**U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT
ENFORCEMENT AND REMOVAL OPERATIONS
ICE HEALTH SERVICE CORPS**

RISK MANAGEMENT DIRECTIVE

**IHSC Directive: 11-06
ERO Directive Number: 11838.2
Federal Enterprise Architecture Number: 306-112-002b
Effective Date: December 2, 2019
Technical Update: August 25, 2021**

**By Order of the Assistant Director
Stewart D. Smith, DHSc, FACHE**   STEWART D SMITH   Digitally signed by STEWART D SMITH
Date: 2019.12.02 10:51:21 -05'00'

1. **PURPOSE:** To set forth the policies and procedures for operating the Risk Management Program (RMP) within the Medical Quality Management Unit (MQMU). RMP's objective is to promote patient safety and the utilization of evidence-based risk analysis within the U.S Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) health care system. RMP promotes a culture of safety that is characterized by non-punitive interactions emphasizing veracity, accountability, and mutual respect. The IHSC facility leadership team collaborates with risk managers (RMs) to identify actual or potential risks to prevent recurrences and harm to IHSC detainees/residents. Specifically, this directive clarifies RMP communication with various stakeholders inclusive of incident reporting, root cause analysis, and tracking and trending of undesirable outcomes.

2. **APPLICABILITY:** This directive applies to all IHSC personnel, including but not limited to, U.S. Public Health Service (PHS) officers, civil service employees, and contract personnel. It is applicable to IHSC personnel supporting health care operations in ICE-owned and contracted detention facilities (CDFs) and to IHSC Headquarters (HQ) staff. This directive applies to contract personnel when supporting IHSC in detention facilities and at HQ. Federal contractors are responsible for the management and discipline of their employees supporting IHSC.

3. **AUTHORITIES AND REFERENCES:**

    3.1. Title 8, Code of Federal Regulations, Section 235.3 (8 CFR § 235.3), Inadmissible Aliens and Expedited Removal.

    3.2. Section 232 of the Immigration and Nationality Act (8 USC § 1222) , Detention of aliens for physical and mental examination.

    3.3. Title 8, Code of Federal Regulations, Section 232 (8 CFR § 232), Detention of Aliens for Physical and Mental Examination.

3.4. Section 322 of the Public Health Service Act (42 USC § 249(a)) , Medical Care and Treatment of Quarantined and Detained Persons.

3.5. Title 42, U.S. Code, Public Health Service Act, Section 252 (42 USC § 252); Medical Examination of Aliens.

3.6. Medical Quality Management Directive; DHS MD Number 248-01 (October 2, 2009)

3.7. Medical Quality Management Instruction; DHS Instruction Number 248-01-001 (September 10, 2012).

3.8. Public Law 91-596, Occupational Safety and Health Act (OSH Act) of 1970.

3.9. Title 29, Code of Federal Regulations, Section 1904, OSHA Injury and Illness Recordkeeping and Reporting Requirements (29 CFR § 1904).

3.10. Privacy Act of 1974, 5 U.S.C. § 552a 5 U.S.C. § 552a, as amended.

3.11. Root Cause Analyses 2 (RCA2): Improving the Root Cause Analyses and Actions to Prevent Harm.

3.12. American Health Society of Risk Management (ASHRM) Handbook: Vol. 1. The Essentials.

4. **POLICY:** The RMP is responsible for assessing and strengthening the culture of safety within IHSC facilities. This policy describes how processes surrounding an unusual occurrence are assessed and analyzed. The RMP derived the concepts within this policy from just culture principles, evidence-based risk analysis, and the Root Cause Analysis 2 (RCA2) method. RMP applies these concepts during the event review process to identify process vulnerabilities preventing their reoccurrence.

5. **RESPONSIBILITIES:**

   5.1   Risk Management Program

   5.1.1   Maintains the Risk Management Program Policy and Guide.

   5.1.2   Coordinates the risk management process in collaboration with various stakeholders with the goal of health care quality and harm reduction to IHSC detainees.

   5.1.3   Reviews incident reports to identify process vulnerabilities and validates an assigned risk score

   5.1.4   Provides guidance to facility health care program managers (FHPM), formerly compliance officer, on referring an incident report to a subject matter expert (SME) or facility leadership for review, as needed.

   5.1.5   Collaborates with the FHPM regarding the action determined once a risk score has been finalized (i.e., track and trend versus root cause analysis).

   5.1.6   Notifies Senior Leadership and MQMU Unit Chief of extreme risk scores to determine if interim actions are

needed.

5.1.7 Notifies the regional compliance specialist (RCS) of high to extreme risk scores.

5.1.8 Notifies the RCS of three or more moderate risk scores.

5.1.9 Tracks and trends process vulnerabilities with low or moderate risk scores.

5.1.10 Maintains and updates the Incident Reporting System, as needed.

5.1.11 Generates incident data report, as needed.

5.2 Facility Health Care Program Manager (FHPM, formerly Compliance Officer)

5.2.1 Manages the local risk management activities related to compliance with policy, guidelines, and correctional standards in collaboration with facility leadership. Reviews incident reports to identify related process vulnerabilities and assigns a risk score.

5.2.2 Refers an incident report to SME and facility leadership for review, as needed.

5.2.3 Collaborates with the RMP regarding the action determined once a risk score has been finalized (i.e., track and trend versus root cause analysis).

5.2.4 Notifies the facility leadership of high to extreme risk scores.

5.2.5 Notifies the facility leadership of three of more moderate risk scores.

5.2.6 Tracks and trends process vulnerabilities with low or moderate risk scores via the local Quality Improvement Program.

5.2.7 Disseminates incident report data to facility triad (Health Services Administrator (HSA), Assistant Health Services Administrator (AHSA), Clinical Director (CD), Nurse Manager (NM)).

5.3 Facility Triad

5.3.1 Comprises the HSA, AHSA(s), NM, and CD.

5.3.2 Supports the FHPM with local risk management activities such as incident reporting and root cause analysis.

5.3.3 Assists with the analysis of an incident report if the FHPM or assigned risk manager requests the analysis.

5.3.4 Participates in the root cause analysis process and ensures action plans are implemented.

5.3.5 Promotes the local culture of safety.

5.4 Subject Matter Expert (SME)

5.4.1 Includes any leader who is responsible for a specific clinical process within a specific discipline (i.e., pharmacy, nursing, and health

information unit personnel).

5.4.2 Assists with the analysis of an incident report when the FHPM or assigned risk manager requests an analysis.

5.4.3 Participates in the root cause analysis process if the FHPM or assigned risk manager requests participation.

5.4.4 Validates process vulnerability identified within the incident report.

5.5 Regional Leadership

The Regional Leadership (consisting of the Regional Health Services Administrator (RHSA), Regional Clinical Director (RCD), and Regional Nurse Manager (RNM)) ensures implementation of the Quality Improvement (QI) and RM programs in their area of responsibility (AOR) to ensure effective leadership decisions are made at the regional level.

5.5.1 Regional Clinical Director

5.5.1.1 Supports the RMP, FHPM, and local administrators with analysis of an incident to identify clinical care concerns.

5.5.1.2 Serves as SME to review and provide feedback to an incident report that has been referred.

5.5.1.3 Participates in case discussion and root cause analysis (RCA), as needed.

5.5.2 Regional Health Services Administrator

5.5.2.1 Supports the facility administrators with analysis of an incident to identify clinical care concerns.

5.5.2.2 Serves as SME to review and provide feedback to an incident report that has been referred, as needed.

5.5.2.3 Participates in case discussion and RCAs, as needed.

5.5.2.4 Collaborates with Regional Compliance Specialist (RCS) and HSA/AHSA to monitor deliverables and health outcomes as necessary.

5.5.3 Regional Nurse Manager

5.5.3.1 Supports the RMP, FHPM, and local administrators with analysis of an incident to identify nursing care concerns.

5.5.3.2 Serves as SME to review and provide feedback to an incident report that has been referred.

5.5.3.3 Participates in case discussion and RCAs as needed.

5.6 Regional Compliance Specialist

5.6.1 Serves as liaison between the FHPM, HSA/AHSA, RHSA

and headquarters.

5.6.2 Oversees the facility's progress and completion of risk management deliverables and health outcomes as detailed in the Quality Improvement Guide.

5.6.3 Participates in RCA meetings.

5.7 MQMU Unit Chief

5.7.1 Reviews extreme risk scores and determines interim actions, as needed, with RMP and Senior Leadership

5.8 IHSC Deputy Assistant Director (DAD) for Health Care Compliance (HCC)

5.8.1 Reviews and makes any recommendations on incident report (IR) statistical analysis and findings.

5.8.2 Provides feedback on action plans, as needed.

5.8.3 Provides final signature on RCAs.

5.9 IHSC Senior Leadership
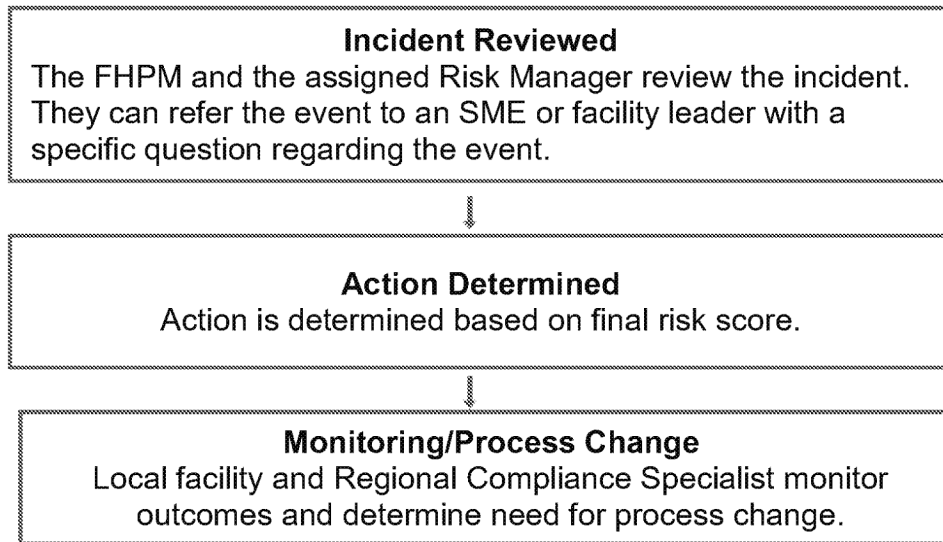
5.9.1 The IHSC Senior Leadership is comprised of the DADs, Chief of Staff (CoS), and IHSC Assistant Director (AD).

5.9.2 Participates in National Quality Assurance (NQA) Committee meeting.

5.9.3 Collaborates with RMP and MQMU Chief on extreme risk scores to determine if interim actions are needed.

5.9.4 Reviews and makes any recommendations on IR statistical analysis and findings.

5.9.5 Provides feedback on action plans, as needed.

6. PROCEDURES

6.1. **Risk Management Event Flow Process:** The event flow process outlines the way in which an unexpected event is managed within the Risk

Management Program (RMP). When a health care staff member identifies an unexpected event, an incident report is generated utilizing the incident reporting system, as soon as possible.

Incident Reported
Health care staff who identify the event submits an incident report in the designated incident reporting system.

Incident Reviewed

The FHPM and the assigned Risk Manager review the incident. They can refer the event to an SME or facility leader with a specific question regarding the event.

Action Determined

Action is determined based on final risk score.

Monitoring/Process Change

Local facility and Regional Compliance Specialist monitor outcomes and determine need for process change.

6.2. **Risk Scoring Procedures:** The FHPM and the assigned risk manager review and analyze the incident to identify process vulnerabilities surrounding the incident and assign a risk score.

6.2.1 Fact Finding: The FHPM and risk manager review the incident report, medical record, and any associated policies. The FHPM speaks with staff involved in the incident in order to obtain necessary information regarding the event.

6.2.2 Analysis of Incident: After all information has been considered, the FHPM determines if there is a process vulnerability related to the incident.

6.2.2.1 If a process vulnerability is identified, the FHPM and the assigned risk manager determine the impact of this vulnerability on the detainee's safety utilizing the severity score chart. (Refer to Appendix C: Severity Score Chart of the Risk Management Guide).

6.2.2.2 If no process vulnerability is identified, then the severity score is one.

6.2.2.3 The FHPM and the assigned risk manager determine the likelihood of the identified process vulnerability reoccurring. The FHPM utilizes the probability score chart to assign a probability score. (Refer to Appendix D: Probability Score Chart of the Risk Management Guide.)

6.2.2.4 If no process vulnerability is identified, the probability score will be zero.

6.2.3 After determining the severity and probability scores, the FHPM calculates the risk score by multiplying the severity score by probability score.

6.2.4 The FHPM utilizes the risk matrix chart to identify the risk category

(Refer to Appendix E: Risk Matrix of the Risk Management Guide).

6.2.4.1
6.2.4.2
6.2.4.3
6.2.4.4

(b)(7)(E)

6.3 **Action Determined:** The risk category indicates the applicable action plan for the incident.

(b)(7)(E)

6.4 **Monitoring/Process Change**

6.4.1 RMP collaborates with the Regional Compliance Specialist (RCS) during the RCA process. The assigned risk manager and RCS facilitate and support the facility in the development of the RCA document and action plans to address identified process issues. The RCS oversees the implementation and completion of action plans associated with RCAs.

6.4.2 During the local quality meetings, the FHPM and the local quality improvement team members, discuss risk management activities to include, review of incident reporting data, discuss extreme risk score events, and provide an update on pending RCA action items.

7. **HISTORICAL NOTES:** This directive replaces IHSC Directive 11-06, Timeframe for Submitting Incident Reports (RCA guide being replaced by RM guide).

   7.1. **Summary of Changes.** Technical Update (8/25/2021) Adds non-punitive language to describe the Risk Management Program;

requires collaboration between RMP, MQMU Unit Chief, and Senior Leadership on Extreme Risk Scores to determine interim actions; and clarifies actions based upon risk categories.

8. DEFINITIONS:

8.2   **Action Plan (AP):** A strategy for correcting or eliminating a problem that has already occurred or been identified (as opposed to a preventive action plan which defines the steps taken to eliminate the root cause of a problem). A CAP may arise from an RCA.

8.3   **Adverse Events:** Any type of error, mistake, incident, accident or deviation, regardless of whether or not it results in patient harm.

8.4   **Culture of Safety**: a combination of attitudes and behaviors towards patient safety that are conveyed in a health care facility.

8.5   **Health Care Personnel or Providers:** Health care personnel or providers are credentialed individuals employed, detailed, or authorized by IHSC to deliver health care services to detainees. The group includes federal and contract staff assigned or detailed (i.e., temporary duty) who provide professional or paraprofessional health care services as part of their IHSC duties. (IHSC Operational Definition).

8.6   **Just Culture**: A concept related to systems thinking which emphasizes that mistakes are generally a product of faulty organizational cultures, rather than solely brought about by the person or persons directly involved.

8.7   **Near Miss:** An event or situation that could have resulted in harm to the patient but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient.

8.8   **Patient Safety:** Avoidance and prevention of patient injuries or adverse events resulting from the processes of health care delivery.

8.9   **Risk Management:** Risk management is a process and system that includes clinical and administrative activities that organizations undertake to identify, evaluate, and reduce the risk of injury to patients, staff and visitors, and the risk of financial loss to the organization. It involves identification of risk potential, prevention of risk exposure, and the management of real or potential adverse incidents and medical malpractice claims.

8.10   **Risk Management Incident Reporting System:** A tool utilized by IHSC health care reporting an unusual or unexpected event, particularly an error or accident that has or may have adverse consequences affecting the health of the detainee. This reporting system should exclude information regarding IHSC health care personnel or provider, government service, and contracted employee injuries, illnesses, and deaths.

8.11   **Risk Score:** The risk score is comprised of severity level and probability of recurrence scores. After determining the level of severity and the probability of recurrence, the RMP and FHPM utilize the Risk Matrix Chart multiplying the level of severity score and probability of recurrence score yielding the overall

risk score. The risk score determines the applicable intervention to the incident. Low and moderate risk scores result in tracking and trending, while high and extreme risk scores result in a root cause analysis.

8.12 **Root Cause Analysis:** A systematic process utilized to identify basic and/or contributing causal factors associated with patient safety and sentinel events.

8.13 **Unusual/Unexpected Event:** An unanticipated event not related to the natural course of the patient's illness or underlying disease condition.

9. APPLICABLE STANDARDS:

9.2 **Performance-Based National Detention Standards (PBNDS)**
9.2.1 Part 4: Care; 4.3- Medical Care; EE. Administration of the Medical Department; 2. Health Care Internal Review and Quality Assurance.

9.3 **Family Residential Standards (FRS)**
9.3.1 Part 4: Care; 4.3- Health Care; EE. Administration of the Medical Department; 2. Health Care Internal Review and Quality Assurance.

9.4 **American Correctional Association (ACA)**
9.4.1 4-ALDF-4D-24: Health Care Internal Review and Quality Assurance.

9.5 **National Commission on Correctional Health Care (NCCHC):** Patient Safety, in the Standards for Health Services in Jails 2018.

9.5.1 J-B-08: Patient Safety

9.5.2 J-A-06: Continuous Quality Improvement Program (Compliance indicators are addressed in 11-02 G-01 Quality Improvement Guide.)

10. PRIVACY AND RECORDKEEPING.
All relevant documents produced or provided in accordance with this Directive must be maintained in accordance with an applicable National Archives and Records Administration (NARA) General Records Schedule (GRS) or a NARA-approved agency-specific records control schedule. If the records are not subject to a records schedule, they must be maintained indefinitely by the agency. In the event the records are subject to a litigation hold, they may not be disposed of under a records schedule until further notification. Prior to the disposition of any records referenced in this directive, ICE Records Officer approval must be obtained.

11. NO PRIVATE RIGHT STATEMENT.
This directive is an internal policy statement of IHSC. It is not intended to, and does not create any rights, privileges, or benefits, substantive or procedural, enforceable against the United States; its departments, agencies, or other entities; its officers or employees; or any other person.

12. POINT OF CONTACT:
Chief, Medical Quality Management Unit (MQMU).