

DEPARTMENT OF THE ARMY  
U.S. ARMY MEDICAL DEPARTMENT ACTIVITY  
FORT HUACHUCA, ARIZONA 85613-7079

MEDDAC MEMORANDUM  
NO. 40-27

22 August 2006

Medical Services  
PATIENT SAFETY (PS)/RISK MANAGEMENT (RM) PROGRAM

	Para	Page
HISTORY-----	1	1
PURPOSE-----	2	1
SCOPE-----	3	2
REFERENCES-----	4	2
GENERAL-----	5	2
GOALS & OBJECTIVES-----	6	3
RESPONSIBILITIES-----	7	3
APPENDIX A, PROCEDURES FOR COLLECTIONS AND ASSESSMENT OF DATA-----		A-1
APPENDIX B, PROCEDURE FOR DISPOSITION OF EQUIPMENT/ MEDICATION INVOLVED IN INCIDENT-----		B-1
APPENDIX C, RISK MANAGEMENT COMMITTEE-----		D-1
APPENDIX D, INDICATORS OF POTENTIAL RISK-----		C-1
APPENDIX E, DA 4106, INCIDENT REPORT-----		E-1
APPENDIX F, SAFETY ASSESSMENT CODE MATRIX-----		F-1
APPENDIX G, ROOT CAUSE ANALYSIS-----		G-1

1. HISTORY. This issue publishes a revision to this publication.

2. PURPOSE. The purpose of the Raymond W. Bliss Army Health Center (RWBAHC) RM program is to prevent harm and ensure the safety of patients, visitors, staff, and to minimize financial loss to the government through identifying, measuring, and controlling undesirable occurrences that place the U.S. Army Medical Department Activity (USA MEDDAC) at risk. In addition, and in coordination with the Patient Safety Program, support an organizational culture that emphasizes cooperation and communication, encourage reporting of potential and actual events, focus on error prevention rather than punishment, and improve medical systems and processes to overcome preventable errors. The PS program defines processes within the performance improvement structure for assessing high-risk functions/processes, i.e., reporting, reviewing, and analyzing risk and safety data and initiating corrective measures to reduce and prevent future occurrences.

---

\*This memorandum supersedes MEDDAC Memo 40-27, 25 January 2001

3. SCOPE. The RWBAHC RM program includes the identification, investigation, measurement, and control of risk at this facility. It applies to all patients, visitors, and staff.

4. REFERENCES.

4.1 AR 40-68, Quality Assurance Administration, current edition.

4.2 AR 27-40, Litigation, current edition.

4.3 MEDCOM Reg 40-41, The Patient Safety Program, current edition.

4.4 JCAHO, Comprehensive Accreditation Manual for Ambulatory Care, current edition.

5. GENERAL.

5.1 Risk occurs when an incident occurs involving a patient, visitor, or staff member that is not consistent with the routine operation of RWBAHC. An adverse event occurs when a patient suffers any unintended or unexpected negative result during patient care. Immediate action will be taken to ensure that the patient is protected from additional injury and to mitigate the untoward effects of the event. The primary provider will inform the patient of the effects of his/her health and the prognosis. Effective medical/health care error reduction requires an integrated approach and a supportive environment in which patients, their families, organization staff, and leaders can identify, manage, and learn from actual and potential risk.

5.2 A successful program facilitates a non-punitive, interdisciplinary approach to decrease unanticipated adverse health outcomes. The RWBAHC fosters and supports an organizational environment that recognizes and acknowledges potential risks and the occurrence of medical/health care errors. When an event occurs, the person in charge of the department/ service will ensure a DA Form 4106, Incident Report, is completed. The DA 4106, Incident Report can be found on Form Flow. (The person in charge may not necessarily be the individual completing the form, but will be ultimately responsible for its completion). All DA 4106s will be completed, be legible, and forwarded to the respective clinic, service, or department chief within 24 hours of discovery. The DA 4106 must be submitted to the Risk Management coordinator (RMC) within 48 hours of the incident. Any employee of the facility may initiate a DA 4106.

5.3 The report should be factual and objective, providing full details in a concise manner. Analysis or speculation regarding the event should not be included in the report. All completed forms are to be maintained by the RMC. These documents are considered quality assurance documents and accessible to authorized personnel only. Entries in the patient medical record should only address evidence of patient injury and treatment provided the patient. The medical record entries should not conclude that an adverse event or accident occurred. In addition, telephonic notification to the RMC facilitates handling of occurrences.

5.4 Indicators of potential risk are at Appendix D.

5.5 Threshold for evaluation: Each indicator will receive 100 percent review.

5.6 All data will be maintained by location, service, and provider. The data will be monitored, on an ongoing basis, by the RM Committee and may warrant a focused review at any time designated by the committee. The JCAHO Integration Committee (JIC) reviews the PS/RM Committee Minutes.

## 6. GOALS AND OBJECTIVES.

6.1 The goals of the RM program are to identify and reduce risk at RWBAHC, to promote beneficial health care practices, and to provide a safe environment for patients, visitors, and staff.

6.2 Meeting these goals is a continuous process undertaken as a major component of the RWBAHC Performance Improvement program. The RM program objectives are:

6.2.1 To assure that each occasion of risk is immediately identified and reported and that appropriate action is taken to reduce the potential of similar incidents/injuries from recurring.

6.2.2 To assure that trends or patterns of risk are identified and that appropriate action is taken to reduce those trends.

## 7. RESPONSIBILITIES

7.1 The RWBAHC Commander:

7.1.1 Is responsible for effective implementation and compliance of the AMEDD PS/RM policy.

7.1.2 Promotes a culture that emphasizes cooperation and communication, encourages reporting of medical errors, focuses on error prevention rather than punishment, and improves medical systems and processes to overcome preventable errors.

7.1.3 Allocate the resources required to sustain a comprehensive, integrated PS/RM program.

7.1.4 Promote strategies to encourage and facilitate staff identification and reporting of close calls/near misses and actual events.

7.1.5 In serious incident of death or serious bodily injury resulting from potentially substandard care, the Commander will:

7.1.5.1 Immediately detail the Health Care Provider (HCP) involved to non-clinical duties. The HCP's privileges will be placed in abeyance until the incident has been reviewed IAW AR 40-68.

7.1.5.2 Initiate an immediate investigation using an investigating officer or an investigating officer requested through Great Plains Regional Medical Command.

7.1.5.3 Telephonically notify USA MEDCOM.

7.1.5.4 Ensure that confidentiality of all records and written reports are protected IAW the National Defense Authorization Act.

7.1.5.5 Initiate Sentinel Event notification procedures as outlined in MEDDAC Memo 40-159, Sentinel Event Policy.

7.2 The Deputy Commanders:

7.2.1 The Deputy Commander for Clinical Services is responsible for oversight of the PS/RM programs and serves as chairperson of the interdisciplinary committee.

7.2.2 Ensure that PS/RM programs activities are implemented, monitored, and evaluated for effectiveness.

7.2.3 Support an organizational culture that emphasizes cooperation and communication, encourages reporting of potential and actual events, focuses on error prevention rather than punishment, and improves medical systems and processes to overcome preventable errors.

7.2.4 Facilitate orientation and ongoing education of all staff regarding their roles and responsibilities.

7.2.5 Promote support/assistance to staff members involved in a sentinel event (SE).

7.2.6 Ensure that a qualified health care professional informs the patient or family member(s), according to the provisions of this regulation, when an event results in an unanticipated outcome of care.

7.3 Chief, Department/Service/Clinic and Management/Supervisory Staff:

7.3.1 Ensure PS/RM activities are implemented, monitored, and evaluated for effectiveness and actively participate in these processes.

7.3.2 Facilitate orientation and ongoing education of all assigned staff regarding their roles and responsibilities in the PS/RM programs.

7.3.3 Actively participate and facilitate the acknowledgement of reports and timely feedback to individuals who report events.

7.3.4 Facilitate coordination, integration, and implementation of inter/intradepartmental PS/RM initiatives.

7.3.5 Make recommendations for improving PS/RM to the Patient Safety Manager/Risk Management Coordinator (PSM/RMC) and/or PS/RM committee/functional team.

7.3.6 Promote support/assistance to staff members involved in SEs.

7.3.7 Designate a qualified health care professional to inform the patient or family member(s) when an event results in unanticipated outcome of care.

7.3.8 Ensure that staff members educate patients/family members on their roles and responsibilities related to the safe delivery of care.

7.4 Chief, Logistics and Pharmacy Service will, in addition to the responsibilities defined for department chiefs, facilitate notification of the PSM/RMC and appropriate department/service chiefs regarding all product liability complaints/recalls.

7.5 Patient Safety Manager may be expected to exercise broad oversight and to collaborate with various key staff to ensure the effective integration of the PS functions by the organization. The PSM should be included in all activities involving PS issues. The PSM will:

7.5.1 Manage and facilitate the successful implementation and sustainment of the AMEDD PS program within RWBAHC.

7.5.2 Provide expertise and guidance, in conjunction with the RMC, to staff members in the areas of risk assessment, prospective analyses, aggregate analyses, RCA, and the development and evaluation of action plans.

7.5.3 Serve as RWBAHC liaison to the USAMEDCOM Patient Safety Center (PSC).

7.5.4 Coordinate, facilitate, and educate all assigned personnel on their roles and responsibilities in PS, to include reporting of all PS events, participating in PS activities, and educating patients/ families regarding all aspects of the safe delivery of care.

7.5.5 Ensure that both staff and beneficiaries are surveyed, according to current DOD guidance, to determine their perceptions of PS within their health care organizations. The PSC will provide the survey tool and instructions for its use.

7.5.6 Implement a process to receive and centrally manage all PS event reports from clinical and administrative staff and/or patients and families.

7.5.7 Evaluate each PS event report, either independently or as part of a RWBACH team and, based on the assigned SAC, determine the appropriate level of review or analysis required.

7.5.8 Acknowledge the receipt of PS reports and provide timely feedback to staff members who submit PS reports and/or plans for process/system improvements.

7.5.9 Oversee the investigation of all SEs to ensure coordination of all data collection activities, completion of a thorough and credible RCA, development of an action plan, and required reporting through channels to the appropriate agencies.

7.5.10 Ensure that PS action plans are implemented, evaluated for effectiveness, and communicated both internally and to the appropriate external organizational entities.

7.5.11 Maintain the PS database and submit information and reports regarding PS events, near-miss/close calls, RCAs, action plans, and aggregate data to the PS committee and USA MEDCOM PSC.

7.5.12 Review, aggregate, and analyze reports of all near-miss/close calls, adverse events, and SEs, to include written findings and recommendations for improvements in systems and processes to reduce the frequency and severity of patient harm.

7.5.13 Serve as a member of the PS committee and provide the committee, as well as all levels of staff, information regarding MTF, corporate, and nationwide PS alerts, updates, and initiatives.

7.5.14 Present opportunities for improvement related to organizational risk assessment(s), with recommendations for identified risks, implementation plans, and follow-up activities to the PS committee and USA MEDCOM PSC for action.

7.5.15 Oversee the education of the beneficiary population regarding the role of patients/family members in the identification of PS-related issues.

7.5.16 Ensure effective feedback to appropriate personnel on lessons learned and process/system improvements that has been or will be initiated.

7.5.17 Coordinate with Risk Management Coordinator on patient safety and risk management issues.

7.6 All RWBAHC Personnel:

7.6.1 Fully understand and take responsibility for their roles in the PS/RM programs.

7.6.2 Actively participate in creating a safe environment for themselves, peers, patients, and families by meeting organizational and professional standards, following identified best/safe practices, and proactively mitigate unsafe conditions or situations.

7.6.3 Complete organization/unit-based orientation and participate in ongoing education related to PS/RM activities.

7.6.4 Voluntarily report all close calls/near misses, adverse events, and/or SEs.

7.6.5 Initiate immediate steps to ensure patient and staff safety and secure any supplies/equipment that may have precipitated a PS event in order to prevent and/or mitigate future patient harm. Initiate a medical materiel complaint in accordance with AR 40-61 if the event was caused or exacerbated by a supply or equipment problem. Submission of this complaint also satisfies the reporting requirement of the Safe Medical Devices Act of 1990.

7.6.6 Educate patient/families in their roles and responsibilities to facilitate the safe delivery of care.

7.6.7 Remain informed of recommended successful best/safe practices and safety alerts.

7.6.8 Immediately report to their supervisor an incident in which he/she has first-hand knowledge. Prepare the report IAW paragraph 5 of this memorandum. The supervisor will report it to the department chief within 24 hours of the event.

7.6.9 Take DA 4106 to the RMC/PSM within 48 hours of the event.

7.6.10 Be alert to preventing accidents and occurrences.

7.6.11 Perform his/her job as safely as possible.

7.6.12 Report potential safety hazards or problems to his/her supervisor and Safety NCO.

7.6.13 Maintain training regarding safety IAW facility safety policy.

7.6.14 Personally correct potential safety hazards whenever possible.

**7.7 Officer-In-Charge/Supervisor:**

7.7.1 Review incidents or accidents, which are reported, then evaluate and make recommendations for any corrective action, which may be required.

7.7.2 Be alert to potential safety hazards and procedural problems.

7.7.3 Ensure that subordinates perform tasks safely using proper procedures and safe equipment.

**7.8. Risk Manager (DCCS)/Risk Management Coordinator will:**

7.8.1 Identify if, in fact, a Sentinel Event has occurred. If so, follow guidelines outlined in MEDDAC Pam 40-159, Sentinel Event Policy.

7.8.2 Screen all incidents listed in Appendix E to determine whether or not they require physician intervention and/or RM peer review.

7.8.3 Promptly investigate all serious incidents and ensure that investigations are completed within 30 days. Obtain written statements from all individuals having significant knowledge of the event.

7.8.4 If warranted, convene a meeting of the RM Committee as soon as possible after the event, ensuring that all personnel having knowledge of the event are present.

7.8.5 Identify any actions needed to preclude recurrence of the incident.

7.8.6 Notify the Claims Judge Advocate (CJA) within 24 hours of identifying a potentially compensable event (PCE) and coordinate further review.

7.8.7 Notify USA MEDCOM of serious medical or sentinel events.

7.8.8 Coordinate with the Chief, Logistics Division quality control procedures for medical material. For incidents involving medical equipment or material, every effort will be made to secure actual material (i.e., needles, drugs, packages (with manufacturer's literature), etc).

7.8.9 Identify Inspector General Requests or Congressional Inquiries, which require Performance Improvement investigation (QA 15-6).

7.8.10 Assess all incidents, occurrences, patient complaints, Inspector General Request and Congressional Inquiries to ascertain if the patient has sustained damage.

7.8.11 If damage has occurred, ensure that proper notification to the patient has been made and documented.

7.8.12 Mitigate the damages to any extent possible through continued medical care, to include use of supplemental funds if necessary.

7.9. Risk Management Coordinator will:

7.9.1 Maintain data on adverse events and claims to include clean copies of all medical records, performance improvement investigative reports, and peer review data. Data files will be maintained IAW USA MEDCOM guidance for RM files.

7.9.2 Ensure medical records involved in litigation, or those where potential litigation has been identified, are placed in special handling and released only at the direction of the Risk Manager.

7.9.3 Compile data to identify trends and report to the RM Committee. Recommend action to correct undesirable trends.

7.9.4 Initiate DA 2562 reporting to USA MEDCOM.

7.9.5 Coordinate with Patient Safety Manager on patient safety and risk management issues.

7.10. Chief, Patient Administration Division.

7.10.1 Determine the completeness of medical records involved in an incident prior to any actions. Records will be copied within

two working days, with consideration of the size of the medical record. Each record will be assembled in the proper order and each page numbered in ink.

7.10.2 Provide official photocopies of records to the RMC.

7.10.3 Secure original copies of all medical records identified by the RMC and release such records only under direction of the Risk Manager or RMC.

7.11. Medical Claims Judge Advocate (MCJA):

7.11.1 Is a non-voting member of the PS/RM Committee, acting in an advisory capacity to assist with the identification of potential claims. It will be the responsibility of the active committee members to assist with identifying potential claims, and once the committee has done so, the CJA becomes responsible for preparing to defend against any claims actually made. Collect additional information as necessary.

7.11.2 In cases of actual or potential claims of medical malpractice, act as the RWBAHC point of contact for release of medical records.

7.11.3 Provide monthly reports to the committee concerning claims and potential claims. Evaluate risk trends and recommend action to improve undesirable trends.

7.11.4 Coordinate with the U.S. Army Claims Service as required.

The proponent of this publication is the Quality Management Div. Users are invited to send comments and suggested improvements on DA Form 2028 directly to USA MEDDAC, ATTN: MCXJ-QM, Fort Huachuca, AZ 85613-7079.

FOR THE COMMANDER:

OFFICIAL

GREGORY A. SWANSON  
LTC, MS  
Deputy Commander for  
Administration

ROBERT D. LAKE  
Information Management Officer

DISTRIBUTION: C

**APPENDIX A**  
**PROCEDURES FOR COLLECTION AND ASSESSMENT OF DATA**

1. Immediately report each incident on DA Form 4106.
2. Complete the DA Form 4106, in original only, and give to the RMC within 48 hours.
3. If the incident has the potential for severe or permanent injury, notify the RMC immediately, by telephone or in person. Complete a DA 4106 and hand carried to the RMC within 48 hours. If the incident occurs after duty hours, deliver the DA 4106 by 0800 the next duty day.
4. All DA 4106s will be neat, legible, accurate, and complete all the blocks that apply. Information on the form should answer the questions Who, What, When, Where, How, and Action Taken. In Section 11, Description of Incident, a narrative will give factual information surrounding the event and information concerning any factors that may have contributed to the incident, such as, condition of equipment, area, etc.
5. When an incident involves a patient, complete documentation in block 13 will include the patient's name, social security number, status, phone number, known allergies, and where their medical record are maintained.
6. Sources of Risk Management or potential quality issues:
  - a. New litigation or claims processed through the CJA.
  - b. DA 4106.
  - c. Complaints registered through the Patient Advocate.
  - d. Physician concerns.
  - e. Peer review.

- f. Occurrence screening.
- g. Sentinel Event Monitors.
- h. Inspector General Complaints.
- i. Congressional Inquiries.

7. Process and Procedures of Risk Management Review: All RM issues will be forwarded to the RMC, Quality Management Division, RWBAHC for assignment of a tracking number and initial screening category:

a. All DA 4106's will be assigned a Safety Assessment Code Matrix Severity Categories and Probability Recurrence (Appendix G).

b. All cases will be brought to the attention of the DCCS, by the RMC, for further disposition. All cases will afford individuals and processes due process.

c. The case and all documentation will be forwarded to the individual or provider of concern for additional information, explanation, and mitigating factors.

d. The case will then be forwarded to the department chief or supervisor for review of all documentation and designation of standard of care.

e. The DCCS will then designate appropriate personnel for peer review of the case, if necessary. This review will also determine standard of care.

f. The DCCS will provide a final review of the case. If Standard of Care is met, the DCCS will determine final disposition of the case. If Standard of Care is Not Met, the DCCS will forward the case to the RM Committee for final disposition.

g. At the RM Committee meeting, the provider of concern will have the opportunity to submit a written statement concerning the case, as well as an opportunity to discuss the case before the RM Committee. The appropriate department chief will present the case. Upon review and deliberation of all facts concerning the case, the RM Committee will vote on the standard of care by secret ballot.

8. Reporting a disposition of cases of substandard care.

a. When the RM Committee determines the standard of care was not met, they will refer the case to the Credentials Committee for action. The provider identified, in the provider factors of the case review, will be referred to in this process as the 'provider of concern'.

b. For privileged providers at RWBAHC, the supervisor shall be the department chief.

c. For nursing personnel at RWBAHC, the supervisor shall be the Deputy Commander for Nursing (DCN).

d. For privileged providers no longer assigned to RWABHC the supervisor will be the DCCS.

e. For nursing personnel no longer assigned to RWBAHC the supervisor will be the DCN.

f. For department chiefs, the supervisor will be the deputy commander in that department chief's chain of command.

g. For members of the RWBAHC chain of command, the entire case will be referred to Quality Management at Great Plains Regional Medical Command.

h. The supervisor will discuss the case with the provider of concern and will advise the provider of his/her opportunity to submit another statement in writing and/or discuss the case before the Credentials Committee. The provider of concern and the supervisor will sign a memorandum for record describing the events of this meeting. Provide a copy of the memorandum to the RMC.

i. The supervisor may initiate administrative or legal action against the provider of concern regardless of the process, if the supervisor deems it necessary. Those actions are separate from and not linked to the risk management process.

j. The Credentials Committee will review the case and interview those involved persons that they deem necessary to form an assessment and determination of what actions to take. The provider of concern may address the committee. This deliberation is a quality assurance proceeding; therefore, counsel will not be included.

k. Following the Credentials Committee review, the committee may recommend several actions to the commander:

(1) Take no action and file all documentation of the RM case in inactive closed files.

(2) File the case in the Provider Activity File (PAF) for tracking and trending purposes.

(3) Proceed with adverse privileging actions, i.e., suspend, revoke or restrict privileges.

(4) Report the case to MEDCOM Quality Management.

(5) Corrective Action Plans to include:

(a) Required provider education.

(b) Required provider's staff education.

(c) Required provider re-certification or re-privileging.

(d) Required staff education.

(e) Required provider corrective action plan.

(f) Monitor provider performance.

(g) Provider initiated Corrective Action Plan.

(h) Prospective/retrospective trending.

(i) Other.

(j) None.

(5) The commander may approve the action, disapprove the action and take alternative action, or return the case for reconsideration.

(6) All documentation concerning the action will be filed with the RMC. Communicate the decision to the provider of concern in writing. The provider of concern will be afforded the right of appeal through the chain of command, or through the provisions of AR 40-68.

l. Patient complaints regarding medical care or alleged injury:

(1) Investigation will be coordinated by the RMC.

(2) A summary reply will be provided to the Patient Advocate and all coordinating documentation maintained in the RM files.

m. Inspector General requests regarding patient care or alleged injury.

(1) The RMC will be notified of the nature of the alleged incident and identity of the patient involved.

(2) A performance improvement review (QA 15-6) of the incident will be conducted and a summary reply will be provided to the Inspector General. All data will be maintained in the RM files.

n. Congressional Inquiry requests concerning patient care or alleged injury.

(1) A performance improvement review (QA 15-6) of the incident will be conducted.

(2) A copy of the reply to the Congressional Inquiry and the performance improvement review will be maintained by the RMC.

**APPENDIX B  
PROCEDURES FOR DISPOSITION OF EQUIPMENT/MEDICATION  
INVOLVED INCIDENT**

The following procedures will be implemented whenever an equipment malfunction results in an injury, or is suspected of causing an injury, to a patient, visitor, or staff member.

a. The RMC will be notified of the incident immediately, Logistics Division will provide a copy of the submitted medical material complaint.

b. The RMC will immediately notify GPRMC that a complaint has been received.

c. The equipment will be secured, at a location determined by the Chief, Logistics Division and not sent to Clinical Engineering without prior approval of the RMC in consultation with the CJA. The equipment will be inspected to determine if an independent appraisal is required. The supplier and manufacturer will be notified and given an opportunity to inspect the equipment. All parts, equipment, purchase records, and maintenance records will be secured by the Chief, Logistics Division.

d. If the incident involves a patient, the injury will be fully documented in the applicable medical record.

e. The following procedure will be implemented whenever a medication is suspected of causing serious injury to a patient:

(1) The Pharmacy will be notified and the suspected medication will be immediately suspended from use, and the adverse reaction reported on DA 4106.

(2) A sample of the suspected medication, with original packaging indicating manufacturer and lot number, will be delivered to the RMC for safekeeping.

(3) Committee minutes will summarize activities to include problem trends with recommendations for resolving them. The minutes will be processed through the Executive Committee. Sensitive information will not be included in the minutes, but will be kept on file in the Quality

Management Division. Health Care Provider specific findings will be reported to the Credentials Committee.

(4) The RMC will, in coordination with the CJA, determine the appropriate disposition of all equipment and/or medication involved in occurrences of this nature.

**APPENDIX C**  
**PATIENT SAFETY/RISK MANAGEMENT (PS/RM) COMMITTEE**

1. The PS/RM Committee is a multidisciplinary committee consisting of a majority of physicians, to include the DCCS (Chairperson); Deputy Commander for Nursing; Chief, Internal Medicine Service; Chief, Department of Specialty Services; Chief, Department of Behavioral Health; Chief, Department of Military Medicine; Chief, Department of Primary Care; Chief, Department of Anesthesia & Perioperative Services; Chief, Ancillary Service; Chief, Preventive Medicine, Wellness & Readiness Service (PMWARS); Chief, Medication Management and CJA. The committee meets monthly. Other services/departments attend when deemed necessary by the chairperson.

2. Committee minutes will summarize activities to include problem trends with recommendations for resolving them. The minutes will be processed through the JIC. Sensitive information will not be included in the minutes, but will be kept on file in the Quality Management Division. Health Care Provider specific findings will be reported to the Credentials Committee. The following reports are reviewed at the RM Committee:

- a. DA 4106s.
- b. CJA Report (status of pending claims).
- c. Panel Conducting a Root Cause Analysis (RCA) will Complete the analysis within 30 days and forward the analysis to the RMC (see Appendix H). The peer reviewer will present the findings to the RM Committee at the next scheduled meeting.

**APPENDIX D**  
**INDICATORS OF POTENTIAL RISK**

1. An unplanned or undesirable event, which occurs on the premises and may or may not occur as a result of USA MEDDAC activities.
2. Medical errors, which are the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim.
3. Medication error: Any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures and systems including prescribing, order communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.
4. Cardiac or respiratory arrest.
5. An unplanned return to the operating room, or unplanned admission after surgery.
6. Patient complaints regarding care received, to include PCM change requests.
7. Incident reports of unusual occurrences.
8. Inspector General requests regarding care received.
9. Congressional Inquiries regarding care received.
10. Litigation brought against the facility or staff.



1. **PURPOSE.** To provide an effective method of documenting events which may have quality assurance/risk management implications involving patients, visitors, or others. The reported data are used to monitor, evaluate, and improve functional processes, the environment of care, as well as the quality and safety of patient care and services. Based on the nature of the incident, other documentation (e.g., Patient Safety, Risk Management, etc.) may be required IAW local policy.
2. **RESPONSIBILITY.** The staff member who discovers the event or incident will initiate this document. All incidents should be recorded as soon after discovery as possible.
3. **DIRECTIONS FOR COMPLETION OF FORM.**
  - a. Block 1-16. Fill in all numbered blocks. If "Not Applicable" or "None", so state. If "Other" is marked for any response, please explain in the blank space provided, or in Block 11, Description of Incident.
  - b. Block 5. For those incidents involving harm, or the potential for harm, to a patient (inpatient or outpatient), refer to MTF Patient Safety guidance for additional documentation requirements.
  - c. Block 6. A patient may be involved in an incident that is *not* classified as a Patient Safety event, i.e., personal harm, or the risk of harm, was not present. Examples include: loss of valuables, a verbal altercation with another patient, etc.
  - d. Block 7.
    - (1) For an adverse drug reaction, also complete FDA Form 1839, Adverse Reaction Report (Drugs and Biologics).
    - (2) For a blood products reaction, also complete the bottom portion of SF 518, Medical Record - Blood or Blood Component Transfusion and any other local documentation IAW MTF policy.
    - (3) For patients who depart AMA/Left without Being Seen, also complete DA Form 5009, Release Against Medical Advice.
    - (4) For medical equipment related incidents, contact Logistics Division for other required action IAW AR 40-61.
  - e. Block 8. Indicate the initial effect or injury (physical or psychological) sustained by those involved in the incident being reported. Individuals who are injured as a result of an incident or adverse event should be referred immediately for medical attention. The facility Risk Manager will be notified of any incident that results in harm to the individual(s) involved.
  - f. Block 9. List any witnesses to the event that may be asked to provide additional verbal or written information.
  - g. Block 10. Note the departments involved with this incident to ensure that corrective action, if appropriate, can be taken.
  - h. Block 11. Provide a brief but concise explanation of what occurred. Avoid speculation related to the cause of the incident.
4. **ROUTING OF FORM.** This document should be forwarded through appropriate local channels. At a minimum, it should be staffed within 24 hours of incident identification through the Departments/Services concerned. This form will be submitted to the MTF Patient Safety Manager, Risk Manager, or other responsible individual IAW local policy, NLT 48 hours after the event.
5. **DEFINITION OF TERMS.**
  - a. Actual Event/Incident - A situation that did occur either with or without harm or injury to the individual(s) involved.
  - b. Harm - Personal injury or damage of a physical or a psychological nature as a result of an incident.
  - c. Near Miss/Close Call - An event or situation that could have resulted in harm or injury to the individual(s) involved but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the individual(s) involved.
6. **ADDITIONAL COMMENTS/DATA.**

**APPENDIX F  
SAFETY ASSESSMENT CODE MATRIX**

**Severity Categories**

Key factors for the severity categories are: extent of injury; length of stay; and level of care required for remedy. The four categories below apply to actual adverse events.

For **actual close calls/adverse events**, assign severity based on the patient's actual condition. Some incidents that occur may have such an overwhelming potential for a catastrophic event that an RCA will also be necessary, but that determination will be left to the discretion of the MTF.

<b>Catastrophic</b>	<b>Major</b>
<p><b><u>Patients with Actual:</u></b> 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).</p> <p>Suicide (inpatient or outpatient)</p> <p>Rape</p> <p>Hemolytic transfusion reaction</p> <p>Surgery/Procedure on the wrong patient or wrong body part</p> <p>Infant abduction or infant discharge to the wrong family</p> <p>Death or major permanent loss of function that is a <b>Direct result</b> of injuries sustained in a fall; <b>or associated With</b> an unauthorized departure from an around-the-clock treatment setting; <b>or the result</b> of an assault or other crime</p>	<p><b><u>Patients with Actual:</u></b> 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).</p> <p>Disfigurement</p> <p>Surgical intervention required</p> <p>Increased length of stay or level of care of 3 days or more</p>
<b>Moderate</b>	<b>Minor</b>
<p><b><u>Patients with Actual:</u></b> Increased length of stay or higher level of care for less than 3 days</p>	<p><b><u>Patients with Actual:</u></b> No increased length of stay or increased level of care</p>

*Adapted (in part) from the VA National Center for Patient Safety*

**Probability Recurrence**

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

In order to assign a probability rating for an adverse event or close call, it is ideal to know often it occurs at your facility. Sometimes, the data will be easily available because it is routinely tracked (e.g., falls with injury, medication errors, etc.). Sometimes, getting a feel for the probability of events which 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.

**High** – Likely to occur immediately or within a short period of time

**Medium** – Likely to occur several times in 1 to 2 years.

**Low** –May happen greater than two years.

**How the SAC Matrix Looks**

PROBABILITY	SEVERITY			
	Catastrophic	Major	Moderate	Minor
High	3	3	2	1
Medium	3	2	1	1
Low	3	2	1	1

**How the SAC Matrix Works**

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

**Notes**

1. All known reporters of events, regardless of SAC score (1,2, or 3), will receive appropriate and timely feedback.
2. The Risk Manager (or designee) will refer adverse events or close calls related solely to staff, visitors or equipment/facility damage to relevant facility experts or services on a timely basis, for assessment and resolution of those situations.
3. A quarterly Aggregated Root Cause Analysis may be used for two types of calls (this includes all events or close calls other than actual SAC 3s, since all actual SAC 3s require an individual RCA). These two types are: falls, and medication errors. The use of aggregated analysis serves two important purposes. First, greater utility of the analysis (i.e., trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases). Second, it makes wise use of the RCA team's time and expertise.

Of course, the facility may elect to perform an individual RCA rather than Aggregated Review on any adverse event or close call that they think merits that attention, regardless of the SAC score.

\*29 CFR 1960.70 requires each federal agency to notify OSHA within 8 hours of a work-related incident which results in the death of an employee or the in-patient hospitalization of 3 or more 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.

*Adapted (in part) from the VA National Center for Patient Safety*

**APPENDIX G  
ROOT CAUSE ANALYSIS (RCA)**

Guidelines for Conducting an RCA:

1. An RCA will be considered acceptable if it has the following characteristics:

a. The analysis focuses primarily on systems and processes, not individual performance.

b. The analysis progresses from special causes in clinical processes to common causes in organizational processes.

c. The analysis identifies changes, which could be made in systems and processes, either through redesign or development of new systems or processes, which would reduce the risk of such events occurring in the future.

d. Analysis of the underlying systems and processes through a series of 'Why?' questions to determine where redesign may reduce risk.

e. Inquiry into all areas appropriate to the specific type of event.

f. Identification of risk points and their potential contributions to this type of event.

g. A 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.

2. To be credible, the RCA must:

a. Include participation by the leadership of the organization and by individuals most closely involved in the processes and systems under review.

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

c. Provide an explanation for all findings of 'not applicable' or 'no problem' and include consideration of any relevant literature.

3. An action plan will be considered acceptable if it:

a. Identifies changes that can be implemented to reduce risk or formulates a rationale for not undertaking such changes.

b. Improvement actions are planned, identify who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated.

c. A Quality Management Review Process for Potential Quality Issues will be followed.