DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
7700 ARLINGTON BOULEVARD
FALLS CHURCH, VA 22042

IN REPLY REFER TO
BUMEDINST 6710.67C
BUMED-M3
19 Dec 2015

BUMED INSTRUCTION 6710.67C

From: Chief, Bureau of Medicine and Surgery

Subj: ADMINISTRATION OF SEDATION AND ANESTHESIA BY NON-ANESTHESIOLOGISTS AND NON-CERTIFIED REGISTERED NURSE ANESTHETISTS IN NAVAL MEDICAL TREATMENT FACILITIES

Ref: (a) American Society of Anesthesia Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who Are Not Anesthesia Professionals (2012)
(b) American Society of Anesthesiology Advisory on Granting Privileges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners (2010)
(c) Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Manual
(d) Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists, Anesthesiology, Volume 96, Number 4, Apr 2002
(e) BUMEDINST 6010.30
(f) BUMEDINST 6010.23
(g) BUMEDINST 6010.21
(h) BUMEDINST 6010.13

Encl: (1) Standards for Conduct of Minimal Sedation (Anxiolysis)
(2) Standards for Conduct of Minimal Sedation with Nitrous Oxide
(3) Standards for Conduct of Moderate Sedation/Analgesia (Conscious Sedation)
(4) Standards for Conduct of Deep Sedation/Analgesia
(5) Standards for General Anesthesia
(6) American Society of Anesthesiologists Physical Status Classifications
(7) Factors Associated With the Difficult Airway
(8) Nothing by Mouth Guidelines

1. Purpose. To establish the responsibilities of Navy Medicine for the oversight, quality assurance (QA), and treatment protocols to be observed by personnel involved in the administration of anxiolysis, sedation, and anesthesia per references (a) through (h) and enclosures (1) through (8). This instruction is not applicable to care delivered within the specialty of Anesthesiology, the practice of Certified Registered Nurse Anesthetists (CRNAs), or sedation of mechanically ventilated patients in intensive care settings. This instruction is a complete revision and should be reviewed in its entirety.

2. Cancellation. BUMEDINST 6710.67B.

3. Scope. This instruction applies to all Naval Medical Treatment Facilities (MTF) and Dental Treatment Facilities (DTF) ashore and afloat. It applies to the spectrum of minimal sedation (anxiolysis) to general anesthesia services and care.

4. Background. References (a) through (h) require healthcare organizations to have the processes in place for the care of patients receiving anesthesia, sedation, and anxiolysis that are consistent with professional standards of care.

5. Discussion. A patient's response to sedation or anesthetic agents is a continuum that ranges from minimal sedation (also known as anxiolysis), to moderate sedation/analgesia (also known as conscious sedation), to deep sedation/analgesia to general anesthesia. It is a dynamic process that can change over time and varies from patient to patient, necessitating the need for clinically established standards and guidelines. This instruction establishes the standards and guidelines for MTF/DTF sedation services to ensure patient safety and does not apply to the sedation of patients being mechanically ventilated in intensive care settings.

6. Definitions

a. Levels of sedation per reference (a): http://www.asahq.org/~/media/sites/asahq/files/public/resources/standards-guidelines/statement-on-granting-privileges-to-nonanesthesiologist-administering-physicians-deep-sedation.pdf#search=%22privileges%22

(1) Minimal Sedation (Anxiolysis). Anxiolysis is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

(2) Moderate Sedation/Analgesia (Conscious Sedation). Conscious Sedation is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands either alone or accompanied by light tactile stimulation. (Note: reflex withdrawal from a painful stimulus is not considered a purposeful response). No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

(3) Deep Sedation/Analgesia. Analgesia is a drug-induced depression of consciousness during which patients cannot be easily roused, but respond purposefully after repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

(4) General Anesthesia. General anesthesia is a drug-induced loss of consciousness during which patients are not rousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway. Positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

b. Pharmacology. The above listed levels of sedation can all be achieved irrespective of either the route of administration or the specific pharmacological agent used. Utilization of certain sedation and anesthetic induction medications noted for narrow therapeutic windows, including: barbiturates such as (Thiopental or Methohexital), as well as, Etomidate and Propofol are limited to those providers credentialed in deep sedation. Those deep sedation credentialed providers can use these agents in the provision of moderate sedation utilizing deep sedation guidelines, (see enclosure (4)). An Oral Maxillofacial Surgeon (OMS) or Emergency Medicine Physician, if appropriately credentialed, may use the above drugs following moderate or deep sedation guidelines.

c. Practitioner. A practitioner is a privileged and credentialed provider. The practitioner will not provide sedation or anesthesia beyond the level allowed by their privileges. Patients who advance into a deeper and not immediately reversible level of sedation should be considered emergent and treated as such.

d. Monitor. A monitor is the member of the sedation/anesthesia team responsible for the direct observation and assessment of the patient's vital signs as prescribed in the standards for each level of sedation or anesthesia.

e. Assistant. An assistant is the member of the procedure/surgical team who assists with the treatment procedures per the training and competencies possessed by the individual, and may be responsible for the recording of vital signs as directed by the practitioner. Assistants cannot be members of the sedation/anesthesia team.

f. Recovery Assistant. A recovery assistant is the member of the sedation/anesthesia team assigned to the designated recovery area. The recovery assistant is responsible for direct observation and assessment of the patient, and for recording and reporting the ongoing patient assessment and vital signs to the responsible provider during the recovery period.

g. Circulator. A circulator is the member of the procedure team who is available in the procedure room and assists the procedure/surgical team as needed. Circulators cannot be members of the sedation/anesthesia team.

h. Graduate Medical Education (GME). MTFs and DTFs with GME programs that include training in the delivery of conscious sedation will ensure such departments adopt language within their respective trainee oversight procedures that is consistent with this instruction, including references (a) through (h) and enclosures (1) through (8), and preserves appropriate patient safety during administration of conscious sedation.

7. Action

a. Commanders, Navy Medicine East and Navy Medicine West, must ensure commands within each region comply with all aspects of this instruction, references (a) through (h), and enclosures (1) through (8).

b. Commanding Officers, MTFs and DTFs; and Senior Medical Department Officers aboard ships must:

(1) Implement the standards and guidelines delineated in references (a) through (h), and enclosures (1) through (8) of this instruction.

(2) Ensure the standards and guidelines outlined in this instruction apply when any patient receives, by any route, medications or pharmacologic agents resulting in a state of sedation or general anesthesia, as defined in paragraphs 6a(1) through 6a(4), provided by non-anesthesiologist/CRNAs. Specific guidelines for the conduct of general anesthesia, as delivered by anesthesiologists and CRNAs in all areas of the facility (including remote sites, operatory suites, and patient recovery areas within the designated Post-Anesthesia Care Unit) will be governed by the facility's Department of Anesthesia.

(3) Ensure when the level of sedation extends to the next deeper level, the standards for deeper levels of sedation or general anesthesia apply.

(4) Ensure the selection of appropriate procedures is the responsibility of the physician or dentist and should be based upon:

(a) Institutional policy, scope of services, and credentialing and privileging of provider.

(b) The patient's medical, anesthetic, and drug history.

(c) The patient's physical status according to the American Society of Anesthesiology classification (ASA), per enclosure (6).

(d) The risks/benefits of the procedure/test.

(5) Ensure providers and support staff are familiar with this instruction, references (a) through (h), and the use of guidance specific to the various levels of sedation as outlined in enclosures (1) through (8) in the performance of anxiolysis, sedation, anesthesia and practice maximum patient safety.

(6) Ensure all adverse events or patterns of adverse events during sedation or anesthesia are analyzed and changes made, if necessary, that improve performance and patient safety following references (d) through (h).

(7) Ensure quality risk management and patient safety information, including the results of ongoing clinical quality monitoring, is forwarded to Bureau of Medicine and Surgery (BUMED) Risk Management per references (d) through (h).

8. Records. Records created as a result of this instruction, regardless of media and format, must be managed per SECNAV M-5210.1 of January 2012.

9. Reports. The reports required in this instruction, are exempt from reports control per SECNAV M-5214.1 of December 2005, part IV, paragraph 7p.

10. Forms

a. The following General Services Administration form OF 517 (07-95), Medical Record - Anesthesia is available electronically at: http://www.gsa.gov/portal/forms/download/115402.

b. The following BUMED forms are available electronically from the "Forms" tab at http://www.med.navy.mil/directives/Pages/NAVMEDForms.aspx.

(1) NAVMED 6710/12 (06/2008), Informed Consent For Sedation.

(2) NAVMED 6710/13 (09/2014), Inhalation/Anxiolysis Sedation Procedure Sheet.

(3) NAVMED 6710/14 (06/2008), Recovery Record.

(4) NAVMED 6710/15 (06/2008), Guideline for Competency Assessment as Monitor for Moderated Sedation/Analgesia.

(5) NAVMED 6710/16 (06/2008), Guideline for Competency Assessment as a Recovery Assistant.

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Distribution is electronic via the Navy Medicine Web site at:
http://www.med.navy.mil/directives/Pages/BUMEDInstructions.aspx

STANDARDS FOR CONDUCT OF MINIMAL SEDATION (ANXIOLYSIS)

1. Definition. Minimal Sedation (Anxiolysis) is a drug-induced state intended to facilitate a procedure, during which patients respond normally to verbal commands. Minimal Sedation entails minimal risk. Minimal Sedation includes peripheral nerve blocks using local or topical anesthesia in conjunction with either (1) less than or equal to 50 percent nitrous oxide in oxygen with no other sedative or analgesic medications by any route or (2) a single oral/nasal sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain. Although cognitive function and coordination may be impaired, the ventilatory and cardiovascular functions are unaffected. The standards set forth in this enclosure do not apply to the prescription of routinely utilized anxiolytic agents to facilitate patient comfort except as noted below. The use of intravenous or multiple oral/nasal sedative/analgesic agents for sedation will require the application of the moderate sedation standards. The use of any additional sedative/analgesic agents in conjunction with nitrous oxide for sedation will require the application of the moderate sedation standards. There are patients who will respond to a drug dose typically associated with anxiolysis with a physiologic response of moderate sedation or deeper. If so, the level of care delivered to such patients must reflect the actual sedation level achieved not the primary level intended.

2. Credentials Requirements. Core or supplemental clinical privileges must be demonstrated for the use of minimal sedation/anxiolysis. Additional specific clinical privileges are required for the utilization of Inhalation Nitrous Oxide for minimal sedation (see enclosure (2)).

3. Equipment Requirements. The location where minimal sedation/anxiolysis is conducted must have the following items readily available:

a. Continuous pulse oximetry for non-invasive monitoring of oxygen saturation.

b. A means of determining blood pressure.

c. Supplemental oxygen delivery system.

4. Emergency Equipment

a. Appropriate emergency equipment reduces risk of adverse events should an emergency occur during minimal sedation (anxiolysis).

b. All equipment should be checked for quality control and inventoried on a regular basis, including:

(1) Equipment to provide positive pressure ventilation with supplemental oxygen.

(2) Automated External Defibrillator.

(3) Suction equipment

(4) A reliable means of two-way communication to call for help is required. Personnel should be familiar with activating emergency response/Code Blue team in their facility. Emergency numbers and applicable support services should be easily accessible.

5. Patient Management

a. Pre-procedural. Preparation of the patient is the responsibility of the credentialed professional and must include:

(1) Patient Evaluation

(a) Appropriate pre-procedure evaluation of the patient's medical history reduces the risk of adverse outcomes.

(b) History - Practitioners must be familiar with pertinent aspects of the patient's medical history including:

1. Past diseases and/or abnormalities of major organ systems.

2. Previous adverse experiences with sedation or anesthesia.

3. Current medications and drug allergies.

4. Time and nature of last oral intake.

5. History of tobacco, alcohol, or substance abuse.

(2) Patient Counseling. Before the procedure, patients (or their legal guardian in the case of a minor or a legally incompetent adult), will be informed of, and give informed consent for, the administration of sedation. Risks and benefits associated with the planned procedure or test, alternative anesthetic options, and risks of both the procedure and the anesthetic plan, must be discussed with the patient or legal guardian and documented on the NAVMED 6710/12, Informed Consent for Sedation Form.

(3) Pre-sedation Fasting. For non-nitrous oxide anxiolysis, nothing by mouth requirements will be determined by the credentialed professional on a case by case basis using current expert consensus and/or guidelines.

(4) Documentation

(a) Peri-procedural plan of care.

(b) Consent for the procedure and anesthetic (NAVMED 6710/12).

(c) Pre-sedation summary to include; age, weight in kilograms, blood pressure, heart rate, respiratory rate, (ASA) classification. Documentation must be recorded in the patient's record.

b. Intra-procedural. No additional monitoring other than continual blood pressure monitoring at an interval of 5 minutes, continuous pulse and oxygen saturation, and respiratory confirmation required unless status of patient changes.

(1) An adult escort is present who understands the post-procedure and post-sedation instructions.

(2) Post-procedural recording of monitored parameters for anxiolysis. Documentation must be recorded on the patient's record.

(a) Record post-procedural vital signs.

(b) Record dosage and route of anxiolytic agent used.

c. Post-procedural

(1) Ability of patient, parent/guardian, escort to verbalize understanding of discharge instructions (if appropriate).

(2) Provision of verbal and written instructions to include:

(a) Activity level or limitations.

(b) Dietary restrictions.

(c) Medication instructions.

(d) A 24-hour phone number where help can be obtained in case of complications.

(e) Follow up instructions if indicated.

(f) Adequate analgesia.

(g) Adequate control of nausea and/or vomiting.

(h) Return to baseline or near baseline mental status.

6. Competency Assessment and Maintenance. Credentialed Professional: Per the routine credentials process and designated departmental criteria.

7. Quality Control Checks

a. Reference (a) requires all departments conducting sedation services to have a system to review and document the care provided. This review must encompass three main components:

(1) Appropriate record review.

(2) Controlled substance utilization review when indicated.

(3) Equipment maintenance review when indicated.

b. Each department that conducts minimal sedation (anxiolysis) for procedures must perform, at the least, a quarterly review of their practice. This review must include a representative sampling of each practitioner's minimal sedation (anxiolysis) cases as determined by the individual command's criteria. Any occurrence of an unintended deeper level of sedation must be reported via the Patient Safety Reporting System (available at: https://patientsafety.csd.disa.mil). Any adverse trends identified must be reported in writing to the appropriate peer review body.

STANDARDS FOR CONDUCT OF MINIMAL SEDATION WITH NITROUS OXIDE

1. Definition. Nitrous oxide used at no more than 50 percent with or without local anesthetic will be considered minimal sedation/anxiolysis. The use of any additional sedative/analgesic agents in conjunction with nitrous oxide for sedation will require application of the moderate sedation standards.

2. Credentials Requirements. Core or supplemental privileges must be demonstrated for use of nitrous oxide. Supplemental privileges may be granted by the command upon completion of training and supervised cases.

a. When administering nitrous oxide, the patient must have a professional trained and privileged in the delivery of nitrous oxide during the initiation of sedation.

(1) The practitioner performs the initial delivery of sedation and concurrently assures the patient's physiological and psychological well-being. For patient administered delivery, the patient assumes control of delivery after being given instruction by a privileged practitioner, and after being observed by the practitioner using the nitrous oxide as directed.

(2) The use of a monitor is not required for Nitrous Oxide administration.

b. The practitioner privileged in Nitrous Oxide Administration.

(1) Ultimately responsible for the patient's welfare.

(2) Must be properly privileged for nitrous oxide administration (per reference (e) or the most current version).

(3) Must be certified in Basic Life Support (BLS).

(4) Strongly recommended to be available at all times until the patient is discharged. Not required to stay at the chairside or bedside during entire administration of nitrous oxide.

3. Equipment Requirements. The location where nitrous oxide minimal sedation/anxiolysis is conducted must have the following items readily available.

a. Continuous pulse oximetry for non-invasive monitoring of oxygen saturation.

b. A means of determining blood pressure.

c. Supplemental oxygen delivery system.

d. Ideally cannot deliver more than 50 percent nitrous oxide concentration.

e. Contains a fail-safe mechanism to shut off nitrous oxide flow if oxygen pressure falls below threshold.

f. Contains functioning flow meters and built-in regulators.

g. Contains a scavenging device to prevent waste gas build-up greater than 50 parts per million or per most current Americans with Disabilities Act of 1990 (ADA) or National Institute for Occupational Safety and Health (NIOSH) guidelines.

h. Displays concentration of nitrous oxide (in percentage) delivered (if delivery systems displays such data) and total flow of gases delivered.

i. Nitrous oxide machines will have periodic dosimetry testing based on usage.

4. Emergency Equipment

a. Appropriate emergency equipment reduces risk of adverse events should an emergency occur during minimal sedation (anxiolysis). All equipment should be checked for quality control and inventoried on a regular basis.

b. Immediately available equipment includes, at a minimum:

(1) Equipment to provide positive pressure ventilation with supplemental oxygen.

(2) Automated External Defibrillator.

(3) Suction equipment.

(4) A reliable means of two-way communication to call for help. Personnel should be familiar with activating emergency response/Code Blue team in their facility. Emergency numbers and support services, such as respiratory therapy and the anesthesia department, should be easily accessible.

5. Patient Management

a. Pre-procedural. Preparation of the patient is the responsibility of the credentialed professional and must include:

(1) Patient Evaluation

(a) Appropriate pre-procedure evaluation of the patient's medical history reduces the risk of adverse outcomes.

(b) History. Practitioners must be familiar with pertinent aspects of the patient's medical history including:

1. Past disease and abnormalities of major organ systems.

2. Previous adverse experience with sedation or anesthesia.

3. Current medications and drug allergies.

4. Time and nature of last oral intake.

5. History of tobacco, alcohol, or substance abuse.

(2) Patient Counseling. Before the procedure, patients (or their legal guardian in the case of a minor or a legally incompetent adult) will be informed of, and give informed consent, for the administration of sedation. Risks and benefits associated with the planned procedure or test, alternative anesthetic options, and risks of both the procedure and anesthetic plan, must be discussed with the patient or legal guardian and documented on NAVMED 6710/12.

(3) Pre-sedation Fasting. For nitrous oxide anxiolysis, nothing by mouth requirements will be determined by the credentialed professional on a case by case basis using current expert consensus and/or guidelines.

(4) Documentation

(a) Peri-procedural plan of care.

(b) Consent for the procedure and anesthetic (NAVMED 6710/12).

(c) Pre-sedation summary to include: age, weight in kilograms, blood pressure, heart rate, respiratory rate, (ASA) classification. Documentation must be recorded on NAVMED 6710/13, Inhalation/Anxiolysis Sedation Procedure Sheet.

b. Intra-procedural. No additional monitoring other than continual blood pressure monitoring at an interval of 5 minutes, continuous pulse, oxygen saturation monitoring, and respiratory confirmation required unless status of patient changes.

(1) Record post-procedural vital signs.

(2) Record percent of nitrous oxide used, and duration of use.

c. Post-procedural

(1) Ability of patient, parent/guardian, or escort, to verbalize understanding of discharge instructions (if appropriate).

(2) Provision of verbal and written instructions to include:

(a) Activity level or limitations.

(b) Dietary restrictions.

(c) Medication instructions.

(d) A 24-hour phone number where help can be obtained in case of complications.

(e) Follow up instructions if indicated.

(f) Adequate analgesia.

(g) Adequate control of nausea and/or vomiting.

(h) Return to baseline or near baseline mental status.

d. An adult escort is required only for a patient who is a minor, or a legally incompetent adult. The adult escort must understand the post-procedure and post-sedation instructions.

e. Post-procedural recording of monitored parameters for anxiolysis. Documentation must be recorded on the NAVMED 6710/13.

6. Competency Assessment and Maintenance. Credentialed Professional: Per the routine credentialing process and designated departmental criteria.

7. Quality Control Checks

a. Reference (a) requires all departments conducting sedation services to have a system to review and document the care provided. This review must encompass four main components:

(1) Appropriate record review.

(2) Appropriate peer review, as needed, to track and trend reportable incidents and adverse outcomes.

(3) Controlled substance utilization review as necessary.

(4) Equipment maintenance review when indicated.

b. The criteria for review are discussed below:

(1) Appropriate record review. Departments that perform minimal sedation with nitrous oxide must perform and document, at the least, a quarterly review of their clinical practice and report the results to the appropriate quality control body. This review should include a representative sampling of each practitioner's minimal sedation with nitrous cases as determined by the individual command's criteria. Required parameters of this review include, at a minimum:

(a) Pre-sedation summary completed.

(b) Patient meets scope/criteria for minimal sedation with nitrous oxide.

(c) Level of patient risk adequately assessed and documented ASA.

(d) Risk/benefits discussed with patient and/or significant other for both procedure and minimal sedation with nitrous oxide.

(e) Intraoperative vital signs adequately monitored according to command/department policy.

(f) Postoperative vital signs adequately monitored according to command/department policy.

(g) Discharge criteria met prior to patient leaving department.

(h) Discharge instructions to patients and/or significant other appropriate and adequate for patient's condition.

(2) Peer review compliance. Each department that conducts minimal sedation (anxiolysis) for procedures must perform, at the least, a quarterly review of their practice. This review should include a representative sampling of each practitioner's minimal sedation (anxiolysis) cases as determined by the individual command's criteria. Any occurrence of an unintended deeper level of sedation must be reported via the Patient Safety Reporting System (available at: https://patientsafety.csd.disa.mil). Any adverse trends identified must be reported in writing to the appropriate peer review body.

STANDARDS FOR CONDUCT OF MODERATE SEDATION/ANALGESIA (CONSCIOUS SEDATION)

1. Definition. A drug-induced depression of consciousness during which patients respond purposefully to verbal commands (note, reflex withdrawal from a painful stimulus is not considered a purposeful response) either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

2. Credentials Requirements. The standards outlined in this instruction must apply when any patient receives, by any route, medications resulting in a state of moderate sedation/analgesia (conscious sedation) as defined in paragraph 6a(2) of this instruction.

a. When under moderate sedation, the patient must have two people in attendance (in addition to the assistant or the circulator) during the procedure and one person during the recovery phase:

(1) The practitioner performing the procedure/test. The monitor cannot be the provider performing the procedure or test.

(2) The monitor (who may be a nurse, corpsman/technician, or other credentialed conscious sedation provider) is responsible for the administration of medications ordered by the practitioner and to continuously assess/record the patient's physiological and psychological status. The monitor cannot serve the function as an assistant or circulator.

(3) The recovery assistant will assist in the recovery of the patient in an appropriately designated recovery area. Corpsmen/technicians may not recover patients without the supervision of a moderate sedation credentialed practitioner or a nurse trained in sedation recovery. The corpsmen/technicians can only discharge the patient under supervision of the above described practitioner or nurse.

b. The Practitioner

(1) Ultimately responsible for the patient's welfare.

(2) Must be properly licensed and credentialed (per reference (e) or the most current version).

(3) Must be certified in BLS.

(4) Must be certified in Advanced Cardiac Life Support (ACLS) for adult care.

(5) Must be certified in Pediatric Advanced Life Support (PALS) or Neonatal Resuscitation Program (NRP) as appropriate if managing the pediatric patient (12 years of age or less).

(6) Must be available at all times until the patient is discharged from the service.

c. The monitor, if not a practitioner, must demonstrate competence for certification by the following:

(1) Must be certified in BLS.

(2) Must be certified in ACLS.

(3) Is certified in PALS, or NRP, as appropriate if managing the pediatric patient (12 years of age or less).

(4) Must be Intravenous (IV) push medication certified.

(5) Successful completion of a command recognized training course in the administration of moderate sedation/analgesia and demonstration in the safe performance of five moderate sedation/analgesia cases under supervision (see, NAVMED 6710/15, Guideline for Competency Assessment as Monitor for Moderated Sedation/Analgesia).

(6) Must be certified as competent by the department service on NAVMED 6710/15.

(7) Must be recertified annually, based upon one of the following:

(a) Safe completion of an adequate number of cases.

(b) Successful completion of a practical exam on moderate sedation/analgesia.

d. The recovery assistant, if not a practitioner, must demonstrate competence for certification by the following:

(1) Must be certified in BLS.

(2) Successful completion of an appropriate rhythm recognition course.

(3) Completion of a sedation course, or documented prior appropriate training (see NAVMED 6710/16, Guideline for Competency Assessment as a Recovery Assistant).

(4) Must be recertified annually, based upon the safe completion of an adequate number of cases per departmental criteria.

(5) Must be certified as competent by the department or service on NAVMED 6710/16.

3. Equipment Requirements. The location where moderate sedation/analgesia (conscious sedation) is conducted, as well as, the location where the patient is recovered must each have the following items:

a. A functional source of oxygen. Piped oxygen is preferred, but an oxygen cylinder may be used if adequate supply and replacement tanks are immediately available. Cylinder oxygen will be readily available in case of pipeline failure.

b. A means of delivering positive pressure ventilation (bag, valve, mask).

c. Suction and appropriately sized suction catheters.

d. Continuous pulse oximetry for non-invasive monitoring of oxygen saturation.

e. Continuous capnography for the non-invasive monitoring of exhaled carbon dioxide.

f. Automated blood pressure determination.

g. Continuous Electrocardiogram (EKG) monitoring.

h. Airway management equipment.

i. Temperature monitoring must be available.

j. A reliable means of two-way communication to summon help if required.

k. Adequate battery powered illumination with extra batteries. Sufficient electrical outlets with clearly labeled emergency power supply outlets, or appropriate battery powered equipment with extra batteries.

l. Additionally, there must be a readily available emergency cart with equipment appropriate for the patient's age and size to include:

(1) Automated External Defibrillator.

(2) ACLS emergency drugs.

(3) Airway equipment.

(4) IV solutions/supplies.

(5) Reversal agents for selected medications if applicable.

4. Patient Management

a. Pre-procedure. Preparation of the patient is the responsibility of the credentialed practitioner and must include:

(1) Patient evaluation

(a) Appropriate pre-procedure evaluation of the patient's medical history and physical examination will reduce the risk of adverse outcomes.

(b) History. Practitioners administering moderate sedation/analgesia (conscious sedation) must be familiar with pertinent aspects of the patient's medical history including:

1. Past disease and abnormalities of major organ systems.

2. Previous adverse experience with sedation or anesthesia.

3. Current medications and drug allergies.

4. Time and nature of last oral intake.

5. History of tobacco, alcohol, or substance abuse.

(c) Practitioners should consider seeking anesthesia consultation when it is believed the patient's pre-existing medical condition may be associated with an increased risk when administering sedation outside of a main operating room ASA 3 or higher.

(d) Physical Examination. Patients presenting for moderate sedation/analgesia (conscious sedation) undergo a physical examination which at a minimum includes:

1. Auscultation of the heart and lungs.

2. Evaluation of the airway to identify factors that may be associated with difficulty in airway management (see enclosure (7)).

3. Pre-procedural laboratory testing is guided by patient's underlying medical conditions and the likelihood results will change the sedation management plan.

4. Medical conditions placing the patient at increased risk should be optimized prior to elective procedures (i.e., electrolyte imbalance, anemia, diabetes, hypertension, coagulopathy).

(2) Patient Counseling. Before the procedure begins, patients (or their legal guardian in the case of a minor or legally incompetent adult) will be informed of, and give informed consent, for the administration of sedation. Risks and benefits associated with the planned procedure or test, alternative sedation options, and risks of both the procedure and sedation plan must be discussed with the patient or legal guardian and documented on NAMVED 6710/12.

(3) Pre-sedation Fasting. Pre-operative preparation of the patient will include counseling and review of fasting guidelines and protocol. Patients undergoing moderate sedation/analgesia (conscious sedation) for elective procedures should not drink or eat solid foods for an ample amount of time to allow for gastric emptying before their procedure (see enclosure (8)). In an urgent or emergent circumstance, where nothing by mouth protocol cannot be adhered to, the risk of injury due to aspiration must be weighed against the benefit of proceeding with the procedure. In the Emergency Department, do not delay procedural sedation for emergent medical needs in the adult or pediatric patients.

(4) Documentation. The history and physical examination, and the results of any indicated diagnostic tests are recorded in the patient's record.

(a) Peri-procedure plan of care.

(b) Consent for the procedure and sedation must be documented on NAMVED 6710/12.

(c) Pre-sedation summary to include airway exam, age, weight in kilograms, blood pressure, heart rate, respiratory rate, temperature, (ASA) classification, sedation choice, previous sedation outcomes, past medical history, and allergies (OF-517, Medical Record – Anesthesia).

(d) OF-517.

(e) NAVMED 6710/14, Recovery Record.

b. Intra-Procedural

(1) Level of Consciousness. Response of patients to commands during procedures performed with moderate sedation/analgesia (conscious sedation) is an indicator of their level of consciousness. Monitoring a patient's response to verbal commands is routine, except with pediatric patients or those having a procedure or test that prevents a verbal response. The ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile sensation is valuable in this patient population and suggests the patient will be able to maintain their airway. The level of consciousness must be documented at least every 5 minutes. The following are useful indicators:

(a) Awake and alert.

(b) Sedate and cooperative.

(c) Asleep and easily rousable.

(d) Asleep, and slow to respond.

(e) Rousable only to pain.

(2) Pulmonary Ventilation and Oxygenation. The primary cause of morbidity associated with moderate sedation/analgesia (conscious sedation) is drug induced respiratory depression. Monitoring of ventilatory function and oxygenation must be achieved by the following monitors:

(a) Continuous observation of spontaneous respiratory activity recorded every 15 minutes. For sedation events shorter than 15 minutes, recording every 5 minutes is appropriate.

(b) Auscultation of breath sounds if direct observation of respiratory activity is unable to be accomplished.

(c) Continuous capnography with appropriate alarm settings recorded every 15 minutes. For sedation events shorter than 15 minutes, recording every 5 minutes is appropriate.

(d) Continuous pulse oximetry with appropriate alarm settings recorded every 15 minutes. For sedation events shorter than 15 minutes, recording every 5 minutes is appropriate.

(3) Hemodynamics

(a) Sedative and analgesic agents may diminish autonomic compensation for hypovolemia and surgical stress. Early detection of change in a patient's heart rate and blood pressure may enable quicker intervention and reduce the risk of cardiovascular collapse.

(b) Required hemodynamic monitoring includes:

1. Blood pressure readings taken and recorded at 5 minute intervals during the procedure.

2. Continuous EKG monitoring recorded every 15 minutes. For sedation events shorter than 15 minutes, recording every 5 minutes is appropriate.

3. Continuous heart rate readings recorded at 5 minute intervals.

(4) Recording of monitored parameters

(a) Simultaneous recording of patient's level of consciousness, respiratory function, and hemodynamics, must be documented on the Sedation Record (OF-517). Manual recording confirms the practitioner caring for the patient is aware of changes in a patient's condition.

(b) The following should be recorded:

1. Type and amount of medication administered.

2. Vital signs, ventilatory and oxygenation status at the intervals prescribed above.

3. Level of consciousness.

4. Patient's ability to maintain their airway.

5. Rate of supplemental oxygen.

6. Emergency interventions (if required).

c. Post-procedural. Patients receiving moderate sedation/analgesia (conscious sedation) must be monitored until appropriate discharge criteria are satisfied. Duration of monitoring must be individualized depending on the level of sedation accomplished, condition of the patient, and nature of intervention for which the moderate sedation/analgesia (conscious sedation) was administered. Patients will be monitored after moderate sedation/analgesia (conscious sedation) and recovery will be appropriately documented and retained in the patient's record. The patient will not be released until the following criteria are met and the patient is no longer at increased risk for cardiopulmonary depression. Utilization of a standing order to discharge the patient when the below criteria are met is appropriate.

(1) Appropriate post-anesthesia recovery score (such as Aldrete or Post-anesthetic Discharge Scoring System (PADSS)).

(2) Stable respiratory status and the ability to maintain a patent airway.

(3) Vital signs within +/- 20 percent of admission, pre-procedure recordings.

(4) No EKG changes.

(5) Ability to ambulate or return to pre-procedure activity level if same day discharge anticipated.

(6) An adult escort is present who understands the post-procedure and post-sedation instructions. The escort will assume the care and monitoring of patient at home and be able to report complications.

(7) Acceptable transportation home.

(8) Two hours have elapsed after the last dose of reversal agents to ensure the patient does not become re-sedated after the reversal effects have abated.

(9) Satisfactory pain management.

(10) Control of nausea and vomiting.

(11) Patients should be alert and oriented, or should have returned to their pre-operative base line.

(12) Patients are provided with written instructions that address the following:

(a) Post-procedure diet.

(b) Medications.

(c) Activities.

(13) Patients/escorts should be able to verbalize an understanding of the instructions.

(14) Patients and escorts should be provided with a 24-hour telephone number where help can be obtained in the event of a complication or emergency.

5. Competency Assessment and Maintenance

a. Practitioner. Per the routine credentials process and designated departmental criteria.

b. Monitor. Annual competency review on NAVMED 6710/15.

c. Recovery Assistant. Annual competency review on NAVMED 6710/16.

6. Quality Control Checks

a. Reference (a) requires all departments conducting sedation services to have a system to review and document care provided. This review must encompass four main components:

(1) Appropriate record review.

(2) Appropriate peer review, as needed, to track and trend reportable incidents and adverse outcomes.

(3) Controlled substance utilization review.

(4) Equipment maintenance review.

b. The criteria for review are discussed below:

(1) Appropriate record review. Departments that perform moderate sedation/analgesia (conscious sedation) must perform and document, at the least, a quarterly review of their clinical practice and report the results to the appropriate quality control body. This review should include a representative sampling of each practitioner's moderate sedation/analgesia (conscious sedation) cases as determined by the individual command's criteria. Required parameters of this review include, at a minimum:

(a) Pre-sedation history and physical completed.

(b) Patient meets scope/criteria for type of sedation/anesthesia selected.

(c) Level of patient risk adequately assessed and documented (ASA).

(d) Risk/benefits discussed with patient and/or significant other for both procedure and type of sedation/anesthesia selected.

(e) Intraoperative vital signs adequately monitored according to command/department policy.

(f) Intentional plane of sedation achieved and maintained.

(g) No requirement for medications to reverse deeper than intended plane of sedation.

(h) Postoperative vital signs adequately monitored according to command/department policy.

(i) Discharge criteria met prior to patient leaving department.

(j) Discharge instructions to patients and/or significant other appropriate and adequate for patient's condition.

(2) Peer review compliance. Any occurrence of an unintended deeper level of sedation must be reported via the Patient Safety Reporting System (available at: https://patientsafety.csd.disa.mil). Any adverse trends identified must be reported in writing to the appropriate peer review body.

(3) Controlled substance utilization review. A system for recording usage and wastage of controlled substances must be used by each department conducting moderate sedation/analgesia (conscious sedation). Documentation of the amount of controlled substances checked out to a specific patient, the amount received by the patient and the amount either wasted or returned to stock must be recorded in the patient's record. (Each department must conduct a quarterly review of each practitioner's controlled substance documentation and report the results to the appropriate peer review body).

(4) Equipment maintenance review. Each department that conducts moderate sedation/analgesia (conscious sedation) must ensure the equipment specified above has met the hospital's biomedical engineering standards and is reviewed for compliance with such standards on a regular basis. Documentation of meeting these standards must be kept within the Biomedical Department.

STANDARDS FOR CONDUCT OF DEEP SEDATION/ANALGESIA

1. Definition. A drug-induced depression of consciousness during which patients cannot be easily roused, but respond purposefully after repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. This instruction does not apply to the delivery of sedation to patients being mechanically ventilated in intensive care settings.

2. Credentials Requirements. The standards outlined in this instruction must apply when any patient receives, by any route, medications resulting in a state of deep sedation/analgesia as defined in paragraph 6a(3) of this instruction.

a. When paragraph 6a(3) of this instruction applies, the patient must have two people in attendance during the procedure (in addition to the assistant or the circulator) and one person during the recovery phase.

(1) The provider practitioner performing the procedure. The monitor cannot be the provider performing the procedure or test.

(2) The monitor must be a practitioner credentialed in the provision of deep sedation/analgesia who is responsible for the administration of medications and continuous assessment/recording of the patient's physiological and psychological status. The monitor cannot serve the function as a surgical assistant or circulator.

(3) The recovery assistant will assist in the recovery of the patient in an appropriately designated recovery area. Corpsmen/technicians may not recover patients without the supervision of a general anesthesia credentialed practitioner or a nurse trained in sedation recovery. The corpsmen/technicians can only discharge the patient under supervision of the practitioner or the recovery nurse.

b. The Practitioner

(1) Shares responsibility with the monitor for the patient's welfare.

(2) Must be properly licensed and credentialed (per reference (h) or the most current version).

(3) Must be certified in BLS.

(4) Is certified in ACLS for adult care.

(5) Is certified in PALS or NRP as appropriate if managing the pediatric patient (12 years of age or less).

(6) Must be available at all times until the patient is discharged from the service unless the monitor assumes responsibility for the patient until discharge.

c. The Monitor

(1) Must be properly licensed and privileged, within the specialties of OMS, Critical Care Medicine, or Emergency Medicine, in the provision of deep sedation/analgesia (according to reference (e) or the most current version).

(2) Must be certified in BLS.

(3) Is certified in ACLS for adult care.

(4) Is certified in PALS or NRP as appropriate if managing the pediatric patient (12 years of age or less).

d. The recovery assistant, if not a practitioner, must demonstrate competence for certification by the following:

(1) Must be certified in BLS.

(2) Successful completion of an appropriate rhythm recognition course or ACLS/PALS certification as appropriate.

(3) Completion of a sedation course or documented prior appropriate training (see NAVMED 6710/16).

(4) Safe completion of an adequate number of cases per departmental criteria.

(5) Must be certified as competent by the department service on NAVMED 6710/16.

3. Equipment Requirements. The location where deep sedation/analgesia is conducted, as well as, the location where the patient is recovered must each have the following items:

a. A functional source of oxygen. Piped oxygen is preferred, but an oxygen cylinder may be used if adequate supply and replacement tanks are immediately available. Cylinder oxygen will be readily available in case of pipeline failure.

b. A means of delivering positive pressure ventilation (bag, valve, mask).

c. Suction and appropriately sized suction catheters.

d. Continuous pulse oximetry for non-invasive monitoring of oxygen saturation.

e. Continuous capnography for the non-invasive monitoring of exhaled carbon dioxide.

f. Automated blood pressure determination.

g. Continuous EKG monitoring.

h. Airway management equipment.

i. Temperature monitoring must be available.

j. A reliable means of two-way communication to summon help if required.

k. Adequate battery powered illumination with extra batteries.

l. Sufficient electrical outlets with clearly labeled emergency power supply outlets or appropriate battery powered equipment with extra batteries.

m. Additionally, there must be a readily available emergency cart with equipment appropriate for the patient's age and size to include:

(1) Automated External Defibrillator or Defibrillator.

(2) ACLS emergency drugs.

(3) Airway equipment.

(4) Intravenous solutions/supplies.

4. Patient Management

a. Pre-procedure. Preparation of the patient is the responsibility of the credentialed practitioner and must include:

(1) Patient evaluation:

(a) Appropriate pre-procedure evaluation of the patient's medical history and physical examination will reduce the risk of adverse outcomes.

(b) History - Practitioners administering deep sedation/analgesia must be familiar with pertinent aspects of the patient's medical history including:

1. Past disease and abnormalities of major organ systems.

2. Previous adverse experience with sedation or anesthesia.

3. Current medications and drug allergies.

4. Time and nature of last oral intake.

5. History of tobacco, alcohol, or substance abuse.

(c) Practitioners should consider seeking anesthesia consultation when it is believed the patient's pre-existing medical condition may be associated with an increased risk when administering sedation outside of a main operating room.

(d) Physical Examination. Patients presenting for deep sedation/analgesia undergo a physical examination which, at a minimum, includes:

1. Auscultation of the heart and lungs.

2. Evaluation of the airway to identify factors that may be associated with difficulty in airway management (see enclosure (7)).

3. Pre-procedural laboratory testing is guided by patient's underlying medical conditions and the likelihood results will change the sedation management plan.

4. Medical conditions placing the patient at increased risk should be optimized prior to elective procedures (i.e., electrolyte imbalance, anemia, diabetes, hypertension, coagulopathy).

(2) Patient counseling. Before the procedure begins, patients (or their legal guardian in the case of a minor or legally incompetent adult) will be informed of, and give informed consent, for the administration of deep sedation. Risks and benefits associated with the planned procedure or test, alternative sedation options, and risks of both the procedure and sedation plan must be discussed with the patient or legal guardian. Informed consent must be documented on the NAVMED 6710/12.

(3) Pre-sedation fasting. Pre-procedural preparation of the patient will include counseling and review of fasting guidelines and protocol. Patients undergoing deep sedation/analgesia for elective procedures should not drink or eat solid foods for an ample period of time to allow for gastric emptying before their procedure (see enclosure (8)). In an urgent or emergent circumstance, where nothing by mouth protocol cannot be adhered to, the risk of injury due to aspiration must be weighed against the benefit of proceeding with the procedure. Do not delay procedural sedation in adult or pediatric patients in the emergency department for emergent medical needs. This assessment should be documented in the patient's health record.

(4) Documentation. The history and physical examination, and the results of any indicated diagnostic tests are recorded in the patient's record. Documentation includes:

(a) Peri-procedural plan of care.

(b) Consent for the procedure and sedation must be documented on the NAVMED 6710/12.

(c) Pre-sedation summary to include airway exam, age, weight in kilograms, blood pressure, heart rate, respiratory rate, temperature, ASA classification, sedation choice, previous anesthetic/sedation outcomes, past medical history, and allergies (OF-517).

(d) OF-517.

(e) NAVMED 6710/14.

b. Intra-Procedure

(1) Level of Consciousness. Response of patients to commands during procedures performed with deep sedation/analgesia is an indicator of their level of consciousness. Monitoring a patient's response to verbal commands is routine, except with pediatric patients or those having a procedure or test that prevents a verbal response. The level of consciousness must be documented at least every 5 minutes. The following are useful indicators:

(a) Awake and alert.

(b) Sedate and cooperative.

(c) Asleep and easily rousable.

(d) Asleep, and slow to respond.

(e) Rousable only to pain.

(2) Pulmonary Ventilation and Oxygenation. The primary cause of morbidity associated with deep sedation/analgesia is drug induced respiratory depression. Monitoring of ventilatory function and oxygenation must be achieved by the following monitors:

(a) Continuous observation of spontaneous respiratory activity recorded every 15 minutes. For sedation events shorter than 15 minutes, recording every 5 minutes is appropriate.

(b) Auscultation of breath sounds if direct observation of respiratory activity is unable to be accomplished.

(c) Continuous pulse oximetry with appropriate alarm settings recorded every 15 minutes. For sedation events shorter than 15 minutes, recording every 5 minutes is appropriate.

(d) Continuous capnography with appropriate alarm settings recorded every 15 minutes. For sedation events shorter than 15 minutes, recording every 5 minutes is appropriate.

(3) Hemodynamics

(a) Sedative and analgesic agents may diminish autonomic compensation for hypovolemia and surgical stress. Early detection in a patient's heart rate and blood pressure may enable quicker intervention and reduce the risk of cardiovascular collapse.

(b) Required hemodynamic monitoring includes:

1. Blood pressure readings taken and recorded at 5 minute intervals during the procedure.

2. Continuous EKG monitoring and recorded every 15 minutes. For sedation events shorter than 15 minutes, recording every 5 minutes is appropriate.

3. Continuous heart rate readings recorded at 5 minute intervals.

(4) Recording of monitored parameters.

(a) Simultaneous recording of patient's level of consciousness, respiratory function, and hemodynamics must be done on the Sedation Record (Medical Record – Anesthesia, OF-517). Manual recording confirms the practitioner caring for the patient is aware of changes in a patient's condition.

(b) The following should be recorded:

1. Type and amount of medication administered.

2. Vital signs, ventilatory and oxygenation status at the intervals prescribed above.

3. Level of consciousness.

4. Patient's ability to maintain their airway.

5. Rate of supplemental oxygen.

6. Emergency interventions (if required).

c. Post-procedure. Patients receiving deep sedation/analgesia must be monitored until appropriate discharge criteria are satisfied. Duration of monitoring must be individualized depending on the level of sedation accomplished, condition of the patient, and nature of

intervention for which the deep sedation/analgesia was administered. Patients will be monitored after deep sedation/analgesia and recovery will be appropriately documented and retained in the patient's record. The patient will not be released until the following criteria are met and the patient is no longer at increased risk for cardiopulmonary depression. Utilization of a standing order to discharge the patient when the below criteria are met is appropriate.

(1) Appropriate post-anesthesia recovery score (such as Aldrete or PADSS).

(2) Stable respiratory status and the ability to maintain a patent airway.

(3) Vital signs within +/- 20 percent of admission, pre-procedure recordings.

(4) No EKG changes.

(5) Ability to ambulate or return to pre-procedure activity level if same day discharge anticipated.

(6) An adult escort is present who understands the post-procedure and post-sedation instructions. The escort will assume the care and monitoring of patient at home and be able to report complications.

(7) Acceptable transportation home.

(8) Two hours have elapsed after the last dose of reversal agents to ensure the patient does not become re-sedated after the reversal effects have abated.

(9) Satisfactory pain management.

(10) Control of nausea and vomiting.

(11) Patients should be alert and oriented. Infants and those with abnormal mental status should have returned to their pre-operative baseline.

(12) Patients are provided with written instructions that address the following:

(a) Post-procedure diet.

(b) Medications.

(c) Activities.

(13) Patient/escort should be able to verbalize an understanding of the instructions.

(14) Patients and escorts should be provided with a 24-hour telephone number where help can be obtained in the event of a complication or emergency.

5. Competency Assessment and Maintenance

a. Practitioner: Per the routine credentials process and designated departmental criteria.

b. Monitor: Per the routine credentials process and designated departmental criteria.

c. Recovery Assistant: Annual competency review on NAVMED 6710/16.

6. Quality Control Checks

a. Reference (a) requires all departments conducting sedation services to have a system to review and document care provided. This review must encompass 4 main components:

(1) Appropriate record review.

(2) Appropriate peer review, as needed, to track and trend reportable incidents and adverse outcomes.

(3) Controlled substance utilization review.

(4) Equipment maintenance review.

b. The criteria for review are discussed below:

(1) Appropriate record review. Departments that perform deep sedation/analgesia must perform and document, at the least, a quarterly review of their clinical practice and report the results to the appropriate quality control body. This review should include a representative sampling of each practitioner's deep sedation/analgesia cases as determined by the individual command's criteria. Required parameters of this review include, at a minimum:

(a) Pre-sedation history and physical completed.

(b) Patient meets scope/criteria for type of sedation/anesthesia selected.

(c) Level of patient risk adequately assessed and documented ASA.

(d) Risk/benefits discussed with patient and/or significant other for both procedure and type of sedation/anesthesia selected.

(e) Intraoperative vital signs adequately monitored according to command/ department policy.

(f) Intentional plane of sedation achieved and maintained.

(g) No requirement for medications to reverse deeper than intended plane of sedation.

(h) Postoperative vital signs adequately monitored according to command/department policy.

(i) Discharge criteria met prior to patient leaving department.

(j) Discharge instructions to patients and/or significant other appropriate and adequate for patient's condition.

(2) Peer review compliance. Any occurrence of an unintended deeper level of sedation must be reported via the Patient Safety Reporting System (available at: https://patientsafety.csd.disa.mil). Any adverse trends identified must be reported in writing to the appropriate peer review body. Any adverse trends found in the performance reviews must be reported on tracking and trending forms and promptly submitted per the command's peer review policy. Examples of reportable incidents include, but are not limited to, the development of unintentional deeper levels of anesthesia and required use of a reversal agent.

(3) Controlled substance utilization review. A system for recording usage and wastage of controlled substances must be used by each department conducting deep sedation/analgesia. Documentation of the amount of controlled substances checked out to a specific patient, the amount received by the patient and the amount either wasted or returned to stock must be recorded in the patient's record. Each department must conduct a quarterly review of each practitioner's controlled substance documentation and report the results to the appropriate peer review body.

(4) Equipment maintenance review. Each department that conducts deep sedation/analgesia must ensure the equipment specified above has met the hospital's biomedical engineering standards and is reviewed for compliance with such standards on a regular basis. Documentation of meeting these standards must be kept within the Biomedical Department.

STANDARDS FOR GENERAL ANESTHESIA

1. Definition. General anesthesia is a drug-induced loss of consciousness during which patients are not rousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

2. Credentials Requirements. The standards outlined in this instruction must apply when any patient receives, by any route, medications resulting in a state of general anesthesia as defined in paragraph 6a(4) of this instruction.

a. When paragraph 6a(4) applies, the patient of general anesthesia must have two people in attendance during the procedure (in addition to the assistant or the circulator) and one person during the recovery phase:

(1) The practitioner performing the procedure/test. The monitor cannot be the provider performing the procedure or test.

(2) The monitor must be a practitioner credentialed in the provision of general anesthesia who is responsible for the administration of medications and who continuously assesses and records the patient's physiological and psychological status. The monitor cannot serve the function as a surgical assistant or circulator.

(3) The recovery assistant will assist in the recovery of the patient in an appropriately designated recovery area. Corpsmen/technicians may not recover patients without the supervision of a general anesthesia credentialed practitioner or Post-Anesthesia Care Unit (PACU) trained recovery nurse. The corpsmen/technicians can only discharge the patient under supervision of the practitioner or the recovery nurse.

b. The Practitioner

(1) Shares responsibility with the monitor for the patient's welfare.

(2) Must be properly licensed and credentialed (per reference (e) or the most current version).

(3) Must be certified in BLS.

(4) Is certified in ACLS for adult care.

(5) Is certified in PALS or NRP as appropriate if managing the pediatric patient (12 years of age or less).

(6) Must be available at all times until the patient is discharged from the service unless the monitor assumes responsibility for the patient until discharge.

c. The Monitor

(1) Must be licensed and privileged within the specialty of OMS, for the provision of general anesthesia (per reference (e) or the most current version).

(2) Must be certified in BLS.

(3) Is certified in ACLS for adult care.

(4) Is certified in PALS or NRP as appropriate if managing the pediatric patient (12 years of age or less).

d. The Recovery Assistant, if not a practitioner, must demonstrate competence for certification by the following:

(1) Must be certified in BLS.

(2) Successful completion of a rhythm recognition course or ACLS/PALS certification as appropriate.

(3) Completion of appropriate training (see NAVMED 6710/16).

(4) Safe completion of an adequate number of cases per departmental criteria.

(5) Must be certified as competent by the department on NAVMED 6710/16.

3. Equipment Requirements. The location where general anesthesia is conducted, as well as, the location where the patient is recovered must each have the following items:

a. A functional source of oxygen. Piped oxygen is preferred, but an oxygen cylinder may be used if adequate supply and replacement tanks are immediately available. Cylinder oxygen will be readily available in case of pipeline failure.

b. A means of delivering positive pressure ventilation (bag, valve, mask).

c. Suction and appropriately sized suction catheters.

d. Continuous pulse oximetry for non-invasive monitoring of oxygen saturation.

e. The use of continuous capnography for the non-invasive monitoring of exhaled carbon dioxide.

f. An automated blood pressure machine recorded at a minimum of every 5 minutes.

g. Continuous EKG monitoring.

h. Airway management equipment.

i. Temperature monitoring must be available.

j. A reliable means of two-way communication to summon help if required.

k. Adequate battery powered illumination with extra batteries is available.

l. Sufficient electrical outlets with clearly labeled emergency power supply outlets or appropriate battery powered equipment with extra batteries.

m. Additionally, there must be a readily available emergency cart with equipment appropriate for the patient's age and size to include:

(1) Automated External Defibrillator.

(2) ACLS emergency drugs.

(3) Airway equipment.

(4) IV solutions/supplies.

4. Patient Management

a. Pre-procedural. Preparation of the patient is the responsibility of the credentialed practitioner and must include:

(1) Patient evaluation

(a) Appropriate pre-procedural evaluation of the patient's medical history and physical examination reduces the risk of adverse outcomes.

(b) History. Practitioners administering anesthesia must be familiar with pertinent aspects of the patient's medical history including:

1. Past disease and abnormalities of major organ systems.

2. Previous adverse experience with sedation or anesthesia.

3. Current medications and drug allergies.

4. Time and nature of last oral intake.

5. History of tobacco, alcohol, or substance abuse.

(c) Practitioners should consider seeking anesthesia consultation when it is believed the patient's pre-existing medical condition may be associated with an increased risk when administering sedation outside of a main operating room.

(d) Physical Examination. Patients presenting for anesthesia undergo a physical examination which includes:

1. Auscultation of the heart and lungs.

2. Evaluation of the airway to identify factors that may be associated with difficulty in airway management (see enclosure (7)).

3. Pre-procedural laboratory testing is guided by patient's underlying medical conditions and the likelihood results will change the anesthesia management plan.

4. Medical conditions placing the patient at increased risk should be optimized prior to elective procedures (i.e., electrolyte imbalance, anemia, diabetes, hypertension, coagulopathy).

(2) Patient counseling. Before the procedure begins, patients (or their legal guardian in the case of a minor or legally incompetent adult) will be informed of, and give informed consent, for the administration of anesthesia. Risks and benefits associated with the planned procedure or test, alternative anesthetic options, and risks of both the procedure and anesthetic plan must be discussed with the patient or legal guardian and documented on the NAVMED 6710/12.

(3) Pre-anesthetic fasting. Pre-operative preparation of the patient will include counseling and review of fasting guidelines and protocol. Patients undergoing anesthesia for elective procedures should not drink or eat solid foods for an ample period of time to allow for gastric emptying before their procedure (see enclosure (8)). In an urgent or emergent circumstance, where nothing by mouth protocol cannot be adhered to, the risk of injury due to aspiration must be weighed against the benefit of proceeding with the procedure. This assessment should be documented in the patient's health record.

(4) Documentation. The history and physical examination, and the results of any indicated diagnostic tests are recorded in the patient's record.

(a) Peri-procedural plan of care.

(b) Consent for the procedure and anesthetic must be documented on NAVMED 6710/12.

(c) Pre-anesthetic summary to include airway exam, age, weight in kilograms, blood pressure, heart rate, respiratory rate, temperature, ASA classification, anesthetic choice, previous anesthetic outcomes, past medical history, and allergies (OF-517).

(d) OF-517.

(e) NAVMED 6710/14.

b. Intra-Procedural

(1) Pulmonary Ventilation and Oxygenation. Monitoring of ventilatory function and oxygenation must be achieved by the following monitors:

(a) Continuous observation of spontaneous respiratory activity recorded every 15 minutes.

(b) Auscultation of breath sounds if direct observation of respiratory activity is unable to be accomplished.

(c) Continuous pulse oximetry with appropriate alarm settings recorded every 15 minutes.

(d) Capnography must be utilized continuously during the delivery of a general anesthetic.

(2) Required hemodynamic monitoring includes:

(a) Blood pressure readings taken and recorded at 5 minute intervals during the procedure.

(b) Continuous EKG monitoring and recorded every 15 minutes.

(c) Continuous heart rate readings recorded at 5 minute intervals.

(3) Recording of monitored parameters.

(a) Simultaneous recording of respiratory function and hemodynamic must be documented on the Anesthetic Record (OF-517).

(b) The following should be recorded:

1. Type and amount of medication administered.

2. IV fluids administered, blood lost and urine output when indicated.

3. Vital signs, as well as, ventilatory and oxygenation status at the intervals prescribed above.

4. Rate of supplemental oxygen, anesthetic gas, air mixture (FiO2).

5. End tidal anesthetic gas amount if utilized.

6. Emergency interventions (if required).

c. Post-procedural. Patients receiving anesthesia must have their vital signs and respiratory function monitored until appropriate discharge criteria are satisfied. Duration of monitoring must be individualized depending on condition of the patient during the recovery period and nature of intervention for which the anesthesia was administered. Patients will be monitored after anesthesia and recovery will be appropriately documented and retained in the patient's record. The patient will not be released until the following criteria are met and the patient is no longer at increased risk for cardiopulmonary depression.

(1) Appropriate post-anesthesia recovery score (such as Aldrete or PADSS).

(2) Stable respiratory status and the ability to maintain a patent airway.

(3) Vital signs within +/- 20 percent of admission, pre-procedure recordings.

(4) No EKG changes.

(5) Ability to ambulate or return to pre-operative activity level if same day discharge anticipated.

(6) An adult escort is present who understands the post-operative and post-anesthesia instructions. The escort will assume the care and monitoring of patient at home and be able to report complications.

(7) Acceptable transportation home.

(8) Two hours have elapsed after the last dose of reversal agents to ensure the patient does not become re-sedated after the reversal effects have abated.

(9) Satisfactory pain management.

(10) Control of nausea and vomiting.

(11) Patients should be alert and oriented. Infants and those with abnormal mental status should have returned to their pre-procedural base-line.

(12) Patients are provided with written instructions which address the following:

(a) Post-procedure diet.

(b) Medications.

(c) Activities.

(13) Patients should be able to verbalize an understanding of the instructions.

(14) Presence of a standing order to discharge the patient when the criteria are met.

(15) Patients and escorts should be provided with a 24-hour telephone number where help can be obtained in the event of a complication or emergency.

5. Competency assessment and maintenance

a. Practitioner: Per the routine credentials process and designated departmental criteria.

b. Monitor: Per the routine credentials process and designated departmental criteria.

c. Recovery Assistant: Annual competency review on NAVMED 6710/16.

6. Quality Control Checks

a. Reference (a) requires all departments conducting sedation services to have a system to review and document care provided. This review must encompass four main components:

(1) Appropriate record review.

(2) Appropriate peer review, as needed, to track and trend reportable incidents and adverse outcomes.

(3) Controlled substance utilization review.

(4) Equipment maintenance review.

b. The criteria for review are discussed below:

(1) Appropriate record review. OMS departments that perform general anesthesia must perform and document, at the least, a quarterly review of their clinical practice and report the results to the appropriate quality control body. This review should include a representative sampling of each practitioner's general anesthesia cases as determined by the individual command's criteria. Required parameters of this review include, at a minimum:

(a) Pre-sedation history and physical completed.

(b) Patient meets scope/criteria for type of sedation/anesthesia selected.

(c) Level of patient risk adequately assessed and documented ASA.

(d) Risk/benefits discussed with patient and/or significant other for both procedure and type of sedation/anesthesia selected.

(e) Intraoperative vital signs adequately monitored per command/department policy.

(f) Intentional plane of sedation achieved and maintained.

(g) No requirement for medications to reverse deeper than intended plane of sedation.

(h) Postoperative vital signs adequately monitored per command/department policy.

(i) Discharge criteria met prior to patient leaving department.

(j) Discharge instructions to patients and/or significant other appropriate and adequate for patient's condition.

(2) Peer review compliance. Any occurrence of improper level of sedation must be reported via the Patient Safety Reporting System (available at: https://patientsafety.csd.disa.mil). Any adverse trends identified must be reported in writing to the appropriate peer review body.

(3) Controlled substance utilization review. A system for recording usage and wastage of controlled substances must be used by each department conducting anesthesia. Documentation of the amount of controlled substances checked out to a specific patient, the amount received by the patient and the amount either wasted or returned to stock must be recorded in the patient's record. Each department must conduct a quarterly review of each practitioner's controlled substance documentation and report the results to the appropriate peer review body as part of the compliance review.

(4) Equipment maintenance review. Each OMS department that conducts anesthesia must ensure the equipment specified above has met the hospital's biomedical engineering standards and is reviewed for compliance with such standards on a regular basis. Documentation of meeting these standards must be kept within the Biomedical Department.

AMERICAN SOCIETY OF ANESTHESIOLOGISTS PHYSICAL STATUS CLASSIFICATIONS

Class 1 – A normal, healthy patient with no systemic disease.

Class 2 – A patient with mild systemic disease.

Class 3 – A patient with severe systemic disease.

Class 4 – A patient with severe systemic disease that is a constant threat to life.

Class 5 – A moribund patient who is not expected to survive without the operation.

Class 6 – A declared brain-dead patient whose organs are being removed for donor purposes.

Class E – Emergency.

FACTORS ASSOCIATED WITH THE DIFFICULT AIRWAY

1. History

    a. Previous problems with anesthesia or sedation.

    b. Stridor, snoring, or sleep apnea.

    c. Dysmorphic facial structure (Pierre-Robin syndrome, craniofacial syndromes, or Trisomy 21).

    d. Advanced rheumatoid arthritis.

    e. Temporomandibular joint disease.

    f. Prior airway surgery.

2. Physical Examination

    a. Habitus - Significant obesity (especially involving the neck and facial structures).

    b. Head and neck - short neck, limited neck extension, previous cervical fusion, decreased hyoidmandible distance (<3 finger breadths in an adult), neck mass, cervical disease or trauma, tracheal deviation.

        Mallampati classification:

        (1) Class I: Soft palate, uvula, fauces, pillars visible.

        (2) Class II: Soft palate, uvula, fauces visible.

        (3) Class III: Soft palate, base of uvula visible.

        (4) Class IV: Only hard palate visible.

    c. Mouth small opening (<3 cm in an adult), edentulous, protruding incisors, loose or crowned teeth, high-arched palate, macroglossia, tonsillar hypertrophy, previous pharyngeal flap, nonvisible uvula.

    d. Jaw - micrognathia, retrognathia, trismus, significant malocclusion.

NOTHING BY MOUTH GUIDELINES

Gastric contents and pH may be influenced by many factors, including anxiety, pain, abnormal autonomic function (diabetes), pregnancy, and mechanical obstruction.

These guidelines do not guarantee complete gastric emptying has occurred. In the Emergency Department, do not delay procedural sedation for emergent medical needs in the adult or pediatric patients, unless contraindicated, pediatric patients should be offered clear liquids until 2-3 hours before anesthesia to minimize dehydration.

	Solids and non-clear liquids*	**Clear liquids**
Adults	6-8 hours or nothing by mouth after midnight	2-3 hours
Children older than 36 months	6-8 hours	2-3 hours
Children 6-36 months	6 hours	2-3 hours
Children younger than 6 months	4-6 hours	2 hours
*** Includes milk, formula, and breast milk (high fat content can delay gastric emptying).**		