VHA NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Handbook provides guidance for minimizing the chance of inadvertent harm to patients consequent to their medical care.

2. SUMMARY OF MAJOR CHANGES. This VHA Handbook is revised to incorporate:

a. New minimum requirements for root cause analyses and aggregated reviews of selected categories of adverse events, and includes other changes based on research findings, and experiences and developments in patient safety improvement since 2002.

b. Inclusion of the following sentence in subparagraph 7c(1): "National Alerts and Advisories must be shared with representatives of the Department of Defense's Patient Safety Program, and other Federal agencies, as appropriate."

3. RELATED DIRECTIVES. VHA Handbook 1058.1, Reporting Adverse Events in Research to the Office of Research Oversight.

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 VHA Handbook 1050.01 dated April 18, 2008, is rescinded.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working date of May 2013.

Michael J. Kussman, MD, MS, MACP
Under Secretary for Health

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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 VHA in the accomplishment of its goal of preventing inadvertent harm to patients consequent to their medical care.

2. BACKGROUND

a. VHA began to put special focus on patient safety improvement in 1997, and began operation in February 1999 of the National Center for Patient Safety (NCPS) to develop and implement VHA's patient safety programs. In late 1999, the Institute of Medicine (IOM) published the "To Err is Human" report, which brought national attention to the problem of adverse events in health care, and included the estimate that adverse events were causing from 44,000 to 98,000 deaths per year. The first version of the VHA Patient Safety Improvement Handbook was developed in 1998. An updated version was distributed in 1999 to provide guidance on preventing adverse events through implementing new methods at Department of Veterans Affairs (VA) medical centers to better understand and address local problems. Then and now, it is necessary for VA administrative and clinical staff members to have a clear picture as to what is actually happening in their health care settings so that appropriate steps can be taken to prevent harm to patients.

b. VHA's patient safety program has implemented a three-step approach to improving patient safety.

(1) First, understanding the health care continuum as a system, and exploring system vulnerabilities that can result in patient harm has been an emphasis in VHA's patient safety improvement initiatives.

(2) Second, encouraging reporting of system vulnerabilities is the mechanism through which VHA can learn about those vulnerabilities and how to address them. Since 2000, VA medical centers have reported over 200,000 adverse events or close calls and performed over 6,000 thorough analyses of selected incidents or groups of incidents.

(3) Third, emphasizing prevention rather than punishment as the preferred method to mitigate system vulnerabilities and reduce adverse events is an important aspect of VHA's patient safety initiatives.

c. The three-step approach promotes the implementation of knowledge-based actions that can be formulated, tested, and implemented at the local and national levels to effectively mitigate system vulnerabilities that can lead to patient harm. ***NOTE:*** *Ultimately, this effort can be successful only if emphasis on safety and responsibility for improving it resides at all levels of the organization; it requires a true team effort.*

d. Incorporation of "root cause analysis" (RCA), a widely understood methodology for dealing with these safety-related issues, has allowed for more accurate and rapid communication

throughout the organization of potential and actual causes of harm to patients, thus building local and national knowledge about systems vulnerabilities and speeding the process of patient safety improvement. ***NOTE:*** *For this to occur training must take place to complement the contents of this Handbook; reading it alone is not sufficient; for upcoming training contact the National Center for Patient Safety at (734) 930-5890.*

e. RCAs do not involve sworn testimony. RCAs can generate written confidential quality assurance documents if this is appropriately indicated in writing by the appropriate official prior to initiation of the review (as in the RCA charter memo).

3. SCOPE

This Handbook:

a. Delineates what types of events are to be considered within the patient safety program and how they should be addressed, 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 or staff; or events involving alleged or suspected patient abuse of any kind.

b. Specifies the method by which the need for conducting an RCA will be determined, and the procedure for communicating related findings throughout the organization. These procedures address the management component and the frontline patient care 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, or to disclose an adverse event to a patient, as defined 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 or complications, completed suicides, parasuicidal behaviors (attempts, gestures, and threats), and missing patient events. ***NOTE:*** *All adverse events require reporting and documentation in the VHA Patient Safety Information System (PSIS), using the "SPOT" software application; the type of review required is determined through the Safety Assessment Code (SAC) Matrix scoring process, as outlined in Appendix B.*

b **Sentinel Events.** Sentinel Events are a type of adverse event defined by The Joint Commission (TJC) as 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. ***NOTE:*** *How to conduct Administrative Investigations (AIs) or Administrative Boards of Investigation (ABIs) is not addressed in this Handbook. These methods are not part of the VHA patient safety program and are described in VA Handbook 0700 and VA Directive 0700. Unlike RCAs, peer reviews, and other selected reviews, AIs and ABIs are not confidential quality improvement documents and are not protected from release by Title 38 United States Code (U.S.C.) 5705. Management may also elect to perform an AI or ABI even in cases that are not perceived to be intentionally unsafe acts as part of their normal supervisory responsibilities. In such cases it is recommended that the AI or ABI be performed prior to the RCA to prevent confidential information derived from an RCA from being improperly used in the AI or ABIs in question as well as to avoid the perception that information from an RCA was used improperly (see subpars. 4d(2) and 4d(3)).*

(2) Some examples of reviewable Sentinel Events include:

(a) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities,

(b) Surgery on the wrong patient or wrong body part, and

(c) Unintended retention of a foreign object in a patient after surgery or other procedure.

(d) Suicide of any patient receiving care, treatment and services in a staffed around-the-clock care setting or within 72 hours of discharge

NOTE: *TJC updated its document describing the required responses to sentinel events in October 2006. In addition to the four preceding examples (see subpars. 4b(2)(a), 4b(2)(b), 4b(2)(c), and 4b(2)(d)), there are six other types of sentinel events presently identified by TJC. In general, events considered to be reviewable "Sentinel Events" are included in the catastrophic severity category of the SAC matrix (see App. B).*

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. 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 prior to the procedure.

(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. They require reporting and documentation in the Patient Safety Information System (PSIS). ***NOTE:*** *Just as for adverse events, the SAC Matrix scoring process and score determines the type of review (see App. B).*

d. **Intentionally Unsafe Acts**

(1) Intentionally unsafe acts, as they pertain to patients, are any events that result from:

(a) A criminal act,

(b) A purposefully unsafe act,

(c) An act related to alcohol or substance abuse by an impaired provider and/or staff, or

(d) Events involving alleged or suspected patient abuse of any kind.

(2) Intentionally unsafe acts must be dealt with through avenues other than those defined in this handbook (i.e., AI or other administrative methods as determined by the facility Director and by applicable directives and regulations such as VA Directive 0700 and Handbook 0700). The goal of these investigations, as it is with RCAs, focuses 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) If an event involves what appears to be an intentionally unsafe act, an AI or similar review may be appropriate and an RCA may be inappropriate. However, in some cases it may be appropriate to do both types of reviews, e.g., an AI might review a procedure or aspect of care performed by a provider who might not have had the appropriate credentials or privileges, and an RCA on the same topic might review the local processes for credentialing and privileging. An RCA can use information gleaned from an AI, but due to confidentiality constraints of RCAs, an AI cannot use information from an RCA. If there is an intention to perform both types of reviews on the same incident, the RCA should normally be performed after the completion of AI. In the event that an AI is performed after an RCA is started, members of the RCA team are not to serve on the AI team or review group to ensure that the confidentiality of the RCA process is appropriately maintained and that the perception of the integrity of the RCA process is preserved.

e. **Patient Safety.** Patient Safety is ensuring freedom from accidental or inadvertent injury during health care processes.

f. **Root Cause Analyses (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 must adhere to the procedures provided in this Handbook. RCAs need to be initiated with a specific charter memorandum, and the term "Root Cause Analysis" needs to be used in documents so that they are protected and deemed confidential under 38 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 the 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, and 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, and

(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 system vulnerabilities or 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 knowledgeable about the processes and systems

under review. ***NOTE:*** *This is not to suggest that the team should consist solely of leaders and individuals with special knowledge of clinical or other processes thought to be associated with the adverse event or close call. Valuable contributions have been made by employees with little background in the clinical or other areas that were thought to be relevant at the outset of the RCA process.* In cases where the facility Director serves on the RCA team, final concurrence must come from the Veterans Integrated Service Network (VISN) Director, or designee.

(b) Exclude individuals directly involved in the adverse event or close call under review. In the interest of objectivity, these individuals are not to be part of the RCA Team. However, their experience and knowledge of the situation is vital to the RCA process, so they need to be interviewed as part of the RCA process and asked for suggestions about how to prevent the same or similar situations from happening again.

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

(d) Include consideration of relevant literature.

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

(f) Meet the NCPS and TJC requirements. NCPS provides a computer-assisted tool that must be used to guide RCA teams, document the RCA, and communicate to NCPS and VISNs. ***NOTE:*** *It is referred to in this Handbook as Patient Safety Information System (PSIS).*

g . **Proactive Risk Assessment.** Proactive Risk Assessment is a method of evaluating a product or process to identify systems vulnerabilities, and their associated corrective actions, before an adverse event occurs. Proactive Risk Assessment models include Healthcare Failure Mode and Effects Analysis (HFMEA^{SM}) and Failure Mode Effect Analysis (FMEA).

5. GOALS

The Patient Safety Program's goal is to prevent harm 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 behaviors designed to prevent adverse events become a part of all-employee behavior. ***NOTE:*** *This is a never-ending process. In this way a "culture of safety" can be formed.* The key building blocks for accomplishing this goal are:

a. Identifying and reporting adverse events (including Sentinel Events), and close calls (see par. 6).

b. Reviewing adverse events and close calls to identify underlying causes and implementing changes needed to reduce the likelihood of recurrence (see par. 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 SAC (see App. B).

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

d. Completing at least one Proactive Risk Assessment per year for each TJC-accredited program.

e. Implementing practices appropriate to VA settings that have shown to be effective in preventing adverse events elsewhere. These include practices from other VA medical centers, or in non-VA hospitals, as described in the published literature, in communications from NCPS (such as through "toolkits" and the NCPS web page), or through publications, notices, and web sites from other organizations.

6. IDENTIFICATION AND REPORTING OF ADVERSE EVENTS, SENTINEL EVENTS, AND CLOSE CALLS AND 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 to the Patient Safety Manager (PSM).

c. Adverse events must be reported within the facility to the PSM, or designee. ***NOTE:*** *Close calls are also to be reported to the PSM.* The PSM uses the SAC Matrix to determine what action is required. The SAC score is not to be determined by any staff other than the PSM, or designee.

(1) This action could range from reporting to the VISN, NCPS, and TJC 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 B details how the SAC score is used and paragraph 7, Figure 1, and Figure 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 necessary, this must be indicated. In addition, events affecting personnel or visitors that could reveal vulnerabilities that could cause adverse events for patients are to be reported directly to the facility PSM, or designee.

d. Any report of an adverse 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 exceptions to this protection would be in cases 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 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 it has already collected confidentially as per 38 U.S.C. 5705. This means that members of the RCA team could not serve on an 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. RCAs that are discontinued, as described in subparagraph 4e are to be recorded as such by using the "Halted" function in the SPOT software application, which is a part of PSIS.

(3) After an AI is completed in response to an adverse event or close call that had been initially referred for RCA, that AI is to be reviewed by the facility PSM. The PSM is to consult with the RCA team, if one had been initially convened to review the adverse event or close call. If the PSM and RCA team are not satisfied that the AI has identified systems issues for follow-up, then the PSM needs to communicate with the facility Director to recommend that an RCA Team be convened or reconvened. The purpose of the ensuing RCA is to identify any systems issues that may not have been identified in the AI.

f. If a crime is suspected to have been committed, appropriate officials (e.g., facility Director, VA Police and Security) must be notified as soon as possible by management consistent with 38 CFR 1.203. (Specific guidance on safeguarding evidence is provided in VA Handbook 0730, Security and Law Enforcement.) To the greatest degree possible, the surrounding area must not be disturbed so that evidence is available for review by the police and other authorities. However, care needed by the patient must always be provided for as quickly as possible, regardless of the effect on the potential evidence.

(1) As required by 38 CFR Section1.203, information regarding actual, or possible, violations of criminal laws related to VA programs, operations, facilities, or involving VA employees, where the violation of criminal law occurs on VA premises, must be reported by VA management officials to the VA police component with responsibility for the VA station or facility in question.

(2) As required by 38 CFR Section1.204, criminal matters involving felonies must be immediately referred to the Office of Inspector General (OIG), Office of Investigation. VA management officials with information about possible criminal matters involving felonies must ensure (and be responsible) prompt referral to the OIG. Examples of felonies include, but are not limited to: theft of Government property valued over $1,000; false claims; false statements; drug offenses; crimes involving information technology; and serious crimes against a person, i.e., homicides, armed robbery, aggravated assault, and serious abuse of a VA patient.

(3) In accordance with 38 CFR Section 1.205, VA police or the OIG, whichever has the primary responsibility within VA for investigation of the offense in question, is responsible for notifying the appropriate United States Attorney's office, pursuant to 28 U.S.C. 535.

(4) Notification must be given to the Deputy Assistant Secretary for Security and Law Enforcement and to the VISN office. The VISN Director, or designee, must inform the Deputy Under Secretary for Health for Operations and Management (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 (for specific guidance regarding the safeguarding of evidence see VA Handbook 0730).

h. Staff who submit close call and adverse event reports that result in an RCA must 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 those reporting adverse events 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. ***NOTE:*** *Feedback must only be given to individuals who remain on staff at the time when the information from the RCA is available.*

i. Each VISN and facility must 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 part of routine practice. Employees need to understand that events that are often referred to as human errors are commonly due to systems problems. They especially need to understand that even the most conscientious, knowledgeable, and competent professionals can make mistakes and that the goal is to understand these in order to prevent them from causing harm to patients.

j. Responding to adverse events that occur in the course of research, rather than during ordinary patient care, is a special topic that is described in VHA Handbook 1058.1, *Reporting Adverse Events in Research to Office of Research Oversight (ORO)*. An adverse event in research can be any unfavorable or unintended occurrence (physical, psychological, social, or economic) in a human research subject that is associated with, but not necessarily caused by, the research. An adverse event reportable to ORO may also be reportable to the VA facility PSM in accordance with the procedures described in Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*. RCAs conducted consistent with the guidance in this Handbook and current VHA policy are not available to, and are not for use by, ORO for compliance oversight activities, nor are they to be released under clinical research agreements.

k. VA medical centers with a Nuclear Regulatory Commission (NCR) 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 e-mail at vhconhpp@med.va.gov.*

l. Laboratory-related incidents must be handled in accordance with the policy and regulatory guidelines identified in VHA Directive 1106, *Pathology and Laboratory Medicine Service,* and VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures.* Serious laboratory-related incidents need to be reported to the local Pathology and Laboratory Medicine Service (P&LMS) Regional Commissioner's office or the P&LMS National Enforcement Program Office as defined in these policies. The regional and national points of contact are identified on the P&LMS national Web site at: http://10.2.51.79/pathologylab/ .

m. The PSIS must be used to track and monitor reported events. Data concerning the reported events must be entered into the PSIS by designated staff at VA medical centers to ensure 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 established 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 through" the event evaluation and reporting process.

(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. B) that then define what further actions are necessary.

(2) Events receiving an actual and potential SAC score of one or two will be acted on as appropriate by the facility. These actions can range from performing an RCA to "no further action required."

(3) All events receiving an actual or potential SAC score of three receive either a traditional RCA or must be included in an Aggregated Review as described in subparagraph 7a(4); the initial report of the event must be entered into the PSIS. 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.

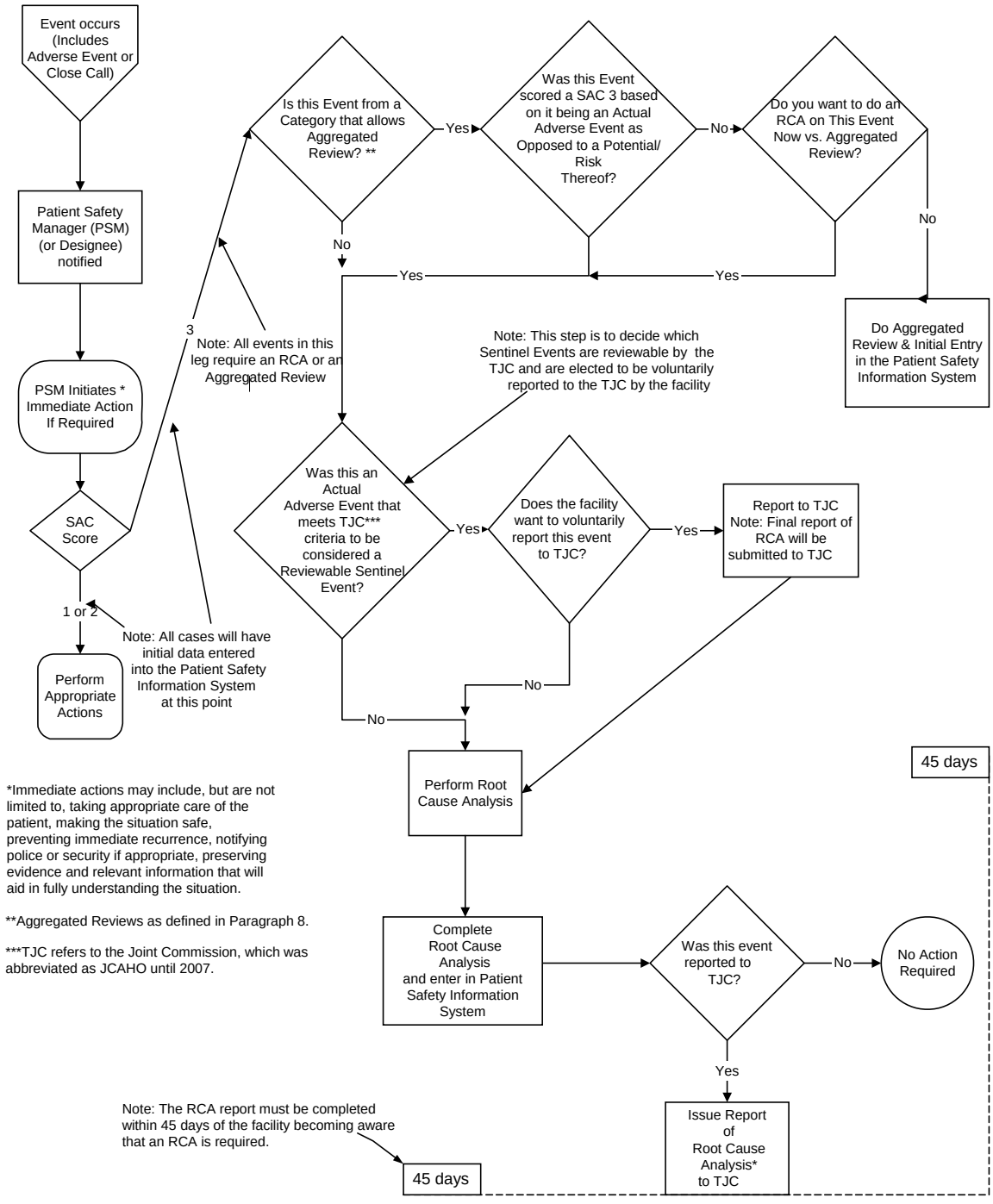
(4) An Aggregated Review may be used for selected events as described in paragraph 8e. The use of aggregated analysis serves two important purposes.

(a) First, this provides a greater utility of the analysis at the facility level as systems vulnerabilities, 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 compares this information with other data and uses it to determine if any immediate action, such as issuing a

Patient Safety Alert, 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.*

Figure 1. A Detailed View of the Event Evaluation and Reporting Process



(5) If the event in question is an actual adverse event meeting TJC definition of Reviewable Sentinel Event, the facility must make the determination as to whether to report it to TJC.

Reporting to TJC is optional and is not required by the VHA Patient Safety Program. Reporting to TJC 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 PSIS and, if previously reported to TJC, to them as well. The report of the RCA's outcome must be completed within 45-calendar days and forwarded as described. To summarize, facilities have the option to report to TJC as explained in TJC policy (see the TJC web page at: http://www.jointcommission.org/SentinelEvents/PolicyandProcedures/).

(6) The RCA report is retained by the facility even after the results have been entered into the PSIS so that the report can be made available for future review and learning as appropriate. For detailed and relevant information on recordkeeping see VHA Records Control Schedule (RCS) 10-1 (RCS 10-1).

(7) All adverse events and close calls must be entered into the PSIS using the "SPOT" software system. In this way all events reported are captured in the PSIS, 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. Only patient safety events, and not intentionally unsafe acts, are to be entered into SPOT.

b. The greatest benefit of this review process is realized after the RCA is completed and corrective actions designed to prevent the future occurrence of similar events are defined and implemented. Individual corrective actions can eliminate, control, or accept identified system vulnerabilities. Once implemented, a plan for evaluating the effectiveness of the implemented change must be enacted to ensure that changes have the desired effects. The subsequent results must also be communicated to the VISN and NCPS through entry in the PSIS. ***NOTE:*** *Figure 2 provides a simplified view of the RCA process.*

c. NCPS is responsible for:

(1) Disseminating important information learned from RCAs and the PSIS. National Alerts and Advisories to VHA facilities are issued by the Deputy Under Secretary for Health for Operations and Management in concert with NCPS. National Alerts and Advisories must be shared with representatives of the Department of Defense's Patient Safety Program, and other Federal agencies, as appropriate.

(2) Providing information based on RCAs using the TIPS Newsletter and using "RCA Topic Summaries."

(3) Providing presentations, based on RCAs, to VHA Central Office managers, Field Advisory Committees, VISN Chief Medical Officers, and other groups of key officials.

NOTE: *Alerts, Advisories, TIPS issues, and RCA Topic Summaries are all available on the NCPS Intranet Web site: http://vaww.ncps.med.va.gov/. Much of this information is also available to the public at the NCPS Internet Web site: www.patientsafety.gov or www.va.gov/ncps/.*

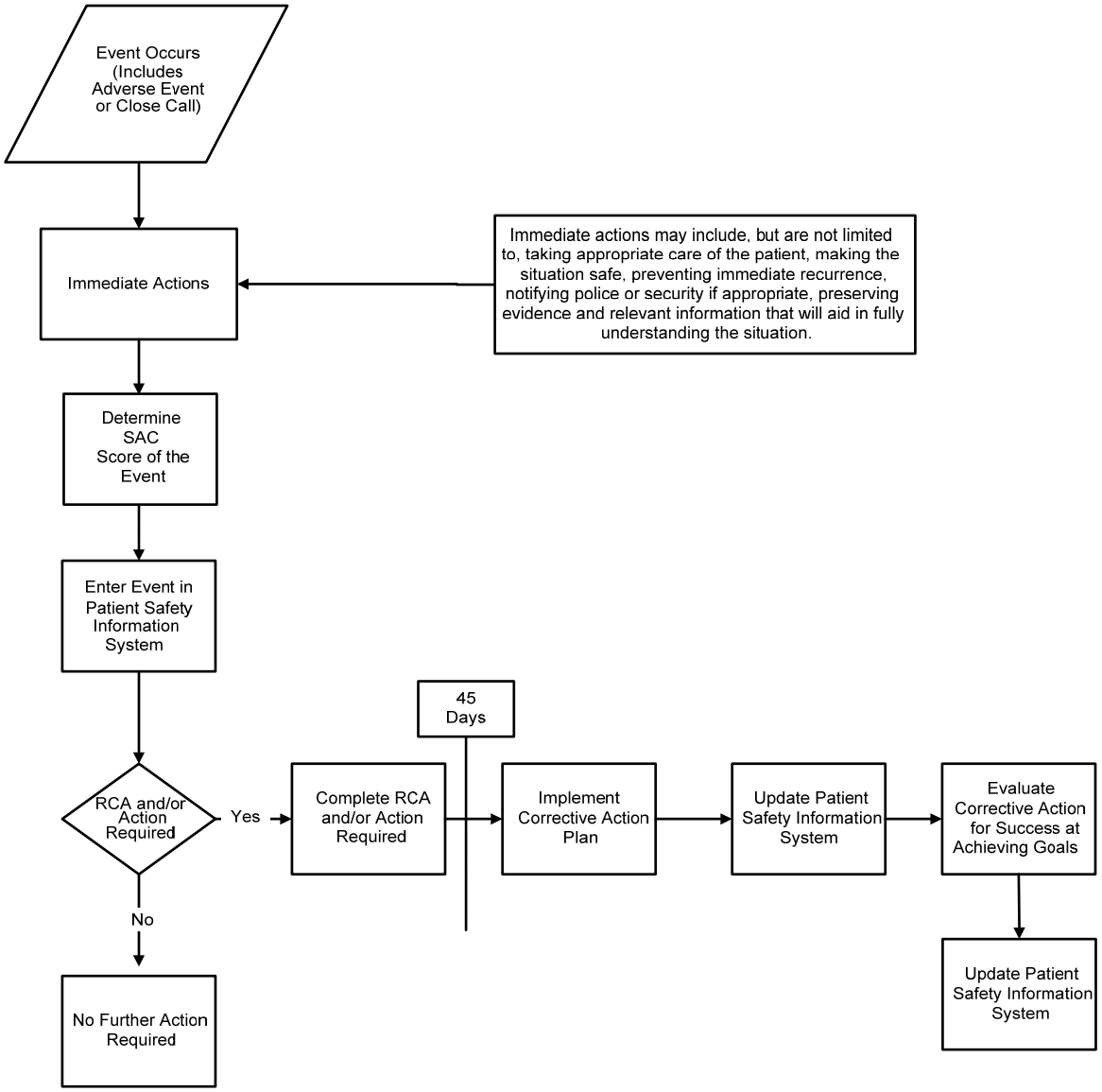
d. The Office of Medical Inspector (OMI) and the OIG monitor RCAs and AIs to assess their adequacy and to identify problems with processes of care that warrant attention. The OMI may

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 for Operations and Management, OIG, 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.

8. MINIMUM THRESHOLDS FOR AGGREGATED REVIEWS AND INDIVIDUAL RCAs

To reduce harm to patients, and with input from key VISN and VA medical center personnel, minimum annual thresholds for Aggregated Reviews and individual RCAs that must be

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



completed by each VA medical center and reported to NCPS have been established. The primary purpose for setting minimum thresholds is to encourage facilities to identify and mitigate vulnerabilities in their systems of care and to share their experiences, analyses, and new knowledge gained with the broader VA community. ***NOTE:*** *These minimum thresholds are subject to modification by the Chief Patient Safety Officer in consultation with the Deputy Under Secretary for Health for Operations and Management.*

a. The facility Director is responsible for ensuring a minimum of eight patient safety analysis processes, i.e., RCAs and Aggregated Reviews, are completed each fiscal year.

(1) At least four of the analyses must be individual RCAs with the balance being Aggregated Reviews or additional individual RCAs (see subpar. 8d). The fiscal year to which the activity is attributed is determined by the date of the Facility Director's signature on the completed document.

(2) Many facilities have longstanding and successful track records for conducting individual RCAs and complete more than the minimum requirement of individual RCAs, based on their actual experience with reports of adverse events and close calls, and as indicated by the SAC scores. Decision-making about whether or not to conduct an individual RCA is guided by the SAC score (see App. B).

b. **Requirements for Individual RCAs**

(1) At a minimum, each facility must conduct four individual RCAs per year.

(2) Determination of whether or not to conduct an individual RCA continues to be guided by the SAC.

(3) Most VA medical centers do more than four individual RCAs per year based upon their experience with reported adverse events and close calls, and use of the SAC matrix (i.e., four is a "floor" not a "ceiling"). ***NOTE:*** *See Appendix B.* There is no set maximum number of individual RCAs.

(4) If a VA medical center has fewer than four events that require RCAs based on their SAC score, local staff must select other adverse events or close calls and complete one or more individual RCAs to achieve the minimum.

c. **Requirements for Aggregated Reviews**

(1) Every fiscal year, each facility must conduct at least one Aggregated Review per quarter in each of four required areas, and in the following order: Falls, Missing Patients, Adverse Drug Events, and Parasuicides and Outpatient Suicides.

(2) A 15-day "close out period" is available immediately following the data cycle for each of the four categories of Aggregated Review. These 15 calendar days are intended to allow PSMs to finalize and organize the data that has been received during the previous 12 months.

(3) If a facility has zero events in one of the four Aggregated Review categories, an Individual RCA or "wild card" Aggregated Review may be performed to achieve the minimum number of eight Individual RCAs or Aggregated Reviews. If only one event is reported in one of the four aforementioned categories then an individual RCA must be performed on the reported event. The wild card aggregated review may be completed on the same schedule as the aggregated review for which it is being substituted, or may be completed at another time during the fiscal year.

(4) "Wild card" Aggregated Reviews are those completed on a category of adverse event other than one of the four Aggregated Review categories. These may be done on a category of adverse event of the facility's choosing. When the actual or potential SAC score is three for an event that is not in one of the four Aggregated Review categories an RCA must be chartered; the adverse event may not be assigned to a "wild card" Aggregated Review.

d. **Flexibility.** Facilities have flexibility in how they achieve the minimum of eight. For example, a facility could complete: four individual RCAs and four Aggregated Reviews, five individual RCAs and three Aggregated Reviews (one additional Individual RCA for a zero event Aggregated Review category), four individual RCAs and four Aggregated Reviews (with one Aggregated Review being a "Wild Card" Aggregated Review for a zero event Aggregated Review).

e. **Aggregate Review Logs.** A set of Aggregate Review Logs for recording relevant data has been constructed by NCPS in collaboration with representatives from facilities and VISNs for each of the four categories. These logs are available as part of the PSIS using the SPOT application. There is no requirement that these particular logs be used, however, the variables in the NCPS logs must be included among the set of variables for which data are collected if a facility chooses to develop their own customized log. A definition of the NCPS variables for each log can be found on the NCPS Intranet site. ***NOTE:*** *Additional information on Aggregated Review and Aggregated Review Logs is on-line at http://vaww.ncps.med.va.gov/Education/AggRev/index.html.*

9. INFORMING PATIENTS ABOUT ADVERSE EVENTS

a. 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. ***NOTE:*** *Further detailed requirements and guidance can be found in current VHA policy regarding the disclosure of adverse events to patients.*

b. 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 providing any additional health care associated with the adverse event.

c. VHA policy requiring disclosure is consistent with TJC requirements that hospitalized patients and their families be told of "unanticipated outcomes" of care. ***NOTE:*** *TJC's requirement demonstrates a policy commitment that clinicians and health care organizations disclose adverse events to patients and families.*

d. Despite the general obligation to disclose adverse events to patients and families, there are legal restrictions that limit disclosures that violate patient privacy.

(1) 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.

(2) 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.

10. COMPENSATION FOR INJURED PATIENTS

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.

a. 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, a monthly payment for survivors, specially adapter housing grants, and automobile and adaptive equipment allowances. ***NOTE:*** *Claims for 38 U.S.C.1151 benefits are processed by Veterans Benefits Administration (VBA) Regional Offices.*

b. 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.*

c. 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 are offset until the amount that would have been paid equals the amount of the tort claim settlement or judgment.

THE JOINT COMMISSION'S DEFINITION OF REVIEWABLE SENTINEL EVENTS THAT MAY BE REPORTED TO THE JOINT COMMISSION

The following criteria define the subset of Sentinel Events that, at the facility's discretion, are voluntarily reportable, to The Joint Commission (TJC). ***NOTE:*** *As TJC policies are dynamic, it is important to be sure that the most recent TJC Sentinel Event Policies and definitions are used in making any determination. The following text was taken from TJC web page at: http://www.jointcommission.org/SentinelEvents ; this site needs to 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 TJC:

a. 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, or

b. The event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition):

(1) Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting, or within 72 hours of discharge;

(2) Unanticipated death of a full-term infant;

(3) Abduction of any patient receiving care, treatment, and services;

(4) Discharge of an infant to the wrong family;

(5) Rape;

(6) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities;

(7) Surgery on the wrong patient or wrong body part;

(8) Unintended retention of a foreign object in a patient after surgery or other procedure;

(9) Severe neonatal hyperbilirubinemia (bilirubin more than (>) 30 milligrams per deciliter);

(10) Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25 percent above the planned radiotherapy dose.

2. TJC provides detailed footnotes on several of the preceding types of events in their document on sentinel events. Links and a guide to up-to-date TJC policies regarding Sentinel Events and Reportable Sentinel Events are on-line at the National Center for Patient Safety Intranet site: http://vaww.ncps.med.va.gov/.

THE SAFETY ASSESSMENT CODE (SAC) MATRIX

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 in the following, and are followed by information on the SAC Matrix.

1. SEVERITY CATEGORIES

a. 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.

b. 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. Any of the adverse events defined by the Joint Commission as reviewable "Sentinel Events" should also be considered in this category (see App. A, subpar. 1b). **Visitors:** A death; **or** hospitalization of three or more visitors **Staff**: A death or hospitalization of three 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: a. Disfigurement b. Surgical intervention required c. Increased length of stay for three or more patients d. Increased level of care for three or more patients **Visitors:** Hospitalization of one or two visitors **Staff:** Hospitalization of one or two staff **or** three 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 one or two patients **Visitors:** Evaluation **and** treatment for one or two visitors (less than hospitalization) **Staff**: Medical expenses, lost time or restricted duty injuries or illness for one or two 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 The Joint Commission's Environment of Care Standards.

2. PROBABILITY CATEGORIES

a. Like the severity categories, the probability categories apply to actual adverse events and close calls.

b. 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 they are routinely tracked (e.g., falls with injury, Adverse Drug Events (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.

Like the severity categories, the probability categories apply to actual adverse events and close calls.

c. 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 is easily available because the events are 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 the best educated guess.

(1) **Frequent** – Likely to occur immediately or within a short period (may happen several times in 1 year).

(2) **Occasional** – Probably will occur (may happen several times in 1 to 2 years).

(3) **Uncommon** – Possible to occur (may happen sometime in 2 to 5 years).

(4) **Remote** – Unlikely to occur (may happen sometime in 5 to 30 years).

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

Probability and Severity	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 a severity category is paired with a probability category for either an actual event or close call, a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk) results. These ranks, or SACs, can then be used for doing comparative analysis and for deciding who needs to be notified about the event.

5. Reporting

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

b. The Patient Safety Manager, or designee, must 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.