DEPARTMENT OF THE ARMY
BROOKE ARMY MEDICAL CENTER
3551 ROGER BROOKE DRIVE
JBSA FORT SAM HOUSTON, TEXAS 78234-4504

MCHE-ZHP-H (Health Physics Service) 30 May 2019

MEMORANDUM FOR Office of the Administrator
USNRC, Region IV
1600 Lamar Blvd.
Arlington TX 76011-4511

SUBJECT: Written Report on the Loss of Licensed Material (Event Notification #53992), USNRC Materials License Number 42-01368-01

1. Summary. This report is submitted to meet the written reporting requirements in Title 10, Code of Federal Regulations, Part 20, Paragraph 2201(b) (10 CFR 20.2201(b)) for the loss of licensed material reported to the Nuclear Regulatory Commission (NRC) Operations Center on 11 April 2019 (Event Notification #53992). On 13 March 2019, the Brooke Army Medical Center (BAMC) Radiation Safety Officer (RSO) determined that two iodine-125 (I-125) seeds from a radioactive seed localization (RSL) procedure were lost. The two seeds were likely lost during specimen grossing performed in the Histology laboratory of the BAMC Anatomical Pathology Service. The two seeds were lost as a direct result of improper specimen preparation and submittal by the Department of Operative Services (DOPS) Operating Room (OR) staff. Corrective actions have been implemented to minimize the likelihood of reoccurrence.

2. Description of licensed material involved.

   a. Source Description: Best Medical International, Inc. Part #2301, Double Wall Best® Iodine-125 Source, I-125 double wall titanium encapsulated seeds for breast localization

   b. Source Identification (Lot # - Seed#): 46461-4 and 46461-5

   c. Quantity: 2

   d. Activity: 0.156 millicuries (mCi) and 0.158 mCi on 16 October 2018

   e. Form: I-125 double wall titanium encapsulated sealed source

3. Investigative activities.

   a. Personnel Interviewed (Name, Department or Section, Position)

      (1) Ms. Leslie Reddic, Histology, Staff Histopathology Technician

      (2) Ms. Gayle Goldsmith, RN, Mammography, Mammography Nurse

      (3) Mr. Dexter Brathwaite, Health Physics Service, Health Physics Technician/ Radioactive Waste Program Manager

(4) COL Lance Taylor, RN, DOPS, Chief, OR Operative Services

(5) LTC Guy Clifton, MC, General Surgery, Responsible Staff Surgeon

(6) Aurelio Castillo, RN, DOPS, #1 (Lead) Circulating Nurse

(7) 1LT Pamela Singleton NC, DOPS, #2 Circulating Nurse

b. Records reviewed.

(1) Radioactive Seed Tracking Form

(2) Mammo Surgical Specimen X-ray Radiology Results 16 Oct 2018 0710

(3) PERIOP Nurse Intraoperative Note 16 Oct 2018 0822

(4) PERIOP Tissue Exam Request 16 Oct 2018 0908

(5) SURG Operative Report 16 Oct 2018 1019

(6) Composite Health Care System Patient Lab Inquiry for 10 May 2018 Record of Specimen Analysis

(7) Operating Room Standard Operating Procedure B-01, Care and Handling of Specimens 5 Jul 2018

(8) Decay-in-storage logs

c. Root Cause Analysis Panel

(1) The BAMC Department of Patient Safety convened a Root Cause Analysis (RCA) panel from 29 April – 1 May 2019 in accordance with BAMC RCA Process and Procedures. The RCA panel was comprised of representatives from Histology, Mammography, General Surgery, DOPS, Health Physics Service, and Patient Safety. The RCA panel conducted a detailed analysis of the incident to identify the root cause(s) and to develop corrective action plans (CAPS).

(2) The results of the RCA will be presented to the BAMC Medical Service Executive Committee (MSEC) on 12 June 2019, and to the BAMC Commanding General (CG) on 28 June 2019. The MSEC and CG will review and approve the RCA report, including the CAPS, as proposed by the panel or revised based on their review).

(3) The corrective actions described in this report are interim corrective actions, implemented for the described duration. BAMC will send an updated report to the NRC if there are any changes to the implemented corrective actions and upon final approval of the RCA and associated CAPS.

4. Background

a. Discovery of the incident. The following are details regarding the discovery of missing sources and determination that the sources were lost.

(1) On Friday, 6 March 2019, a Histology Laboratory Technician found a partially complete Radioactive Seed Tracking (RST) Form (Enclosure 1) which had been left at the Histology specimen receiving window by an unknown Operating Room (OR) technician.

(2) The RST Form was for a 16 October 2018 radioactive seed localization (RSL) guided lumpectomy involving two I-125 seeds.

(3) Ms. Leslie Reddic, Staff Histopathology Technician, the Histology laboratory and examined the archived specimens from the procedure.

(4) On Monday, 9 March 2019, Ms. Reddic notified, BAMC Radioactive Waste Program Manager, Mr. Dexter Brathwaite, and the BAMC Radiation Safety Officer (RSO), Mr. Kevin Martilla, to report the missing sources.

(5) From 9 to 13 March 2019, Health Physics Service personnel attempted to locate the missing sources, which included the following activities:

(a) Searching use and storage areas, including the Histology Laboratory; BAMC facility waste consolidation and holding areas; the BAMC Operating Room, and the BAMC Radioactive Waste/Decay-in-Storage building.

(b) Reviewed radioactive waste and decay-in-storage logs.

(c) Met with Histology, Mammography, DOPS, and General Surgery personnel to discuss the circumstances surrounding the RSL procedure in question and RSL procedures in general.

(d) Conducted radiation detection surveys of areas where the RSL seeds may have separated and fallen from the specimen during handling or preparation. This included specimen handling and preparation areas within the Histology Laboratory and Operating Room.

(6) On 13 March 2019, the final radiation detection survey of the Histology Laboratory failed to locate either of the missing sources. Upon completion of this final survey, the sources were concluded to be lost.

(7) The BAMC RSO continued investigation activities to identify the root cause(s) of the lost RSL seeds and to determine any corrective actions.

(8) On 11 April 2019, the BAMC RSO reported the loss of the radioactive seeds to the NRC Operations Center.

b. Previous Incidents Involving Loss of RSL Seeds. Two previous incidents involving the loss of radioactive seed localization I-125 seeds occurred in calendar year (CY) 2015. Both incidents occurred in the Histology laboratory, after the specimens with seeds had been appropriately submitted by Operating Room staff.

(1) First lost seed, 6 May 2015

(a) The first seed was lost on 6 May 2015 in the Histology laboratory during transfer of the specimen from the specimen grid to the Formalin filled specimen cup. The seed was loosely embedded in the specimen and remained on the specimen grid. The specimen grid with the seed was subsequently disposed through normal waste streams.

(b) Cause. Specimen handling procedure needed improvement.

(c) Corrective Action(s). Histology's standard operating procedure was amended to include verification of seed presence within the specimen cups following transfer from the specimen grid. Pathology's Neoprobe (radiation detector) would be used to verify the seed's presence.

(2) Second lost seed, 17 November 2015

(a) The second seed was lost on 17 November 2015, also in the Histology laboratory. The seed was lost when a resident did not complete the accompanying Radioactive Seed Tracking Form nor verify the seed's removal from the specimen in accordance with the standard operating procedure. The seed was contained with the specimen when it was grossed and submitted (entirely) for sectioning. The seed was likely disposed through normal waste streams.

(b) Cause. A lack of training and supervision of new Resident participation in the specimen grossing process.

(c) Corrective Action. The standard operating procedure was revised to include verification by grossing staff pathologist that the Resident has completed the required paperwork and verified seed removal using the NeoProbe.

5. Description of circumstances under which the loss occurred. The following is a summary of events leading to the loss of the RSL seeds. A more detailed timeline of events is presented in Enclosure 2.

a. On 15 October 2018, the patient underwent a bi-lateral mammography guided radioactive seed localization of non-palpable lesions, with two I-125 seeds (nominal activity of 0.154 mCi) implanted in Mammography. Mammography initiates the Radioactive Seed Tracking Form.

b. The patient returned on 16 October 2018 for RSL partial lumpectomy.

c. The surgical team discussed details of all procedures to be performed that day. The case in question was discussed as a radioactive seed localization, which prompted the surgical team to ensure that the Trident Specimen Radiography System (referred to as the 'mammo box') was placed in the room and the package from mammography was on-hand.

d. The surgeon excised the seed localized tissue specimens. Each specimen placed on a specimen grid and given to the OR nurses for imaging and preparation for submittal to Histology. Imaging confirmed both seeds to be present in excised tissue specimens. The Mammo Surgical Specimen X-ray Radiology Results are included as Enclosure 3.

e. Upon imaging, the circulating nurses erringly placed the specimens in specimen cups processed as normal 'permanent' (vice 'fresh') tissue specimens. The specimens were staged in the Central OR Specimen Room and submitted to Histology along with other 'permanent' specimens.

f. Histology processed the specimens as normal (not containing radioactive seeds) since, contrary to standard operating procedures, the specimens were not submitted as 'fresh' on specimen grids; the specimens were not labeled as radioactive; the presence of radioactive seeds was not indicated in the SF515 Tissue Exam Request; and the Radioactive Seed Tracking Form did not accompany the specimens.

6. Probable disposition of the licensed material involved. Histology did not notice or recognize the seeds during specimen preparation. The seeds may not have been noticed due to their small size. If noticed, the seeds could have been mistaken for other benign metallic objects typically contained within surgical tissue specimens, such as surgical staples. In either case, the seeds would have been collected and placed with other waste from the grossing process for disposal as normal or regulated medical waste.

7. Exposure of individuals to the lost licensed material in unrestricted areas.

a. The RSL seeds, lot numbers 46461-4 and 46461-5, had initial activities of 0.322 mCi and 0.326 mCi respectively, as assayed on 15 August 2018. The calculated activities on 16 October 2018 (date of loss) were 0.156 mCi and 0.158 mCi, respectively. Enclosure 4 is the Certificate for Independent Calibration for I-125 Sources.

b. The sources were assumed to have been placed with normal or regulated medical waste within the Histology laboratory.

c. The maximally exposed individual was assumed to be the BAMC Environmental Services employee that collects and transports the waste containing the discarded seeds from Histology to the basement loading dock waste consolidation bins. The dose to the individual would be a result of external radiation exposure to gamma and X-ray emissions at a distance of 1 meter from the source for a duration of 4 hours.

d. The dose rate constant for Iodine-125 is 0.275 mrem/hr/mCi at 1 meter[1]. The estimated dose to the maximally exposed individual from the lost sources is 0.345 mrem, or approximately 0.34% of the annual dose limit for members of the public from exposure resultant from licensed operations.

e. Based on this minimal dose, the hazard posed to the maximally exposed individual from unknowing exposure to the lost sources is therefore considered negligible.

8. Actions taken to recover the lost licensed material. As described in paragraph 4.a., all likely locations within BAMC where the sources may have been stored or lost were searched and surveyed. No further actions to recover the lost seeds are planned.

9. Causal factors (CF) contributing to the loss of licensed material.

a. CF1. Contrary to standard operating procedures (SOPs) (Enclosure 5), the requested tissue exams on the PERIOP Tissue Exam Request (Enclosure 6) did not include the word ‘seed’ to indicate to Histology the presence of a radioactive seed within the corresponding specimen.

b. CF2. Contrary to SOPs, the specimens were placed in specimen cups containing formalin. Specimens with seeds are supposed to be placed on a specimen grid then in a specimen bag. Specimen bags provided by Mammography as part of the patient packet have “Radioactive Material” labels affixed to them. Histology recognizes specimens submitted on specimen grids as normally associated with radioactive seed localization procedures.

c. CF3. Contrary to SOPs, the specimens were submitted to Histology as ‘permanent’ specimens (preserved in formalin) in batch with other staged ‘permanent’ specimens from the OR. Normally, the seed containing specimens are submitted as ‘fresh’, which are delivered to Histology by runner at the first available opportunity. Histology would

[1] From 7.432E-5 mSv/hr/MBq value listed in Shleien B, Slaback Jr L A, Birky B K, Handbook of Health Physics and Radiological Health, 3rd Ed. Baltimore, MD, Williams & Wilkins, 1998, p. 6-11

not expect seed containing specimens to be submitted with the batch delivery of OR 'permanent' specimens

d. CF4. Contrary to SOPs, the Radioactive Seed Tracking Form was not submitted with the seed specimens. Histology would ensure appropriate handling of radioactive seeds for specimens submitted with a Radioactive Seed Tracking Form.

e. CF5. Contrary to SOPs, no "time-out" was called by the Surgeon after specimen removal. According to procedure, the surgeon is supposed to call a "time-out" to ensure the exact time is documented on the breast specimen label affixed to the SF 515, Tissue Exam Request. The surgeon may have prevented or recognized the errant specimen preparation during such a time-out.

f. CF6. Contrary to SOPs, complete disposition of the procedure's specimens was not reviewed and confirmed by the surgeon during the post-procedure debrief. Full discussion of specimen disposition during the post procedure debrief would have revealed the errors in specimen preparation and submittal.

g. CF7. Histology laboratory personnel handling the specimens were not aware that radioactive seeds were present, nor did they recognize the seeds if found in the specimens. Although all Histology personnel are trained annually on handling of specimens containing radioactive seeds, personnel who are downstream from the grossing process are not expected to handle any sample containing a seed and may easily mistake any seed for other metal debris (e.g surgical staples) typically found at their stage of specimen preparation. Additionally, without any indication that seeds are present in the specimens, Pathology residents that accomplish initial specimen preparation and grossing could likewise mistake a seed for other medical debris.

10. Root causes (RC)

a. RC1. For CF1, CF2, CF3, CF4, CF5, CF6, and CF7: The RSL procedure is performed infrequently by any one of the potential circulating nurses. This case was only the second exposure to an RSL procedure for the lead circulating nurse, who had just completed orientation earlier in October 2018. The lead circulating nurse's first exposure to an RSL procedure was in July 2018 while in orientation. This was the first exposure to an RSL procedure for the second circulating nurse, who was still in orientation status.

b. RC2. For CF1, CF2, CF3, CF4, CF5, CF6, and CF7: The RSL procedure checklist affixed to the mammo box (Enclosure 7) was ineffectual. Neither circulating nurses followed the checklist. The checklist is not concise or easily noticed. "Checklist fatigue" may have also contributed to checklist not being used. Additionally, the important

specimen handling requirements may have been forgotten due to the infrequent participation in RSL procedures and the lack of emphasis during mammo box in-service training.

c. RC3. For CF5 and CF6: Enforcement to ensure time-outs and debriefs are conducted appropriately, if at all, needs improvement. This is an issue that extends to all OR procedures. Of the numerous safety concerns addressed in OR policies and procedures, radioactive seed localization safety is infrequently encountered and of lower priority compared to patient safety concerns. The high surgery volume and scheduling demands prohibit limitation of the population of surgeons that perform the RSL related procedures. In addition, surgeons had a false impression that the circulating nurses knew the correct procedures for handling RSL seed specimens.

11. Other findings (OF)

a. OF1. The CHCS did not provide the option to enter the procedure as a 'Radioactive Seed Localization'. The ordered procedure was listed as "Mammo Guided Needle Loc" which was subsequently printed on patient labels. A patient label was placed on Radioactive Seed Tracking Form. The procedure description in the CHCS order did describe the requested procedure was a radioactive seed localization, however, associated patient labels contained only the inaccurate procedure name, with no indication of radioactive seed presence. Although not contrary to any policy or procedure, the procedure name is not accurate and may have caused confusion or failed to prompt actions required for radioactive seed specimen handling.

b. OF2. For CF7: Future training of Histology staff and Pathology residents will include and emphasize visual identification of RSL seeds considering the possibility to unexpectedly encounter the seeds in mislabeled specimens.

c. OF3. For CF2, CF3, CF4, and CF5: There was a lack of communication from Histology to the Operating Room Services staff. Specifically, the OR staff was not provided feedback regarding on-going errors in RSL specimen submission by OR runners. OR runners had occasionally attempted delivery of 'fresh' RSL seed specimens without an accompanying Radioactive Seed Tracking Form. Per Histology's policy, RSL seed specimens are not accepted without the accompanying Radioactive Seed Tracking Form. OR runners were being turned away and directed to return with the required Radioactive Seed Tracking Form, which was typically left in the OR. Even though this had occurred multiple times in the preceding 6 months, Histology had not communicated these discrepancies to the OR staff. If informed, the OR staff could have adjusted training and briefings to address the errors.

12. Corrective actions (CA). The following corrective actions have been or will be implemented to ensure against recurrence of the loss of licensed material.

a. CA1. For RC1: Improved training of surgical staff on RSL procedures.

(1) Health Physics Service participated in April 2019 OR nurse in-service training on RSL procedures, with increased emphasis on specimen handling and seed accountability. Health Physics Service will continue to participate in this quarterly in-service training.

(2) The Radiation Safety Officer will conduct initial and annual refresher training for Surgeons that will participate in RSL surgical procedures. General Surgery has identified the population of surgeons to be trained. The RSO will schedule multiple training sessions ensure all surgeons participating in RSL procedures are trained no later than 30 June 2019.

(3) Recognizing that training and re-training surgical staff will necessarily take time, Health Physics Service staff is monitoring each scheduled RSL surgical procedures to verify proper disposition of seeds until staff is fully trained.

b. CA2. For RC1, RC2, RC3, and OF2: Install area radiation monitor at Histology specimen receipt window. Health Physics Service has submitted a purchase request through Medical Logistics for an area radiation monitoring system. This system will ensure that Histology is alerted to any specimen received containing radioactive seeds, preventing recurrence of the subject incident. The system is expected to be received no later than the end of the current fiscal year, 30 September 2019. In the interim, Histology has instituted a policy to monitor any breast tissue specimen received using their Neoprobe.

c. CA3. For RC2: A label with a simplified checklist has been added to the specimen grids provided by Mammography (Enclosure 8). These checklists are intended to be more noticeable to OR Nurses preparing seed specimens and will emphasize key radioactive seed control measures.

d. CA4. General. Pending Executive Staff and hospital commander approval, the Surgical and Mammography Staff is proposing to switch from a licensed radioactive material-based to an radiofrequency radiation-based localization technology. Such a system would eliminate radioactive material control licensing requirements. The proposed corrective action will be presented to the Medical Staff Executive Committee on 5 June 2019, and to the BAMC Commander on 14 June 2019.

e. CA5. For OF1: A CHCS order selection option has been added for 'Radioactive Seed Localization'.

f. CA6. For OF3: Health Physics Service is monitoring scheduled RSL procedures and communicating identified instances of non-compliance with seed handling and control requirements.

13. The point of contact for this memorandum is the undersigned at 210-539-0371 or kevin.e.martilla.civ@mail.mil.

Kevin E. Martilla
MARTILLA.KEVIN.E.1128579326
2019.05.30 11:33:19 -05'00'

KEVIN E. MARTILLA
Radiation Safety Officer

8 Encls
1. Radioactive Seed Tracking Form
2. Detailed Timeline
3. Mammo Specimen X-ray Results
4. I-125 Calibration Certification
5. OR SOP B-01
6. Tissue Exam Request
7. Mammo Box Checklist
8. Specimen Card Label

SANDOVAL, ESTHER
30/449-88-6063
DOB: 31 Oct 1955 AGE: 63
MAMMO GUIDED NEEDLE LOC WIRE P
EXAM: 15 Oct 2018 EXAM#: EX18397958

L

I-125 Seed Tracking Form:

Revised 28 March 2016

Mammography:

Date seed placed: 10-15-18
Number of seeds total: 1 (2) 3 4 (circle one)
Seed (s) placed in which breast? (Right) (Left) Quadrant/Location: R-medial L-lateral
If Bilateral: (# of seeds on Right) 1 (# of seeds on Left) 1
Seed locations other than breast: none
Seed verified in needle: ✓✓ Yes _____ No
After implant, needle verified void of seed: ✓✓ Yes _____ No
Seed verified in the breast by xray: ✓✓ Yes _____ No
Radioactive materials label placed on specimen grid: ✓✓ Yes _____ No
Seed placed/procedures performed by (Authorized User): Dr. Gerszewski
Lot Number of Seed: Right - 416461-4, Left 416461-5

Surgeon/OR Nurse:

Staff Surgeon: Dr. Clifton, Guy Date: 16 Oct 2018
Seed verified in tissue sample: ✓✓ Yes ___ No Total # of seeds removed: 2
Patient verified void of seed: ✓ Yes _____ No
Radioactive materials label remains with specimen: ✓ Yes _____ No
Person taking specimen/Seed tracking paperwork to Histology: N/A

SPECIMEN IMAGE REVIEWED BY ATTENDING: SURGEON/RADIOLOGIST DR. Clifton

SANDOVAL, ESTHER
30/449-88-6063
DOB: 31 Oct 1955 AGE: 63
? MAMMO GUIDED NEEDLE LOC WIRE P
EXAM: 15 Oct 2018 EXAM#: EX18397957

P

Histology:

Specimen/Seed(s) received by: _____ Date: _____

1. # Seed(s) ____ verified in specimen on radiology grid Initials: _____
2. Specimen placed in specimen container/formalin/radiation label Initials: _____
3. Seed(s) verified in specimen container/formalin/radiation label Initials: _____
4. Radiology grid verified void of seed(s) after specimen removal Initials: _____
5. Specimen and this form placed in secured cabinet for fixation Initials: _____

Seed(s) removed from specimen by: _____ Date: _____

1. # Seed(s) ____ recovered/removed from specimen Initials: _____
2. Recovered seed(s) sealed in radiation label with date/time/initials Initials: _____
3. Seed(s) placed in lead container in secured cabinet with this form Initials: _____

Health Physics contacted for seed(s) pick-up by: _____ Date: _____
Seed(s) released to Health Physics by: _____ Date: _____

Health Physics

Seed(s) ____ received by: _____ Date: _____

Emergency Procedures:

In the case of a lost seed: **STOP** and contact the Health Physics Service. **DO NOT** allow anyone to enter or exit the area until Health Physics arrives.

1. **Mr. Dexter Brathwaite:** 210-215-4314
2. **Ms. Laura Eline:** 210-916-8322 or 210-288-5789

Loss of Licensed Material, Event Notification #53992
October 2018 Radioactive Seed Localization Specimen Procedure Lost Seeds
Timeline of Events

DATE/TIME	EVENT
15 Oct 18 / 0858	**Bilateral radioactive seed localization procedure by Mammography**. Two I-125 RSL seeds implanted in patient by Mammography staff. Mammography nurse initiates a Radioactive Seed Tracking Form. Mammography nurse assembles the surgical procedure packet, consisting of the Radioactive Seed Tracking Form, two specimen grids, two radioactive material labels, and RSL procedure x-ray images. This packet is picked up by an Operating Room (OR) staff member the morning of the scheduled surgical procedure (RSL partial lumpectomy).
16 Oct 18	**Patient returns for RSL partial lumpectomy**. The patient returns for a bilateral RSL partial lumpectomy.
16 Oct 18 / 0700	**Surgery team discusses RSL lumpectomy at morning briefing**. The surgery team for the case in question included a general surgeon (LTC Guy Clifton, 'MD1'), a supervising nurse (Mr. Aurelio Castillo, 'RN1'), an orientee nurse (1LT Pamela Singleton, 'RN2'), and two scrub technicians, (AMN Theo Kekllas, 'RT1'; and SSGT Jennifer Torres, 'RT2'). MD1 states that the case details were discussed during the AM Brief according to the hospital's TeamSTEPPS®[1] Universal Protocol, including details regarding the RSL seeds.
16 Oct 18 / 0813-0838	**Four specimens are removed during the RSL procedure**. During the procedure, MD1 removed four tissue specimens, which were given to the RN1 or RT1.
16 Oct 18 / 0838	**Specimen images confirmed the presence of seeds in specimens**. Specimens were each placed on a specimen grid and imaged using the Trident Specimen Radiography System ('Mammo Box'). MD1 viewed each specimen image and confirmed the presence of the seeds in the specimens, one each in tissue specimen B and tissue specimen C. Images and notes from the BAMC IMPAX system corroborates presence of seeds in the specimens and show that specimens were each imaged on specimen grids.
16 Oct 18 / 0838-0954	**Specimens prepared and delivered to Histology for evaluation**. MD1 recalls observing RN2 placing one of the specimens in a cup instead of on a specimen grid. RN1 or RN2 prepared the specimens as 'permanent' specimens, placing them in cups containing Formalin. The Radioactive Material labels were not placed on any of the specimen containers. The specimens were then staged with other permanent specimens in the central OR Specimen Room, with the associated standard form (SF) 515, Tissue Exam Request, without the Radioactive Seed Tracking Form. A DOPS staff member submitted the specimens to the Histology laboratory along with the other staged 'permanent' specimens during the afternoon specimen delivery time.

[1] TeamSTEPPS® - Team Strategies and Tools to Enhance Performance and Patient Safety

Loss of Licensed Material, Event Notification #53992
October 2018 Radioactive Seed Localization Specimen Procedure Lost Seeds
Timeline of Events

DATE/TIME	EVENT
16 Oct 18 / 1510	**Histology processed the specimens using normal (non-radioactive) handling procedures**. Without any indication of the presence of the RSL seeds, Histology received and evaluated the specimens using normal non-radioactive) handling procedures.
6 Mar 19	**Radioactive Seed Tracking Form delivered to Histology**. Ms. Leslie Reddic found the Radioactive Seed Tracking, which had been left at the Histology specimen receiving window by an unknown OR technician.
9 Mar 19	Ms. Reddic searches the Histology laboratory, including the RSL seed storage cabinet and archived specimens. Missing seeds not found.
10 Mar 19	Ms. Reddic informs Mr. Dexter Brathwaite, Health Physics Service, of the missing seeds.
10 Mar 19	Mr. Brathwaite searches Histology Laboratory and RSL seeds inventory in the decay-in-storage shed. Missing seeds not found.
10 Mar 19	Mr. Brathwaite informs Mr. Kevin Martilla, BAMC radiation safety officer (RSO) of the missing sources.
11-12 Mar 19	RSO interviews Histology, OR, and Mammography staff.
13 Mar 19	RSO surveys Histology laboratory and operating room with GM detector/meter. Missing sources not found and now considered lost.
11 Apr 19 / 1819	RSO notifies NRC Operations Center of lost sources.

Note Type: Radiology_Results (MAMMO SURGICAL SPECIMEN XRAY)
Note Time: 0710 16 Oct 2018
Last Stored: 1544 16 Oct 2018
Stored By: CHCS HL7 -> CIS Link

RADIOLOGY RESULTS

[redacted] GEN SURGERY BAMC

ROUTINE Verified Results Exam #: 18395365
Procedure: MAMMO SURGICAL SPECIMEN XRAY Exam Date: 0710 16 Oct 2018
Reason for Order: Seed localization bilateral breast
Result Code: SEE RADIOLOGIST'S REPORT

CLINICAL HISTORY:
[redacted]

MAMMO SURGICAL SPECIMEN XRAY: October 16, 2018 - Accession #:
0109-18395365
Left specimen: Single specimen radiograph demonstrates an open coil biopsy marker and radioactive seed with 1.4 cm of adjacent residual calcifications. Biopsy marker and radioactive seed appear away from specimen edge on this single view.
Right specimen: 8 specimen radiographs were taken. Four specimen radiographs demonstrate a radioactive seed with an adjacent coarse calcification which correlate to findings on the right postprocedure mammogram. The right breast open coil biopsy marker is not noted.
3 of the specimen radiographs demonstrate the same image seen in the left specimen jacket demonstrating the open coil biopsy marker, radioactive seed and residual left breast calcifications.
A single image demonstrates piece a of fibroglandular tissue without biopsy marker or radioactive seed.
IMPRESSION:Bilateral Intraoperative specimen radiographs as detailed above.
Dictating radiologist was not present during the operation.
MAMMO SURGICAL SPECIMEN XRAY: October 16, 2018 - Accession #:
0109-18399756
RECOMMENDATION:
Diagnostic mammogram of both breasts in 6 months.

Interpreted by: GOSSWEILER, MARISA L Transcription Date/Time: 1543 16 Oct 2018
Approved by: GOSSWEILER, MARISA L Approved Date/Time: 1543 16 Oct 2018
Supervised by:

[redacted]

Certificate for Independent Calibration of I-125 Sources

Hospital Name:	Brooke Army Medical Center				**Lot Number:**	46461	
Patient Name:	N/A				**Implant Date:**	20-Aug-18	
Ind. Assay Date:	15-Aug-18				**Number of Seeds:**	6	
Act. on Assay Date:	0.318	mCi			**Required Activity:**	0.3	mCi.
Acceptable Range:	0.302	To	0.334	mCi	**Mfg. Ref. Date:**	20-Aug-18	
(Based on +/- 5%)					**Mfg. Mean Activity:**	0.300	mCi

Assay Values (mCi and Air Kerma) as of the Calibration Date

	mCi.	Air Kerma		mCi.	Air Kerma		mCi.	Air Kerma		mCi.	Air Kerma		mCi.	Air Kerma		mCi.	Air Kerma
1	0.330	0.419	26			51			76			101			126		
2	0.312	0.396	27			52			77			102			127		
3	0.324	0.411	28			53			78			103			128		
4	0.322	0.409	29			54			79			104			129		
5	0.326	0.414	30			55			80			105			130		
6	0.324	0.411	31			56			81			106			131		
7			32			57			82			107			132		
8			33			58			83			108			133		
9			34			59			84			109			134		
10			35			60			85			110			135		
11			36			61			86			111			136		
12			37			62			87			112			137		
13			38			63			88			113			138		
14			39			64			89			114			139		
15			40			65			90			115			140		
16			41			66			91			116			141		
17			42			67			92			117			142		
18			43			68			93			118			143		
19			44			69			94			119			144		
20			45			70			95			120			145		
21			46			71			96			121			146		
22			47			72			97			122			147		
23			48			73			98			123			148		
24			49			74			99			124			149		
25			50			75			100			125			150		

Summary and Comparisons

Data Based On Implant Date of : **20-Aug-18**

Decay Factor	0.9434			
Manufacturer's Mean:	0.300	mCi	0.381	Air Kerma
Independent Mean:	0.305	mCi	0.387	Air Kerma
Percent Variation:	1.57%			

Certified By: _____ Health Physicist

Date: 15th AUGUST 2018.

DEPARTMENT OF THE ARMY
BROOKE army MEDICAL CENTER
3551 ROGER BROOKE DRIVE
JBSA FORT SAM HOUSTON, TEXAS 78234-4504

REPLY TO
ATTENTION OF

MCHE-ZSC 05 JULY 2018

OPERATING ROOM STANDARD OPERATING PROCEDURE
B-01
CARE AND HANDLING OF SPECIMENS

1. PURPOSE: To provide guidelines for the care and handling of specimens in the operating room and to provide guidelines for the completion of the Essentris PERIOP Tissue Exam Request or SF 515.

2. SCOPE: The responsibility for the proper care and handling of specimens in the OR is on the surgeon, the circulating nurse, the scrub technician and any staff transporting specimens from one location to another.

3. ROUTINE SPECIMENS:

3.1. During TeamSTEPPs brief, the surgeon will discuss any anticipated specimens. This information will be written on the TeamSTEPPs Board. **If a specimen is anticipated**, the surgeon or member of the surgical team will fill out the Brief Clinical History (pertinent to the case) and Preoperative Diagnosis on the Essentris PERIOP Tissue Exam Request. The circulating nurse can add the individual specimens, special instructions or any other information appropriate to the disposition of the specimen. If a tissue form is not initiated by the surgeon, the circulating nurse can initiate and complete a specimen form **with direct verbal input from the surgeon**. The surgeon is responsible for clearly identifying each specimen to the scrub and circulating nurse for proper labeling.

3.1.1. In all instances, when any tissue or foreign body is removed from a patient, the surgical technician will ask if the tissue passed to them is to be saved as a specimen and how the surgeon wants the specimen labelled.

3.1.2. The surgical technician will verify every specimen with the circulating nurse when the specimen is passed off the back table.

3.1.3. The scrub will always ask the surgeon if the specimen can be passed off the sterile field. (***NOTE: If a single specimen is to be sent for multiple tests, i.e. pathology and culture, the specimen must be split on the back table by the surgeon prior to being passed to the circulator and then placed in separate containers.***
NOTE FOR SURGEONS: DO NOT cut into or alter the specimen in any way if requesting margins. It disrupts the "inking" process for pathology.)

3.1.4. Whenever a specimen is passed from one person to another, the name/ID and disposition should be verified.

3.1.5. The circulator verifies with the surgeon the identification of the specimen before it leaves the OR.

3.2. The circulating nurse is responsible for verifying with the surgeon how each specimen is to be sent to the lab, i.e. frozen, fresh, permanent, culture, etc.

3.3. The circulating nurse is responsible for properly labelling, documenting and "sending" each specimen.

3.3.1. Each specimen will be placed in a separate, appropriately labeled container.

3.3.2. A patient identification label will be placed on each container. Each **TISSUE** specimen will be given a sequential **letter**. The sequence starts in the order the specimens are sent to

pathology (i.e. First specimen off the field is a permanent specimen. Second specimen off the field is a FROZEN, which will be the FIRST specimen to go to Pathology. Therefore, the frozen specimen is labelled “A”.) Each specimen container label must have the following information on it:

3.3.2.1. Date.

3.3.2.2. Surgeon's first and last name.

3.3.2.3. Name of the specimen, site (i.e. left, right).

3.3.2.4. The sequential letter.

3.3.2.5. Initials of the circulator.

3.3.2.6. If applicable, “FRESH” or “FROZEN”.

3.3.3. All FROZEN and FRESH specimens must be given a designated sequential letter PRIOR to ANY permanent specimens being labelled with a letter (See Appendix A). Each section (Tissue, Cultures/Microbiology or Cytology) on PERIOP Tissue Exam Request will have its own sequence of identifiers. (See Appendix A)

3.3.4. Another label will be made for the Specimen Book with the exact same information on it, as well as the sequence letter and name of EACH specimen.

3.3.5. The EXACT name of specimen and sequence letter MUST match on ALL documentation: Container label

3.3.5.1.Tissue request form (PERIOP Tissue Exam Request).

3.3.5.2. PERIOP Intraoperative documentation.

3.3.5.3. Specimen book labels.

3.3.6. The circulator will ensure that the tissue exam form has all of the required information needed:

3.1.3.6. 1. Complete patient identification.

3.1.3.6. 2. Date/Time (if applicable).

3.1.3.6. 3. Surgical Service submitting specimen.

3.1.3.6. 4. Brief Clinical History(***pertinent information*** includes age, sex, ethnicity, diagnosis, how long issue existed, other recent treatments related to diagnosis).

3.1.3.6. 5. Preoperative diagnosis.

3.1.3.6. 6. Operative findings (“see operative report” is NOT acceptable).

3.1.3.6. 7. Postoperative Diagnosis (“see operative report” is NOT acceptable).

3.1.3.6. 8. Surgeon’s first and last name (legible).

3.1.3.6. 9. Surgeon’s pager number or Operating Room suite number and phone number.

3.3.6. 10. Surgeon’s signature and title (on the PERIOP Tissue Exam Request this information is provided electronically).

3.3.7. All specimens will be entered in the Essentris PERIOP Intraoperative document, the PERIOP Tissue Exam Request (or SF 515 (Tissue Examination Form)) and in the appropriate specimen logbook.

3.4. At the conclusion of the case, all specimens and the disposition of the each specimen is reviewed and confirmed with the surgeon during the TeamSTEPPs Debrief.

3.5. After the procedure, the circulator will take permanent specimen(s), along with the corresponding tissue exam request form, to the specimen room.

3.5.1. Formalin 10% will be added to each PERMANENT specimen container, completely covering the specimen with a formalin/specimen ratio of 10:1. A mask, eye protection and gloves must be worn when dispensing formalin. It is not necessary to completely fill the specimen container with formalin solution; however the specimens need to be completely covered.

3.5.2. A formalin label is affixed to the side of the container when the formalin is added.

3.5.3. The specimens are logged into the appropriate specimen book, using the labels that were made earlier.

3.5.4. The circulator will print his/her name in the log book, next to the appropriate specimen label.

3.6. EXCEPTION: Disposition of Large Amputated Specimens (i.e. leg or arm)

3.6.1. Double bag the specimen in red plastic bags.

3.6.2. Secure a label with patient and specimen data, as prepared in paragraph 4.b., to the outside of *both* bags.

3.6.3. Enter specimen in the Fresh/Frozen logbook.

3.6.4. During duty hours take to Anatomic Pathology Section (Monday - Friday, 0700 to 1630 hours).

3.6.5. **After duty hours/weekend –** Contact the NCOD (NCO of the day) and request access to the Morgue on the lower level and for specimen processing and refrigeration. Be sure to have the NCOD sign specimen log book. Make out a card for the front of the refrigerator, annotating that a body part is inside the refrigerator. The tissue exam form should be left in pathology with the Annotation on the form that the specimen has been transported to the morgue.

3.7. **Transporting "Permanent" specimens** - Prior to taking specimens to the lab, the staff member assigned to this detail will identify and confirm that all specimens have a complete tissue exam form and are entered in the logbook. If there are any discrepancies, notify the charge nurse before removing the specimen from the OR. Specimens will be taken to the lab on a covered table.

3.7.1 Monday through Friday, permanent specimens and their corresponding tissue exam forms are delivered to the Anatomic Pathology laboratory at **1000**, **1400** & **1600**. Specimens can be delivered earlier if necessary. The specimen book must accompany the specimens. The OR specimen transport person and the laboratory personnel receiving the specimens will print their names in the specimen book (using a personal ID stamper is also acceptable). The specimen logbook should always be returned to the OR with the transport person.

3.8. **Routine specimens obtained during weekend cases** will be taken to the lab at first opportunity on Monday morning. Specimens should be checked for complete coverage with formalin, as well as the correct 10:1 ratio.

3.9. **Hardware removed from the patient** will be discarded into the sharps container except, if it is known that the patient or the surgeon wants the hardware returned to them. Such hardware will have bioburden removed by Surgical Tech and handed off to Circulator. Hardware will then be wiped off and rinsed in 70% Alcohol, wiped dry, placed into specimen bag, and sealed. The hardware will then be secured to patient chart or given to surgeon, prior to leaving room. You must then document that the hardware was given to the patient or surgeon in Essentris. If the hardware is being removed for medical/legal reasons, confer with the surgeon and product rep for proper handling.

3.10. Any specific questions should be referred to Anatomic Pathology Section at (916-2160).

4. SENTINEL NODES:

4.1. Definition: Sentinel nodes are the first few lymph nodes into which a tumor drains. Sentinel node biopsy involves injecting a tracer material that helps the surgeon locate the sentinel nodes during surgery.

4.2. Per lab preference, sentinel nodes are sent fresh or surgeon's preference. A history of radiation should be noted for sentinel nodes. Document gamma probe reading for each node on the specimen sticker and on the PERIOP Tissue Exam Request. (NOTE: When the reading becomes 1/10 of the reading of the first sentinel node, it is no longer considered a sentinel node and should be labelled "lymph node".

5. DEPLETED URANIUM:

5.1. Specimens containing depleted uranium should have the time and date of extraction written on the container by the circulating nurse.

5.2. Specimens containing depleted uranium should be clearly labeled on the container and SF 515 to alert lab personnel.

5.3. Specimens with depleted uranium are then sent as to surgeon's preference e.g. permanent, fresh, or frozen.

6. **FROZEN SECTION AND FRESH SPECIMENS:**

6.1. The FROZEN section lab is to be notified (916-2160) as soon as the circulator knows that a frozen section will be obtained during a surgical case. A second notification will be called in when the specimen is on the way to the lab. (If the surgeon requests a frozen after 1630, the pathologist on-call is to be called by the OR, at the surgeon's direction, at 916-0626.)

6.2. The lab is provided with the following information when being notified:

3.4.2.1. Patient name, prefix, last four of sponsor's SSN.

3.4.2.2. Surgeon requesting frozen.

3.4.2.3. OR # and phone #.

3.4.2.4. *Approximate* time specimen will be obtained.

6.3. The circulator will prepare a patient identification label for the specimen container and the specimen book. The labels will match EXACTLY and contain the name of the specimen, the sequential letter, the operating room number, date, time, surgeon's full name, and the word "FROZEN".

6.4. The PERIOP Tissue Exam Request form in Essentris will be filled out completely, with a copy sent with each frozen section or fresh specimen. In the "COMMENTS" section, ask the surgeon specifically

what she/he is looking for – i.e. malignancy, margins, etc. On the top of the form legibly PRINT “FROZEN” or “FRESH”. The form must also contain the following:

6.4.1. Complete patient identification.

6.4.2. Date/Time (if applicable).

6.4.3. Surgical Service submitting specimen.

6.4.4. Brief Clinical History (includes age, sex, ethnicity, diagnosis, how long issue existed, other recent treatments related to diagnosis). This information should come DIRECTLY from the surgeon and not a “copy&paste” from the H&P.

6.4.5. Preoperative diagnosis.

6.4.6. Operative findings (“see operative report” is NOT acceptable).

6.4.7. Postoperative Diagnosis (“see operative report” is NOT acceptable).

6.4.8. Surgeon’s first and last name (legible).

6.4.9. Surgeon’s pager number or Operating Room suite number and phone number.

6.4.10. Surgeon’s signature and title (on the PERIOP Tissue Exam Request this information is provided electronically).

6.5. SEQUENTIAL LABELLING OF FRESH AND FROZEN SPECIMENS – ALL Fresh and Frozen specimens should be given their sequential letter BEFORE any permanent specimens are given a letter.

6.6. TRANSPORT OF FRESH or FROZEN SPECIMEN TO LAB – When the circulating nurse is ready to send a specimen, he/she will call the front desk and ask for a runner to come to the room with the appropriate specimen book. The nurse gives the transport person the specific instructions on where to take it. A sticker is placed in the book. Both the nurse and the transporter print their names next to the sticker! A printed copy of the PERIOP Tissue Exam Request form will accompany the FROZEN or FRESH specimen. The specimen and paper work are verified with the surgeon one more time before the transporter leaves the room.

6.7. For FROZEN SECTIONS, the circulator should immediately document on the count board the time the specimen left the room.

6.8. Formalin WILL NOT be added to fresh or frozen section specimens. Small amounts of saline may be added only at the request of the surgeon. The type of fluid added to container should be annotated on the label.

7. BREAST SPECIMENS (except breast reductions & gynecomastia)

7.1. Breast specimens will have a PINK breast sticker placed on the PERIOP Tissue Exam Request.

7.2. When the breast tissue is removed from the body, the surgeon (or tech) will call a “Time out” to ensure the time is documented properly and accurately on the sticker.

7.3. For permanent specimens (i.e. mastectomy tissue), the time the specimen was placed in formalin should be documented on the PINK breast tissue sticker. Whenever possible, put specimen in formalin at first opportunity. Ensure it is within one hour of leaving the body.

7.4. **NOTE: ALWAYS ask surgeon BEFORE placing specimen in formalin!**

7.5. **RADIOACTIVE SEED LOCALIZATION of BREAST LESIONS:**

7.5.1. Radioactive seeds are placed in patient up to 2 weeks prior to surgery and a mammogram is taken to confirm placement.

7.5.2. On DOS, the RSL packet is picked up from Mammography by a surgery department representative. Nurse should ensure packet is in room before starting the case!

7.5.2.1. **Contents of packet** must include:
-post-seed placement mammogram films,
-Seed Tracking form (See APPENDIX A) and written directive,
-"Caution – Radioactive" sticker or tape
-Specimen grid in a biohazard bag with a patient sticker on it.

7.5.3. The surgeon will verify the disposition of the specimen with the circulator and surgical technician.

7.5.4. Prior to prepping the patient for surgery, the surgeon will scan the breast for seed activity using a portable survey instrument equipped with a thin crystal sodium iodide (NaI) probe or equivalent (NeoProbe). The presence of the seed and the number of seeds will be discussed during the "TIMEOUT" and documented on the "Timeout" form and the Radioactive Seed Tracking Form.

7.5.5. When the specimen is removed from the body, the surgeon will call a "Time-out" to ensure the exact time is documented on the PINK Breast sticker. The PINK Breast sticker is placed on the PERIOP Tissue Exam Request.

7.5.6. The specimen will be scanned for radioactivity with the thin crystal sodium iodide (NaI) probe or equivalent (NeoProbe) BEFORE being passes off the sterile field to ensure seed is in the specimen. Then the specimen will be passed off the field by the surgeon or tech onto a specimen grid. The grid will remain flat and be placed into a biohazard bag and labelled in accordance with policy. A "Caution - Radioactive Material" sticker or tape will be placed on the container/bag.

7.5.7. The specimen, on the grid in the bag, will be placed in the Trident Specimen Imaging machine. The specimen will be x-rayed and the surgeon must confirm the presence of the seeds in the specimen BEFORE sending the specimen to Pathology. The # of seeds will be noted on the patient sticker. (NOTE: If the Trident Specimen Imaging machine is not working correctly or is unavailable, the specimen may be taken to Mammography for seed confirmation xrays. Those x-rays will follow the specimen to Pathology. If there are multiple RSL cases scheduled for the same day, every effort will be made to schedule those cases in the MAIN OR and the Trident Specimen Imager will be centrally located in the Specimen room. In this situation, the surgeon will break scrub and view the specimen image in the alternate location. When the Imaging machine is moved from the Specimen room to an OR or to it's storage area, it will be completely wiped down with Cavi-Wipes.)

7.5.8. The following items will accompany the FRESH specimen to Pathology.

7.5.8.1. PERIOP Tissue Exam Request identifying specimen and # of seeds in the specimen. (APPENDIX B)

7.5.8.2. Radioactive Seed Tracking Form, with # of seeds documented on it. (APPENDIX A)

7.5.9. The specimen will be sent to Pathology as a "FRESH" specimen. The circulator will call the front desk to request a runner to come to the room with the appropriate specimen book. The runner and circulator will verify the specimen and place a sticker in the appropriate specimen book. Both will print their names next to the sticker.

7.6. WIRE LOCALIZATION BREAST BIOPSY

7.6.1. On rare occasions a “Needle Loc” breast biopsy may be done. Follow the same protocol as above for the RSL, EXCEPT there is no Seed Tracking form.

8. **PELVIC WASHINGS:**

8.1. Surgeon is responsible for completing the PERIOP Tissue Exam Request in Essentris and giving it to the circulator prior to the beginning of the case.

8.2. The specimen will be collected in a suction trap or syringe and placed in a biohazard bag or large container. A patient identification label, completed per policy, will be placed on both the inner and outer container.

8.3. Cytology washings should be sent to lab **within 1 hour**. If this is not possible to send to lab within an hour, ask surgeon if washings should be placed on ice or Heparin added.

8.4. Call for a transporter and send specimen to lab according to policy.

8.5. After duty hours, contact the pathologist on-call for further directions. The pager number for the **on-call pathology resident is 513-0626**. The number for **Cytology Processing is 916-3130**, and for the **Histology Gross room it is 916-2160/9847**.

9. CULTURES:

9.1. Culture tubes are located in each room and in the Pyxis’ in each core. CHECK expiration dates on culture tubes prior to use.

9.2. Tissue for culture can come to lab in a sterile specimen cup.

9.3. Aerobic and anaerobic cultures, gram stains, AFB, fungal cultures, etc. must be taken to Clinical Lab as soon as possible. **During daytime hours**, the circulating nurse will call for a runner to come the room to have the cultures transported to Lab ASAP. **After duty hours and on weekends**, the technician or nurse will transport the cultures to the lab ASAP after the case is finished.

9.4. Cultures will be labeled sequentially (1,2,3….).

9.5. A label will be placed on each culture tube with the following information:

9.5.1. Patient’s name, FMP, and sponsor’s SSN.

9.5.2. Date and Time.

9.5.3. Surgeon’s first and last name.

9.5.3. Culture source (site).

9.5.4. Type of test being requested (i.e. aerobic, anaerobic, AFB, gram stain.)

9.6. The PERIOP Tissue Exam Request form in Essentris will be filled out in the “Culture/Microbiology Exam” section, indicating Site/Name and Type of culture. In the “Comments” section, indicate if any antibiotic therapy has been given and/or results of previous cultures, if applicable.

10. UROLOGY SPECIMENS

10.1. All extracted stones, i.e. ureteral, kidney, bladder, etc., will be sent as FRESH specimens. DO NOT place them in formalin.

10.2. Testis biopsy specimens go in Bouin's solution, as a general rule. But ALWAYS ask/verify!

10.3. Urine cytology specimens go in Cytolyt (found in the Urology Clinic).

11. CARTILAGE BIOPSY:

11.1. PRECAUTION**: It is very important to collect medical allergy information. Known allergies to bovine products are contraindicated; precautions should be taken with known histories of anaphylaxis to Gentamicin.**

11.2. Upon receipt of the Cartilage Biopsy Transport Kit:

11.2.1. DO NOT DISCARD THE TRANSPORT KIT (box). KEEP IT INTACT. IT IS USED TO MAIL THE SPECIMEN ONCE TAKEN.

11.2.2. Remove the square foam insert from the top of the shipping container (do not discard).

11.2.3. Remove the plastic biopsy transport cylinder from the kit and twist off lid.

11.2.4. Remove biopsy transport medium tube from cylinder. (Caution: the **Exterior** of the tube is not sterile).

11.2.5. Check biopsy transport medium tube for expiration date, color, particulates, turbidity, and leakage. Do not use if the tube is expired (expiration date is indicated on each tube) or if the tube has leaked. Do not use the tube if the color of the medium is yellow, or if obvious particulate matter, precipitate or turbidity is evident in the medium.

11.2.6. Replace the tube in the cylinder. **Store the cylinder with transport kit** and the refrigerant packs at+2°C to +8°C (36°F to 46°F) until use. **Do not Freeze** Biopsy Transport Kit Cylinder or refrigerant packs. Store in the medications refrigerator.

11.3. Day of the Surgery:

11.3.1. Remove the cylinder and transport kit from the refrigerator and then remove the plastic biopsy transport cylinder from the transport kit (box) and twist off the orange lid.

11.3.2. Keep the two gel packs in the refrigerator until ready to seal package.

11.3.3. Remove biopsy transport medium from cylinder. (Caution: the **Exterior** of the tube is not sterile).

11.3.4. Check biopsy transport medium tube for expiration date, color, particulates, turbidity, and leakage. Do not use if the tube is expired (expiration date is indicated on each tube) or if the tube has leaked. Do not use the tube if the color of the medium is yellow, or if obvious particulate matter, precipitate or turbidity is evident in the medium.

11.3.5. Twist off tube cap.

11.3.6. Using sterile technique, coordinate placement of the biopsy into the transport medium tube.

11.3.7. Place the cap on the tube and twist to secure. Note that the cap has a two stage seal. **ENSURE CAP IS SEALED TIGHTLY!**

11.3.8. Enter the patient name and date of biopsy on the label on Cartilage Biopsy Transmittal Notice (Part No. 65007). See Annex A. The Genzyme Biosurgery Patient ID number is preprinted on that same label. Place the label on the biopsy transport medium tube. Physician's copy of Cartilage Biopsy Transmittal Notice with patient's name, date of biopsy, and preprinted Genzyme Biosurgery Patient ID number should be filed with patient's permanent records.

11.4. PACKAGING A BIOPSY FOR TRANSPORT**:**

11.4.1. Insert biopsy transport medium tube containing cartilage sample back into the foam insert within the plastic cylinder, return the upper foam insert into the top of the cylinder, and place the lid on the cylinder and twist to secure.

11.4.2. Insert cylinder into the shipping container.

11.4.3. Remove the two cold refrigerant gel packs from the refrigerator and place them on either side of the cylinder.

11.4.4. Place square foam insert on top of the cylinder.

11.4.5. Complete and enclose the Biopsy Transmittal Notice found in one of the Tyvek envelopes.

11.4.6. Secure the shipping container with tape.

11.4.7. Call Genzyme Biosurgery Customer Care at 800-453-6948 or 617-494-8484 (24 hours a day and seven days a week) to arrange biopsy pick-up.

12. REFERENCES:

12.1. BAMC Pamphlet 40-04. Guide for Obtaining Laboratory Support, 02 Feb 2015

12.2. Genzyme Corporation Direction to Use Cartilage Biopsy Transport Kit 03/2003

12.3 "Guideline for Specimen Management", AORN GUIDELINES FOR PERIOPERATIVE PRACTICE, Current Edition

12.4. Texas Commission on Environmental Quality (TCEQ) Title 25 Part 1 Ch 1 Subchapter K Rule 1.133

12.5. SAMMC GUIDELINES RADIOACTIVE SEED LOCALIZATION OF NON-PALPABLE BREAST LESIONS, 10 NOVEMBER 2014

13. DATE REVISED:

13.1. JUL 2018/S. HAMILTON, BSN, RN, CNOR

14. ATTACHMENTS:

APPENDIX A - I-125 Seed Tracking and Survey Form

APPENDIX B – SAMPLE PERIOP TISSUE EXAM REQUEST FORM

APPENDIX A

I-125 Seed Tracking and Survey Form:

Pre and Post Implant Survey
Radiation survey performed by: _____ Date: _____
Number of seeds total: **1 2 3 4 (**circle one)
Seed (s) placed in which breast? Right Left. Quadrant / Location: _____
If Bilateral: (# seeds on right) (# seeds on the left)_____
Seed verified in needle: ____YES ____ NO
After implant, needle verified void of seed: ____YES ____ NO

Implant
Source placement verified by x-ray: ____YES ____ NO
Seed placed / procedure performed by (Authorized User): Dr. _____

Explant and Survey
Explant / surgery performed by: Dr.MARTIN
Radiation survey performed by: Dr Martin Date: 3AUG2017
Seed verified in sample: __x__YES ____ NO Total Number of Seed(s): 2
Patient verified void of seed: __x__YES ____ NO
Radioactive materials label placed on specimen container: __x__YES ____ NO
Person taking specimen to Mammography / pathology: SPC Snuffy

Pathology
Person in pathology receiving the specimen: _____
Specimen placed in formalin and secured in marked cabinet: ____YES ____ NO Date: _____
Radioactive materials label placed on specimen container: ____YES ____ NO
Seed removal performed by: _____ Date: _____
Seed verified in sample: ____YES ____ NO Total Number of Seed(s) recovered: _____
Sample verified void of seed after removal: ____YES ____ NO
Seed placed in trefoil sticker and dated: ____YES ____ NO
Seed placed in lead container: ____YES _____ NO Date: _____
Health Physics contacted for seed pick-up: ____ YES ____ NO Date: _____

Health Physics
Health Physics personnel picking up seed: _____ Date: _____

Emergency Procedures

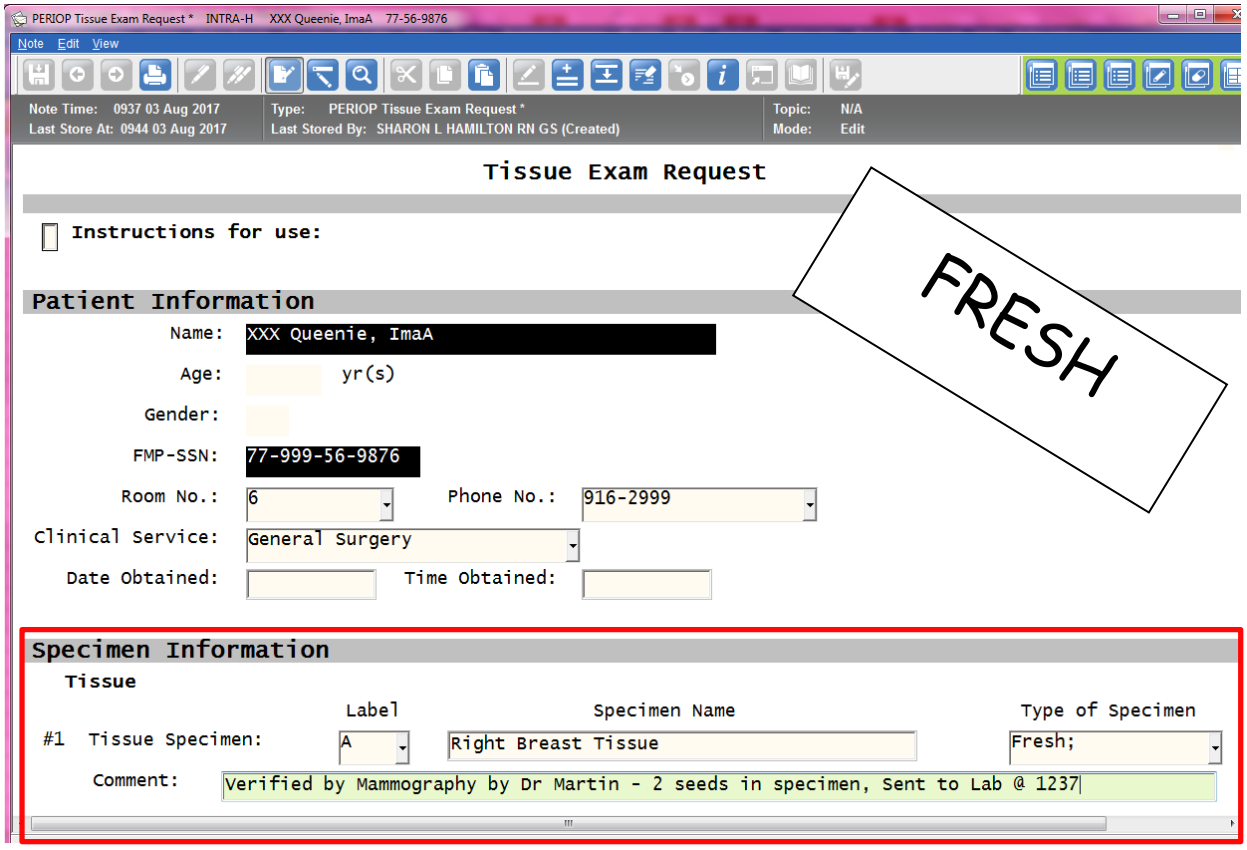
In the case of a lost seed, "**STOP"** and contact the Health Physics Service. Keep everyone in the area until Health Physics arrives.

CPT DAVID W. BYRD:
Phone: 210-916-7625 Cell: 979-229-9462

LAURA ELINE:
Alternate numbers (210) 916-8322 OR (210) 288-5789.

APPENDIX B

1. **PERIOP TISSUE EXAM REQUEST FORM:**



Note Type: PERIOP Tissue Exam Request *
Note Time: 0908 16 Oct 2018
Last Stored: 0949 16 Oct 2018
Stored By: PAMELA A SINGLETON 1LT NC

Rev. 2017.05.25.1630 (R3)

Tissue Exam Request

Patient Information

Name: [redacted]
Age: [redacted] yr(s)
Gender: [redacted]
Room No.: 27 Phone No.: 916-6527
Clinical Service: General Surgery
Date Obtained: 16Oct2018 Time Obtained: 0838

Specimen Information

Tissue

	Label	Specimen Name	Type of Specimen
#1 Tissue Specimen:	A	Right pectoralis fascia	Permanent;
#2 Tissue Specimen:	B	Right breast mass, long suture-lateral, short suture-superior, double suture-deep	Permanent;
#3 Tissue Specimen:	C	Left breast mass, long suture-lateral, short suture-superir, double suture-deep	Permanent;
#4 Tissue Specimen:	D	New anterior/inferior margin right side	Permanent;

Brief Clinical History:
[redacted] w/ biopsy proven and rad-path correlative right breast DCIS and left breast discordant pathology for her cerning imaging.

Preoperative Diagnosis: Breast cancer
Operative Findings: See operative note
Postoperative Diagnosis: saa
Surgeon/Provider: GUY T CLIFTON LTC MC Contact No.: 228-6307

Signatures

Signature: GUY T CLIFTON LTC MC Time/Date: 0910 16Oct2018

[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted] cal Center (0109)

CliniComp, Intl.

printed Wed Apr 17 13:08:56 2019

Radioactive Seed Localization (RSL)

1. Case should be booked and consented as a Radioactive Seed Localization case.

2. The patient should have a packet with them in Pre-Op **OR** the surgical team (resident, intern, med student) should have it. It is NOT our responsibility to go get it in Mammography. ***It is the surgical team's responsibility, per policy.***

3. CONTENT OF PACKET:

   -Post-RS placement mammogram films

   -"Caution - Radioactive" tape or sticker to put on specimen container/bag

   -AccuGrid® specimen grid in a biohazard bag with the patient's sticker on it

   -RSL Tracking form.

4. WHAT TO SEND TO PATHOLOGY: SEND specimen "FRESH"!!

   -**Tissue Exam Request** form with a **Pink sticker** annotating the **TIME** the specimen was removed from the body and the **# of seeds** in the specimen.

   -**Radioactive Seed Tracking Form** with Explant section filled out and # of seeds annotated.

   -RSL Breast Tissue **Specimen** with **"Caution" Radioactive"**

ATTENTION

FRESH RADIOACTIVE SEED SPECIMEN

SPECIAL HANDLING

ONE SPECIMEN PER GRID

SPECIMEN & GRID MUST STAY TOGETHER

WITH RADIOACTIVE LABEL