

VHA NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK

- 1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Handbook provides precedence 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 new minimum requirements for root cause analysis and Aggregated Reviews of selected categories of adverse events.
- 3. RELATED DIRECTIVES.** VHA Handbook 1058.1, Requirements for Reporting Research Events to Facility Oversight Committees and the Office of Research Oversight; VA Directive 0700, Administrative Investigations; VA Handbook 0700, Administrative Investigations.
- 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 RESCISSION.** VHA Handbook 1050.1 dated May 23, 2008, is rescinded.
- 6. RECERTIFICATION.** This VHA Handbook is scheduled for recertification on or before the last working date of March 2016.

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VHA NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK

1. PURPOSE

This Veterans Health Administration (VHA) Patient Safety Improvement Handbook provides a procedures used in the accomplishment of VHA's 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 facilities 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 which includes:

(1) Understanding the health care continuum as a system, and exploring system vulnerabilities that can result in patient harm; this being an emphasis in VHA's patient safety improvement initiatives.

(2) Reporting of adverse events and close calls. This is the primary mechanism through which VHA NCPS learns about system vulnerabilities and how to address them. Since 2000, more than 700,000 adverse events and close calls have been reported to the VHA NCPS from VA medical facilities. These reports have provided valuable opportunities to evaluate the identified root causes and contributing factors, as well associated actions and outcome measures to mitigate future events from reoccurring within that facility.

(3) Emphasizing prevention rather than punishment this is 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 the responsibility for improving it resides at all levels of the organization; it requires a 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:** *Training is highly recommended for all Patient Safety Manager’s (PSM) and other identified key staff involved in RCA’s to complement the contents of this Handbook; reading it alone is not sufficient to achieve maximum desired outcomes. Experience has shown that individuals who have not undergone appropriate training have been unable to perform in a consistent and adequate manner. For upcoming training opportunities 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. Additionally, the appropriate issuance of the charge memo invokes this protection.

3. SCOPE

This Handbook:

a. Delineates what types of events are to be considered within the patient safety program and how they need to 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 is 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.*

c. Applies to all VA medical facilities, Community-based Outpatient Clinics (CBOCs), Consolidated Mail Outpatient Pharmacies (CMOPs) and any other VA facility providing medical care to Veterans.

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 facility, 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, and missing patient events. All adverse events require reporting and documentation in the VHA Patient Safety Information System (PSIS), using the “WebSPOT” software application; the type of review required is determined through the Safety Assessment Code (SAC) Matrix scoring process (see App. B).

b. **Aggregated Review.** The Aggregated Review process is a method of analyzing a group of similar incidents or event types to determine common causes, thereby facilitating coordinated actions to prevent recurrences. Issues and incidents reviewed via Aggregated Reviews are those that do not require individual RCAs. The determination of common causes through the use of Aggregated Reviews provides the opportunity to correct minor issues before they lead to serious adverse events. Aggregated Reviews are required in three categories of incidents: falls, adverse drug events and missing patients as described in paragraph 13.

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 WebSPOT. ***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., Administrative Investigative Boards (AIBs)), or other administrative methods as determined by the facility Director and by applicable directives and regulations such

as VA Directive 0700, VA 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 can be done to prevent it from happening again. Unlike RCAs, AIBs can result in individually directed action in addition to systems improvement.

(3) If an event involves what appears to be an intentionally unsafe act, an AIB 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 AIB 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 AIB, but due to confidentiality constraints of RCAs, an AIB 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 AIB. In the event that an AIB is performed after an RCA is started, members of the RCA team are not to serve on the AIB 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. **NOTE:** *The process of conducting AIBs 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, Administrative Investigations.*

(4) Unlike RCAs, peer reviews, and other selected reviews, AIBs 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 AIB 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 AIB be performed prior to the RCA to prevent confidential information derived from an RCA from being improperly used in the AIB in question as well as to avoid the perception that information from an RCA was used improperly (see subpars. 4d(2) and 4d(3)).

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

f. **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 Effect Analysis (HFMEASM) and Failure Mode Effect Analysis (FMEA).

g. **Root Cause Analysis (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 (see par. 7).

h. **Wild Card.** Wild card Aggregated Reviews are those completed on a category of adverse event other than one of the three required Aggregated Review categories. These may be done on a category of adverse event of the facility's choosing. Only actual or potential events with a SAC score of one or two can be used as a wild card aggregate review. When the actual or potential SAC score is three for an event that is not in one of the three Aggregated Review

categories, an individual RCA must be chartered and the adverse event may not be assigned to a wild card Aggregated Review.

5. GOALS

The Patient Safety Program's goal is to prevent harm to patients. This is accomplished by taking 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 requirements 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. 10). The determination of cause is aimed at the system issues and is not to be used as a punitive tool. **NOTE:** *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. 10) in an effective manner.

d. Completing at least one Proactive Risk Assessment, also known as HFMEA per year for each of the TJC-accredited programs. **NOTE:** *The VHA requirement remains one per year (every 12 months) despite the fact that TJC requirement changed to one every 18 months beginning in 2009 and modified or may modify which programs are expected to complete this requirement. (Standard LD.04.04.05 EP10).*

e. Implementing practices appropriate to Department of Veterans Affairs (VA) settings that have shown to be effective in preventing adverse events elsewhere. These include practices from other VA medical facility, 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.

f. At minimum, submitting an end of fiscal year Patient Safety Annual Report to facility leaders that provides an overview of Patient Safety program status. Information may include: program successes, areas for improvement, reports of RCAs, Aggregated Reviews, Sentinel Events, alerts and advisories, etc.

6. RESPONSIBILITY OF THE FACILITY DIRECTOR

The Facility Director is responsible for:

- a. Designating the PSM, and back up, as the point of contact for the distribution and tracking of Patient Safety Alerts and Patient Safety Advisories within the facility, including any impacted CBOCs, domiciliaries and contract care facilities providing care to Veterans.
- b. Ensuring Patient Safety Alert actions and Patient Safety Advisory recommendations are assigned and completed within the timeframes provided with the document.
- c. Ensuring that the NCPS is notified when an issue is detected that could affect other VHA facilities and may require the development of a Patient Safety Alert or Patient Safety Advisory.
- d. Ensuring a minimum of eight patient safety analysis processes, i.e., RCAs and Aggregated Reviews, are completed each fiscal year.

7. ROOT CAUSE ANALYSIS (RCA)

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 must be initiated with a specific charter memorandum, and the term “Root Cause Analysis” must be used in documents so that they are protected and deemed confidential under 38 U.S.C. 5705, and it’s 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 and may include staff with varying levels of experience and educational background.
- (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 must be considered when developing root cause statements:

- (a) Root cause statements must include the cause and effect,
- (b) Negative descriptions will not 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 must 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 must not 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) Identify at least one root cause with a corresponding action and outcome measure.

(f) Include signed concurrence by the facility Director.

(g) Meet NCPS and TJC requirements. WebSPOT must be used to guide teams through the RCA process, document the RCA, and provide information to NCPS and the VISN Patient Safety Officer (PSO).

(5) To be timely, an RCA must be completed, signed by the facility Director and submitted to the NCPS within 45 days of the facility becoming aware that an RCA is required.

8. SENTINEL EVENTS

Sentinel Events are a type of adverse event defined by 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.

(2) Some Sentinel Events are considered reviewable and include the following (see App. A.):

(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,

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

(d) 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.

NOTE: The Joint Commission (TJC) updated its document describing the required responses to sentinel events in July 2007. In general, events considered to be reviewable “Sentinel Events” are included in the catastrophic severity category of the SAC matrix (see App. B).

9. 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) Close Calls (see subpar. 4c).

(3) Sentinel Events (see par. 8).

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 and close calls must be reported within the facility to the PSM, or acting PSM.

d. Any report of an adverse event or close call as defined in subparagraphs 4a, 4c, and paragraph 8, received by the PSM, is protected from disclosure under 38 U.S.C. 5705, as part of a medical quality assurance program. The only exceptions to this protection are 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 must 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 4d are to be recorded as such by using the “Halted” function in the WebSPOT software application.

(3) After an AIB is completed in response to an adverse event or close call that had been initially referred for RCA, that AIB 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 AIB 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 AIB.

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 C.F.R. 1.203. **NOTE:** *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 C.F.R. Section 1.203, 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 Section 1.204, 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 for) 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, rape, aggravated assault, and serious physical abuse of a VA patient.

(3) In accordance with 38 C.F.R. 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 must be made acutely aware that their effort of reporting was not just a paperwork drill. 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 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 must understand that events that are often referred to as human errors are

commonly due to system problems. They must especially 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 described in VHA Handbook 1058.01, Research Compliance Reporting Requirements. An adverse event in research is any untoward physical or psychological occurrence in a human subject participating in research. An adverse event in research can be unfavorable and unintended event, including an abnormal laboratory finding, symptom, or disease associated with the research or the use of a medical investigational test article. An adverse event in research reportable to the Office of Research Oversight (ORO) may also be reportable to the VA facility PSM in accordance with the procedures described in this 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 facilities with a Nuclear Regulatory Commission (NRC) 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 must 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://vaww.lab.med.va.gov/>. **NOTE:** *This is an internal Web site and is not available to the public.*

m. WebSPOT must be used to track and monitor reported events. Data concerning the reported events must be entered into WebSPOT by designated staff at VA medical facilities 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.*

10. 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 App. C, which provides a detailed view of the RCA process. The following description will describe 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 score (see App. B) that then defines what further actions are necessary.

(2) Events receiving an actual and potential SAC score of one or two are to be addressed appropriately 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 an individual RCA or must be included in an Aggregated Review as described in subparagraph 4b; and the initial report of the event must be entered into WebSPOT. Events with a potential SAC score of three that occur in the required Aggregated Review areas (i.e. medications, falls and missing patients), may receive either an Aggregated Review or an individual RCA. Events that receive an actual SAC score of three, and those with a potential SAC score of three that are **not** in the aforementioned three categories, must have an individual RCA completed; an Aggregated Review may not be used.

(4) An Aggregated Review may be used for selected events as described in paragraph 13. The use of aggregated analysis serves two important purposes, it:

a. 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. 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 an individual 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 TJC definition of Reviewable Sentinel Event, the facility must make the determination as to whether they care 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 defined by local policy. **NOTE:** *Additional information on TJC policy can be found at:* http://www.jointcommission.org/Sentinel_Event_Policy_and_Procedures/

(6) The greatest benefit of the RCA process is realized after all the proper steps have been completed and corrective actions defined and implemented, to prevent future occurrences of similar events. 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 WebSPOT. **NOTE:** *APP. D provides a simplified view of the RCA process.*

11. RCA PROCESS REQUIREMENT FOR AGGREGATED REVIEWS AND INDIVIDUAL RCAs

a. To reduce harm to patients, and with input from key VISN and VA medical facility personnel, minimum annual requirements for Aggregated Reviews and individual RCAs that must be completed by each VA medical facility and reported to NCPS have been established. The primary purpose for setting minimum requirements is to encourage facilities to identify and mitigate vulnerabilities in their systems of care and to share their experiences, analysis, and new knowledge gained with the broader VA community. **NOTE:** *These minimum requirements are subject to modification by the Chief Patient Safety Officer in consultation with the Deputy Under Secretary for Health for Operations and Management.*

b. The requirement for a total of eight RCAs and Aggregated Reviews is a minimum number, as the total number of RCAs is driven by the events that occur and the SAC score assigned to them (see App. B). At least four analysis per fiscal year must be individual RCAs, with the balance being Aggregated Reviews or additional individual RCAs. If VA personnel complete the three Aggregated Reviews (i.e., medications, falls, missing patients), then at least five other individual RCAs, or four individual RCAs and a wild card Aggregated Review must be completed within the fiscal year. **NOTE:** *The fiscal year to which the activity is attributed is determined by the date of the facility Director's signature on the completed document.*

12. REQUIREMENTS FOR INDIVIDUAL RCA'S

- a. At a minimum four individual RCAs per year must be conducted at each facility.
- b. Determination of whether or not to conduct an individual RCA is guided by the SAC score, as determined by the PSM.
- c. Most VA medical facilities 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"). There is no set maximum number of individual RCAs.
- d. The following provides a summary of how suicide and suicide attempts are to be evaluated for an RCA.

(1) As a catastrophic event, any inpatient suicide requires an RCA.

(2) All outpatient suicides completed within 72 hrs of discharge from status as an inpatient are TJC Sentinel Events and must be treated as such (i.e., an RCA is required). As of April 2010 VHA requires an RCA for any completed suicide that occurs within 7 days (168 hrs) of discharge from inpatient psychiatric treatment. Specific information on this policy guidance from the Deputy Under Secretary for Health for Operations and Management is online at: <http://vaww.ncps.med.va.gov/Dialogue/pslog/view.asp?eid=571>. **NOTE:** *This is an internal Web site and is not available to the public.* Additional clarification from the Deputy Under Secretary for Health for Operations and Management on the transition of suicide behavior

aggregated review and reporting from patient safety to the suicide prevention coordinators can be found online at <http://vaww.ncps.med.va.gov/Dialogue/pslog/view.asp?eid=446>. **NOTE:** *This is an internal Web site and is not available to the public.* Paragraph 3 of the Deputy Under Secretary for Health for Operations and Management memo from February 10, 2009, states, “PSMs may decide to conduct individual RCAs for out-patient suicides as deemed appropriate; these will remain the responsibility of the patient safety program.” These RCAs will continue to be submitted as part of the patient safety database. **NOTE:** *Additional FAQs can be found at: <http://vaww.ncps.med.va.gov/Dialogue/pslog/attachments/464/FAQs%20Suicide%20Agg%20Transition.pdf> .* **NOTE:** *This is an internal Web site and is not available to the public.*

13. REQUIREMENTS FOR AGGREGATED REVIEWS

- a. Every fiscal year, each facility must conduct at least one Aggregated Review in each of three required areas: falls, missing patients, and adverse drug events according to the NCPS schedule.
- b. A 15-day “close out period” is available immediately following the data cycle for each of the Aggregated Review categories. These 15 calendar days are intended to allow PSMs to finalize and organize the data that has been received during the previous 12 months.
- c. If a facility has zero events in one of the three 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 (see subpar. 4i).
- d. If only one event is reported in one of the three 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.

14. AGGREGATED REVIEWS LOGS

A set of Aggregated Review Logs for recording relevant data has been constructed by NCPS in collaboration with representatives from facilities and VISNs for each of the three categories. These logs are available using the WebSPOT application. **NOTE:** *Additional information on Aggregated Review and Aggregated Review Logs is online at <http://vaww.ncps.med.va.gov/Education/AggRev/index.html> .* **NOTE:** *This is an internal Web site and is not available to the public.*

15. CORNERSTONE RECOGNITION

NCPS recognizes high levels of performance on RCAs and Aggregated Reviews. There are three performance levels, Bronze, Silver and Gold. The basic criteria required for recognition is on time completion of eight patient safety analysis made up of the required RCAs and Aggregated Reviews. There are additional criteria specified for higher level awards. **NOTE:** *Refer to the NCPS Cornerstone Recognition Program requirements for additional information.*

16. PATIENT SAFETY ALERTS AND PATIENT SAFETY ADVISORIES

Patient Safety Alerts and Patient Safety Advisories are issued by the Office of the Deputy Under Secretary for Health for Operations and Management to notify the field when actual or potential threats to the life or health of VHA patients have been identified. Patient Safety Alerts disseminate urgent notices that require specific, mandatory, and timely action on the part of the recipient(s). Patient Safety Advisories are issued when a potential threat due to equipment design, procedural issues, or training has been identified. Patient Safety Advisories provide recommendations that are general in nature and implementation of the recommendations are subject to local conditions and judgment, facilities must either implement the recommendations or implement equivalent or higher level of safety than provided by the recommendations.

17. RESPONSIBILITIES OF THE PATIENT SAFETY MANAGER (PSM)

The PSM is responsible for:

- a. Serving as the point of contact for Patient Safety Alerts and Patient Safety Advisories within the facility, including CBOCs, domiciliaries and contract facilities providing care to Veterans.
- b. Establishing a method to disseminate Patient Safety Alert actions and Patient Safety Advisory recommendations to individuals assigned by the facility Director to carry them out.
- c. Maintaining documentation showing Patient Safety Alert actions and Patient Safety Advisory recommendations have been completed.
- d. Documenting completion of the Patient Safety Alert actions and Patient Safety Advisory recommendations on the VHA Alerts and Recalls Web site within the timeframes specified in the documents.
- e. Using the SAC Matrix to determine what action is required regarding a reported adverse event or close call. The SAC score is not to be determined by any staff other than the PSM, or acting PSM.
 - (1) This action could range from reporting to the VISN PSO, 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 while Appendix C and Appendix D 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 are to be taken.
 - (3) If a safety alert to other facilities seems necessary, the PSM must inform the VISN PSO and NCPS staff within a timely manner either by means of a phone call or by indicating so within WebSPOT question 6. **NOTE:** *Selection of this box will alert NCPS and will open additional required fields to be completed.*

18. RESPONSIBILITIES OF THE NATIONAL CENTER OF PATIENT SAFETY (NCPS)

The NCPS is responsible for:

a. Disseminating important information learned from RCAs and WebSPOT. National Alerts and Advisories to VHA facilities are issued by the Deputy Under Secretary for Health for Operations and Management in concert with NCPS.

b. Providing information based on RCAs using the TIPS Newsletter and using “RCA Topic Summaries.”

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

d. Cooperating with the Office of Medical Inspector (OMI) and the Office of the Inspector General (OIG) as they monitor RCAs and AIBs 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. **NOTE:** Alerts, Advisories, TIPS issues, and RCA Topic Summaries are all available on the NCPS Intranet Web site: <http://vaww.ncps.med.va.gov/index.html>. This is an internal VA link, not available to the public). Much of this information is also available to the public at the NCPS Internet Web site: www.patientsafety.gov or www.va.gov/ncps/.

e. Monitoring the internal VHA Patient Safety Information database, other internal communication channels, and external publications (including those from organizations such as Federal Drug Administration (FDA) and TJC) for information that may require the development of a Patient Safety Alert or Patient Safety Advisory.

f. Prioritizing and researching potential Patient Safety Alert and Patient Safety Advisory topics to determine if dissemination of a Patient Safety Alert or Patient Safety Advisory is required.

g. Distributing Patient Safety Alerts and Advisories that are generated by the NCPS to the Deputy Under Secretary for Health for Operations and Management.

h. Consulting with other VHA program offices, national subject matter experts, other Federal agencies and manufacturers in the development of Patient Safety Alerts and Patient Safety Advisories.

i. Managing the VHA Alert and Recall Management System Web site and ensuring that Patient Safety Alerts and Patient Safety Advisories are posted for tracking and follow up activities.

j. Distributing targeted Patient Safety Alerts when it is determined that 10% or fewer facilities are impacted by the Alert topic.

k. Sharing Alerts and Advisories with representatives of the Department of Defense's Patient Safety Program, other federal agencies, and via the internet, as appropriate.

19. 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 should 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.

(1) Specifically, confidentiality laws such as the Privacy Act, HIPAA, and several provisions of title 38, limit 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.

(3) For more detail regarding disclosures of patient medical records, see VHA Handbook 1605.1.

20. COMPENSATION FOR INJURED PATIENTS

The two primary options available to injured Veterans, 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. Benefits under 38 U.S.C. 1151 are available only for injuries or deaths resulting from treatment of a Veteran (not non-Veteran patients, such as a spouse receiving treatment due to CHAMPVA eligibility). 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 potentially provide for the payment of a monthly benefit based on the percentage of disability, a monthly payment for survivors, specially adapted housing grants, clothing, 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 cases paid either through settlement or judgment, VHA's Office of Medical-Legal Affairs (OMLA) will conduct a review that 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. When proper procedures are followed (see VHA Directive 2008-077, Quality Management (QM) and Patient Safety Activities that can Generate Confidential Documents) information contained in RCAs and other quality improvement materials is protected from disclosure to claimants in response to tort claims under 38 U.S.C. 5705 and will 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/Sentinel_Event_Policy_and_Procedures/; 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/> (**NOTE:** *This is an internal VA link, not available to the public.*)
http://www.jointcommission.org/Sentinel_Event_Policy_and_Procedures/ .

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 <u>Patients with Actual or Potential:</u> 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).	Major <u>Patients with Actual or Potential:</u> 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: <ul style="list-style-type: none"> 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
Moderate <u>Patients with Actual or Potential:</u> Increased length of stay or increased level of care for one or two patients	Minor <u>Patients with Actual or Potential:</u> No injury, nor increased length of stay nor increased level of care

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:

(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).

(5) **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.

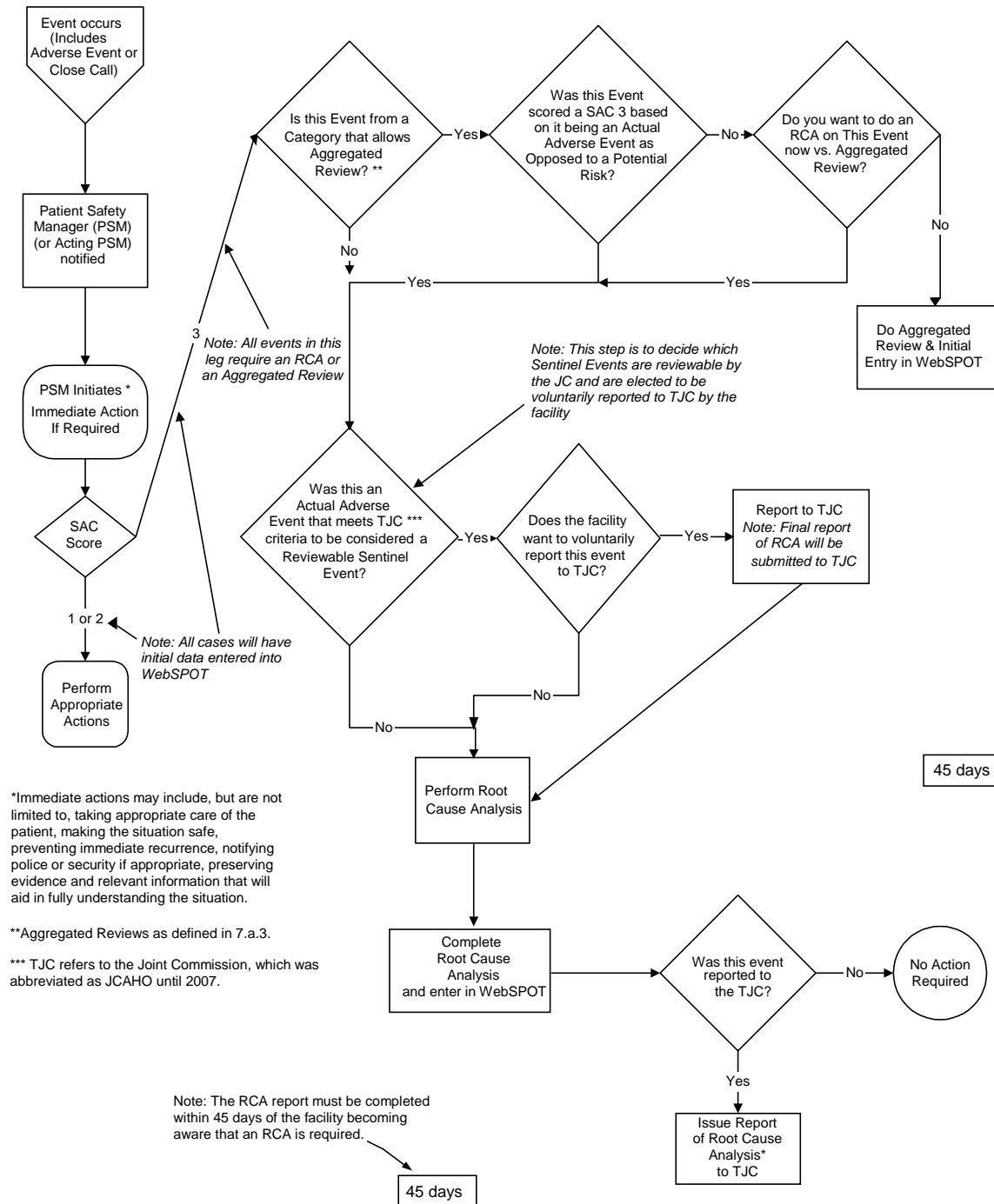
5. REPORTING

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 (PSM), or acting PSM, 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.

Detailed View of the Event Evaluation and Reporting Process

NOTE: This does not apply to events thought to be intentionally unsafe



Simplified View of the Root Cause Analysis (RCA) Process

NOTE: This does not apply to events thought to be intentionally unsafe

