

Defense Health Agency

ADMINISTRATIVE INSTRUCTION

NUMBER 6025.16 January 6, 2022 Incorporating Change 1, December 29, 2022

DAD-MA

SUBJECT: Surgical and Procedural Patient Safety Practices

References: See Enclosure 1.

- 1. PURPOSE. This Defense Health Agency-Administrative Instruction (DHA-AI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (h), establishes the Defense Health Agency's (DHA) procedures to improve the quality and safety of medical care provided to beneficiaries by standardizing processes focusing on: universal protocol (UP) to ensure right invasive 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 DHA 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 invasive procedure. This DHA-AI assigns responsibility and establishes procedures for implementing, measuring, and sustaining these practices for all elements of quality and safety in accordance with accreditation requirements for all invasive procedures performed in the operating room (OR), as well as those invasive procedures conducted outside the OR. Invasive procedures in dental clinics will follow the guidance in Reference (e). Dentists performing any invasive procedure in an OR setting requiring intubation, or with significant medical conditions requiring an OR setting for patient safety (PS), will follow the policies and procedures outlined in this DHA-AI.
- 2. <u>APPLICABILITY</u>. This DHA-AI applies to the DHA Enterprise (components and activities under the authority, direction, and control of the DHA) to include: assigned, attached, allotted, or detailed personnel.
- 3. <u>POLICY IMPLEMENTATION</u>. It is the 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-AI provides healthcare team members a standardized approach, to include use of UP checklists and other checklists where appropriate, to harm prevention for surgical or other invasive procedures.

- 4. RESPONSIBILITIES. See Enclosure 2.
- 5. PROCEDURES. See Enclosures 3 through 5.
- 6. <u>PROPONENT AND WAIVERS</u>. 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. <u>RELEASABILITY</u>. **Cleared for public release**. This DHA-AI 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. <u>EFFECTIVE DATE</u>. This DHA-AI:
 - 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. <u>FORMS</u>. The following UP Checklists are available at: https://info.health.mil/cos/admin/DHA Forms Management/Lists/DHA%20Forms%20Manage ment/AllItems.aspx.
 - a. DHA Form 228, DHA Universal Protocol Checklist Operating Room Version
 - b. DHA Form 229, DHA Universal Protocol Checklist Procedure Version
- 10. <u>SUMMARY OF CHANGES</u>. As the DHA has the worldwide authority, direction, and control over all MTFs, this Procedural Instruction has been converted to an Administrative Instruction and responsibilities for the Secretaries of the Military Departments has been removed. Additional changes to this publication are a result of substantive and administrative

edits identified by the UP Change Management Board. Processes in UP procedures have been updated to include a Pre-Anesthesia Pause, as well as clarification on when UP Checklists should be used.

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Enclosures

- 1. References
- 2. Responsibilities
- 3. Universal Protocol Procedures
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- 5. Retained Foreign Objects Prevention

Glossary

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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, as amended
- (c) DHA-Procedural Instruction 5025.01, "Publication System," April 1, 2022
- (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) The Joint Commission, "Sentinel Event Policy," 1996²

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

² This reference can be found at: https://www.jointcommission.org/resources/sentinel-event/sentinel-event-policy-and-procedures/.

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 PS processes in all areas where invasive procedures are conducted, as outlined in this DHA-AI.
- b. Support the 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 the DHA.
- c. Assign responsibility for tracking compliance with the standard procedures and criteria outlined in this DHA-AI to the DAD-MA.
- 2. <u>ASSISTANT DIRECTOR, HEALTHCARE ADMINISTRATION</u>. The Assistant Director, Healthcare Administration will ensure compliance with the standards and procedures in this DHA-AI.
- 3. DAD-MA. The DAD-MA will:
- a. Ensure implementation of the requirements of the surgical and procedural safety practices established by this DHA-AI within the MTFs.
- b. Collaborate with Health Informatics (HI) Standards and Workflow regarding guidance from the Clinical Communities.
- c. Manage standardization of data collection and key processes to reduce variation in safety practices across MTFs.
 - d. Submit an annual update, including adherence metrics, to the Director, DHA.
- 4. <u>DIRECTOR, HI</u>. The Director, HI will standardize workflows, provide technology management, and integrate end user engagement for potential updates to this instruction.
- 5. <u>DIRECTORS, MARKETS, SSO, AND DHARS</u>. The Directors, Markets, SSO, and DHARs, will:

- a. Review quarterly data collection related to surgical and procedural safety adherence and provide a quarterly status update to the DAD-MA.
 - b. Submit to the 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-AI and all updates to all MTF Directors.
- 6. <u>DIRECTOR, MTF</u>. The Director, MTF, is responsible for the care provided at the MTF, and will:
 - a. Submit a quarterly 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-AI.
 - c. Disseminate this DHA-AI and all updates to all MTF providers and healthcare personnel.
 - d. Ensure all MTF staff will comply with procedures detailed in this DHA-AI.

UP PROCEDURES

- 1. <u>UP OVERVIEW</u>. 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 that includes a Pre-Anesthesia Pause, marking the operative/procedural site, and a time-out immediately before starting an invasive procedure, found in Reference (g).
- a. Implementation of these UP procedures is required for all operative and other invasive procedures that expose patients to risk of harm. This DHA-AI applies to invasive procedures that occur in the following settings: ORs, procedural areas, inpatient settings, and outpatient settings. This policy applies to all surgical and other medical invasive procedures involving incisions, drilling, removal of implanted devices, or insertion that are invasive and require written informed consent (e.g., hernia surgery, vasectomy, bone marrow biopsy).
- b. To prevent wrong site, person, or invasive procedure, verification of the correct person, correct site, and correct invasive procedure occurs at the following times (as applicable):
 - (1) At the time the invasive 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 invasive 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 or invasive procedure, the team must conduct an inperson 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 plan and team formation, assign roles and responsibilities, establish expectations and climate, and anticipate outcomes and likely contingencies.
- e. Simultaneous/concurrent surgery occurs when a licensed independent practitioner utilizes clinicians not credentialed and privileged to perform all or a critical portion of the surgical

procedure in order to leave the OR and actively supervise or participate in a surgical or invasive procedure in another OR/procedure room. Simultaneous surgery is never permitted.

- f. Overlapping surgery, in which a licensed independent practitioner is responsible for invasive procedures occurring within the same time frame and is present for all the critical portions of both invasive procedures is permitted when the clinicians performing the invasive procedure are trained and qualified to perform the non-critical portions. The critical portions are those in which the essential technical expertise and surgical judgement of the surgeon is required to achieve an optimal patient outcome. The licensed independent practitioner of record is ultimately responsible for all aspects of both invasive procedures whether they are present or not.
- 2. <u>PRE-PROCEDURE VERIFICATION</u>. The pre-procedure verification is an interdisciplinary collaborative process to ensure that the correct patient receives the intended invasive 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 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. Physical or electronic filing of UP Checklists vary, based on EHR requirements.
- a. For invasive procedures in the OR, the elements of the pre-procedure verification will be completed by a licensed staff member. For invasive procedures outside the OR, the elements of the pre-procedure verification are completed by a licensed staff member or, in the case of physicians assistants, by a certified staff member. A licensed staff member is an MTF staff member with a professional healthcare license.
- 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. If an armband has been provided, (e.g., Outpatient Primary Care Clinic invasive procedure) the patient will be asked to provide identification documentation during their appointment and verbally state their two-patient identifiers prior to the initiation of the invasive procedure. It also confirms that the patient's identification is consistent with signed consent(s) and other relevant documents.
- d. When the patient is in the pre-procedure area and immediately prior to moving the patient to the procedural area, the invasive 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 invasive procedure):

- (1) Relevant documentation (e.g., consent form, history and physical/progress notes, preanesthesia assessment)
 - (2) Correct and properly labeled diagnostic laboratory and radiology test results
- (3) Any required blood products, implants, devices, and/or special equipment for the invasive procedure
- e. The patient will not be transferred to the surgical area until the provider marks the site (or an alternate marking method, such as patient's identification band, is in place) and resolves any discrepancies noted by the procedure team members.
- f. Where there is no pre-procedural area (e.g., in a clinic), the provider will ensure the invasive procedure will have the verifications described above.
- 3. <u>MARKING THE OPERATIVE/PROCEDURAL SITE</u>. 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 alternate 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 invasive 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 invasive procedure and must be present at the time the invasive procedure is performed. As permitted by the MTF's policy, residents in Graduate Medical Education (GME) programs may mark the site if present and actively involved in the invasive procedure.
- c. If it is not possible for the operating provider to mark the site using their initials, an alternate marking method will be used and documented appropriately.
 - d. Marking specifics.
- (1) When possible, the patient/legally authorized representative should participate in marking the site by verifying the invasive procedure and site to be marked.
- (2) The site will be marked prior to moving the patient to the procedural area. If the invasive 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 invasive 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 invasive 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 invasive 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 invasive 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 invasive procedures conducted outside the OR, except those where the patient is conscious, and the following is true:
- (a) Interventional invasive procedures for which the insertion site is not predetermined; e.g., cardiac catheterization or central line placement,
 - (b) The invasive procedure will be performed on a midline structure or single organ,
- (c) The invasive 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 invasive 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 identification band.
 - (a) The alternate marking method will be used for the following situations:
- $\underline{1}$. When it is technically or anatomically impossible or impractical to mark the site (e.g., mucosal surfaces, teeth, and perineum).

- <u>2</u>. 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 invasive procedure incision or entry site on the patient's identification band (as opposed to marking it on the patient's skin). In this case, the operating provider must be privileged to perform the invasive procedure, and must be directly involved in the invasive procedure, and must be present during the invasive procedure. As permitted by the MTF, residents in GME programs may use the alternate marking method if the resident is present and actively involved in the invasive procedure.
- (c) The operating provider will place the patient's identification band on the patient (typically on the patient's wrist).
- (d) For patients who are not candidates for the patient's 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. <u>PRE-ANESTHESIA PAUSE</u>. The Pre-Anesthesia Pause serves as the official anesthesia UP procedural time-out and will take place before every invasive procedure requiring all types of anesthesia that are administered in the main OR setting. The Pre-Anesthesia Pause can be utilized as a time-out for a regional anesthetic that is being performed in the OR.
- a. The Pre-Anesthesia Pause is conducted in the OR when the patient has monitors on, prior to surgical time-out and induction of anesthesia.
- b. The Pre-Anesthesia Pause should have the attention of all team members present. The mandatory participants for the Pre-Anesthesia Pause are the anesthesia provider and circulating nurse. Other individuals in the room should not distract from the Pre-Anesthesia Pause.
 - c. Discussion includes, but is not limited to:
 - (1) Patient identity
- (2) Confirmation of invasive procedure and consent(s) being given to include in-depth discussion related to the right patient, invasive procedure, procedural modalities, time, team, and equipment.
 - (3) Site marked, if applicable
 - (4) Patient allergies
 - (5) Patient specific concerns such as:

- (a) Difficult airway
- (b) Aspiration risk
- (c) Risk of blood loss
- (6) Equipment is available such as:
 - (a) All required medication
 - (b) Availability of blood products
 - (c) Any special equipment required
- 5. <u>TIME-OUT</u>. A time-out is required for all invasive procedures. It is a pause immediately before the outpatient invasive procedure or surgery begins during which the team verbally agrees that the correct patient, site, and invasive procedure are identified. Completion of time-outs must be documented on the DHA UP Checklists, as applicable.
- a. The time-out is the final check and is conducted prior to the actual start of the informed consented invasive procedure. The time-out must be completed by the operating or procedural team immediately prior to the incision, insertion, or start of the invasive procedure. Time-outs are required for all invasive procedures, and in some instances, multiple time-outs are required. For example, surgical invasive procedures done under spinal anesthesia will require two time-outs: one for anesthesia and a second for the actual surgical invasive procedure. If two or more invasive 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 or procedural provider and involves the entire team that is participating in the invasive 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 invasive procedure or the operating provider leaves the room and then returns to resume the invasive procedure.
- c. All members of the healthcare team have the responsibility and authority to stop the invasive 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 invasive 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's identification (name and date of birth) and allergies, using the patient's armband against the informed consent.
 - (2) The informed consent documentation is correct, complete, and present.
- (3) The patient's position is appropriate for the planned invasive procedure and provider's initials are visible at or near the consented invasive procedure site(s) or an alternate marking method was used.
- (4) The correct and relevant imaging, implants (as required), labeled medication, devices, specialty equipment, and blood products are available as requested by the operating/procedural provider.
- (5) The initial counts of surgical sponges, sharps, instruments, and miscellaneous items were completed and are accurate.
- (6) The team has labeled and placed the correct antibiotics and back table medication (if required). The team is ready and will address the need for antibiotic re-dosing medications or specific irrigation fluids.
- (7) The safety precautions based on patient's history or medication use, anticipated critical events (e.g., non-routine steps, length of invasive procedure, blood loss, patient-specific concerns, sterility), and relief plan, for surgical and anesthesia personnel have been identified. The team agrees and understands relief and the contingency plan.
- (8) The Fire Risk Assessment is complete and need for identified mitigation strategies addressed before the start of the invasive procedure. See Enclosure 4 for information on Fire Risk Assessments.
 - (9) The team agrees on procedure to be done.
- 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 invasive procedure will be stopped immediately, and appropriate PS documentation completed.

6. SPECIAL VERIFICATIONS

- a. Regional anesthesia procedures verification processes. Regional anesthesia procedures, including those procedures performed by non-anesthesia personnel (e.g., surgeons), performed in conjunction with other invasive 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 surgical/procedural technician or medical assistant, an anesthesia surgical/procedural technician or medical assistant, or a pain surgical/procedural technician or medical assistant. 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 OR/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 invasive 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. Surgery sub-specialty verification/checks. Certain sub-specialties require additional documentation of equipment and verifications/checks. Providers should identify, verify, and document these elements as part of their UP process. Examples of these surgical sub-specialty verifications/checks include lens sizes, power and refractive targets for Ophthalmologic procedures.
- e. For surgical cases lasting over four hours, conduct a "Four Hour Surgical Team Check-In" called and led by the OR Nurse and documented in the Intra-Operative Nurse's document. Every four hours, the OR Nurse will re-evaluate the patient's positioning, conduct a skin integrity check, and conduct a circulation check. Additional considerations for this second (and any subsequent) time-out(s) include: maintaining a sterile field, discussion of the surgical progress, antibiotic re-dosing, fluids, and any other patient-specific needs.

- 7. <u>SURGICAL DEBRIEF</u>. A debrief must be conducted for all invasive 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 or patient 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. The OR nurse will document the debrief on the physical or electronic version of the UP checklist. The debrief should verify, at minimum, that:
 - a. The final invasive 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.
- 8. <u>DOCUMENTATION</u>. The DHA UP Checklist must be used for all invasive procedures, regardless of whether they are completed in the Main OR in non-OR procedural areas. Invasive procedures conducted in the Main OR or Labor and Delivery must be documented on a physical or electronic version of DHA Form 228. Invasive procedures conducted in non-OR procedural areas must be documented on a physical or electronic version of DHA Form 229. For non-OR invasive procedures that are complex or require regional, and/or moderate to deep sedation, providers must use a physical or electronic version of the DHA Form 228. 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. If there is an outage or the EHR is unable to be accessed, a physical version of DHA Form 228 or DHA Form 229 must be completed and scanned into the EHR.
- 9. <u>COMPLIANCE AND REPORTING</u>. High reliability requires consistent excellence in the implementation and sustainment of quality and safety practices. Each MTF will conduct

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quarterly monitoring and reporting of use of the UP and debrief protocols, reporting findings to the appropriate Market.

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SURGICAL FIRE PREVENTION AND SAFETY

- 1. <u>SURGICAL FIRE PREVENTION OVERVIEW</u>. 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. <u>FIRE PREVENTION</u>. 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 invasive 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. <u>FIRE RISK ASSESSMENT</u>. 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 or procedural area, four key risks are: 1) surgical site or incision above the xiphoid; 2) open oxygen (O2) source (e.g., patient receiving supplemental O2 via face mask or nasal cannula); 3) available ignition source (e.g., electrosurgery unit, laser, or fiberoptic light source); and 4) use of flammable agents/solutions (e.g., fuel). 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 or above 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 invasive 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, or an ignition source without supplemental O2 administration. Routine fire risk mitigation practices must be implemented.
- 4. <u>FIRE RISK MITIGATION</u>. 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 procedures.
- (7) Protecting all heat sources when not in use (e.g., cautery pencil holster, laser in standby 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 invasive procedures within the oral cavity.
 - c. Head and neck invasive 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 held 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 or

surgical/procedural technician or medical assistant must maintain positive control of light sources, lasers, and ESU at all times.

- 6. <u>FIRE RESPONSE</u>. 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 (e.g., 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. <u>INTERVENTIONS FOR A FIRE ON A PATIENT</u>

- 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) Lift the material used to smother the flame to vent heat.
 - (4) Remove burning material from the patient.
 - (5) Assess the surgical field for a secondary fire on the underlying drapes or towels.
 - (6) Assess the fire extinguisher and bring toward the patient—do not use unless ordered.
 - (7) Assess the patient for injuries and report to the operating provider.
- (8) 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.

(9) Notify the appropriate supervisory chain. A PS event shall be reported in the Joint Patient Safety Reporting (JPSR) system. Additionally, a Department of Defense Reportable Event (DoD RE) shall be submitted to the DHA Patient Safety Program (PSP) if the fire event meets the definition of fire found in Reference (h). For guidance on how to report a JPSR or DoD RE, refer to Reference (f).

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 gases to the patient.
- (3) If drapes are involved, remove the drapes to the ground, rolling them 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. Additionally, a DoD RE shall be submitted to the DHA PSP if the fire event meets the definition of fire found in Reference (h). For guidance on how to report a JPSR or DoD RE, refer to Reference (f).

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. Additionally, a DoD RE shall be submitted to the DHA PSP if the fire event meets the definition of fire found in Reference (h). For guidance on how to report a JPSR or DoD RE, refer to Reference (f).

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. Additionally, a DoD RE shall be submitted to the DHA PSP if the fire event meets the definition of fire found in Reference (h). For guidance on how to report a JPSR or DoD RE, refer to Reference (f).

10. <u>INTERVENTIONS FOR FIRES WITHIN THE OPERATING ROOM BUT NOT NEAR</u> 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 you are, where the fire is located, 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, e.g., 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.

RETAINED FOREIGN OBJECTS PREVENTION

1. <u>SURGICAL/PROCEDURAL COUNTS OVERVIEW</u>. 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 surgical/procedural technician or medical assistant is responsible for knowing where counted materials are at all times. Both circulating nurse and scrub surgical/procedural technician or medical assistant are responsible for performing counts as directed in this DHA-AI. 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 invasive procedure begins, before the closure of a cavity within a cavity, before closure of the fascia for intra-abdominal invasive procedures, before wound closure begins, before skin closure, and when there is a change of the scrub surgical/procedural technician or medical assistant.
- e. For invasive procedures outside of the OR (e.g., Clinic Procedures), counts are to be conducted in a similar fashion: 1) prior to the start of the invasive procedure or delivery, when additional items are added to the field and 2) at the end of the invasive 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 invasive 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 surgical/procedural technician or medical assistant.
- 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 (e.g., item closest to the patient) and work distal (e.g., item furthest from the patient).
- i. An incorrect count for any item will require suspending the invasive 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 invasive 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 surgical/procedural technician or medical assistant.

- 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 invasive 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 surgical/procedural technician or medical assistant 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.
- 1. A vaginal sweep for unintended retained objects will be done at the end of all vaginal invasive 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. <u>SHARPS COUNTS</u>. 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 invasive procedures.
- b. Sharps broken during an invasive 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 surgical/procedural technician or medical assistant. 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 invasive 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 surgical/procedural technician or medical assistant, 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. <u>INSTRUMENT COUNTS</u>. Instruments should be counted for all invasive 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 surgical/procedural technician or medical assistant prior to the start of an invasive procedure, prior to closure of the surgical wound, and upon closure of the wound in all surgical invasive 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 surgical/procedural technician or medical assistant, 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. <u>MISCELLANEOUS COUNTS</u>. Miscellaneous items are dependent on the type of invasive 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 invasive 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 or invasive 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. <u>WAIVED PROCEDURES</u>. 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. Confirm with the operating provider before cavity closure that the count is not going to be performed.
 - c. Operating provider explores the cavity prior to closure.
- d. The nurse notifies the radiology department that count was not performed, and they need to conduct an intraoperative X-ray for retained item(s) if the patient's condition allows. A PS event for the waived count shall be reported in the JPSR system. Additionally, if an unintended retained foreign object is identified, an additional DoD RE shall be submitted to the DHA PSP, regardless of the harm level. As with all PS events, any member of the care team may report the event in JPSR. For guidance on how to report a JPSR or DoD RE, refer to Reference (f).

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 surgical/procedural technician or medical assistant 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 surgical/procedural technician or medical assistant.
- 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. <u>DEVICE FRAGMENTS</u>

- a. Measures should be taken to prevent retention of device fragments. Instruments and devices should be inspected before and after use. Defective items should not be used.
- b. If a broken or separated item is noted, the scrub surgical/procedural technician or medical assistant 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. <u>RADIO FREQUENCY (RF) DETECTION SYSTEM</u>. 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. An orange armband must be placed on the patient's wrist to indicate the patient has intentionally retained soft goods. The orange 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. When the patient is returned to the OR for removal of the retained items, an x-ray is necessary if the initial amount of intentionally retained items is not known with certainty during placement. If the patient's condition allows prior to closing, the x-ray should be obtained.
- g. 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-AI Defense Health Agency-Administrative Instruction

DHAR Defense Health Agency Region

DoD RE Department of Defense Reportable Event

EHR electronic health record ESU Electrical Surgical Unit

GME Graduate Medical Education

HI Health Informatics

JPSR Joint Patient Safety Reporting

MA Medical Affairs

MTF Military Medical Treatment Facility

N2O nitrous oxide

O2 oxygen

OR operating room

PS patient safety

PSP Patient Safety Program

RF radio frequency

SSO Small Market and Stand-Alone Medical Treatment Facility Organization

UP Universal Protocol

PART II. DEFINITIONS

<u>emergency</u>. An acute injury or illness that poses a potential threat to a person's life, limb, eyesight and/or threaten permanent disability.

35 GLOSSARY

<u>informed consent</u>. 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 in which skin or mucous membranes and/or connective tissue are incised or punctured, an instrument is introduced through a natural body orifice, or foreign material is inserted into the body for diagnostic or treatment-related purposes. Examples of invasive procedures include central line and chest tube insertions, biopsies and excisions, and all percutaneous procedures (for example, cardiac, electrophysiology, interventional radiology). Exclusions include venipuncture, which is defined as a collection of blood from a vein. This exclusion is still considered a PS event and should be reviewed by the appropriate local quality and safety teams.

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

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

<u>operating/procedural provider</u>. As used in this DHA-AI, includes the individual performing the invasive 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.

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

<u>overlapping surgery</u>. Occurs when a licensed independent practitioner is responsible for invasive procedures occurring within the same time frame but is present for all the critical portions of both procedures, is permitted when the clinicians performing the invasive procedure are trained and qualified to perform the non-critical portions. The licensed independent practitioner of record is ultimately responsible for all aspects of both procedures whether s/he is present or not.

patient identification. Full name and date of birth.

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

<u>procedural area</u>. 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.

36 GLOSSARY

<u>provider</u>. 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 surgical/procedural technician or medical assistant.

<u>regional anesthesia</u>. 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.

<u>simultaneous/concurrent surgery</u>. Occurs when a licensed independent practitioner utilizes clinicians not credentialed and privileged to perform all or a critical portion of the surgical invasive procedure in order to leave the OR and actively supervise or participate in a surgical or invasive procedure in another OR/procedure room. Simultaneous surgery is never permitted.

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

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