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BUREAU OF MEDICINE AND SURGERY
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BUMEDINST 5100.16
BUMED-N44
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BUMED INSTRUCTION 5100.16

From: Chief, Bureau of Medicine and Surgery

Subj: SAFETY MANAGEMENT SYSTEM

Ref: (a) DoD Instruction 6055.01 of 14 October 2014
(b) SECNAVINST 5100.10L
(c) OPNAV M-5100.23 of 20 September 2023
(d) OPNAV M-5102.1 of 27 September 2021
(e) OPNAVINST 3500.39D

Encl: (1) Definitions and Acronyms

1. Purpose. Establish policy and procedures to implement and manage the Safety Management System (SMS), per references (a) through (c), that supports the mission and vision of Bureau of Medicine and Surgery (BUMED) by avoiding unnecessary harm to people and damage to equipment across the entire scope of operations, training, and activities.

2. Applicability. This instruction applies to all BUMED commands, activities, and personnel. This instruction only applies to occupational safety; it does not apply to clinical safety, which is covered in other instructions.

3. Background

a. Avoiding unnecessary loss of personnel and equipment resources is paramount to the optimization of our organization. This SMS will establish a framework for unified and resilient safety management, predicated on a risk control system that delivers decisive management of risks and enables leaders at all levels to make timely, informed risk decisions. The SMS will ensure operational excellence through continuous improvement and will support the Navy Medicine goal to strengthen our people, the platforms we operate from, and the high-reliable performance to deliver the necessary health services to prepare and fight when and where needed.

b. The BUMED SMS marks an organizational shift in how we conceptualize and carry out safety risk management, ensuring we manage all safety risks in the organization as a single system, rather than having multiple, competing processes and programs. The safety program has traditionally been viewed as the single source to capture and manage all safety risks within a command, even though it is designed to address safety risks only for specific safety hazards (e.g., motorcycle safety, recreational off duty safety, respiratory protection, laser safety, etc.). However, safety risks can arise from many processes or programs that are not managed under the

safety program (e.g., staffing, personnel qualifications, personnel certifications, facilities, training, physical readiness, etc.), and failure to assess and manage safety risks from all sources, together in an integrated fashion, does not provide an accurate, holistic picture of a command's cumulative or composite safety risk. Indeed, mishap analysis invariably reveals weaknesses in an organization's ability to identify, assess, and control cumulative safety risk as a root cause.

c. The BUMED SMS is not a safety program; it is a management system that is predicated on systemic policies, procedures, and processes to drive an organization-wide approach to managing all safety risks and assuring the effectiveness of risk controls. The shift in management strategy outlined in this instruction will result in an integrated, composite, safety risk picture that leaders can use to make informed and effective risk decisions, continuous improvements to processes and programs that reduce safety risk, and to better safety risk communication. Part of the process will also include the monitoring of controls and of the SMS itself for effectiveness. The SMS will help commands comply with existing regulations while predicting the need for future action by sharing knowledge and information.

d. When properly implemented, the BUMED SMS will allow commanders to determine whether their organization is safe-to-operate and operating safely, which are the two, overarching goals of SMS. The two foundational processes of the SMS used to achieve these goals are the Risk Control System (RCS) and safety assurance (SA).

e. Desired outcomes. To be safe-to-operate, a command must ensure all processes, procedures, policies, and controls are in place and functioning as designed and required. To operate safely, a command must be operating within the established safety envelope, or measures of safety performance, contained in governing policies and procedures. To achieve these goals, the RCS and SA processes are designed to deliver four desired outcomes, or 4Ps. The 4Ps represent the system controls of the BUMED SMS. When we achieve the 4Ps, we reduce safety risk to acceptable limits and the command is safe-to-operate and operating safely. The 4Ps are:

(1) Safe Place. Safe workplace or working environment from a benign office environment to high-risk operational, field, or training environments. Ensure safe entry, safe working conditions, and safe egress, including in an emergency. Ensure emergency protocols and systems are operable and tested regularly.

(2) Safe People. People and their supervisors are trained and qualified on all aspects of conducting their work properly and are experienced, proficient, current, procedurally compliant, risk-aware and fit to work (general health and wellbeing). This outcome includes working safely, regardless of role, level, or position in the organization.

(3) Safe Property and Material. Proper and available tools, equipment, machinery, infrastructure, and whole equipment systems that are safe-to-operate and operated safely.

(4) Safe Processes and Procedures. Proper and accessible policies, standard operating procedures (SOP), emergency procedures, safety procedures, maintenance standards, etc.

f. Framework. To design and execute an effective SMS that delivers the 4Ps, all BUMED commands must use the Office of the Chief of Naval Operations responsibility structure, and Plan, Do, Check, Act (PDCA) principles as an acceptable means of compliance with this instruction. Table 1 specifies how the BUMED SMS structures the PDCA cycle and lists the components in each functional area of the cycle.

	Echelon 2	Echelon 3	Echelon 4 and 5
PLAN Policies and Governance	BUMED SMS, BUMEDINST 5100.13F, and BUMED Safety and Occupational Health Management Evaluation (SOHME) SOP	Regional SMS, regional instructions, and SOPs	Command Safety Management Plan (SMP), command safety instructions, SOPs, and host installation instructions
DO Risk Control	BUMED accountable person (AP)	Echelon 3 APs and directors	Commanders or APs, OICs, directors, department heads, and individuals
CHECK Assurance	Occupational Safety and Health Administration (OSHA), Navy Inspector General, Naval Audit Service, Naval Safety Command audits, self-assessment	OSHA, BUMED SOHME, Medical Inspector General (MEDIG), self-assessment	OSHA, BUMED SOHME, MEDIG, self-assessment, zone inspection, industrial health (IH) survey
ACT Performance	Commander's Update Brief (CUB), Strategic Planning Meeting, Navy Safety Quality Council, Navy Executive Safety Board, Defense Safety Oversight Council	Executive Steering Committee (ESC), CUB	ESC, safety council meeting

Table 1. BUMED SMS PDCA Structure

4. Policy. All commands will adopt, develop, and implement the risk control and continuous improvement systems outlined in this instruction as the primary means to eliminate the unnecessary loss of personnel and equipment resources.

5. Responsibilities

a. BUMED

(1) The Surgeon General of the Navy is the accountable person (AP) for the organization and therefore, ultimately responsible and accountable for ensuring that budget submitting office (BSO) 18 commands are both safe-to-operate and operating safely (execution of hazardous activities).

(2) Specifies risk communication thresholds and guidelines for SMS implementation throughout BSO-18 commands based on the principles and requirements contained in this instruction.

(3) Ensures BSO-18 commands implement and maintain a robust SMS or SMP that provides a resilient, defense-in-depth based system that:

(a) Inculcates continuous learning;

(b) Identifies and corrects problems while they are small before growing into deeper, more systemic issues;

(c) Indicates risk ownership;

(d) Elevates risks if unacceptable or unable to effectively correct or mitigate at the current level;

(e) Communicates hazards and near misses formally; and,

(f) Establishes accountability at the appropriate level.

(4) Ensures all leaders and managers understand the responsibility for the proper training of their people, identifying and fixing problems under their control, communicating, and taking account for unmitigated risk at the appropriate level in the chain of command.

(5) Identifies and addresses potential risks to readiness and operations by collecting and analyzing organizational-wide mishap, near-miss, hazard, exercise, operational, and related data.

(6) Where available resources prevent mitigating a risk to as low as reasonably achievable (ALARA), raises the risk to the next higher AP in the chain of command

(7) Appoint the Safety Manager who will:

(a) Assess the effectiveness of the SMS throughout the organization including subordinate commands;

(b) Communicate risks and unmitigated risks up and down the chain of command;

(c) Conduct a hazard review board, per reference (d);

(d) Establish annually the key risk indicators (KRIs), key performance indicators (KPIs) and their tolerance limits which define the parameters for safe-to-operate and operating safely for the organization; and,

(e) Establish a quarterly SMS report that captures data from across the organization appointed Safety Manager and conducts ongoing data and trend analysis to determine the effectiveness of the SMS and the cumulative safety risk to the organization.

b. BUMED Echelon 3 Commanders

(1) Be the AP and therefore ultimately responsible and accountable for ensuring their organization and subordinate commands are safe-to-operate (across the 4Ps) and operating safely (execution of hazardous activities).

(2) Where available resources prevent mitigating risk to ALARA, raise the risk to the BUMED AP.

(3) Appoint a Safety Manager to:

(a) Produce a complementary SMS or SMP to meet BUMED SMS requirements or adopt and comply with the provisions and requirements contained in the BUMED SMS;

(b) Assess the effectiveness and compliance of the SMS and SMP throughout the organization and subordinate commands;

(c) Ensure the organization is properly resourced to execute unit level safety programs; and,

(d) Collect and aggregate data as required for the quarterly BUMED SMS report.

c. Echelon 4 and 5 Commanders, Commanding Officers (CO), and Officers in Charge (OIC) will:

(1) Be the AP and therefore ultimately responsible and accountable for ensuring their command complies with this SMS and is safe-to-operate (across the 4Ps) and operating safely (execution of hazardous activities).

(2) Produce a complementary SMP to meet BUMED SMS requirements.

(3) After all efforts to mitigate risk through the chain of command have been exhausted and have not achieved ALARA conditions, raise the risk to the BUMED regional AP.

(4) Communicate to the BUMED regional AP any identified hazard or operation with an initial risk assessment code (RAC) of 1 or 2 prior to the commencement of the operation.

(5) Ensure the organization is properly resourced to execute unit level safety programs.

(6) Ensure risk assessments are conducted and approved by the risk owner based on the initial RAC as required in Table 2 of subparagraph 6c.

(7) Provide data as requested for the quarterly SMS report.

(8) Comply with BUMED KRI and KPI benchmarks and communicate with the next higher AP in the chain of command when tolerance limits are not met to include a risk assessment and corrective action plan.

(9) Conduct annual self-assessments of the compliance and effectiveness of the command SMP; to include assessment of the command safety program, and analysis of safety risk data, and develop improvement plans and goals.

(10) Provide and market opportunities for personnel to anonymously submit safety concerns and suggestions for improvement (e.g., CO suggestion boxes, command SharePoint, milSuite, etc.).

(11) Review the command risk registry quarterly and communicate hazards and risks up the chain of command as required in subparagraph 6c.

d. Command Safety Managers, Command Safety Officers, or Collateral Duty Safety Officers (CDSOs)

(1) Primary advisor to the CO for the execution, oversight, and assessment of the command SMP.

(2) Provide advice to other leaders, supervisors, and individuals on SMP related matters.

(3) Maintain the command risk registry and brief the CO quarterly as required in this instruction.

e. All BSO-18 personnel

(1) Comply with this SMS and command SMP.

(2) Take reasonable care of themselves and others that are affected by their actions.

(3) Exercise risk management before commencing both on-and off duty tasks and operations. When the risk is not ALARA or mitigated, stop activities until controls are in place and the risk has been communicated as specified in subparagraph 6c.

(4) Report all injuries, illnesses, near misses, and hazards to their immediate supervisor.

6. BUMED RCS. The BUMED RCS adopts the resilience model outlined in reference (c), which employs our desired outcomes as the four pillars (4P) of network controls working together as an integrated system to ensure no one control becomes a single point of failure. When properly implemented, the BUMED RCS will effectively identify; assess, and manage known safety risks, predict, or identify unknown and emergent risks; ensure safety risks are owned at the appropriate level; and provide relevant, actionable risk information that leaders at all levels can use to make risk decisions and communicate risk considerations up and down the chain of command. The BUMED RCS will be adopted and implemented by all commands as the primary method for effective safety risk management and control, and to achieve the 4Ps.

a. Operational Risk Management (ORM). The BUMED RCS will fully leverage and apply the processes and principles of reference (e), ORM. Reference (e) requires that ORM be applied to all aspects of command operations and activities, both on and off duty. Furthermore, commands must conduct a deliberate risk assessment for all high-risk training events, command operations, tasks, and activities including new or complex evolutions. BUMED commands will use the Joint Risk Assessment Tool (JRAT) Web-based software application to complete all deliberate risk assessments. The JRAT is available via a link on the Naval Safety Command's ORM Web page, and fully supports the Navy's, required five-step ORM process (identify hazards, assess hazards, make risk decisions, implement controls, supervise).

b. All BUMED commands will:

(1) Specifically address each of the four system controls (4Ps: safe people, safe places, safe property or material, safe processes or procedures) in all deliberate risk assessments. Deliberate risk assessments are comprehensive and include a range of mission-critical safety issues relating to the 4Ps, such as staffing gaps, training deficiencies, lack of certified or experienced personnel, infrastructure or facility issues, field environment concerns, personnel acclimatization, adequate policies, SOPs, or emergency procedures in place, safe equipment or training aids, etc.

(2) Ensure all hands receive required ORM training.

(3) Appoint a command ORM manager and two ORM assistants and ensure they are properly trained.

(4) Evaluate the command ORM program annually for gaps and best practices; implement change management strategy as necessary, and to include a review of deliberate risk assessments.

(5) Mitigate or reduce risk to ALARA levels before proceeding with any operation, task, or activity.

c. Risk Ownership. Risk is inherent in all activities, tasks, and operations. Because we cannot eliminate risk, we must manage and control risk to acceptable levels before proceeding with activities, tasks, and operations. In general, as the complexity and degree of hazards in an operation increase, the less risk we will be able to eliminate, and the more resources must be expended to reduce or control the risk. Therefore, decisions must be made regarding the level of risk that will be accepted to complete an activity, task, or operation based on the available resources, level of risk involved, and the importance of the activity, task, or operation. Therefore, risks must be owned at the appropriate level depending on the initial RAC and whether the risk owner has the proper authority to obligate resources to mitigate the risk and accept the risk based on importance of the mission. Leaders at all levels must ensure personnel know how much risk they can accept and when to elevate the decision to a higher level. Ensuring risk decisions are made at the appropriate level will also establish clear accountability. Table 2 outlines minimal levels of risk ownership for BSO-18 commands; however, activities, tasks, or operations can be elevated to higher echelons if initial risk owner deems it appropriate.

RISK OWNER	INITIAL RAC
Echelon 3 AP	1 and 2
Echelon 4 AP	3
Echelon 5 AP	4
Director, DCOS	4
Department Head	5

Table 2. Minimal Levels of Risk Ownership

d. Risk Communication. Risk communication is critically important to the viability of the RCS. For the RCS to function effectively and protect personnel and equipment, safety risks and hazards must be reported to supervisors and leaders, who must then report risks to appropriate risk owners as identified in Table 2 of subparagraph 6c to ensure risk decisions are made at the appropriate level by personnel with the authority to commit resources and accept or deny the risk.

(1) All hands are expected to identify and report all injuries, illnesses, near misses, and identified hazards to their immediate supervisor.

(a) Supervisors will report all hazards using the command's established procedures for employee reports of unsafe and unhealthful working conditions, per reference (c).

(b) All identified hazards must be entered into the risk registry as outlined in this instruction.

(c) All injuries, illnesses, and near misses will be reported and recorded, per reference (d).

(2) All hands are expected to exercise risk management as outlined in this instruction before commencing both on and off duty tasks and operations.

(3) Risks will be reported or communicated to the appropriate risk owner as outlined Table 2 of subparagraph 6c, prior to commencement of the task or operation.

e. Risk Registry. The risk registry is a repository in which all hazards and risks for a command are recorded, assessed for risk, and interim controls and corrective actions or recommendations are documented and tracked to completion. Hazards and risks are identified through several means, including facility and programmatic oversight evaluations, self-assessments, inspections from higher headquarters and third-party compliance inspections from regulatory agencies (OSHA, U.S. Environmental Protectional Agency, etc.), as well as reports of unsafe or unhealthful working conditions.

(1) To ensure a consistent template enabling oversight, decision making and risk communication up and down the chain of command, all BUMED commands will utilize Risk Management Information (RMI) as the risk registry for cataloging the aggregate risk impacting the command.

(2) The command safety officer, safety manager, or CDSO will maintain the risk registry.

(3) APs will be briefed on all open items in the risk registry and the corrective action plans at least quarterly.

f. Hazard Review Board

(1) The Hazard Review Board process will be implemented to effectively identify, communicate, and account for organizational risks.

(2) The Hazard Review Board process will review and approve all RAC 1 and 2 items in the Risk Registry and Class A and B mishaps reported in the Risk Management Information Streamlined Incident Reporting (RMI SIR) system.

(3) The Hazard Review Board will follow reference (d), which provides procedures for mishap and safety investigations, reporting, and recordkeeping.

7. SA and Organizational Learning. To ensure the BUMED SMS is a unified and resilient system, processes will be implemented to continually monitor the effectiveness of risk controls in each pillar (4Ps), as well as the effectiveness of the RCS itself, evaluate compliance with safety and SMS policy and standards, and capitalize on data collection and analysis to identify and correct risks before they become issues and ensure the system is self-correcting and continually improving. SA is the process by which commands monitor the effectiveness of risk controls and the RCS, evaluate safety policy and SMS compliance, and identify risks before they become issues. SA involves routine and formal SMS assessments, as well as continual monitoring of leading and lagging key indicators of risk and safety performance.

a. The BUMED SMS will implement a resilient, layered defense system of auditing and assessment to ensure compliance and identify risk vulnerabilities. This will involve assessments, evaluations, and inspections at multiple levels, from within and outside the chain of command.

(1) First-party audits or assessments are self-awareness, self-assessment, and self-correction. It is in compliance with policy (orders, routines, and processes) and risk management practices. First-party audits and assessments are tools to assure the CO and their immediate chain of command that the unit is safe-to-operate and operating safely. The CO will identify the appropriate person to perform audits on their behalf. Emergent risks or issues discovered at this level should be registered locally and mitigations actively tracked by the CO and communicated up and down the chain of command.

(2) Second-party audits or assessments must be conducted by APs in the chain of command to ensure compliance with the principles of this instruction and other policy relevant to the echelon 2 environment. Second-party audits or assessments assure the echelon 2 AP and their subordinate commands that they are safe-to-operate, operating safely and resilient, and provides a formal mechanism for the chain of command to engage risks and issues that may more broadly impact the organization at the enterprise level or require resources and support not accessible at lower echelons.

(3) First- and second-party auditing and assessments are inherent responsibilities within the chain of command to ensure that they and their subordinates are safe-to-operate and operating safely.

(4) Third-party audits or assessments are independent assessments of echelon 2 (and below) commands conducted periodically by Naval Safety Command on behalf of the Chief of Naval Operations that determine if the SMS is performing as designed, is resilient, and therefore safe-to-operate and operating safely.

(5) All BUMED echelon APs will perform a self-assessment of their SMS or SMP at least annually to ensure compliance with this instruction using standardized SMS or SMP assessment criteria and guidance published by BUMED. SMS or SMP deficiencies or vulnerabilities will be entered in the risk registry along with corrective actions and tracked to

completion. Commanders will be briefed for approval on the results of SMS or SMP self-assessments to include corrective action and improvement plans. Self-assessments will be completed in September and forwarded to BUMED through the chain of command no later than 31 October.

(6) Each BUMED echelon AP, commander, and CO (excluding OICs) will perform a formal SMS or SMP assessment for the next lower echelon AP at least every 3 years to ensure compliance with this instruction and other policy relevant to the echelon 2 environment. These second-party audits will also ensure risks are owned at appropriate levels, communicated properly, and will provide justifiable confidence to the echelon 2 AP that the organization is safe-to-operate and operating safely. SMS or SMP assessments will be conducted concurrently with the SOHME.

(7) Findings from safety program self-assessments, SOHME, third-party audits and inspections, zone inspections, etc., will be entered in the risk registry along with corrective actions and tracked to completion of corrective actions. These documents will be retained for a minimum of 3 years.

b. KRIs and KPIs are measures of risk management and safety performance that provide objective data to determine if we are meeting safety performance goals or if our cumulative risk exposure is within acceptable limits. KPIs are generally lagging indicators, such as mishap statistics, that indicate how well the SMS performed. KPI benchmarks developed during SMS planning and goal setting establish the safety envelope, or boundaries for acceptable safety performance. KRIs are primarily leading indicators of the effectiveness of our RCS, and includes data derived from assessments and inspections, hazard reports, training compliance reports, staffing and competency information, medical surveillance compliance, etc. KRIs are metrics that can provide an early warning system of increasing risk exposure and the potential to miss a KPI. KPIs and KRIs work together and are established in tandem; KPIs are first established to define acceptable safety performance boundaries. KRIs are then established as leading indicators of when performance is operating outside of acceptable tolerance ranges and therefore indicating risk to the achievement of the desired outcome. The goal of the BUMED SMS is to leverage KRIs (leading indicators) to the maximum extent possible to identify and correct risks and hazards when they are small and before they become an issue. This will rely on establishment of relevant KPIs and KRIs, collection of reliable data from multiple sources throughout the organization, and accurate data and trend analysis.

(1) BUMED will establish minimum requirements for KPI and KRI criteria and benchmarks annually. Subordinate commands will collect and report KPI and KRI data using the BUMED SMS quarterly report.

(2) The KPI and KRI information reported in the BUMED SMS quarterly report represents the minimum requirement with which commands must comply. Commands may implement more stringent and robust requirements locally as desired to address risk due to specific, local situations and operations.

c. Organizational learning. The BUMED SMS adopts a continuous process improvement (CPI) cycle outlined in reference (a). Effective organizational learning is dependent upon gathering and capitalizing on lessons learned from others' experiences. Continuous self-evaluation to the recognized standard is required to prevent organizational drift and the normalization of deviation from safe practices. Organizational learning is also about responsive and flexible organizations working hard to identify shortfalls and enact improvements to maintain resilience. Individuals and leaders at all levels need to self-correct; find and fix small problems before they become larger, systemic issues. The CPI cycle supports this need by perpetually gathering reports from all available sources, analyzing risk control efficacy, and then capitalizing on that knowledge. There are many ways to learn that provide early warning of weaknesses in the safety system, such as analysis of mishap investigations, hazard reports, near misses, assessments and inspections, reports of unsafe unhealthful working conditions, etc. RMI, as the mandatory reporting application for mishaps, hazard reports and near misses, as well as the mandatory risk registry in which all hazards and risks for a command are recorded, will be the primary resource for collecting safety information for organizational learning.

(1) Commands will ensure all safety, mishap, near-miss, and hazard data is properly entered with proper risk assessment and analysis in RMI.

(2) BUMED will establish minimum reporting requirements annually for the BUMED SMS quarterly report. Commands will ensure all required information is submitted in the BUMED SMS quarterly report through the chain of command.

(3) Commands will provide and market opportunities for personnel to anonymously submit safety concerns and suggestions for improvement (e.g., CO suggestion boxes, command SharePoint, milSuite, etc.).

(4) BUMED will analyze CPI data across the enterprise and develop plans to address systemic issues, as well establish overall, enterprise-wide safety performance improvement goals.

(5) Requirements for the BUMED SMS quarterly report will be developed and revised annually.

8. BUMED SMS Requirements Matrix

Echelon 2 Requirement	BUMED Compliance Method
Produce SMS directives that specify risk communication thresholds and guidelines for SMS implementation throughout the organization and lower echelons based on the principles and requirements contained in OPNAV M-5100.23, Navy Safety and Occupational Health Manual	BUMEDINST 5100.16, Safety Management System
Inculcate continuous learning	KPIs and KRIs, self-assessments and improvement plans, SMS quarterly report and data analysis, hazard reporting, near miss reporting, best practices
Identify and correct problems while they are small before growing into deeper, more systemic issues	KPIs and KRIs, self-assessments, SMS quarterly report and data analysis, hazard reporting, near miss reporting
Clearly indicate risk ownership	BUMEDINST 5100.16
Elevate risks if unacceptable	BUMEDINST 5100.16
Formally communicate hazards and near misses	OPNAV M-5102.1, SMS quarterly report
Establish accountability at the appropriate level	Table 2 of subparagraph 6b
Assess the effectiveness of the SMS throughout the command including lower echelons	Triennial SOHME, annual self-assessment
Ensure all leaders and managers understand the responsibility for the proper training of their people, identifying and fixing problems under their control, communicating and taking account for unmitigated risk at the appropriate level in the chain of command	BUMEDINST 5100.16, BUMEDINST 5100.13F BUMED Safety and Occupational Health Program, OPNAV M-5100.23
Identify and address potential risks to readiness and operations by collecting and analyzing organizational-wide mishap, near-miss, hazard, exercise, operational and related data	SMS quarterly report, RMI, ESAMS
Openly communicate risks and uncorrected hazards up and down the chain of command	BUMEDINST 5100.16, SMS quarterly report, Hazard Review Board.

Table 3. BUMED SMS REQUIREMENTS MATRIX

9. Records Management

a. Records created as a result of this instruction, regardless of format and media, must be maintained and dispositioned per the records disposition schedules located on the Department of the Navy Assistant for Administration, Directives and Records Management Division portal page at <https://portal.secnav.navy.mil/orgs/DUSNM/DONAA/DRM/Records-and-InformationManagement/Approved%20Record5%Schedules/Forms/AllItems.aspx>.

b. For questions concerning the management of records related to this instruction or records disposition schedules, please contact the local records manager or the OPNAV Records Management Program (DNS-16).

10. Review and Effective Date. Per OPNAVINST 5215.17A, BUMED-N44 will review this instruction annually around the anniversary of its issuance date to ensure applicability, currency, and consistency with Federal, Department of Defense, Secretary of the Navy, and Navy policy and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will be in effect for 10 years, unless revised or cancelled in the interim, and will be reissued by the 10-year anniversary date if it is still required, unless it meets one of the exceptions in OPNAVINST 5215.17A, paragraph 9. Otherwise, if the instruction is no longer required, it will be processed for cancellation as soon as the need for cancellation is known following the guidance in OPNAV Manual 5215.1 of May 2016.

11. Information Management Control. Reports required in paragraphs 5, 6, 7, and 8 of this instruction are exempt from reports control per Secretary of the Navy Manual 5214.1 of December 2005, part IV, subparagraph 7k.



D. K. VIA

Releasability and distribution:

This instruction is cleared for public release and is available electronically only via the Navy Medicine Web site, <https://www.med.navy.mil/Directives/>

DEFINITIONS AND ACRONYMS

1. Accountable Person (AP). The individual who is personally accountable with the authority and responsibility for the effective execution of the SMS or SMP. This individual owns the risks within their command. This responsibility cannot be delegated.
2. As Low as Reasonably Achievable (ALARA). ALARA means making every reasonable effort to maintain risk exposure as low as practical, consistent with the purpose for which the activity is undertaken, taking into account the state of equipment, competency of the workforce, expense of elimination or mitigation efforts and other societal and socioeconomic considerations, in relation to mission accomplishment. "Reasonable" requires the degree of risk (likelihood x severity) of a particular activity or environment to be balanced against the costs to both avoid the risk and potential outcome of failure. The greater the risk, the more likely it is that it will be reasonable to go to very substantial expense to reduce it. If the consequences and the extent of a risk are small, the same substantial expense would be considered disproportionate to the risk and it would be unreasonable to have to incur them to address a small risk.
3. Key Performance Indicator (KPI). KPIs measure safety performance with objective data to determine if safety performance goals are met or if cumulative risk exposure is within acceptable limits. KPIs are generally lagging indicators that indicate how well the SMS performed. KPI benchmarks establish the boundaries for acceptable safety performance.
4. Key Risk Indicator (KRI). KRIs measure risk management with objective data to determine if safety risk management goals are met or if cumulative risk exposure is within acceptable limits. KRIs are primarily leading indicators of the effectiveness of our RCS and provide an early warning system of increasing risk exposure.
5. Operate Safely. The CO, unit leadership team and operators all have a duty to operate safely by preserving safe-to-operate conditions. Operate safely is executing the mission within the designed safety envelope, while controlling unforeseen anomalies as they arise. The safety envelope is normally maintained by operating within established procedures. When unplanned or unforeseen safety risks manifest outside of the approved safety envelope and the military benefit (operationally defined objective) of taking the risk outweighs the cost of the risk exposure, then commands should apply the principles of operational risk management to control risk.
6. Risk. Chance of adverse outcome such as failed or degraded mission, injury, illness, or loss. Risk level is expressed in terms of hazard probability and severity.
7. Risk Control System. Risk control system is a collective term encompassing risk identification and assessment, management of risk, response to emergent threats and issues, measures to preserve established risk controls including record keeping and continual self-assessment and correction. All these efforts enable a resilient system.

8. Risk Registry. A repository for capturing and recording risks and associated information. AP should document risks and issues in a risk register, using a consistent template to enable oversight, decision making, and risk communication up and down the chain of command. BUMED will utilize the RMI system to record and manage all risks.
9. Safe-to-Operate. The as-designed safety for places, property and materiel, people, and processes and procedures. It is the defining design, policy, engineering, resourcing, and expectation management that sets the safety risk envelope for the hazardous activity or activities for a given command or operating environment.
10. Safety Management Plan (SMP). Policy framework for implementing the SMS to achieve the desired outcomes of the SMS. SMPs are the documents that implement the desired outcomes of the SMS. SMPs define and communicate performance expectations and may include additional guidance on risk accountability and communication expectations.
11. Safety Management System (SMS). A formal, top-down, or bottom-up, organization-wide approach to managing safety risk and assuring the effectiveness of risk controls. SMSs often involve a system of systems approach that inculcates procedures and policies throughout the organization working together to achieve the SMS desired outcomes.