

DEPARTMENT OF THE ARMY
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MEDCOM Regulation
No. 40-49

21 January 2015

Medical Services
SURGICAL COUNTS

Supplementation of this regulation and establishment of forms other than MEDCOM forms are prohibited without prior approval from HQ MEDCOM, ATTN: MCHO-CP-A.

- 1. History.** This issue publishes a major revision of this regulation.
- 2. Purpose.** This regulation provides guidelines for accountability of items used during operative and other invasive procedures (inclusive of minimally invasive procedures) to ensure they are not retained in a patient. This regulation addresses which items will, at a minimum, be counted, as well as when, how, and by whom the surgical count will be performed.
- 3. References.** References are listed in appendix A.
- 4. Explanation of abbreviations and terms.** Abbreviations used in this regulation are explained in the glossary.
- 5. Applicability.** This policy applies to all U.S. Army Medical Command (MEDCOM) facilities involved in inpatient and outpatient care where operative and other invasive procedures (inclusive of minimally invasive procedures) are performed, irrespective of where in the medical treatment facility (MTF) they are performed.
- 6. Responsibilities**
 - a. The Commander, MEDCOM has overall responsibility for clinical quality management including all policies and procedures addressed by this regulation.
 - b. MTF commanders are responsible for execution and sustainment of all training and oversight activities required by this regulation.

*This regulation supersedes MEDCOM Regulation 40-49, 14 July 2008.

c. The circulating nurse is responsible for the “act” of performing the count and documenting the status of the count; however, the overall process for accountability lies with the entire surgical procedural team.

7. Background

a. The Army Medical Department recognizes patient safety as the highest priority. All measures will be taken to prevent the unintended retention of foreign objects in the surgical site.

b. The goal for this policy is to prevent the unintended retention of foreign objects.

c. As defined by The Joint Commission, unintended retained foreign objects refer to any item or foreign object related to any operative or invasive procedure that is left inside a patient.

d. The surgical team shares a common ethical, legal, and moral responsibility to promote an optimal patient outcome. Prevention of unintended retained foreign objects requires communication among the team as well as consistent application and adherence of the standardized counting procedures.

e. The surgical/procedural team, as referenced in this regulation, consists of—but is not limited to—a circulating nurse; surgical assistant (that is, surgical technician, registered nurse first assistant (RNFA), physician assistant (PA), surgical assistant); anesthesia provider; and/or surgeon/provider.

f. Risk factors that may increase the likelihood of an incorrect count or retained item include the following:

- (1) Emergency surgical procedures.
- (2) Unexpected changes in the scope of the surgical procedure.
- (3) Unplanned procedures.
- (4) Procedures involving more than one surgical team.
- (5) Extended procedural length of time.
- (6) Patients with high body mass index.

g. Set assembly is the first step in supporting the instrument count process and begins within central materiel services. Annotation of this process consists of the identification of the instruments contained within the set and an identifier of the person(s) assembling the set (that is, printed name and signature of the person

putting up the set) for accountability purposes only. If sets are assembled incorrectly, a patient safety report (PSR) must be generated (via an electronic reporting system) annotating the incorrect assembly of the instrument set for purposes of trending and for purposes of providing additional training to improve the process when necessary.

8. Policy

a. Counts are fundamental to the surgical process and are the responsibility of the entire surgical/procedural team.

b. A counting procedure will be performed audibly and visibly by two persons engaged in the process, usually the scrub tech and circulating nurse. The surgical team will verbally acknowledge verification of the count.

c. Counts will be performed—

(1) Before the procedure begins (to establish baseline).

(2) Before the closure of a cavity within a cavity.

(3) Before wound closure begins.

(4) Before skin closure.

(5) Where there is a change of the scrub technician or circulating nurse.

(6) Anytime a count needs to be reassessed for accuracy by any member of the operative team.

d. Examples of counted items include instruments, radiopaque sponges, sharps, sutures, needles, radiopaque-equipped towels; safety pins; scalpel blades, cautery tips; hypodermic needles; vessel loops; bulldog clamps; umbilical tapes; cottonoids; scratch pads; kitners; vessel clamps; ligaclips; fish hooks; tonsil and stick sponges; and other items deemed necessary to be counted by anyone on the surgical team.

e. If items are packaged in multiples and the number of items in the package is incorrect based on the manufacturer's standard for packaging, then the entire package contents will be removed from the sterile field, bagged, labeled, and isolated from the rest of the items in the operating room (OR)/procedure room.

f. The circulating nurse is responsible for recording each item added to the sterile field on the count sheet/count board. Relief personnel will initial all items they add to the sterile field.

g. All pieces of instruments that can be disassembled will be inspected and counted and recorded on the count sheet and count board before and after use. The surgical team will account for instruments that break or parts that become separated; the team must verify all pieces are accounted for to prevent accidental retention. If unable to account for all pieces, an x-ray of the surgical site is mandatory.

h. Before wound closure, methodical wound exploration—including visual and whenever possible mechanical examination—will be completed for all surgical sites to include laparoscopic procedures.

i. A separate count will be taken during each phase of a two-phase procedure (for example, laparoscopy – laparotomy).

j. In emergent life- or limb-threatening situations, where time is a critical factor, it may not be possible to perform a full count. Counts omitted due to a life- or limb-threatening emergency must be documented in a DA Form 5179-1 (Medical Record - Intraoperative Document)) for procedures occurring in the OR and on the SF 509 (Medical Record Progress Notes) or equivalent form for those procedures occurring outside the OR). If electronic charting is being utilized, this documentation will be entered in the appropriate field documenting counts. In those cases where the protocol was not followed and counts were omitted, the incorrect count protocol must be initiated and followed (as described in para 10 of this regulation) and documented in a PSR.

k. The following situations require an x-ray of the surgical site:

(1) All procedures in which an incorrect or an incomplete count occurred. The x-ray of the surgical site will occur before wound closure begins and prior to the patient leaving the OR. (See additional requirements in para 10c.)

(2) If an initial count is not performed. In this case, the x-ray is done at the end of the case, prior to wound closure. Justification for the omission of the count must be documented using the PSR.

(3) When the operative procedure is determined by the surgical team to be at high risk for unintended retained surgical objects.

(4) On patients transported for more definitive care from theater to a designated MTF. (See para 9g for additional guidance.)

(5) When needles, sharps, instruments, or miscellaneous items are broken or cut during a procedure and efforts to retrieve the item(s) have failed.

(6) When a broken or incomplete piece of equipment has been identified in the sterile field, regardless of whether or not it has been utilized on the patient.

l. All counted items will remain within the OR procedure room until the conclusion of the procedure and after all items are accounted for and documented.

m. When a patient expires in the OR suite, a final count is performed for inventory control purposes.

n. If the patient enters the operative area with an external device (for example, fetal scalp wire, external fixation device) that will be removed during the operative procedure, it is considered a countable item. During this circumstance, the presence of the item will be identified by the surgeon, and annotated on the count sheet or count board by the circulating nurse before beginning the surgical procedure.

o. Sponge, sharps, and instrument counts will be documented in the patient's intraoperative record and included in the patient's chart. The documentation will include:

(1) Types of counts.

(2) Names and titles of surgical team members who performed the counts.

(3) Results of the counts (correct, incorrect).

(4) Measures taken to resolve incorrect items.

p. Unintended retention of a foreign object after surgery or other invasive procedure is reportable to The Joint Commission as a sentinel event.

9. Procedures

a. Like items. All like items will be counted together.

b. Order of counts. All counts 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.

c. Pre-printed count sheets. Pre-printed count sheets used by individual central materiel service departments that are identical to the standardized instrument sets (detailing each item within the set) will be used to record the counted items within the instrument sets. Each MTF will have an established procedure in place for generating these count sheets.

d. Closing counts. At the completion of each closing count, the surgeon and anesthesia provider will be informed of the count status. Closing counts must be completed before closure of surgical site and/or procedural access routes.

e. Procedures outside the OR. For procedures performed outside the OR, at a minimum needles and sharps (to include guidewires) used during the procedure, must be accounted for before closure of the surgical site or procedural access routes.

f. Final count. A final count will be conducted verifying the accuracy of all counts before closure of the surgical site or procedural access routes. The surgeon/provider will assist with the count of items on the sterile field; the surgical assistant will assist with the count of items on the mayo stand and sterile back table; and the circulating nurse will assist in the count of items off the sterile field. Once the "team-focused final count" is completed, this process will be documented on DA Form 5179-1. An incorrect count for any countable item will require suspending the surgical procedure, if the patient's condition permits, to allow time for a team-focused count whereby the entire surgical team is involved in the count process. (See para 10 for additional information on incorrect counts.)

g. Counts in theatre. Due to the emergent nature of many procedures performed in theatre, counts are often not performed and when performed may be questionable. Additionally, complete records may not accompany the patient from theatre. For these reasons, all patients transported from theatre to the designated MTF for more definitive care must have x-rays taken of their surgical site(s) to rule out/document any retained foreign objects (intentional or otherwise). These x-rays will be used to verify that no foreign objects are present and/or to locate and validate the number of items/sponges that must be removed by those rendering the next level of care. The results of x-rays taken on all patients once back at the MTF who have had an operative or other invasive procedure in theatre must be documented in the patient's medical record.

h. Lap sponges. If the patient's wound is packed with lap sponges, note the number and type of sponges left in the wound on the DA Form 5179-1 (for procedures in the OR) or on SF 509 or equivalent form (for those procedures occurring outside the OR). The count is considered correct if this mandatory nursing documentation has been completed.

i. Sponges.

(1) All sponges used during surgical procedures will be x-ray detectable. Each sponge is checked for an x-ray-detectable element.

(2) Individual sponges will be left in their original configuration and not cut.

(3) Each sponge will be opened (separated from the other sponges) and visualized individually during the count process to ensure there is only one.

(4) Radiopaque sponges will be placed separately in a location (for example, count bags) that can be readily seen by anesthesia personnel for calculating blood loss.

(5) The scrub technician 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 and lap tapes using standard precautions.

(6) Sponge bag holders must be used on all major procedures. For major surgical cases, sponges passed off the surgical field will be placed in sponge bag holders that render each sponge visible for verification or in kick buckets for minor procedures.

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

(8) Radiopaque stick sponges will be used on sponge forceps and kitners on an appropriate instrument (that is, Kelly or Rochester Pean, not on Criles or tonsil clamps). Place stick sponges and kitners on an instrument prior to use.

(9) Lap tapes and 4x8 radiopaque sponges will be separated on the sterile field. Non-radiopaque sponges will not be placed on the sterile field until completion of the procedure to eliminate the potential for their use during the procedure.

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

(11) Counted sponges will not be used as packing.

(12) 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.

(13) 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.

(14) A vaginal sweep will be done at the end of all vaginal deliveries and documented according to local policy.

j. Surgical towels.

(1) If towels are used during the procedure, they will be impregnated with radiopaque markers and included in the count documentation. The radiopaque impregnated surgical towels will be counted in the same way that sponges are counted. Towels impregnated with radiopaque markers must be a different color than the towels used as wrappers, liners, and drying cloths. This will minimize the potential for using non-x-ray-detectable towels during the procedure.

(2) Only radiopaque-marked surgical towels will be passed to the surgeon for use as packing or for placement under a retractor (for example, O'Connor - O'Sullivan retractor). When used, these radiopaque-equipped surgical towels are accounted for at all times. If an x-ray-detectable towel is used for purposes of packing to enhance visibility during the procedure, the surgeon will verbalize their placement and location to the surgical team for purposes of tracking those items to ensure their removal prior to closure at the end of the procedure.

k. Sharps.

(1) Surgical assist personnel will provide all "sharps" (for example; needles, blades, sharp retractors) to the surgeon on a one-for-one exchange basis using a "neutral zone" or "hands free" technique unless it interferes with the conduct of the procedure or during times in which the surgeon is operating under the microscope, using surgical loops, or in trauma situations. A neutral zone or hands-free technique will be used for all high-risk patients.

(2) All needle packets must be opened, counted, and verified prior to actual use.

(3) The surgical assistant (that is, the surgical technician, RNFA, PA, surgeon assistant) will be held accountable for all loose needles on the surgical/sterile field and will ensure that for every suture or needle packet opened, there is a corresponding needle or needles.

(4) Opened and unopened suture packets will be retained on the sterile field to aid in validating counts and identifying the type of needle unaccounted for if any are determined to be missing.

(5) Used needles on the sterile field should be kept in a disposable, puncture-resistant needle container to ensure safe sharps containment, minimize the risk of injury to the scrubbed person, and increase efficiency and accountability of sharps management on the sterile field.

l. Cottonoids.

(1) Cottonoids will be counted individually and annotated by size (for example, 1/4 x 1/4).

(2) Cottonoids will be left in their original configuration and not cut.

m. Instruments.

(1) Individual pieces of assembled instruments (for example, suction tips, trocar and sleeve, wing nuts, blades, and sheathes) will be accounted for as a separate line item on the count sheet. Disposable items with removable pieces

used in the surgical site will also be accounted for as separate line items on the count sheet (for example, thoracic/vascular/gastrointestinal stapling devices).

(2) Any instrument removed from the OR to be autoclaved must be returned to the room. If the instrument is removed permanently from the room, a note will be made on the count sheet explaining why, where taken, and who removed the instrument from the room.

(3) Instrument sets should consist of the minimum essential number of instruments required to perform the procedure.

n. Conclusion of procedure. The provider must perform a visual exploration of the cavity at the completion of the procedure to verify the removal of the item(s). This “post-procedure pause” and subsequent results will be documented in the procedure notes. If objects are intentionally left in the orifice (for example, vaginal packing), the provider will document this information in the provider note along with an estimated date for removal of the object. Examples of instances where a post-procedure examination will occur are listed in (1)-(3), below. (*Note:* The listed examples represent a sampling, and not an all-inclusive listing, of circumstances in which this post-procedure examination must occur.)

(1) Vaginal deliveries. The provider will include a “post-delivery pause” or “pause for the gauze” after delivery of the placenta when all repairs are completed. The pause will include a vaginal sweep to ensure that no sponges, gauze, or any other foreign object remains in the vagina.

(2) Vaginal insertions. Any time a procedure requires the insertion of a device into the vagina, a “post-procedure pause” examination will be done to verify the removal of that item (for example, after hysterosalpingograms).

(3) Throat packs. In cases involving the use of throat packs, a “pause for the gauze” will also occur after the procedure is completed and prior to extubation, before patient transfer to phase I recovery.

10. Procedures for incorrect count

a. An incorrect count for any countable item will be reported to the surgeon or responsible provider as well as entire surgical team. This notification process will be completed immediately so that appropriate corrective actions can be initiated.

b. An Item that cannot be located is subject to additional searches/x-ray as follows:

(1) The circulating nurse will make a thorough search of the room, including but not limited to trash receptacles, linen hampers, and the area underneath the OR tables.

(2) The surgical assistant will make a thorough search of the sterile field.

(3) The surgeon will recheck the operative field, cavity, and methodically explore the surgical site.

(4) In the event the searches are unsuccessful before the wound is surgically closed, an x-ray is mandatory prior to surgical site closure and the patient leaving the OR. The x-ray request must identify the item(s) that is missing along with the size of the item(s) to aid the radiologist in detecting the missing item(s).

c. All procedures in which an incorrect or an incomplete count occurred due to the patient's condition precluding accurate counting require an x-ray of the surgical site before wound closure begins and prior to the patient leaving the OR. The x-ray results must be documented (on DA Form 5179-1 (for procedures in the OR) or on the SF 509 or equivalent form (for those procedures occurring outside the OR) prior to the patient leaving the OR or procedure room except when, in the surgeon's opinion, the additional time required to wait for the x-ray results would be detrimental to the patient. In this case, the surgeon is responsible for clearing the operative site and re-exploration if the results warrant this action. The surgeon is also responsible for providing justification to the circulating nurse for this deviation from protocol so that the justification for closing the site before an accurate count has been performed will be documented in the PSR or equivalent report.

d. In every instance where counts are incorrect, a PSR must be completed by a licensed and/or privileged provider within the surgical team (for example, by a registered nurse, RNFA, PA, nurse practitioner, surgeon) annotating the incorrect count and actions taken.

e. If the staff change-over count is incorrect, the nurse and/or technician who is being relieved will not leave until appropriate incorrect count procedures outlined in this paragraph have been completed.

11. Documentation. This regulation requires documentation in response to various activities/incidents during the surgical count process. The following summarizes documentation requirements:

a. The PSR is initiated and appropriately annotated as follows:

(1) Every instance where counts are incorrect and actions are taken in response to incorrect counts.

(2) When an initial (baseline) count is not done.

(3) Deviation from surgical count policy occurred.

- (4) Central materiel set assembly was incorrect.
- (5) Patient's condition precluded waiting on x-ray results.
- (6) Lost needle and decision by the surgeon or provider not to obtain an x-ray.
- (7) Inability to account for broken/cut items.
- (8) When an x-ray is not performed prior to leaving the OR due to a clinically based decision made by the surgeon after the missing item is not found.

b. Documentation is required on the DA Form 5179-1 (for procedures in the OR), on the SF 509 or equivalent form (for those procedures occurring outside the OR), or within the electronic documentation for the following activities/incidents:

- (1) Counts omitted due to a life- or limb-threatening emergency.
- (2) All counts and names of those performing them.
- (3) Number and type of lap and packing sponges retained in the surgical site.
- (4) X-ray results in response to an incomplete/incorrect count.
- (5) Final count process.

Appendix A References

Section I Required Publications

There are no entries in this section.

Section II Related Publications

A related publication is a source of additional information. The user does not have to read it to understand this publication.

AORN Standards, Recommended Practices, and Guidelines

2014 edition, Denver: AORN, Inc.

Army Regulation 40-68

Clinical Quality Management

Hospital Accreditation Standards

The Joint Commission, current version

Identifying Lost Surgical Needles Using Radiographic Techniques

Macilquham, M., Riley, R., Grossberg, P.; AORN Journal, July 2003, pp. 73-78

Implementing AORN recommended practices for prevention of retained surgical items

Goldberg, J. and Feldman, D., 2012. AORN Journal, 95(2) pp. 205-219

MEDCOM Regulation 40-54

Universal Protocol: Procedure Verification Policy

Recommended Standard of Practice for Counts

Association of Surgical Technologists; available online:

www.ast.org/pdf/standards_of_practice/RSOP_counts.pdf

Serious Reportable Events in Healthcare – 2011 Update National Quality Forum (NQF)

A Consensus Report, Washington, DC: NQF; 2011

Statement on the prevention of retained foreign bodies after surgery

American College of Surgeons; [ST-51] available online:

http://www.facs.org/fellows_info/statements/st-51.html

The Joint Commission Sentential Event Alert: Preventing Unintended Retained Foreign Objects

Issue 51, October 17, 2013

Update on the Prevention of Retained Surgical Items

Martindell, D, Pennsylvania Patient Safety Advisory, Vol 9, No. 3, September 2012, pp. 106-110

Section III

Prescribed Forms

There are no entries in this section.

Section IV

Referenced Forms

DA Form 5179-1

Medical Record - Intraoperative Document

SF 509

Medical Record Progress Notes

Glossary

Section I Abbreviations

AORN

Association of PeriOperative Registered Nurses

MEDCOM

United States Army Medical Command

MTF

medical treatment facility

OR

operating room

PA

physician assistant

PSR

patient safety report

RNFA

registered nurse first assistant

Section II

Terms

This section contains no entries.

The proponent of this publication is the Clinical Performance Assurance Directorate. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, U.S. Army Medical Command, ATTN: MCHO-CP-A, 2748 Worth Road, JBSA Fort Sam Houston, TX 78234-6010.

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