



Defense Health Agency

PROCEDURAL INSTRUCTION

NUMBER 6025.44

January 6, 2022

DAD-MA

SUBJECT: Surgical and Procedural Patient Safety Practices

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Procedural Instruction (DHA-PI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (i), establishes the Defense Health Agency's (DHA) procedures for a policy to improve the quality and safety of medical care provided for beneficiaries within the Military Health System by standardizing processes focusing on: universal protocol (UP) to ensure right procedure, person, and site surgery; briefs and debriefs; prevention of surgical fires; and prevention of retained foreign objects. Specific to UP, the accrediting body for the Military Health System requires implementation of UP, which has three major components: a pre-operative/pre-procedure verification process, marking the operative/procedural site, and a time-out immediately before starting the procedure. This DHA-PI assigns responsibility and establishes procedures for implementing, measuring, and sustaining these practices in accordance with accreditation requirements for all procedures performed in the operating room (OR), as well as those procedures conducted outside the OR that expose patients to more than minimal risk. Procedures in dental clinics will follow the guidance in Reference (e). All Oral and Maxillofacial Surgery (OMFS) procedures, conducted in the OR and/or outside the OR, will follow the guidance in this DHA-PI.

2. APPLICABILITY. This DHA-PI applies to:

a. The DHA, DHA components (activities under the authority, direction, and control of DHA), the Military Departments (MILDEP), and all Military Medical Treatment Facilities (MTF).

b. All personnel, to include: assigned or attached Active Duty and Reserve Component members, federal civilians, members of the Commissioned Corps of the Public Health Service, contractors (when required by the terms of the applicable contract), and other personnel assigned temporary or permanent duties at DHA and DHA components.

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to References (a) through (i), to delineate procedures for standardization, to include UP processes, prevention of wrong site surgery, prevention of surgical fires, and prevention of unintended retained foreign objects. The DHA is committed to the delivery of safe, highly reliable, person-centered care to all beneficiaries. An essential feature of that commitment is to continuously assess and improve the quality and safety of surgical care. This DHA-PI provides healthcare team members a standardized approach, to include use of UP checklists, to harm prevention for surgical or other invasive procedures.

4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosures 3 through 5.

6. PROPONENT AND WAIVERS. The proponent of this publication is the Deputy Assistant Director (DAD), Medical Affairs (MA). When Activities are unable to comply with this publication the activity may request a waiver that must include a justification, to include an analysis of the risk associated with not granting the waiver. The activity director or senior leader will submit the waiver request through their supervisory chain to the DAD-MA to determine if the waiver may be granted by the Director, DHA or their designee.

7. RELEASABILITY. **Cleared for public release**. This DHA-PI is available on the Internet from the Health.mil site at: <https://health.mil/Reference-Center/Policies> and is also available to authorized users from the DHA SharePoint site at: <https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx>.

8. EFFECTIVE DATE. This DHA-PI:

a. Is effective upon signature.

b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (c).

9. FORMS. The following DHA Forms are available at:

https://info.health.mil/cos/admin/DHA_Forms_Management/Lists/DHA%20Forms%20Management/AllItems.aspx.

a. DHA Form 228, DHA Universal Protocol Checklist - Operating Room Version

b. DHA Form 229, DHA Universal Protocol Checklist - Procedure Version

/S/
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Director

Enclosures

1. References
2. Responsibilities
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ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5136.01, “Assistant Secretary of Defense for Health Affairs (ASD[HA]),” September 30, 2013, as amended
- (b) DoD Directive 5136.13, “Defense Health Agency (DHA),” September 30, 2013
- (c) DHA-Procedural Instruction 5025.01, “Publication System,” August 24, 2018
- (d) DHA-Procedural Instruction 6025.45, “Ready Reliable Care Safety Communication Bundle” January 3, 2022
- (e) DHA-Procedural Instruction 6410.02, “Dental Universal Protocol,” May 21, 2021
- (f) DHA-Procedures Manual 6025.13, Volume 2, “Clinical Quality Management in the Military Health System, Volume 2: Patient Safety,” August 29, 2019
- (g) The Joint Commission, “Universal Protocol”¹
- (h) Association of Perioperative Registered Nurses’, “AORN Comprehensive Surgical Checklist”²
- (i) Association of Perioperative Registered Nurses, “Guidelines for Perioperative Practice” 2020

¹ “This reference can be found at: <https://www.jointcommission.org/en/standards/universal-protocol>.”

² “This reference can be found at: <https://www.aorn.org/surgicalchecklist>.”

ENCLOSURE 2
RESPONSIBILITIES

1. DIRECTOR, DHA. The Director, DHA, will:

a. Ensure Markets, Small Market and Stand-Alone Military Medical Treatment Facility Organization (SSO), and Defense Health Agency Regions (DHAR) assign responsibilities to implement surgical and procedural patient safety (PS) processes in all areas where invasive procedures are conducted, as outlined in this DHA-PI.

b. Support the MILDEPs, Markets, SSO, DHARs, and MTFs by identifying standard clinical, business, and administrative process changes or requirements and assign required resolution to the appropriate directorate within DHA.

c. Assign responsibility for tracking compliance with the standard procedures and criteria outlined in this DHA-PI to the DAD-MA.

2. ASSISTANT DIRECTOR, HEALTHCARE ADMINISTRATION. The Assistant Director, Healthcare Administration will establish, direct implementation of, and ensure compliance with standards and procedures in this DHA-PI.

3. DAD-MA. The DAD-MA will:

a. Ensure implementation of the requirements of the surgical and procedural safety practices established by this DHA-PI within the MTFs.

b. Manage standardization of data collection and key processes to reduce variation in safety practices across MTFs.

c. Submit an annual update, including adherence metrics, to the Director, DHA.

4. SECRETARIES OF THE MILDEPS. The Secretaries of the MILDEPs will assist DHA in ensuring compliance with the guidance in this publication.

5. DIRECTORS, MARKETS, SSO, AND DHARS. The Directors, Markets, SSO, and DHARs, will:

a. Review monthly data collection related to surgical and procedural safety adherence and provide a quarterly status update to DAD-MA.

- b. Submit to DAD-MA an annual update, including adherence metrics.
 - c. Provide consultation, subject matter expertise, and coaching support for implementation, measurement, and sustainment of the safety practices at MTFs.
 - d. Disseminate this DHA-PI and all updates to all MTF Directors.
6. DIRECTOR, MTF. The Director, MTF, is responsible for the care provided at the MTF, and will:
- a. Submit a monthly data collection report to the Director, Market, SSO, or DHAR.
 - b. Hold leaders, providers, and staff accountable for implementation, measurement, and sustainment of the surgical and procedural safety practices as outlined in this DHA-PI.
 - c. Disseminate this DHA-PI and all updates to all MTF providers and healthcare personnel.
 - d. Ensure all MTF staff will comply with procedures detailed in this DHA-PI.

ENCLOSURE 3

UP PROCEDURES

1. UP OVERVIEW. The DHA UP procedures focus on evidence-based strategies designed to optimize PS and prevent wrong site surgery. These procedures are based on the major components of The Joint Commission's UP: a pre-operative/pre-procedure verification process, marking the operative/procedural site, and a time-out immediately before starting a procedure.

a. Implementation of these UP procedures is required for all operative and other invasive procedures that expose patients to more than minimal risk of harm. This DHA-PI applies to procedures that occur in the following settings: ORs, procedural areas, inpatient settings, and outpatient settings. This policy addresses all operative and other medical procedures involving incisions, percutaneous puncture, drilling, or insertion (e.g., biopsies, cardiac and vascular cauterizations, endoscopies, intra-articular injections). Routine minor procedures (e.g., venipuncture, peripheral IV line placement) are not within the scope of the policy.

b. To prevent wrong site, person, or procedure surgery, verification of the correct person, correct site, and correct procedure occurs at the following times (as applicable):

- (1) At the time the procedure is scheduled,
- (2) At the time of pre-admission testing and assessment,
- (3) Upon admission or entry into the facility,
- (4) Any time a caregiver transfers responsibility of the patient to another clinical staff member (e.g., care transition or handoff), and
- (5) Before the patient leaves the pre-operative area or enters the operating/procedural room and immediately before the provider begins the procedure, as part of the time-out.

c. If any component of UP cannot be completed due to an emergency surgical procedure, then the operating provider will note in the electronic health record (EHR) that the protocol could not be followed, as well as the reason it was not completed.

d. Note, prior to initiation of a surgical procedure, the surgical team must conduct a brief per the guidance provided in Reference (d) on Ready Reliable Care Safety Communication Bundle. The brief is a short, team planning session prior to the start of a surgical or invasive procedure to discuss the surgical plan and team formation, assign roles and responsibilities, establish expectations and climate, and anticipate outcomes and likely contingencies.

2. PRE-PROCEDURE VERIFICATION. The pre-procedure verification is an interdisciplinary collaborative process to ensure that the correct patient receives the intended procedure at the intended site with all necessary equipment or supplies available. It is purposefully designed with multiple redundancies in place to decrease the risk of preventable harm events. Every member of the surgical team has the responsibility to actively engage in this process. Documentation will be completed using the appropriate DHA UP Checklist: DHA Form 228, DHA Universal Protocol Checklist - Operating Room Version or DHA Form 229, DHA Universal Protocol Checklist - Procedure Version.

a. For surgical procedures, the elements of the pre-procedure verification will be completed by a licensed staff member. A licensed staff member is an MTF staff member with a professional healthcare license. For procedures outside the OR, it is recommended that the elements of the pre-procedure verification are completed by a licensed staff member if available.

b. Whenever possible, pre-procedure verification should occur with the patient (or legally authorized representative) involved, awake, and aware and be performed prior to the administration of medications that may result in an altered level of consciousness or orientation (e.g., sedation).

c. Pre-procedure verification confirms the patient's identification (the patient's full name and date of birth) verbally with the patient (or legally authorized representative), and visually inspecting the patient armband. It also confirms that the patient's identification is consistent with signed consent(s) and other relevant documents.

d. The applicable team members will verify the patient's planned procedure and site and match relevant documented procedural plans (e.g., procedure informed consent).

e. When the patient is in the pre-procedure area and immediately prior to moving the patient to the procedural area, the procedure team members verify that the following items are available and accurately matched to the patient (any discrepancy will be immediately reported to the provider performing the surgery or procedure):

(1) Relevant documentation (e.g., history and physical/progress notes, pre-anesthesia assessment)

(2) Accurate and complete consent form, signed by both the provider and patient, and completed within the last 30 days

(3) Correct and properly labeled diagnostic laboratory and radiology test results

(4) Any required blood products, implants, devices, and/or special equipment for the procedure

f. The patient will not be transferred to the surgical area until the provider marks the site (or an alternative marking method; e.g., procedure identification band, is in place) and resolves any discrepancies noted by the procedure team members.

g. Where there is no pre-procedural area (e.g., in a clinic), the provider will ensure the procedure will have the verifications described above.

3. MARKING THE OPERATIVE/PROCEDURAL SITE. The site marking component of the UP is performed in the pre-procedural setting and used to prevent wrong site surgery.

a. Site marking or the alternative marking method is required for all operative and invasive procedures unless noted as exceptions. Markings must be legible and unambiguous.

b. The operating provider who is privileged to perform the procedure will mark the site using, at a minimum, the first and last initials of the marking provider. This individual must be directly involved in the procedure and must be present at the time the procedure is performed. As permitted by the MTF, residents in Graduate Medical Education (GME) programs may mark the site if present and actively involved in the procedure.

c. If it is not possible for the operating provider to mark the site using their initials, an alternative marking method will be used.

d. Marking specifics.

(1) When possible, the patient/legally authorized representative should participate in marking the site by verifying the procedure and site to be marked.

(2) The site will be marked prior to moving the patient to the procedural area. If the procedure is performed in an area other than a surgical suite, such as a clinic office, the site will be marked prior to the time-out.

(3) The mark must be made with an indelible marker that remains visible after site prepping and draping are completed. If the mark is removed during prepping, the operating provider must mark the surgical site again prior to the time-out.

(4) For procedures that involve laterality of organs with incision(s) or approaches from the midline or from a natural orifice, the entry/incision site will be marked and laterality of the organ indicated.

(5) For spinal procedures, in addition to skin marking of the general spinal region, special intra-operative radiographic techniques must be used to mark the exact vertebral level.

(6) For procedures involving the eye, the skin next to the appropriate eye will be marked.

(7) For skin biopsies, when site marking with initials could lead to potential specimen mishandling, alternate skin marking such as circling the lesion is acceptable.

(8) For procedures involving burns, sites shall be marked according to the UP unless contraindicated. If skin marking is contraindicated due to the skin integrity, or due to the possibility of causing a permanent mark on fragile skin, or on skin that will be used for grafting, the provider will pause and point to the incision site while the circulating nurse reads the informed consent and intended surgical site (to include laterality) during the time-out.

(9) Exceptions to marking outside the OR—Site marking is required for all procedures conducted outside the OR, except those where the patient is conscious and the following is true:

(a) Interventional procedures for which the insertion site is not predetermined; e.g., cardiac catheterization or central line placement,

(b) The procedure will be performed on a midline structure or single organ,

(c) The procedure is without intended laterality (e.g., endoscopy, cystoscopy, colposcopy, trans-nasal esophagoscopy) or,

(d) The wound or lesion is obvious. (Note: If there are multiple wounds or lesions and only some of them are to be treated, and the decision and direction for which ones are to be treated is determined prior to the procedure, then the sites to be treated must be marked).

(10) Alternate marking method. The alternate marking method is used in cases when it is not possible for the provider to mark the site with their initials. The primary alternate marking method is to mark the patient's procedure identification band.

(a) The alternate marking method will be used for the following situations:

1. When it is technically or anatomically impossible or impractical to mark the site (e.g., mucosal surfaces and perineum).

2. With premature infants.

3. When the patient refuses the marking.

(b) The operating provider will write the location (side, level, and/or site) of the procedure incision or entry site on the procedure identification band (as opposed to marking it on the patient's skin). In this case, the operating provider must be privileged to perform the procedure, and must be directly involved in the procedure, and must be present during the procedure. As permitted by the MTF, residents in GME programs may use the alternative marking method if the resident is present and actively involved in the procedure.

(c) The operating provider will place the procedure identification band on the patient (typically on the patient's wrist).

(d) For patients who are not candidates for the procedure identification band placement on their body (e.g., neonates), the band will be co-located with the patient during the pre-procedure verification and time-out.

4. TIME-OUT. A time-out is required for all procedures. It is a pause immediately before the outpatient procedure or surgery begins during which the team verbally agrees that the correct patient, site, and procedure are identified. Completion of time-outs must be documented on the proper DHA UP Checklist.

a. The time-out is the final check and is conducted prior to the actual start of the informed consented procedure. The time-out must be completed by the operating or procedural team immediately prior to the incision, insertion, or start of the procedure. Time-outs are required for all procedures and, in some instances, multiple time-outs are required. For example, surgical procedures done under spinal anesthesia will require two time-outs: one for anesthesia and a second for the actual surgical procedure. If two or more procedures are conducted on the same person, a separate time-out must be conducted for each procedure.

b. The time-out is led by the operating provider and involves the entire team that is participating in the procedure to include the patient in some settings. All procedural team members must be actively listening and engaged during the time-out. Activities, conversations, and ambient noise are suspended to the extent possible, so that team members can focus on active confirmation of the elements of the time-out. The time-out must be repeated if there is an interruption in the procedure or the operating provider leaves the room and then returns to resume the procedure.

c. All members of the healthcare team have the responsibility to stop the procedure and request clarification if there is any question, difference, or discrepancy. The operating provider establishes an inclusive climate to ensure all team members are encouraged to speak up. The procedure does not start until all questions or concerns are resolved.

d. The time-out confirms that:

(1) The correct patient is present by confirming the patient identification band against the informed consent.

(2) The correct informed consent is present and team members agree on the planned procedure.

(3) The correct site is identified and marked with the provider's initials, or an alternate marking method is used.

- (4) The patient's position is appropriate for the planned procedure.
 - (5) Relevant images and test results are properly labeled and appropriately displayed.
 - (6) The required items are available and functional (e.g., imaging, implants, labeled medication, devices, specialty equipment and blood products).
 - (7) The need to administer antibiotics and/or fluids for irrigation purposes has been addressed.
 - (8) Safety precautions based on patient's history or medication use have been identified.
 - (9) The Fire Risk Assessment is complete and need for identified mitigation strategies addressed before the start of the procedure. See Enclosure 4 for information on Fire Risk Assessments.
- e. Each team member is accountable for speaking up and working toward reconciling any discrepancy with the information exchanged during the time-out. If a discrepancy cannot be reconciled, the procedure will be stopped immediately, and appropriate PS documentation completed.

5. SPECIAL VERIFICATIONS

a. Regional anesthesia procedures verification processes. Regional anesthesia procedures performed in conjunction with other procedures are subject to the following:

- (1) All pre-procedure verifications must be completed and documented prior to performing the regional procedure time-out.
- (2) All the operative site(s) (including those for the primary procedure, the regional anesthesia procedure, and any secondary procedure) must be marked prior to the placement of regional anesthesia.
- (3) Regional anesthetic procedures require a second clinical verifier. Examples of a second verifier include, but are not limited to, another anesthesia provider, a registered nurse, an OR technician, an anesthesia technician, or a pain technician. The second clinical verifier should not perform or supervise the regional anesthetic procedure.
- (4) The Regional Anesthesia Procedure time-out will be documented by a licensed staff member.

b. Concurrent or sequential surgeries in the same operative event.

(1) If a patient is undergoing concurrent or sequential surgeries during the same operative event, all surgeries must be listed on the DHA UP Checklist. The second operating provider will document the pre-verification processes on this form prior to the patient being transported to the procedural area.

(2) If the surgeries are concurrent, the time-outs will occur immediately one after the other with the second time-out documented.

(3) If the surgeries are sequential, upon completion of the first surgery another time-out will take place before the start of a subsequent procedure.

c. Spinal surgery additional time-out. An intra-operative x-ray with placement of immovable markers will be used to determine the exact location and level of surgery. Once marked in this way, a second time-out will occur.

d. For surgical cases lasting over 4 hours, conduct a “Four Hour Surgical Team Check-In” called and led by the Operating Room Nurse. At an appropriate time, the Operating Room Nurse will re-evaluate the patient positioning, conduct a skin integrity check, and a circulation check. Additional considerations for this second time-out include: maintaining a sterile field, discussion of the surgical progress, antibiotic re-dosing, fluids, and any other patient-specific needs.

6. SURGICAL DEBRIEF. A debrief must be conducted for all procedures conducted in the OR. Every surgical case will be debriefed by the team involved in the case. The debrief occurs at the conclusion of the case before any team member leaves the room. Recommended timing of the debrief is during skin closure or at the end of the case. As the team lead, it is the responsibility of the operating provider to ensure the debrief occurs; however, anyone can initiate the debrief. Typically, the OR nurse documents the debrief on the UP Checklist. The debrief should verify, at minimum, that:

- a. The final procedure name is correct and recorded.
- b. The instrument, sponge, and needle counts are complete in accordance with the surgical counts procedures specified in Enclosure 5.
- c. Specimens are labeled correctly.
- d. Safety issues are identified.
- e. Any equipment or instrument problems are identified in order to be addressed.
- f. The operating provider, anesthesia provider, and OR nurse reviewed key concerns for recovery and management of the patient.
- g. Wound classification is confirmed.

- h. The team discusses opportunities for improvement and/or what went well.
- i. Disposition planning for the patient is complete.

7. DOCUMENTATION. The DHA UP Checklist must be used for all invasive procedures, regardless of where they are completed. Procedures conducted in the OR should be documented on DHA Form 228. Procedures conducted outside the OR should be documented on the DHA Form 229. Documentation of pre-procedural verifications, time-outs, surgical debriefs, and completion of site marking will be recorded on the appropriate checklist. The completed checklist must be included in the patient's medical record.

8. COMPLIANCE AND REPORTING. High reliability requires consistent excellence in the implementation and sustainment of quality and safety practices. Each MTF will conduct quarterly monitoring and reporting of use of the UP and debrief protocols, reporting findings to the appropriate Market.

ENCLOSURE 4

SURGICAL FIRE PREVENTION AND SAFETY

1. SURGICAL FIRE PREVENTION OVERVIEW. This enclosure provides guidelines and mitigation practices for preventing fires during invasive procedures and appropriate response if a fire occurs. Fires are considered a preventable occurrence and all team members are responsible for preventing fires.

2. FIRE PREVENTION. There are four main concepts involved in a fire prevention plan:

a. Culture of Safety—No deviation from the fire prevention plan will be tolerated. It is the responsibility of the entire team to maintain a low-risk environment.

b. Fire Risk Assessment—Prior to all procedures, a fire risk assessment will be performed.

c. Routine Risk Minimization Interventions—Interventions specifically developed to minimize the risk of surgical fire, defined in conjunction with the risk assessment.

d. Alternate Risk Minimization Interventions—Defined in conjunction with the risk assessment to customize the fire prevention plan based on the uniqueness of each surgical patient. The decision to include these alternate minimization interventions takes place during the risk assessment by the surgical team.

3. FIRE RISK ASSESSMENT. Fire risk is initially assessed during the surgical briefing for each case. It is re-assessed as the final element of the surgical time-out and led by the provider.

a. In the OR, three key risks are: 1) surgical site or incision above the xiphoid; 2) open oxygen (O₂) source (i.e., patient receiving supplemental O₂ via face mask or nasal cannula); and 3) available ignition source (i.e., electrosurgery unit, laser, or fiberoptic light source). In the fire risk assessment, each of these risks is given a score of 1. The individual scores are then tabulated to determine a total fire risk score.

b. A score of 3 indicates high risk because all three key fire risks are present. High risk mitigation practices must be implemented.

c. A score of 2 indicates low risk with potential to convert to high risk. This score is given when the procedure is in the thoracic cavity, the ignition source is remote from an open O₂ source, the ignition source is close to a closed O₂ source, or no supplemental O₂ is used. Routine fire risk mitigation practices must be implemented.

d. A score of 1 indicates low risk. Only supplemental O₂ is being used with no ignition source. Routine fire risk mitigation practices must be implemented.

4. FIRE RISK MITIGATION. The following strategies should be considered to mitigate fire risk.

a. Routine fire risk mitigation strategies include:

- (1) Checking all electrical equipment before use.
- (2) Ensuring all flammable prepping solutions are completely dry and fumes have dissipated (a minimum of three minutes) before applying surgical drapes. This should be timed and verified by the operating provider and circulating nurse.
- (3) Not allowing prep solutions to pool on, around, or beneath the patient.
- (4) Closing open bottles of flammable agents and removing all bowls of volatile solutions from the sterile field as soon as possible after use.
- (5) Assessing the flammability of all materials used in, on, or around the patient.
- (6) Utilizing standard draping procedure.
- (7) Protecting all heat sources when not in use (e.g., cautery pencil holster, laser in stand-by mode).
- (8) Activating heat source only when active tip is in line of sight.
- (9) Deactivating the unit before tip leaves the surgical site.
- (10) Properly positioning multiple foot controls and removing when not in use.

b. High risk mitigation practices include:

- (1) Following all routine mitigation practices as well as the additional practices below.
- (2) Arranging drapes to minimize O₂ buildup underneath.
- (3) Keeping O₂ concentrations below 30 percent if this can be safely accomplished.
- (4) Using an adherent incise drape, if possible, to help isolate head, face, neck, and upper chest incisions from O₂-enriched atmospheres and from flammable vapors beneath the drapes.
- (5) Minimizing the Electrical Surgical Unit (ESU) setting.

(6) Using wet sponges as appropriate.

(7) Having a basin of sterile saline and/or bulb syringe readily available for suppression purposes.

(8) Having a syringe full of saline readily available to anesthesia provider for procedures within the oral cavity.

c. Head and neck procedure strategies include:

(1) Stopping supplemental O₂ at least one minute before and during the use of ESU/laser/disposable cautery.

(2) Using air or Fraction of Inspired Oxygen (FiO₂) of 30 percent for open delivery, if applicable.

(3) Using appropriate laser-resistant endotracheal tubes during upper airway/facial surgery implementing a laser.

(4) Using wet gauze or sponges with cuffed endotracheal tubes to minimize leakage of O₂ into the oropharynx; keep wet.

(5) If endotracheal tube cuff leaks are found during surgery in the oropharynx, wet sponges around the tube cuffs may provide extra protection to help retard fire potential. Do not use the ESU/laser for at least one minute after stopping cuff leak.

5. PREVENTION OF FIRE ON/IN EQUIPMENT

a. Inspect electrical cords and plugs for integrity and remove them from service if they are broken.

b. Check biomedical inspection stickers on equipment for inspection due date and remove from service if expired.

c. Keep fluids off all electrical equipment and cords (e.g., OR table, ESU, laser).

d. Do not bypass or disable ESU or laser safety features (e.g., turning audible alarms down).

e. Use medical devices according to manufacturers' recommendations.

f. Activated light cables must remain attached to the light source or telescope; detached cables have been known to ignite surgical drapes and gowns as well as cause serious tissue burn.

g. Fiber optic light sources should never be left on top of the patient drapes while turned on or illuminated. They must remain on standby if not actively in use, and the provider must maintain positive control of light sources, lasers, and ESU at all times.

6. FIRE RESPONSE. Upon discovery of a fire on or near the patient, personnel should immediately take the following action:

- a. Halt the procedure, yell FIRE.
- b. Have the anesthesia provider stop the flow of gases (i.e., O₂, nitrous oxide (N₂O), Desflurane).
- c. Immediately smother/put out the fire (if safe to do so).
- d. Remove the burning material from contacting the patient (e.g., drapes, endotracheal tubes).
- e. If alcohol or alcohol base solution is fueling fire and non-woven drapes are on the field do not extinguish with water, it may spread.
- f. Activate the fire alarm (pull station) and call the fire department.
- g. Implement the R.A.C.E. (Rescue, Alarm, Contain, Evacuate) procedure.

7. INTERVENTIONS FOR A FIRE ON A PATIENT

- a. Small flames or a small area:
 - (1) Communicate the presence of the fire to team members.
 - (2) Pour saline or water on the fire slowly to prevent spreading.
 - (3) Place your arm between the patient's head and the fire, then lay a wet towel or sponge over the flame and sweep it toward the patient's feet.
 - (4) Lift the material used to smother the flame to vent heat.
 - (5) Remove burning material from the patient.
 - (6) Assess the surgical field for a secondary fire on the underlying drapes or towels.
 - (7) Assess the fire extinguisher and bring toward the patient—do not use unless ordered.
 - (8) Assess the patient for injuries and report to the operating provider.

(9) Activate the fire alarm as required. Complete fire response actions in accordance with the Authority Having Jurisdiction (AHJ) for fire and safety (e.g., the Federal Fire Department) and local fire response procedures and requirements.

(10) Notify the appropriate supervisory chain. A PS event shall be reported in the Joint Patient Safety Reporting (JPSR) system.

b. Large flames or a large area:

(1) Communicate presence of the fire to team members.

(2) Communicate with the anesthesia provider to stop the flow of breathing gases to the patient.

(3) If drapes are involved remove the drape to the ground, rolling it on itself to smother the fire.

(4) Avoid moving the drape into what may need to be the team members' route to evacuate the room.

(5) Assess the surgical field for a secondary fire on the underlying drapes or towels.

(6) Assess the patient for injury and report injuries to the operating provider.

(7) Verify the flames are extinguished and use a fire extinguisher, if necessary.

(8) Activate the fire alarm as required. Complete fire response actions in accordance with the AHJ for fire and safety (e.g., the Federal Fire Department) and local fire response procedures and requirements.

(9) Notify the appropriate supervisory chain. A PS event shall be reported in the JPSR system.

8. INTERVENTIONS FOR HANDLING A FIRE IN A PATIENT AIRWAY

a. Communicate presence of the fire to all team members.

b. Consult with anesthesia to determine the necessary actions to take to extinguish an airway fire.

c. Assist the anesthesia provider with disconnecting and removing the breathing circuit and turning off the flow of O₂.

d. Remove the endotracheal tube and any segments of the burned tube that remain in the airway.

- e. Pour saline or water into the airway, if instructed.
- f. Re-establish the airway.
- g. Examine the airway.
- h. Assess the surgical field for a secondary fire on the underlying drapes or towels.
- i. Activate the fire alarm as required. Complete fire response actions in accordance with the AHJ for fire and safety (e.g., the Federal Fire Department) and local fire response procedures and requirements.
- j. Notify the appropriate supervisory chain. A PS event shall be reported in the JPSR system.

9. INTERVENTIONS FOR HANDLING A FIRE ON EQUIPMENT

- a. Communicate presence of the fire to all team members.
- b. Disconnect equipment from its electrical source.
- c. Shut off electricity to the piece of equipment at the electrical panel if it is not possible to remove the plug from the outlet. If the panel is locked or in a restricted electrical room, request assistance from the on-duty electrician.
- d. Shut off gases to equipment (if applicable).
- e. Assess the size of the fire and determine whether equipment can be removed from the room safely or if the room needs to be evacuated.
- f. Extinguish the fire using a fire extinguisher, if appropriate.
- g. Activate the fire alarm as required. Complete fire response actions in accordance with the AHJ for fire and safety (e.g., the Federal Fire Department) and local fire response procedures and requirements.
- h. Notify the appropriate supervisory chain. A PS event shall be reported in the JPSR system.

10. INTERVENTIONS FOR FIRES WITHIN OR BUT NOT NEAR PATIENT

- a. In case of a fire, OR staff shall implement the R.A.C.E. procedure.
- b. Staff are not to risk their life during containment efforts.

c. Staff will not evacuate until directed by the clinical coordinator or Department Head after ordered by the Fire Department. Complete fire response actions in accordance with the AHJ for fire and safety (e.g., the Federal Fire Department) and local fire response procedures and requirements.

11. INTERVENTIONS FOR HANDLING A FIRE IN ANOTHER AREA OF THE BUILDING

a. All operating, and procedure rooms will be notified of the presence of a fire in another area of the building.

b. No elective cases will be started.

c. Prepare to evacuate.

12. PROCEDURE FOR EVACUATION. Use R.A.C.E.:

a. Rescue

(1) Determine the best method to remove the patient (e.g., procedure bed, gurney, carry) from the area.

(2) Determine the safest location to receive the patient.

(3) Get adequate assistance.

(4) Remove the patient and staff members from the room containing the fire or smoke.

b. Alarm

(1) Communicate to the entire perioperative suite, especially the adjoining rooms.

(2) Follow the hospital-wide procedure for activating the organizational alarm system.

(3) Dial 911, notify operator of fire, state who, where, and type of fire.

c. Contain

(1) Close the doors to the involved room.

(2) Shut off medical gases to the involved room.

(3) Turn off electricity to the involved room.

d. Evacuate

(1) Evacuate when danger is posed to patients in adjoining areas from fire or smoke. If a case is in progress, prepare the patient for evacuation (e.g., cover surgical site, pack wound).

(2) Transfer the patients to an area that is beyond the first set of smoke barriers. Determine the best area in which surgery may be finished safely.

(3) Transfer patients by carrying them, using a gurney, or moving the procedure bed with the patient remaining on the bed.

(4) Cases in progress will need to prepare to evacuate, i.e., prepare minimum instruments to close, cover surgical site, pack wound, etc. In addition, ensure to account for the retained packing if applicable.

e. Save any material/devices for follow-up investigation.

ENCLOSURE 5

RETAINED FOREIGN OBJECTS PREVENTION

1. SURGICAL COUNTS OVERVIEW. This enclosure provides guidelines for performing counts of all items used during operative and other invasive procedures (to include sponges, sharps, small items, and instruments) in order to ensure safe practices that will reduce the risk of surgical items being unintentionally retained in the procedural site.

2. GENERAL

a. The circulating nurse is responsible for initiating counts, documenting results of those counts, and taking the necessary action if incorrect. The scrub technician/nurse is responsible for knowing where counted materials are at all times. Both circulating nurse and scrub technician/nurse are responsible for performing counts as directed in this DHA-PI. The entire surgical/procedural team is accountable for the overall counts process.

b. The circulating nurse must participate in every count and will document measures taken to prevent retained surgical items in the intraoperative documentation. The documentation should include, but is not limited to: type and number of completed counts, the result of counts, actions taken for discrepancies, name of personnel performing counts, explanation of waived counts, and intentionally retained items.

c. Examples of counted items include: instruments, sponges, sharps, sutures, needles, radiopaque-equipped towels, safety pins, scalpel blades, cautery tips, hypodermic needles, vessel loops, bulldog clamps, umbilical tapes, Cottonoids, scratch pads, Kittner Dissector sponges, vessel clamps, ligating clips, fish hooks, tonsil and stick sponges, parts of instruments that could break off or separate, and any other items deemed necessary to be counted by anyone on the surgical/procedural team.

d. In the OR, counts are to be conducted before the procedure begins, before the closure of a cavity within a cavity, before closure of the fascia for intra-abdominal procedures, before wound closure begins, before skin closure, and when there is a change of the scrub technician/nurse or circulating nurse.

e. Outside of the OR (e.g., Labor and Delivery), counts are to be conducted prior to the start of the procedure or delivery, when additional items are added to the field, and at the end of the procedure or delivery.

3. COUNTING PROCEDURES

a. Each count conducted during the intraoperative period will be counted audibly and viewed concurrently by two individuals, one of whom is the circulating nurse.

b. The initial (first) counts of surgical sponges, sharps, instruments, and miscellaneous items will be conducted prior to the patient entering the OR, when possible, to minimize distractions. If the initial count is not completed, then the patient should be x-rayed before leaving the surgical suite.

c. Counts in the OR will proceed in the following order: start at the surgical field, progress to the mayo stand, then sterile back table, and off the sterile field.

d. Initial count shall be completed before incision. The initial count establishes the baseline for subsequent counts for all procedures performed during the surgical encounter.

e. Surgical counts must occur before a closure of a cavity within a cavity, before closure of the fascia for intra-abdominal procedures, before wound closure begins, and at the time of permanent relief of either the scrub technician/nurse or circulating nurse.

f. Subsequent counts shall be performed depending on the type of surgical case (e.g., counts for a cesarean delivery would include initial, uterine, second, and final count).

g. Final closing count must be performed prior to skin closure. At the completion of each closing count in the OR, the operating provider and anesthesia provider will be informed of the count status.

h. The counting sequence must be in a logical progression, starting with sponges, followed by sharps, then instruments. All counts should start proximal (i.e., item closest to the patient) and work distal (i.e., item furthest from the patient).

i. An incorrect count for any item will require suspending the procedure—if the patient's condition permits—to allow time for a team-focused count whereby the entire team is involved in the process.

4. SPONGE COUNTS

a. All sponges used during any OR procedure will be x-ray detectable. Each sponge is checked for an x-ray detectable element.

b. Sponges (Raytecs and laparotomy sponges) are to be separated and opened prior to counting. Radiopaque markers should be visible to both the scrub technician/nurse and the circulating nurse.

c. Sponges will be listed by type and amount on an erasable white board or count sheet. The circulating nurse will place the white board or count sheet in a prominent place that is visible to all team members. As sponges are added during the procedure, the numbers will be added to the original count.

d. Used sponges will be placed separately in a location (e.g., count bags) that can be readily seen by the surgical team and by the anesthesia provider to aid in the estimation of blood loss during surgery.

e. In the OR, the scrub technician/nurse will discard used sponges into an appropriately placed kick bucket or other location determined by the circulating nurse. The circulating nurse will then collect the discarded sponges, Raytecs, and laparotomy sponges (lap tapes) using standard precautions.

f. Radiopaque stick sponges will be used on sponge forceps and Kittner Dissector sponges on an appropriate instrument. Place stick sponges and Kittner Dissector sponge on an instrument prior to use.

g. Lap tapes and 4x8 radiopaque sponges will be kept away from other articles such as ligating clips and needles that could inadvertently hook onto a sponge and be transported into the wound.

h. Because 4x8 radiopaque sponges are susceptible to retention, they should not be used within the peritoneum or deep cavities.

i. Counted sponges will not be used as packing.

j. Counted sponges will not be used for the prep. Upon completion of the prep, remove and close the kick bucket liner with prep sponges and place in a bag for trash in the room.

k. X-ray-detectable sponges will not be used as dressing sponges on any wound where the skin is closed, unless used as packing for a second look procedure, in which case it must be documented.

l. A vaginal sweep for unintended retained objects will be done at the end of all vaginal procedures to include vaginal deliveries.

m. If surgical towels are requested to be used within a body cavity, the circulating nurse will ensure that radiopaque towels are utilized and counted prior to being placed in the cavity.

n. Packages of sponges containing an incorrect number of items should be excluded from the count, removed from the sterile field, labeled, and/or removed from OR before patient's entry.

o. Radiopaque soft goods should not be cut or altered in any way. Altering a sponge invalidates subsequent counts.

p. Radiopaque soft goods are not to be used for dressings. Non-radiopaque gauze sponges (dressing) should be withheld from the field until the incision site is closed, and final count is complete, and correct. Dressing sponges included in surgical packs should remain sealed and separated until final counts have been completed.

5. SHARPS COUNTS. Sharps are items with edges or points capable of cutting/puncturing through other items. These include but are not limited to: suture needles, scalpel blades, hypodermic needles, cautery tips, saw blades, and safety pins.

a. Sharps must be counted on all procedures.

b. Sharps broken during a procedure should be accounted for in their entirety and sequestered in a visible location.

c. Sharps will be contained in approved needle/sharps counters to ensure appropriate and safe disposal.

d. Multipack needles must be opened and the number verified between the circulating nurse and the scrub technician/nurse. Packages of sharps containing an incorrect number of items should be excluded from the count, removed from the sterile field, labeled, and/or removed from OR before patient's entry.

e. Types and amounts of sharps will be listed on an erasable white board/count sheet that is prominently placed and visible to all team members by the circulating nurse. As sharps are added during the procedure, the numbers will be added to the original count.

f. If a sharp is passed or dropped from the sterile field, the circulating nurse should retrieve it using standard precautions, show it to the scrub technician/nurse, isolate it from the field in a visible location, and include it in the final count. Do not subtract or remove items from the count.

6. INSTRUMENT COUNTS. Instruments should be counted for all procedures where there is a possibility of an instrument being retained or a procedure that could possibly convert to an open procedure (including laparoscopic cases).

a. Instruments will be counted in the assembly room as the sets are prepared, in the OR by the circulating nurse and the scrub technician/nurse prior to the start of a procedure, prior to closure of the surgical wound, and upon closure of the wound in all surgical procedures.

b. Preprinted, standardized instrument set count sheets should be used during the set assembly to provide an initial inventory and should be included with the set for performing initial and all subsequent surgical counts. If a surgical instrument is opened to the sterile field after an instrument count has been performed, it must be added to the instrument count.

c. Special attention should be given to those instruments that can be disassembled (e.g., Bookwalter, uterine manipulator). All pieces of these instruments should be accounted for prior to insertion into a body cavity as well as after they are removed. Staff handling these instruments will become familiar with proper assembly/disassembly prior to handling.

d. If an instrument is passed or dropped from the sterile field, the circulating nurse should retrieve it using standard precautions, show it to the scrub technician/nurse, isolate it from the field, and include it in the final count. Do not subtract or remove items from the count. No instruments will be removed from the room unless to be reprocessed due to contamination.

7. MISCELLANEOUS COUNTS. Miscellaneous items are dependent on the type of procedures being performed. They include, but are not limited to: catheter sheaths, clip racks, vessel loops, umbilical tape, vascular inserts, reload cartridges, cautery tips, scratch pads, implant, and any other items the surgical team deems a potential hazard to become a retained surgical item.

a. Miscellaneous items that are opened onto the sterile field should be accounted for during all procedures for which miscellaneous items are used. Miscellaneous items may be non-radiopaque and unintentionally retained in the surgical wound. Accurately accounting for miscellaneous items during a surgical procedure is a primary responsibility of the circulating nurse and the perioperative team members.

b. Non-radiopaque dressing gauze included in custom packs should be kept sealed and isolated on the sterile field until the surgical wound is closed.

8. WAIVED PROCEDURES. In the event of a life-threatening emergency, waived counts are ultimately at the discretion and professional judgment of the operating provider. In these events:

a. Document reason for not performing the count in the comment section of the EHR.

b. Notify operating provider before cavity closure that count was not performed.

c. Operating provider explores the cavity prior to closure.

d. The nurse notifies radiology department of incorrect count in the OR and the need for an intraoperative X-ray for retained item is necessary if patient condition allows. The nurse completes a PS event report in the JPSR system.

9. COUNT DISCREPANCY PROCEDURE

a. Count discrepancies will be reported to the operating provider and entire team as soon as the discrepancy is discovered. Closing of the surgical site is to stop until the item is located, as long as this does not compromise PS. All perioperative team members should take immediate action to resolve a count discrepancy. Incorrect counts are reconciled with two consecutive correct counts.

b. The scrub technician/nurse will organize the sterile field, search the sterile field (including drapes and tables), and recount with the circulating nurse.

c. The circulating nurse will search the room including the area surrounding the surgical field (including floor, kick buckets, and linen and trash receptacles) and recount with the scrub technician/nurse.

d. The operating provider should perform a methodical wound examination, participate in attainment of the intraoperative imaging, and remain in the OR until the item is found or determined not to be in the patient.

e. If the missing item is not located, and the patient's condition allows, intraoperative radiological imaging shall be performed to rule out any retained foreign object prior to the patient being removed from the OR.

f. In the event of a life threatening emergency, if an accurate count of any surgical items was not possible during the case, then intraoperative imaging shall be performed as soon as the life-threatening emergency is resolved and before the patient is transferred out of the OR to verify no foreign bodies remain in the patient. If the emergency is not resolved in the OR, imaging should be conducted as soon as the patient is stable upon leaving the OR. The operating provider is responsible for final determination that there is not a retained foreign object.

g. Unresolved count discrepancies must be documented in the EHR including all measures taken to recover the missing item, description, and location of the item (if known), patient notification/consultation, and plan for follow-up care.

h. A PS event shall be reported in the JPSR system.

10. DEVICE FRAGMENTS

a. Measures should be taken to prevent retention of device fragments. Instruments and devices should be inspected before use. Defective items should not be used.

b. If a broken or separated item is noted, the scrub technician/nurse should immediately notify the perioperative team.

c. If the clinical situation allows, the team should immediately make an attempt to locate and retrieve all parts of the item.

d. Removed implants should be reviewed by the operating provider to confirm their integrity.

e. Non-retrieved device fragments must be documented in the EHR to include size, composition, manufacturer of the fragment, location of the fragment, measures taken to recover the fragment, and patient notification.

f. Instrument/device fragments and packaging must be placed in a red biohazard bag, stored in a red biohazard bin, and given to the supply office to consult with DHA Logistics and/or manufacturer for further disposition.

11. RADIO FREQUENCY (RF) DETECTION SYSTEM. If RF detection system technology is available at the MTF, the following procedures must be followed:

- a. The RF scan is to be used in conjunction with, not in place of, a manual count process.
- b. The RF scan will not be used in place of an x-ray in the case of an incorrect count.
- c. The RF scan will be conducted after the final count is complete, prior to the patient transferring off the operating table. Additional scans may be conducted at any time that any member of the surgical team deems necessary.
- d. An RF scan shall be done on all open surgical incision sites and body cavities (e.g., abdomen, vagina) for cases in which RF identification tagged sponges are within the sterile field.
- e. When an RF scan is conducted, it must be documented in the EHR.

12. INTENTIONALLY RETAINED SURGICAL SOFT GOODS

a. When surgical soft goods are used as therapeutic packing and the patient leaves the OR with this packing in place, appropriate communication should take place between the surgical team and the team receiving the patient. Only radiopaque packing should be used. The operating provider should inform the patient or legally authorized representative of this same information. Information should include location, type, and number of sponges used for packing as well as the plan for eventual removal of packing. This information will also be noted on the EHR in the nursing intraoperative record.

b. A black armband must be placed on the patient's wrist to indicate the patient has intentionally retained soft goods. The black armband will remain until the soft goods are removed, at which point the armband can be removed. The operating provider should also inform the patient or legally authorized representative of the purpose of the armband.

c. If radiopaque soft goods are intentionally left behind as therapeutic wound packing, the surgical count will be marked as correct when this information is known with certainty or incorrect if the number and type of sponges used for therapeutic packing is not known with certainty. Documentation in EHR will note the type and number of soft goods retained with rationale.

d. The number and type of soft goods used for packing should be communicated to the Post Anesthesia Care Unit or Intensive Care Unit nurse as part of the transfer of care information and documented in the EHR.

e. When the patient is returned to the OR for a subsequent procedure or removal of the packing, the number and type of soft goods removed should be documented in the EHR.

f. The removed soft goods should be isolated and not included in the counts for the removal procedure.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

AHJ	Authority Having Jurisdiction
DAD	Deputy Assistant Director
DHA	Defense Health Agency
DHA-PI	Defense Health Agency-Procedural Instruction
DHAR	Defense Health Agency Region
EHR	electronic health record
ESU	Electrical Surgical Unit
GME	Graduate Medical Education
JPSR	Joint Patient Safety Reporting
MA	Medical Affairs
MILDEP	Military Department
MTF	Military Medical Treatment Facility
N2O	nitrous oxide
O2	oxygen
OR	operating room
PS	patient safety
RF	radio frequency
SSO	Small Market and Stand-Alone Medical Treatment Facility Organization
UP	Universal Protocol

PART II. DEFINITIONS

informed consent. Agreement or permission accompanied by full notice about the care, treatment, or service that is the subject of consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient then either consents or refuses such a procedure or treatment.

invasive procedure. Procedures requiring informed consent and involving insertion of objects into the body that purposely disrupts a skin or mucosal layer in order to provide treatment, study function, or deliver or remove fluids (e.g., central line placement, chest tube placement, stent placement, cardiac catheterization, joint injections, and cryotherapy).

laterality. The side of the body identified as “right” or “left.”

licensed staff member. An MTF staff member with a professional healthcare license.

operating provider. As used in this DHA-PI, includes the individual performing the procedure, regardless of the setting. Examples of operating providers include, but are not limited to, anesthesiologists, nurse anesthetists, surgeons, dentists, pulmonologists, endocrinologists, podiatrists, intensivists, emergency physicians, radiologists, advanced nurse practitioners, and physician assistants.

outpatient clinic. Ambulatory clinic settings including, but not limited to, family practice, general surgery, gynecology, orthopedic, or podiatry clinics.

patient identification. Full name and date of birth.

pre-operative/pre-procedural medication. Any narcotic, analgesic, sedative, hypnotic, or amnesiac medication administered prior to a surgery or procedure.

procedural area. An OR, cardiac catheterization or interventional suite, radiation or nuclear medicine area, treatment or procedure room, patient room, emergency room, clinic room, or any other location where surgical or invasive procedures occur.

provider. Military (Active Duty and Reserve Component members) and civilian (General Schedule and those working under contractual or similar arrangement) personnel who are engaged in the delivery of healthcare and are—

Privileged provider. An individual who possesses appropriate credentials and is granted authorized clinical privileges to diagnose, initiate, alter, or terminate regimens of healthcare with defined scope of practice.

Non-privileged provider. An individual who possesses a license, certification, or registration by a state, commonwealth, territory, or possession of the United States, and is only permitted to engage in the delivery of healthcare as defined in their granted scope of practice.

Examples include registered nurse, licensed vocational nurse, registered dental hygienist, and medical technician.

regional anesthesia. The rendering of a specific area of the body insensate to stimulus of surgery or other instrumentation. Types of regional anesthesia may include topical, local/field, intravenous blocks, peripheral, plexus, or central neuraxial. Examples of these blocks include, but are not limited to, local infiltration, digital, retrobulbar, upper/lower extremity, interscalene, femoral sciatic, lumbar plexus, cervical plexus, subarachnoid block, and epidural.

verification. A process that involves checking for consistency among patient identification, information contained on the procedural consent form, any diagnostic study reports, the pre-operative checklist, and the marked anatomical site; all confirmed with the response of the patient or legally authorized representative.