culture of safety" can be formed. The key building blocks for accomplishing these goals are:

a. Comprehensive identification and reporting of Adverse Events, Sentinel Events, and Close Calls (see par. 6).

b. Reviewing Adverse Events, Sentinel Events, and Close Calls to identify underlying causes and system changes needed to reduce the likelihood of recurrence (see paragraph 7). The determination of cause is aimed at the system issues and is not to be used as a punitive tool. The requirements for initiating a review is determined by the prioritization method defined by the Safety Assessment Code (see App. D).

c. Disseminating patient safety alerts and lessons learned regarding effective system modifications throughout VHA (see par. 7) in an effective manner.

d. Prospective analysis of service delivery systems before an Adverse Event occurs to identify system redesigns that will reduce the likelihood of harm. These would include potential system weaknesses that were identified through prospective hypothetical analyses ("what if" types of questions) using techniques such as Healthcare Failure Mode and Effects Analysis (HFMEA™).

6. IDENTIFICATION AND REPORTING OF ADVERSE EVENTS, SENTINEL EVENTS, AND CLOSE CALLS; HOW TO ADDRESS INTENTIONALLY UNSAFE ACTS

a. Each VISN must ensure that its designated facilities report at least the following events to NCPS (and to the local VISN, if this is the VISN policy):

(1) Adverse Events (see subpar. 4a).

(2) Sentinel Events (see, subpar. 4b).

(3) Close Calls (see, subpar. 4c).

b. Facility staff must report, as per local policy, any unsafe conditions of which they are aware, even though the conditions have not yet resulted in an Adverse Event or Close Call.

c. Adverse Events and Sentinel Events shall be reported within the facility to the Patient Safety Manager (PSM), or designee. Facility staff are strongly encouraged to report Close Calls to the PSM, or designee. The PSM, or designee, then uses the Safety Assessment Code Matrix (SAC) to determine what action is required.

(1) This action could range from reporting to the VISN, NCPS, and JCAHO with the associated RCA performed and corrective action plan, to a decision to do nothing at the present time due to the low priority accorded the event from its SAC score.

(2) Appendix D details how the SAC score is used and paragraph 7 and Figures 1 and 2 show the procedure that must be followed for handling events that are reported along with the associated time constraints and products required, as well as what actions will or may be taken. If a safety alert to other facilities seems needed, this needs to be indicated. Events affecting personnel or visitors that could reveal vulnerabilities that could cause Adverse Events to patients need to be reported within the facility to the PSM, or designee.

d. Any report of an Adverse Event, Sentinel Event, or Close Call, as defined in subparagraphs 4a, 4b, and 4c, received by the PSM, or designee, is protected from disclosure under 38 U.S.C. 5705, as part of a medical quality assurance program. The only exception to this protection would be in the case of an intentionally unsafe act as defined as a criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse by an impaired provider and/or staff; or events involving alleged or suspected patient abuse of any kind (see subpar. 4d).

e. If in the course of conducting an RCA it appears that the event under consideration is the result of an Intentionally Unsafe Act, the RCA team must refer the event to the facility Director for appropriate further consideration as described in subparagraph 4d. In such a situation the RCA team discontinues their efforts, since the facility Director has assumed the responsibility for any further fact finding or investigation.

(1) The RCA team still maintains the information they have already collected confidentially as per 38 U.S.C. 5705. This means that members of the RCA team in question

could not serve on an Administrative Investigation (AI) team that might be convened by the Facility Director to consider this particular issue**.**

(2) All facilities must maintain a record of all events that have been referred to top management for consideration and the final disposition of the case.

f. If a crime is suspected to have been committed, appropriate officials (e.g., facility Director, Department of Veterans Affairs (VA) Police and Security) are to be notified as soon as possible by management (Title 38 Code of Federal Regulations (CFR) Sections 14.560 and 14.563, MP-1, Pt. I, Ch. 16, and MP-1, Pt. I, Ch. 2, subpar. 208.02). To the best extent possible, the surrounding area is not disturbed so that evidence is available for review by the police and other authorities. However, care needed by the patient is always to be provided as quickly as possible, regardless of its effect on the facility.

(1) As required by 38 CFR Sections 14.560 and 14.563, allegations of crimes against the person or property, or other non-fraudulent criminal matters must be referred to the Regional Counsel, who then refers the matter to the appropriate law enforcement agency.

(2) Serious crimes (felonies or misdemeanors) committed on hospital or domiciliary grounds must be reported directly to the United States Attorney, or a local agent of the Federal Bureau of Investigation.

(3)Allegations of fraud, corruption, or other criminal conduct involving VA programs and operations must be referred to the Office of the Inspector General. ***NOTE:*** *Notification is also to be given to the Deputy Assistant Secretary for Security and Law Enforcement and to the VISN office. The VISN office must inform the Assistant Deputy Under Secretary for Health (10N).*

g. If a crime is suspected to have been committed, facility security and medical staff may need to assist law enforcement agencies with preserving evidence (e.g., blood alcohol levels, weapons, controlled substances, etc.). Local policies and procedures for maintaining the chain of custody of evidence apply in these instances.

h. Staff who submit Close Call and Adverse Event reports that result in an RCA will receive feedback on the actions being taken as a result of their report. The feedback is to be of a timely nature and come from the PSM, or other appropriately designated party. Prompt feedback to reporters has been credited, in other reporting systems, with being one of the cornerstones that establishes trust in the system. It demonstrates the seriousness and commitment on the part of the organization to the importance of the reporting effort. Reporters are to be made acutely aware that their effort of reporting was not just a paperwork drill. The nature of this feedback can range from a simple acknowledgement that the event is under consideration, to providing information as to the corrective action that is planned or has been accomplished. ***NOTE:*** *Feedback should only be given to individuals that remain on staff at the time when the information from the RCA is available.*

i. Each VISN and facility is to adopt strategies to encourage and advocate staff identification and reporting of Adverse Events and Close Calls. Emphasis is to be placed on the value of Close Calls in identifying needed system redesigns. Identification and reporting

of Adverse Events and Close Calls, including those that appear to result from practitioner error, need to be a routine part of everyday practice. Employees need to understand that events that are often referred to as human errors are commonly due to systems-type problems. They especially need to understand that even the most conscientious, knowledgeable, and competent professionals can make errors and that the goal is to understand these in order to prevent them from causing harm to patients.

j. VA medical centers with a Nuclear Regulatory Commission license or other authorization to use radioactive materials must ensure compliance with the license and pertinent regulations. The VHA National Health Physics Program (NHPP) is to be contacted for assistance, if needed, to clarify license or regulatory requirements. ***NOTE:*** *The NHPP can be contacted by telephone at (501) 257-1571, by e-mail at vhconhpp@med.va.gov.*

k. The Patient Safety Information System must be used to track and monitor reported events. Designated staff at VA medical centers will enter data into the Patient Safety Information System, thereby ensuring the accuracy of the data recorded. ***NOTE:*** *This may also avoid translation and transcription errors that could occur if others performed this function.*

7. REVIEW AND ANALYSIS OF REPORTED EVENTS

a. A procedure has been worked out so that the review and analysis system for handling reports proceeds in an understandable manner and takes into account the various requirements of VHA and accrediting organizations. The RCA process is detailed schematically in Figure 1, which provides a detailed view of the RCA process. The following description will 'walk you through' Figure 1:

(1) When an Adverse Event or Close Call occurs, VA personnel may use any available or locally accepted method to notify the PSM and begin the facility's consideration of the event. The first step taken by the PSM after any required immediate action is to assign actual and potential SAC scores (see App. D) that then define what further actions are necessary.

(2) Events receiving a score of one or two will be acted on as thought appropriate by the facility. One needs to eliminate, control, or accept the risks associated with these events. These actions can range from performing an RCA to "no further action required."

(3) All events receiving a SAC score of three will receive either a traditional RCA or an Aggregated Review as described in subparagraph 7a(4) and the initial report of the event must be entered into the Patient Safety Information System. Events that have received a SAC score of three based on what has actually occurred, must have an RCA performed; the aggregated approach may not be used.

(4) A quarterly Aggregated Review may be used for the events as described in Appendix C, Aggregated Reviews. The use of aggregated analysis serves two important purposes.

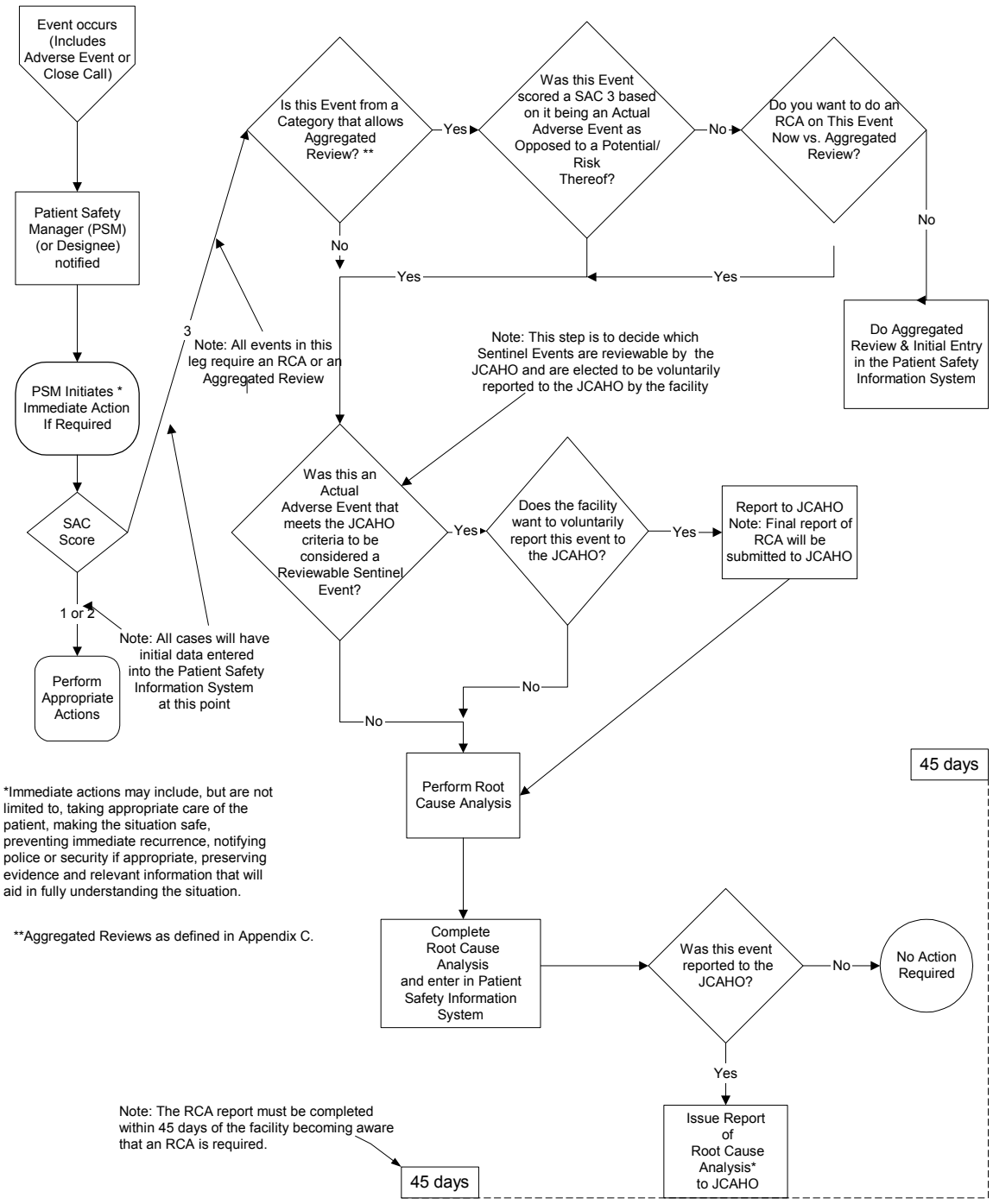

Figure 1. A Detailed View of the Root Cause Analysis Process

(a) First, this will provide a greater utility of the analysis as trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases.

(b) Second, it makes wise use of the RCA team's time and expertise. NCPS uses this information to compare with other data and to determine if any immediate action as far as the

issuance of alerts or other action is indicated. ***NOTE:*** *Any event may be subjected to a traditional RCA if this course of action is thought to be appropriate, even though it is in a category that permits an aggregated review.*

(5) If the event in question is an actual Adverse Event meeting the JCAHO definition of Reviewable Sentinel Event, the facility makes the determination to report it to JCAHO. This may entail consultation with other entities such as the VISN as is defined by local policy. In either case, the event receives an RCA and results are reported to the Patient Safety Information System and if previously reported to JCAHO, to them as well. The report of the outcome of the RCA must be completed within 45 calendar days and forwarded as described.

(6) To summarize, facilities have the option to report to JCAHO as explained in JCAHO policy (see App. B and the JCAHO web page: http://www.jcaho.org/ptsafety_frm.html). The RCA report will be retained by the facility even after the results have been entered into the Patient Safety Information System so that the report can be made available for future review and learning as appropriate.

(7) All events must be entered into the Patient Safety Information System. In this way all events reported are captured in the Patient Safety Information System even if they have SAC scores less than three. Those that receive a score of three (actual or potential) must receive RCA or aggregate review. Accordingly, the opportunity will then exist to better understand the system and appropriately focus attention in the future.

b. The real benefit of this review process is realized after the RCA is completed and the corrective actions are defined and implemented that prevent the future occurrence of similar events. These corrective actions are classified as eliminate, control, or accept based upon their projected impact on the identified system vulnerabilities. Once implemented, a plan for evaluating the effectiveness of the implemented change must be enacted to ensure that this change has the desired effect. The subsequent results must also be communicated to the VISN and NCPS through entry in the Patient Safety Information System or through other appropriate means. ***NOTE:*** *Figure 2, provides a simplified view of the RCA process.*

c. NCPS is responsible for disseminating important information learned from RCAs and the Patient Safety Information System. National Alerts and Advisories to VHA facilities are issued by the Office of the Assistant Deputy Under Secretary for Health in concert with NCPS.

d. The Office of Medical Inspector (OMI) monitors RCAs and AIs to assess their adequacy and to identify problems with processes of care that warrant attention. The OMI may conduct reviews and site visits at the request of the Secretary of Veterans Affairs, the Under Secretary for Health, the Deputy Under Secretary for Health, the Inspector General, veterans and their families, the VISNs and medical facilities, and to other stakeholders, such as Congress and Veterans Service Organizations. The OMI may also conduct reviews and site visits based on its own judgment.

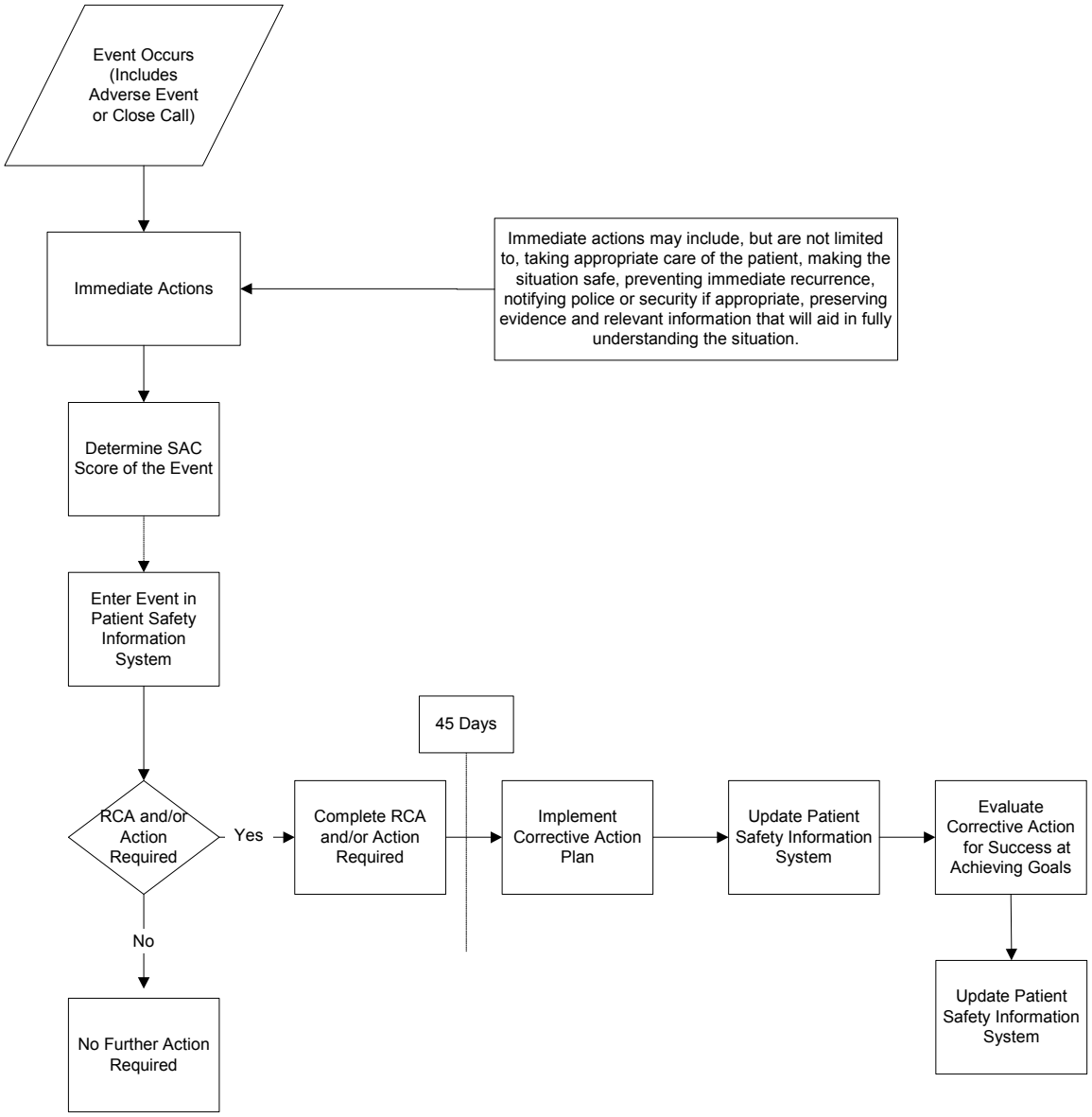

Figure 2. A Simplified View of the Root Cause Analysis Process

8. INFORMING PATIENTS ABOUT ADVERSE EVENTS

a. Background Information

(1) Clinicians and organizational leaders must work together to ensure that disclosure is a routine part of the response to Adverse Events. Telling patients that their health has been harmed rather than helped by the care provided is never easy, and disclosure must be undertaken with skill and tact. Nonetheless, VHA requires disclosure to patients who have been injured by Adverse Events.

(2) Disclosing Adverse Events to patients and their families is consistent with VHA core values of trust, respect, excellence, commitment, and compassion. Clinicians are ethically obligated to be honest with their patients. Honestly discussing the difficult truth that an Adverse Event has occurred demonstrates respect for the patient and a commitment to improving care. Disclosure of Adverse Events can be combined with reaffirming VHA's commitment to continuing to provide health care.

(3) VHA policy requiring disclosure is consistent with JCAHO requirements that hospitalized patients and their families be told of "unanticipated outcomes" of care (Standard RI 1.2.2, July 2001). JCAHO's requirement demonstrates a policy commitment that clinicians and health care organizations are disclose Adverse Events to patients and families.

(4) Despite the general obligation to disclose Adverse Events to patients and families, there are legal restrictions that limit disclosures that violate patient privacy. Specifically, the Privacy Act limits disclosures to families, and 38 U.S.C. 7332 limits disclosures related to the patient's treatment for substance abuse (including alcohol), sickle cell anemia disease, and Human Immunodeficiency Virus (HIV) status even after a patient's death. Similarly, there are legal limitations on disclosure of information obtained from RCAs and other quality improvement activities protected under 38 U.S.C. 5705. VHA may not disclose information obtained from RCAs and other quality improvement activities protected under 38 U.S.C. 5705 to patients and families. ***NOTE**: Questions about release of information to the patient and the patient's family are to be referred to the facility's Health Information Service; consultation with local or regional counsel may also be necessary.*

b. Communication with Patients Regarding Adverse Events

(1) VISNs must ensure that their facilities have a process in place to promptly inform patients and their families about pertinent clinical facts associated with injuries resulting from Adverse Events. The patient and family need to be assured that measures have been taken to minimize the impact of the Adverse Event. The attending physician, or a designated member of the treatment team, needs to initially communicate the Adverse Event to the patient or family. Further disclosures and discussions of the Adverse Event need to be undertaken with input from regional counsel, risk management staff, patient safety officers, facility leaders, and members of the treatment team. Disclosure of Adverse Events to patients and/or family members need to be undertaken using methods similar to those used by clinicians to give other types of "bad news."

(2) VISNs and facilities must ensure that their staff provides appropriate and timely communication with patients and their families regarding Adverse Events that involve potential organizational liability. Potential organizational liability is to be assessed based on discussions with practitioners and the Regional Counsel. The patients and their families must be advised of appropriate remedial options. These options can include locally available interventions (e.g., arranging for second opinions, expediting clinical consultations, inpatient admission) and referral of patients to the 38 U.S.C. 1151 claims process and the tort claims process.

(3) A collaborative relationship between Regional Counsel and VA medical center staff is necessary to ensure appropriate and timely communication with patients. Each VISN needs to ensure that their staffs develop an understanding with its Regional Counsel regarding the procedures for obtaining Regional Counsel input prior to discussing an Adverse Event with a patient.

9. COMPENSATION FOR INJURED PATIENTS

a. The two primary options available to injured patients, or their survivors, are claims for compensation under 38 U.S.C., Chapter 11, Section 1151, and tort claims under the Federal Tort Claims Act, 28 U.S.C., Sections 1346 (b), 2671-2680.

(1) Claims under 38 U.S.C. 1151 can result in payment of monthly benefits for additional disability or death incurred as the result of VHA facility care, medical or surgical treatment or examination, if the disability or death was proximately caused by negligence or an unforeseen event. Claims under 38 U.S.C. 1151 provide for the payment of a monthly benefit based on the percentage of disability and eligibility for VA medical care. ***NOTE:*** *Claims for 38 U.S.C.1151 benefits are processed by Veterans Benefits Administration (VBA) Regional Offices.*

(2) Tort claims may result in a settlement by Regional Counsels, General Counsel, United States Attorney, or in a judgment by a Federal court which has determined that negligence by medical practitioners caused injury or death (and jurisdictional requirements are met). ***NOTE:*** *Tort claims are processed by the Regional Counsels. In some cases subsequent review by the VHA Forensic Medicine Strategic Healthcare Group's (11F) Office of Medical-Legal Affairs may result in a recommendation that a practitioner be reported to the National Practitioner Data Bank based on a finding of substandard care, professional incompetence, or professional misconduct. Information contained in RCAs and other quality improvement materials is protected from disclosure in response to tort claims under 38 U.S.C. 5705 and may not be used by the VHA Office of Medical-Legal Affairs.*

(3) Veterans and survivors may pursue both 38 U.S.C 1151 and tort claims. However, if both claims are successful, 38 U.S.C. 1151 benefits will be offset until the amount that would have been paid equals the amount of the tort claim settlement or judgment.

CLOSE CALL SYSTEM DEFINITIONS

What is a Close Call?

1. A Close Call is an event or situation that could have resulted in an adverse event but did not, either by chance or through timely intervention.

2. All have experienced Close Calls on the job, whether they have recognized them or not. Two examples are listed as follows:

a. A nurse almost gives an overdose of insulin, but recognizes it and prevents the overdose when double-checking the order. ***NOTE:*** *During the double-check, they realize that they had confused the "U" for units, with a "0."*

b. An environmental management employee notices a jug of industrial strength cleaner mistakenly left in the shower stall on a locked psychiatric unit. They return it to proper storage before any patient can use it inappropriately.

THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS' (JCAHO) DEFINITION OF REVIEWABLE SENTINEL EVENTS THAT MAY BE REPORTED TO JCAHO

The following criteria define the subset of Sentinel Events that are voluntarily reportable, at the facility's discretion to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). ***NOTE:*** *As JCAHO policies are dynamic, it is important to be sure that the most recent JCAHO Sentinel Event Policies and definitions are used in making any determination. The text below was taken from the JCAHO web page: http://www.jcaho.org/ptsafety_frm.html, and this site should be checked periodically for updates or changes in policies.*

1. Only those Sentinel Events that affect recipients of care (i.e., patients, clients, and Veterans Health Administration (VHA) nursing home and domiciliary residents) and that meet the following criteria fall into the subset of Sentinel Events that are voluntarily reportable to JCAHO:

2. The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition. ***NOTE:*** *A distinction is made between an adverse outcome that is related to the natural course of the patient's illness or underlying condition (not reviewable under the Sentinel Event Policy) and a death or major permanent loss of function that is associated with the treatment, or lack of treatment, of that condition (reviewable). "Major permanent loss of function" means sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life-style change. When "major permanent loss of function" cannot be immediately determined, applicability of this policy is not established until either the patient is discharged with continued major loss of function, or two weeks have elapsed with persistent major loss of function, whichever occurs first.*

Or

3. The event is one of the following (even if the outcome was not death or major permanent loss of function):

a. Suicide of a patient in a setting where the patient receives around-the-clock care (e.g., hospital, residential treatment center, crisis stabilization center).

b. Infant abduction or discharge to the wrong family.

c. Rape. ***NOTE:*** *The determination of "rape" is to be based on the healthcare organization's definition, consistent with applicable law and regulation. An allegation of rape is not reviewable under the policy. Applicability of the policy is established when a determination is made that a rape has occurred.*

d. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

e. Surgery on the wrong patient or wrong body part. ***NOTE:*** *All events of surgery on the wrong patient or wrong body part are reviewable under the policy, regardless of the magnitude of the procedure.*

QUARTERLY AGGREGATED REVIEWS
FALLS, ADVERSE DRUG EVENTS, MISSING PATIENTS, AND PARASUICIDAL BEHAVIOR

1. **Quarterly Aggregated Reviews**. Quarterly Aggregated Reviews completed within 45 days of the end of the quarter and conducted by a chartered Root Cause Analysis (RCA) Team, may be used for four types of reported Adverse Events or Close Calls (potential Safety Assessment Code (SAC) score of three). The four types of events that may be handled by Aggregated Reviews are falls, adverse drug events, missing patients, and parasuicidal behaviors. All Adverse Events with an actual SAC score of three require individual RCAs.

a. The use of Aggregated Reviews serves two important purposes. First, it provides greater utility of the analysis as trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases. Second, it makes wise use of the RCA team's time and expertise.

b. Of course, a facility may elect to perform an individual RCA rather than an Aggregated Review on any of these four types of Adverse Events or Close Calls that they think merits that attention, regardless of the actual SAC score.

c. A tailored, real-time minimum data set (Aggregated Review Log) must be compiled for falls, missing patients, adverse drug events, and parasuicidal behaviors by designated staff in follow-up to reported events or Close Calls, during each quarter. Capturing this data may require medical record review, medication administration record review, and a brief discussion with staff members most knowledgeable about the events or Close Calls. The Aggregated Review Logs are to be provided to the designated RCA Teams as soon as they are convened, and serve as their initial data source. ***NOTE:*** *By using these logs the RCA teams may not routinely need to retrospectively consult individual patient profiles or individual medical records.*

d. It is anticipated that by utilizing this aggregated approach and building the reviews over succeeding quarters, common themes may be more readily identified enabling evaluation of the effectiveness of actions taken to prevent these events or Close Calls. ***NOTE:*** *Descriptions of each Aggregated Review Log are provided on the following pages. See the National Center for Patient Safety (NCPS) website for the most current form of the aggregate logs at* *http://vaww.ncps.med.va.gov/training/AggRevLog.doc*.

2. Falls. Falls are defined according to local or facility definition.

a. An individual RCA must be performed for any reported inpatient or outpatient fall occurring on facility property that results in an actual SAC 3, for all enrolled patients.

b. Reported falls and Close Calls (potential SAC score of 3) involving enrolled patients will be included in an Aggregated Review on a quarterly basis (completed by the RCA Team within 45 days after the end of the quarter). These Aggregated Reviews will be entered in the Patient Safety Information System. Of course, a facility may elect to perform an individual RCA rather than an Aggregated Review on any Adverse Event or Close Call that merits that attention,

regardless of the actual SAC score.

c. The following elements are included in the Falls Aggregated Review Log:

(1) Case number.

(2) Age.

(3) Sex.

(4) Event (day, date, time).

(5) OPT or INPT/Unit (designation of outpatient or inpatient status at time of event, and if inpatient, unit where the patient was assigned at the time of the event).

(6) Functional and cognitive factors (a listing of factors related to falls, requires a "yes" or "no" response for all applicable items: prior fall; designation as "high risk" for falls; needs assistance with activities of daily living (ADLs) mobility, transfer, toileting, dressing, eating; gait or balance limitations; incontinence; confused or memory limitations; related medical conditions; medication effect, etc.).

(7) Assistive Devices (a listing of devices related to falls, requires a "yes" or "no" response for all applicable items: cane; crutches; transfer device; walker; wheelchair; bathing device; mechanical lift; eye glasses; hearing aid, etc.).

(8) Communication Issues (a short list of areas where communication or information exchange can break down, requires a "yes" or "no" response for all applicable items: staff to staff, staff to patient, and staff to family and/or other).

(9) Environmental Factors (a listing of physical plant issues related to falls, requires a "yes" or "no" response for all applicable items: use of restraints, use of protective devices, inadequate footwear, bed side rails, floor condition, obstacles, fall while the patient was reaching for a needed item, inadequate patient or family or other education, unfamiliarity with the environment, inadequate lighting, and other).

(10) A free narrative entitled “What Happened and Treatment Plan Changes.”

(11) Comments (free narrative).

NOTE: *The current forms of the aggregated review logs can be seen at* *http://vaww.ncps.med.va.gov/training/AggRevLog.doc*

3. Adverse Drug Events. The VHA report: “Consensus Report for Nomenclature and Taxonomy of Adverse Drug Events (ADEs),” issued December 27, 2000 defines an ADE as “an injury associated with the use or nonuse of a drug.”

a. An individual RCA mustbe performed for any reported inpatient or outpatient ADE that

results in an actual SAC 3, for all patients receiving pharmaceutical care from a Department of Veterans Affairs (VA) health care system provider.

b. Reported ADEs or Close Calls (potential SAC 3 score) involving patients receiving pharmaceutical care from a VA health care system provider will be included in an Aggregated Review on a quarterly basis (completed by the RCA Team within 45 days after the end of the quarter). These Aggregated Reviews will be entered in the Patient Safety Information System. Of course, a facility may elect to perform an individual RCA rather than an Aggregated Review on any Adverse Event or Close Call that merits that attention, regardless of the actual SAC score.

c. The following elements are included in the Medication Aggregated Review Log:

(1) Case number.

(2) Age.

(3) Sex.

(4) Event (day, date, time).

(5) OPT or INPT/Unit (designation of outpatient or inpatient status at time of event, and if inpatient, unit where the patient was assigned at the time of the event)

(6) Processes related to the event (i.e., a listing of key steps in the medication process, requires a "yes" or "no" response for all applicable items: ordering, transcribing, dispensing, administering, and documenting).

(7) What happened? (A listing of ADEs, requires a "yes" or "no" response for all applicable items: medication given despite known allergy, omission, overdose, incorrect patient identification, incorrect medication identification, incorrect dose, incorrect route, incorrect schedule, and equipment failure.)

(8) Medication (name, dose, route, schedule for the correct medication, and the actual and/or Close Call medication).

(9) Treatment plan changes (free narrative).

(10) Comments (free narrative).

NOTE: *The current forms of the aggregated review logs can be seen at* *http://vaww.ncps.med.va.gov/training/AggRevLog.doc*

4. Parasuicidal Behaviors. There are two primary categories of suicidal events: completed suicides, and parasuicidal events (any suicidal behavior with or without physical injury [i.e., short of death], including the full-range of known or reported attempts, gestures, and threats).

a. An individual RCA will be performed for any completed inpatient suicide (at the time it

occurs) and for any completed outpatient suicide (at the time of facility notification) for all enrolled patients who have received clinic care services from VA. In other words, all actual known suicides of enrolled patients who have received clinic care services from VA must receive an RCA and must be reported in the Patient Safety Information System.

b. All reported parasuicidal events or Close Calls (potential score of three) involving enrolled patients who have received clinic care services from VA will be included in an Aggregated Review on a quarterly basis. The RCA Team will complete this within 45 days after the end of the quarter. These Aggregated Reviews must be entered in the Patient Safety Information System. Of course, a facility may elect to perform an individual RCA rather than an Aggregated Review on any Adverse Event or Close Call that merits that attention, regardless of the actual SAC score.

c. The following elements are included in the Parasuicidal Aggregated Review Log:

(1) Case number.

(2) Age.

(3) Sex.

(4) Event (day, date, time).

(5) OPT or INPT/Unit (designation of outpatient or inpatient status at the time of event, and if inpatient, unit where the patient was assigned at the time of the event).

(6) Date of last OPT TX (date of most recent prior outpatient treatment; this does not include an appointment that was scheduled, but was a "no show").

(7) Diagnoses (a listing of current and active diagnoses).

(8) Tx Team (a short list of treatment team options for providers that were assigned to the patient at the time of the event; requires a "yes"/"no" response for all applicable items: mental health and/or psychiatry, specialty and/or sub-specialty, and primary care).

(9) What happened? (free narrative).

(10) Family and other supports (free narrative).

(11) Treatment plan changes (free narrative).

(12) Comments (free narrative).

NOTE: *The current forms of the aggregated review logs can be seen at* *http://vaww.ncps.med.va.gov/training/AggRevLog.doc*

5. Missing Patients. A missing patient is "a high-risk patient who disappears from an inpatient or outpatient treatment area or while under control of VA, such as during transport." A high-risk patient is one who is "incapacitated because of frailty, or physical or mental impairment."

a. An individual RCA must be completed for any missing patient who is classified as an actual 3 using the SAC matrix. All missing patients that receive a SAC potential score of three must be included in the Aggregated Review on a quarterly basis. The RCA Team must complete the Aggregate Review RCA within 45 days after the end of the quarter. The Aggregated Reviews must be entered in the Patient Safety Information System. Of course, a facility may elect to perform an individual RCA rather than an Aggregated Review on any Adverse Event or Close Call that merits that attention, regardless of the actual SAC score.

b. The following elements are included in the **Missing Patient Aggregated Review Log:**

(1) Case number.

(2) Age.

(3) Date reported missing (day, date).

(4) Time reported missing.

(5) Location reported missing from.

(6) Length of time missing (days, hours).

(7) Level of privileges (full, partial, none).

(8) Previous episodes.

(9) Order of treatment plan required supervision (Yes or No).

(10) Primary diagnosis.

(11) Person notified (name, date, and time).

(12) Type of search conducted (general, grid).

(13) Date found.

(14) Location found.

(15) Condition (injuries).

(16) Barriers to prevent escape or elopement.

(17) Activity at time of elopement or escape.

NOTE: *The current forms of the aggregated review logs can be seen at* *http://vaww.ncps.med.va.gov/training/AggRevLog.doc*

THE SAFETY ASSESSMENT CODE (SAC)

The Severity Categories and the Probability Categories that are used to develop the Safety Assessment Codes (SACs) for Adverse Events and Close Calls are presented below, and are followed by information on the SAC Matrix.

SEVERITY CATEGORIES

1. Key factors for the severity categories are extent of injury, length of stay, level of care required for remedy, and actual or estimated physical plant costs. These four categories apply to actual Adverse Events and potential events (Close Calls). For **actual Adverse Events**, assign severity based on the patient's actual condition.

2. If the event is a **Close Call**, assign severity based on a reasonable "worst case" systems level scenario. ***NOTE:*** *For example, if you entered a patient's room before they were able to complete a lethal suicide attempt, the event is catastrophic, because the reasonable "worst case" is suicide.*

Catastrophic	**Major**
Patients with Actual or Potential: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) **not related to the natural course of the patient's illness or underlying condition** (i.e., acts of commission or omission). This includes outcomes that are a direct result of injuries sustained in a fall; or associated with an unauthorized departure from an around-the-clock treatment setting; or the result of an assault or other crime. Or any of the following: • Suicide (inpatient or outpatient) • Rape • Hemolytic transfusion reaction • Surgery or procedure on the wrong patient or wrong body part • Infant abduction or infant discharge to the wrong family **Visitors:** A death; **or** hospitalization of 3 or more visitors **Staff**: A death or hospitalization of 3 or more staff* **Fire**: Any fire that grows larger than an incipient stage‡	**Patients with Actual or Potential:** Permanent **lessening** of bodily functioning (sensory, motor, physiologic, or intellectual) **not related to the natural course of the patient's illness or underlying conditions** (i.e., acts of commission or omission) **or** any of the following: • Disfigurement • Surgical intervention required • Increased length of stay for 3 or more patients • Increased level of care for 3 or more patients **Visitors:** Hospitalization of 1 or 2 visitors **Staff:** Hospitalization of 1 or 2 staff **or** 3 or more staff experiencing lost time or restricted duty injuries or illnesses **Equipment or facility:** Damage equal to or more than $100,000**,♦
Moderate	**Minor**
Patients with Actual or Potential: Increased length of stay **or** increased level of care for 1 or 2 patients **Visitors:** Evaluation **and** treatment for 1 or 2 visitors (less than hospitalization) **Staff**: Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff **Equipment or facility:** Damage more than $10,000 but less than $100,000**,♦ **Fire** – Incipient stage or smaller‡	**Patients with Actual or Potential:** No injury, nor increased length of stay nor increased level of care **Visitors:** Evaluated and no treatment required **or** refused treatment **Staff:** First aid treatment only with no lost time, nor restricted duty injuries nor illnesses **Equipment or facility**: Damage less than $10,000 or loss of any utility without adverse patient outcome (e.g., power, natural gas, electricity, water, communications, transport, heat and/or air conditioning)**,♦

*Title 29 Code of Federal Regulations (CFR) 1960.70 and 1904.8 requires each Federal agency to notify the Occupational Safety and Health Administration (OSHA) within 8 hours of a work related incident that results in the death of an employee or the in-patient hospitalization of three or more employees. Volunteers are considered to be non-compensated employees.
**The Safe Medical Devices Act of 1990 requires reporting of all incidents in which a medical device may have caused or contributed to the death, serious injury, or serious illness of a patient or another individual.
‡ An incipient fire is a fire that is smaller than a burning waste paper basket. It is easily extinguished by using a single portable fire extinguisher (or equivalent) and it is not necessary to take evasive action (stooping, etc.) when approached to avoid heat or smoke.
♦The effectiveness of the facilities disaster plan must be critiqued following each implementation to meet the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Environment of Care Standards.

PROBABILITY CATEGORIES

1. Like the severity categories, the probability categories apply to actual Adverse Events and Close Calls.

2. In order to assign a probability rating for an Adverse Event or Close Call, it is ideal to know how often it occurs at your facility. Sometimes the data will be easily available because it is routinely tracked (e.g., falls with injury, ADEs, etc.). Sometimes, getting a feel for the probability of events that are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. Sometimes it will have to be your best educated guess.

a. **Frequent** – Likely to occur immediately or within a short period (may happen several times in 1 year).
b. **Occasional** – Probably will occur (may happen several times in 1 to 2 years).
c. **Uncommon** – Possible to occur (may happen sometime in 2 to 5 years).
d. **Remote** – Unlikely to occur (may happen sometime in 5 to 30 years).

3. How the Safety Assessment Codes (SAC) Matrix Looks

Severity & Probability	Catastrophic	Major	Moderate	Minor
Frequent	**3**	**3**	**2**	**1**
Occasional	**3**	**2**	**1**	**1**
Uncommon	**3**	**2**	**1**	**1**
Remote	**3**	**2**	**1**	**1**

4. How the SAC Matrix Works. When you pair a severity category with a probability category for either an actual event or Close Call, you will get a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk). These ranks, or SACs can then be used for doing comparative analysis and for deciding who needs to be notified about the event.

5. Notes

a. All known reporters of events, regardless of SAC score (one, two, or three), will receive appropriate and timely feedback.

b. The Patient Safety Manager, or designee, will refer Adverse Events or Close Calls related solely to staff, visitors, or equipment and/or facility damage to relevant facility experts or services on a timely basis, for assessment and resolution of those situations.

c. A quarterly Aggregated Root Cause Analysis (RCA) may be used for four types of events (this includes all events or Close Calls other than actual SAC score of three, since all actual SAC score of three require an individual RCA). These four types are falls, adverse drug events, missing patients, and parasuicidal behavior. The use of aggregated analysis serves two important purposes. First, it provides greater utility of the analysis as trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases. Second, it makes wise use of the RCA team's time and expertise. ***NOTE:*** *Of course, the facility may elect to perform an individual RCA rather than Aggregated Review on any Adverse Event or Close Call that merits that attention, regardless of the SAC score*