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### 1.1 MISSION STATEMENT

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To provide the highest valued surgical pathology services in an environment of education and scholarly achievement.
1.2 BUSINESS HOURS

A. Rhode Island Hospital

1. Business hours for Surgical Pathology are between 8:00 AM and 4:30 PM, Monday through Friday. The Administrative Office can be contacted at 444-5151. The Bridge Building Surgical Suite can be contacted at 444-5441 (RIH Bridge Building Surgical Suite) or by paging the staff pathologist on call (CALL CENTER X33232).

2. A staff pathologist is also on-call during other hours and on holidays and can be available in the Hospital within 30 minutes after contact by pager or through the CALL CENTER X33232 who maintains a current call schedule for the Pathology Department.

B. The Miriam Hospital

1. Business hours for Surgical Pathology are between 8:00 AM and 4:30 PM, Monday through Friday. The Administrative Office can be contacted at 793-4245. The Surgical Suite can be contacted at 793-4244 or by paging the staff pathologist on call the CALL CENTER X33232.

2. A staff pathologist is also on-call during other hours and on holidays and can be available in the Hospital within 30 minutes after contact by pager or through the CALL CENTER X33232 who maintains a current call schedule for the Pathology Department.
1.3 PERSONNEL

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A. **Staff Pathologists** are physicians licensed to practice in the State of Rhode Island, who are board certified or eligible in Anatomic Pathology, who are members of the Medical Staff of the Hospital in which they deliver service and who are credentialed to perform surgical pathology by that institution. All staff pathologists are cross credentialed at the Rhode Island Hospital and The Miriam Hospital.

B. **Neuropathologists** are physicians licensed to practice in the State of Rhode Island, who are board certified in Anatomic Pathology and Neuropathology, or in Neurology and Neuropathology who are members of the Medical Staff of the Hospital in which they deliver service and who are credentialed to perform surgical pathology by that institution.

C. **Pathologist Assistants** are certified and are either graduates of an accredited training program or qualify by direct experience. They are trained to handle the full spectrum of surgical specimens and are therefore expected to process, under the supervision of a pathologist, all types of gross specimens received in the laboratory. The pathologist assistant is expected to exercise good judgment and ask for direct supervision, as necessary, especially with complex specimens. Any unusual or especially complex specimen should be discussed with the staff pathologist who is present in the Surgical Pathology Suite at the Rhode Island Hospital or The Miriam Hospital. All gross dictations are reviewed by the staff pathologist and resident responsible for the case sign out.

D. **Surgical Pathology Technologists** are college graduates with specialized training in the grossing of specimens and in autopsy prosection who function under the supervision of a Pathologist or Pathologist Assistant. They typically gross biopsies and small specimens with light supervision provided by the Pathologist Assistants and by the Attending Pathologists.

1. Surgical Pathology technologists follow Gross Dissection Protocol for the following specimens:
   a) Biopsies (specimens that do not require dissection)
   b) Skin biopsies
   c) Gallbladder
   d) Appendix
   e) Tonsils and adenoids
   f) Teeth
   g) Hardware
   h) Gross only specimens

E. **Pathology Residents** are expected to assume graduated responsibility for grossing more complex specimens as they progress in their training. The pathology resident is expected to exercise good judgment and ask for direct supervision, as necessary, especially with complex specimens. Any unusual or especially complex specimen should be discussed with the staff pathologist or surgical pathology fellow. Both of these individuals are present in the Surgical Pathology Suite at Rhode Island and The Miriam Hospitals.
1.4 TRAINING GUIDE FOR NON-PATHOLOGISTS WHO PERFORM GROSSING

Prepared by

Revised

Reviewed

Reviewed

Lifespan Academic Medical Centers
Department of Laboratory Medicine
Anatomic and Surgical Pathology

Competency Testing for Pathologists’ Assistant Who Perform Gross Tissue Examination, Description and Dissection

All non-pathologist personnel who perform gross examination, description and dissection of human tissues received in Surgical Pathology do so under the supervision of a qualified pathologist, and all such personnel meet or exceed CLIA ’88 requirements as delineated in the United States Federal Register: Rules and Regulations, Volume 60, No 78, Washington, April 24, 1995.

Pathologists’ Assistant Competency Worksheet

Pathologists’ Assistant: _________________________________________________
Pathologist Evaluator: __________________________________________________
Date: ________________________________________________________________

The pathologists’ assistant(s) follows Gross Dissections Protocol for the following specimens:

Type of Specimen | Direct Observation

I. Biopsies

| Bone marrow aspirates and cores | yes | no | n/a |
| Endoscopic biopsies (including polyps) | yes | no | n/a |
| Fine needle aspirates | yes | no | n/a |
| Gynecological biopsies | yes | no | n/a |
| Muscle biopsies | yes | no | n/a |
| Myocardial/endomyocardial biopsies | yes | no | n/a |
| Needle biopsies (Renal, prostate, liver, etc.) | yes | no | n/a |
| Nerve biopsies | yes | no | n/a |
| Nondescript biopsies (gut, bronchus, nasal, bladder, etc.) | yes | no | n/a |
| Skin biopsies (Curettings, shave, punch, excisional, incisional, less than 1.0 cm.) | yes | no | n/a |
| Temporal artery biopsies | yes | no | n/a |
II. Skin and Subcutaneous Tissues

All dermatological specimens greater than 1.0 cm. (including redundant skin, debridements, etc.)

III. Endocrine Organs

Partial or total lobectomies
Total thyroidectomies
Thyroglossal duct cysts and other ectopic thyroid tissues
Parathyroid gland resections
Adrenal gland resections
Pancreactectomies (Whipple procedures, etc.)

IV. Lymph-Hematopoietic System

Lymph node specimens (for lymphomas, cancers, etc.)
Bone marrow aspirates, cores, etc.
Splenectomies
Thymic resections
Tonsils and adenoids

V. Gastrointestinal System and Related Organs

A. The Mouth

Resections, biopsies, etc. of lip, alveolar ridge, gingiva, buccal mucosa, tongue, floor of mouth, etc.
Hemimandibulectomies
Hemiglossectomies
Radical neck dissections
Teeth and bone

B. Esophagus

Localized resections for diverticulum, stricture, and benign neoplasms
Radical resections for malignant neoplasms

C. The Stomach

Localized resections for gastric polyps, ulcers and tumors
Gastrostomy repairs, etc.
Subtotal or total gastrectomies for ulcer disease or tumor
Esophagogastrectomies with/without duodenum, regional
Lymph node dissections, splenectomy, and omentectomy

D. The Small Intestine

Local resections for diverticulae, benign tumors and trauma
Resections for inflammatory disease, infarction, malignant tumors and intussusception

E. The Large Bowel

Ostomy revisions or closure
Segmental resections for tumor, IBD, bleed, etc.
Subtotal/total colectomy for extensive IBD or neoplastic disease, with lymph node dissection
F. The Vermiform Appendix

Simple appendectomy (incidental)       yes  no  n/a
Appendectomy for inflammation, diverticulum    yes  no  n/a
Appendectomy with right colectomy        yes  no  n/a
Radical appendectomy for primary tumor   yes  no  n/a

G. The Rectum and Anus

Local resections for polyps, hemorrhoids, anal tags, fistulectomies, etc. yes  no  n/a
Abdominoperineal resections for malignancy yes  no  n/a
Resections for megacolon                   yes  no  n/a

H. The Liver

Wedge resections for diagnosis       yes  no  n/a
Lobectomies for hemangiomas, localized tumor, and to control traumatic bleeding yes  no  n/a

I. The Gallbladder and Extrahepatic Bile Ducts

Cholecystectomy for cholecystitis, cholelithiasis, choledocholithiasis and malignancy yes  no  n/a

J. The Pancreas

Partial pancreatectomy for pseudocysts yes  no  n/a
Radical pancreatectomy and Whipple procedure for tumor yes  no  n/a

VI. Ear, Nose and Throat Region

Nasal cavity biopsies, nasal septal reconstructions, paranasal sinus biopsies, polypectomies, etc. yes  no  n/a
Nasopharyngeal biopsies, adenoidectomies, middle ear and sinus curettings, bone fragments and polyethylene tubes yes  no  n/a
Oropharyngeal biopsies, palatine tonsillectomies and radical dissections for tumor yes  no  n/a
Hyopharyngeal biopsies and radical dissections for tumor yes  no  n/a
Endolaryngeal biopsies, polypectomies, vocal cord stripplings and radical resections for tumor yes  no  n/a
Salivary gland biopsies and sialolith removals; subtotal/total resections, and radical dissections yes  no  n/a
Radical neck dissections and/or "Commando" procedures yes  no  n/a

VII. The Breast

Needle biopsies                      yes  no  n/a
Incisional biopsies: Wedge biopsies, lumpectomies, duct excisions, etc. yes  no  n/a
Mastectomies; Subcutaneous, simple, modified radical or radical for tumor yes  no  n/a
### VIII. The Chest Domain

<table>
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<tr>
<th>Procedure</th>
<th>Yes</th>
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<tr>
<td>Bronchial washings, brushings, fine needle aspirates and biopsies</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Transbronchial, mediastinal and lung biopsies</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Pleural stripplings and bullaectomies</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Segmental and mediastinal resections</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Scalen node resections</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Lobectomies for malignant disease</td>
<td>yes</td>
<td>no</td>
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<tr>
<td>Pneumonectomies for malignant disease</td>
<td>yes</td>
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### IX. The Female Reproductive System

#### A. Vulva

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<tbody>
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<td>Biopsies of skin and mucous tissues</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Urethral carunclectomies and hymenectomies</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Bartholin's gland cystectomies</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Partial or radical vulvectomies for malignant disease</td>
<td>yes</td>
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<td>n/a</td>
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#### B. Vagina

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<th>Yes</th>
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<tr>
<td>Biopsies of mucosal tissues</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Anterior/posterior repair mucosal fragments</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<td>Partial or radical vaginectomies for malignant disease, with/without uterus, bowel, fallopian tubes and ovaries, and regional lymph node resection</td>
<td>yes</td>
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#### C. Cervix

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<th>Yes</th>
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<tr>
<td>Biopsies, blind or directed</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Endocervical currettings</td>
<td>yes</td>
<td>no</td>
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<td>Conizations</td>
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<td>LEEP conizations</td>
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#### D. Uterus

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<th>Procedure</th>
<th>Yes</th>
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<td>Biopsies (D&amp;C)</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Myomectomies</td>
<td>yes</td>
<td>no</td>
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<td>Total hysterectomies</td>
<td>yes</td>
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<td>Radical hysterectomies</td>
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#### E. Fallopian Tubes

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<tr>
<td>Tubal ligations</td>
<td>yes</td>
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<tr>
<td>Salpingectomies, with or without oophorectomies and/or lymphadenectomies</td>
<td>yes</td>
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#### F. Ovaries

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<tr>
<td>Biopsies</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Wedge resections</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Cystectomies/subtotal resections</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Oophorectomies</td>
<td>yes</td>
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#### G. Fetoplacental Unit

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<td>Therapeutic or spontaneous abortions</td>
<td>yes</td>
<td>no</td>
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<td>Deliveries</td>
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**X. Urinary and Male Genital Systems**

**A. Kidney, Pelvis and Ureter**

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<td>Needle or open biopsies</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<td>Ureteropelvic junctions resections</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<td>Renal arterioplasties</td>
<td>yes</td>
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<td>n/a</td>
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<tr>
<td>Partial or total nephrectomies, with/without</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>ureterectomy and node dissection</td>
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**B. Urinary bladder, Urethra**

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<td>Transurethral biopsies and resections</td>
<td>yes</td>
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<td>n/a</td>
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<tr>
<td>Carunculectomies of urethra</td>
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<tr>
<td>Segmental resections</td>
<td>yes</td>
<td>no</td>
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<tr>
<td>Total cystectomies with/without lymph node dissection</td>
<td>yes</td>
<td>no</td>
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**C. Prostate, Seminal Vesicles**

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<th>Yes</th>
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<tr>
<td>Transurethral resections</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Suprapubic resections</td>
<td></td>
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<tr>
<td>Radical prostatectomies</td>
<td>yes</td>
<td>no</td>
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**D. Testis, Epididymis, Vas Deferens, Spermatic Cord**

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<tr>
<td>Testicular biopsies</td>
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<tr>
<td>Spermatocoelectomies/Hydrocelectomies/varicocelectomies</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Vasectomies</td>
<td>yes</td>
<td>no</td>
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<tr>
<td>Orchiectomies</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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**E. Penis, Scrotum**

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<th>Procedure</th>
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<tr>
<td>Biopsies</td>
<td>yes</td>
<td>no</td>
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<tr>
<td>Circumcisions</td>
<td>yes</td>
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<tr>
<td>Subtotal to total penectomies</td>
<td>yes</td>
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**XI. Cardiovascular System**

**A. Vascular**

<table>
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<tr>
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<tr>
<td>Embolectomies</td>
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<tr>
<td>Veins (grafts, stripings)</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Arteries (A-V repairs, bypass grafts, arterioplasties)</td>
<td>yes</td>
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**B. Cardiac**

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<tr>
<td>Biopsies of pericardium and endomyocardium</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
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<tr>
<td>Valves (removal and/or replacement)</td>
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<tr>
<td>Prosthetic devices (valves, pacers, pacing wires, etc.)</td>
<td>yes</td>
<td>no</td>
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**XII. Extremities, Bone, Joints, and Soft Tissues**

**A. Extremities**

<table>
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<tr>
<th>Procedure</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
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<tbody>
<tr>
<td>Digits, parts of hands or feet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varieties of amputation of hands, feet, legs and arms</td>
<td>yes</td>
<td>no</td>
<td>n/a</td>
</tr>
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</table>
B. Bones and Joints

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
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<tbody>
<tr>
<td>Fracture fragments and foreign material</td>
<td></td>
<td></td>
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<tr>
<td>Orthopedic hardware</td>
<td></td>
<td></td>
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<tr>
<td>Bone curettage fragments, patellar shavings</td>
<td></td>
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<tr>
<td>Menisci</td>
<td></td>
<td></td>
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<tr>
<td>Femoral heads</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Whole joints</td>
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<tr>
<td>Segmental resections for neoplasia</td>
<td></td>
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</tbody>
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XIII. Nervous System and Associated Tissues

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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<tbody>
<tr>
<td>Skull and/or soft tissues for traumatic fractures, defect repairs or tumor removal</td>
<td></td>
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<tr>
<td>Spinal canal tissues (laminectomies, diskectomies)</td>
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<tr>
<td>Meninges for subdural hematomas, repair of trauma, removal of tumor</td>
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<tr>
<td>Brain, spinal cord, nerves, ganglia, etc. for evacuation of hematomas, removals of tumor</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Pituitary (ablations, removals of cysts and tumors)</td>
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<td></td>
<td></td>
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<tr>
<td>Muscle biopsies</td>
<td></td>
<td></td>
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<tr>
<td>Eye (biopsies, removal of lens, subtotal excisions and orbital exenterations)</td>
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</table>
1.5 EVALUATION FORM FOR NON-PATHOLOGIST WHO GROSS

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<tr>
<td>Revised</td>
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<td>Reviewed</td>
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*As required by CAP-this evaluation is performed yearly at personnel’s annual review.

Lifespan Academic Medical Centers
Departments of Laboratory Medicine
Anatomic and Surgical Pathology
Pathologists’ Assistant Evaluation Form

Pathologists’ Assistant:_________________________________________
Evaluator’s Name:_____________________________________________
Date of Evaluation:_____________________________________________

I. Evaluate the skills listed below and rate by circling the appropriate number:
"1"=Fails to Meet Job Requirements
"2"=Requires Development
"3"=Meets Job Requirements
"4"=Exceeds Job Requirements
"5"=Exceptional
"N/A"=Not Applicable

1. **Cognitive Skills:** General medical and pathology knowledge base.
2. **Technical Skills:** Appropriate triage and dissection of gross specimens.
3. **Gross Diagnostic Skills:** Appropriate recognition of disease process and decision making ability.
4. **Communication Skills:** Quality and clarity of oral and written records.
5. **Interpersonal Skills:** Ability to work effectively with peers, team members and all other Lifespan "clients".
6. **Problem Solving Skills:** Ability to collect and analyze data, to make and act on appropriate decisions, to manage time effectively and to ask for help when appropriate.
7. **Work Habits:** Initiative, enthusiasm, intellectual curiosity, etc.

1 2 3 4 5 N/A
8. **Teaching Skills:** Ability to effectively teach others.
   
   1 2 3 4 5 N/A

9. **Integrity:** Ethics, honesty, etc.
   
   1 2 3 4 5 N/A

II. Please review answers to the first nine questions and rate overall by circling the appropriate number according to the same rating system utilized above:

10. **Overall Assessment:**
    
    1 2 3 4 5 N/A

III. Evaluator Comments on Strengths/Weaknesses of Pathologists’ Assistant: (If additional space is needed, please use separate sheet.)

IV. Pathologists’ Assistant Comments on Evaluation:

Pathologist’s Signature: ____________________________ Date: ________

Pathologist Assistant’s Signature: ____________________________ Date: ________
**2.0 SURGICAL SERVICES POLICY AND PROCEDURE**

**Purpose**: To ensure that every specimen removed from the surgical patient is appropriately and accurately identified and properly preserved.

**Policy**: Tissue and foreign bodies with certain exceptions (see list) removed from patients in the operating room must be sent to the Surgical Pathology, Cytology, or Microbiology Laboratory for examination with the exception of foreign bodies involving the police.

**Procedure**:

1. **General Considerations**
   a) Specimens should be passed from the surgical field only with the permission of the surgeon
   b) The surgeon must verify the type and location of specimen for proper labeling
   c) Unless specifically contraindicated, specimens should be kept moist with saline until ready for permanent preservation
   d) Specimens are handled with gloves

2. **Specimens for Surgical Pathology**
   a) It is the responsibility of the scrub person, after a specimen is obtained to:
      1) Verify identification of the specimen with the surgeon
      2) Verify type of solution media and pathological examination desired
      3) Hand-off the specimen to the circulating nurse
   b) It is the responsibility of the circulating nurse, once the specimen is received to:
      1) Place specimen in specimen container with preservation solution (10% formalin) if appropriate
2) Attached addressograph label to container

3) Enter anatomical identification of specimen, numerical order, and date, on label and pathology form

4) Document specimen on operative record

5) Ensure that pathology form is completed by the surgeon or his or her designee at the completion of the surgery

6) Enter specimen in specimen log – information to include:
   - Patient addressograph label
   - Anatomical identification
   - Numerical order
   - Date
   - Initials of person entering specimen

7) Place specimen in designated refrigerator after 3:00 pm, Monday through Friday and on weekends and holidays:
   - Amputated extremities are recorded and promptly transported to the pathology laboratory (RIH) (NPT) or Morgue (TMH)
   - Frozen sections are recorded and immediately transported to the pathology laboratory
   - After hours amputation specimens should be brought to the Morgue for refrigeration. The completed requisition form should be left in Davol SP

8) Specimens are routinely transported to the pathology laboratory at established intervals during the day

9) Specimens removed on evening or night shifts are stored in the specimen refrigerator until the first daily pick up.

3. Foreign Bodies
   
a) All foreign bodies, except bullets (see separate policy) removed from a patient must be labeled; recorded on the operative record, on the pathology form and in the specimen log and transported directly to the pathology laboratory
4. Specimens for Frozen Section/Special Studies
   a) Specimens for frozen section must be labeled; recorded on the operative record in the specimen log and on the pathology form; maintained fresh and transported immediately with a completed pathology slip to the laboratory
      1) The letters “F.S.” are added to the specimen label
   b) When a frozen section is anticipated on evening or night shifts when the pathology laboratory is not normally open, the surgeon is responsible for making arrangements with the pathology department to examine the specimen
   c) When frozen section results are available, the pathologist shall call the operating room and speak directly with the surgeon
   d) Frozen Section results are written on the FS Consultation form

5. Specimens for Cytology
   a) Cytology specimens must be placed in an appropriate container with preservative; labeled, recorded on the operative record, on the cytology slip and in the specimen log and are promptly transported to the cytology laboratory
   b) Cytology specimens are not stored in the specimen refrigerator

6. Specimens for Culture
   a) All microbiology specimens are labeled; recorded on the operative record and on the microbiology form and are promptly transported to the microbiology laboratory
   b) Microbiology specimens are not stored in the refrigerator
   c) All microbiology specimens must be kept sterile and placed in a sterile container.
      1) Culture tube for swabs, tissue
      2) Sterile specimen container for tissue too large for culture tube
      3) Screw topped tubes for fluids
      4) Culture medium tubes for anaerobic cultures
### 2.1 OPERATING ROOM POLICIES

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To ensure the proper handling and the safe delivery of surgical specimens.
I. PURPOSE:

The purpose of this policy is to ensure the proper handling and safe delivery of surgical specimens.

II. DEFINITIONS:

**Surgical Specimen**: Tissues removed from the body surgically by knife, biopsy forceps, or tru-cut needle biopsy devices.

**Clinical Specimen**: A sample of blood, urine, sputum, or drainage collected from the patient for testing.

**Pathology Requisition form**: A surgical pathology requisition form is a three-page form that is required when submitting any surgical specimens to the laboratory.

**Intraoperative Consultation form**: A three-page form that is completed for an intraoperative consultation, and a request for frozen section tissue examination or occasionally examined grossly while the surgeon waits.

**Surgical Specimen log**: The third pink copy of the Pathology Requisition and Intraoperative consultation form.
III. POLICY:

All surgical specimens removed from patients in the Operating Room will be delivered to the Surgical Pathology department. Clinical specimens obtained from the patient will be delivered to the laboratory for processing.

It is the responsibility of the circulating nurse in collaboration with the anesthesia care provider and the surgical team, to ensure that all specimens procured in the operating room is properly identified, labeled and documented on the anesthesia/nurse’s intra-operative record. The surgical technician/scrub nurse is responsible for the delivery of the specimen to the appropriate laboratory department.

- All specimens will be identified with a patient addressograph label.
- All specimens going to Surgical Pathology will be described identically on the patient addressograph label, the surgical pathology requisition sheet, and in the intra-operative nursing record.
- Surgeons, technicians, anesthesia care providers, and nurses work in concert to ensure that all specimens will be described accurately and will be delivered to the appropriate laboratory department (i.e. pathology, chemistry).

IV. PROCEDURE for obtaining specimens in an intraoperative procedure:

1. The surgeon will inform the Surgical Technician/Scrub Nurse and the Circulating Nurse when a specimen is obtained from the patient.
2. The surgeon will specify the specimen description. Identification of the specimens is confirmed verbally between the surgeon and the circulating nurse. A read back for verification of specimen information will take place prior to documentation on the appropriate lab slip, label and in the intraoperative record.
3. The surgeon will specify the relevant laboratory study for the specimen and any special medium necessary for management of the specimen (e.g. frozen section, formalin immersion, "gross exam only", weight, culture and sensitivity, fungus smear, type and erosion tissue, histology, etc.).
4. The Surgical Technician/Scrub Nurse is responsible for the specimen while it is on the sterile field.
5. The Surgical Technician/Scrub Nurse will pass the surgical specimen from the sterile field only with the permission of the surgeon.
6. The circulating nurse will prepare the specimen container with a patient label and specimen description. The patient label will be attached to the specimen container when the specimen is received from the surgical field by the circulating nurse (no pre-labeling of specimen container).
7. The circulating nurse will verbally confirm the specimen description with the Surgical Technician/Scrub Nurse when the specimen is passed from the field.
8. The circulating nurse will immediately send all stat specimens to their relevant destinations and/or place permanent surgical specimens, and non-stat microbiology specimens in a protected location under the responsibility of the circulating nurse.
9. The circulating nurse will weigh surgical specimens when instructed to do so by the surgeon.
10. The circulating nurse will prepare the frozen specimen, complete the intraoperative consultation requisition and notify the OR assistant to transport the specimen from the OR and deliver it immediately and directly to Surgical Pathology for immediate
processing as directed by the surgeon. The circulating nurse will notify Pathology that a frozen section specimen is en route.

a. The Circulating Nurse will provide the OR Assistant with the frozen specimen requisition Intraoperative Consultation form along with the specimen each time a frozen specimen is transported.

b. The Pathology clerk or designee will date and initial the pathology form and identify the specimen that is received according to the letter designation for the specimen.

c. The third page pink copy will be delivered back to the Circulating Nurse for confirmation of acceptance of the specimen. The pink copy of the form will be sent to pathology at the end of the case.

d. In situations when the Pathologist is called to the room to pick up a stat specimen, the Pathologist will date and initial the pathology requisition form and identify the specimen received.

e. In the event the surgeon opts to bring the specimen to Surgical Pathology personally, the circulating nurse will ensure that the surgeon has the requisition form that will be accepted by the Pathology clerk and the pink copy will be brought back to the Circulating nurse for confirmation that the specimen was received in pathology.

f. The Pathology Clerk or designee will date and initial the pathology requisition form and identify the specimen that is received on the Intraoperative consultation form and return the pink copy to the transporter.

11. The circulating nurse will contact the Surgical Pathologist when the surgeon requests an intraoperative consultation.

12. The circulating nurse will document all specimens sent to Surgical Pathology and Laboratory on the Perioperative Nursing Record.

13. The surgeon/resident has the responsibility to ensure the Surgical Pathology requisition form is completed.

14. Individual specimens should be identified with a letter and are listed individually on the surgical pathology requisition form; the letters on the request must correspond with the letters on the specimen labels. Information to be completed includes:

- Addressograph patient information
- Preoperative diagnosis
- Postoperative diagnosis
- Surgical findings
- Date of request
- Name of physicians to receive copy of report
- Identification of specimen
- Special handling instructions

15. At the end of the surgery and during the Degriefing Process, the circulating nurse will initiate communication with the attending physician regarding the identity and status of each specimen. This communication will be a verbal READ BACK, with review of the Surgical Pathology requisition form. The Circulating Nurse will also communicate with the Surgical Tech/Surgeon Nurse and physician the location and destination along with visualization of each specimen. The Circulating nurse will also confirm with the Surgical Tech/Surgeon Nurse responsibility for transportation of the specimen's. If a Surgical Tech/Surgeon Nurse is not in attendance for a procedure, the responsibility for specimen delivery will belong to the
Circulating Nurse.

V. Procedure for delivery of specimens to the Pathology Department

A. During normal working hours M-F, 7am-4:30pm (except for holidays and weekends)

16. At the completion of the procedure, the Surgical Tech/Scrub Nurse or designee will deliver the specimen/s directly to the Pathology Department along with the Pathology Requisition form.

17. The Pathology Clerk or designee will reconcile all specimens and document receipt of the specimen/s on the Pathology Requisition Form. The pink copy of the form will be placed in the Pathology log. Any discrepancies with specimens and/or surgical pathology requisition forms will require the Pathology Clerk to notify the OR charge nurse at extension (45657) and return unacceptable or un-reconciled specimen/s to the OR for corrective action.

B. Ambulatory Center Procedure

18. The Ambulatory Surgery Center will temporarily store patient specimen/s in their refrigerator at the completion of each case. The pink copy of the Pathology Requisition form will be placed in the OR logbook. The Charge Nurse will reconcile specimens with the OR assistant regularly during the day and deliver these specimen/s directly to pathology per policy. The pink copy of the form will be initialed by the ORA with date and time of delivery to pathology. The pink copy will be placed in the pathology logbook at time of delivery. During off hours, if the specimen is not in formalin, the on call resident is pagod to accept the specimen in the pathology department. At the end of the day, the ASC charge nurse will reconcile all remaining specimen/s and ensure that they will be delivered to the pathology department refrigerator (following the off hours procedure listed below).

C. During off hours 4:30pm -7am and on weekends and holidays:

19. Specimen/s obtained during off hours, weekends and holidays will be placed in the OR refrigerator at the completion of the procedure. The Surgical Tech/Scrub Nurse will deliver the specimen to the OR refrigerator. The pink copy of the Pathology Requisition form will be placed in the OR logbook with the (signed) person name and location of the specimen. The specimen with the Surgical Pathology requisition form will be placed in the OR refrigerator. If frozen sections are sent to Surgical Pathology during the course of the procedure, the pink copy of the Pathology Requisition Form that had been initialed by the pathology department who received the specimen will also be entered into the OR log book with the relevant information (signature of person and location of the specimen).

D. Reconciliation of specimen/s at the change of shift:

20. Reconciliation of specimen/s collected during off hours, weekends and holidays will be done during the change of shift, Fridays at or before 11pm, Saturday, Sunday and holidays at/ or before 7pm. The Charge Nurse/designee will reconcile all specimen/s with the relief Charge Nurse/designee that remain in the OR refrigerator. Both the Charge Nurse/designee and the oncoming nurse/designee will initial the Pathology Requisition Form for each specimen that will be sent to pathology.
21. Once the specimens have been reconciled the Charge Nurse will place the specimens into the transport box and notify the OR assistant that the specimens are ready for transportation to the Pathology Department refrigerator.

21. The OR assistant/designee will transport all reconciled specimens via the transport box to the Pathology Department.

22. The specimen transport box is placed in the Pathology Department refrigerator. The pink copy of the requisitions forms is placed in the Pathology log located next to the refrigerator in pathology.

E. Reconciliation of specimens by Pathology:

23. The Pathology Department or designee will reconcile all specimens with the Pathology Requisition forms and pink copy log, including any specimens in the custody of the Pathology lab by way of stat transport or weekend, holiday delivery, and sign the Pathology Requisition Form for each specimen to acknowledge receipt. Any discrepancies with specimens and/or surgical pathology form will require the receptionist to notify the OR charge nurse at extension (4-5657) and return unacceptable or un-reconciled specimens to the OR for corrective action.

24. Specimens that are removed from either the OR refrigerator and/or Pathology refrigerator by the Pathology Department will be documented on the Pink copy of the Pathology Requisition Form located in the OR and/or pathology log book. When Pathology takes custody of those unstored specimens, any additional specimens for those patients must also be taken.

25. Completed Pathology Requisition Forms are filed in the department of pathology for a period of two years.

26. The pathology department will return all transport boxes to the OR specimen refrigerator room once the specimens have been processed in pathology.

a. V. Pathology examination guidelines:

Any specimen can be sent for pathologic examination at the discretion of the surgeon.

1. Any specimens should be sent for pathologic examination if there are any clinically or radiologically unusual features or if the surgeon has any specific questions, e.g., with regard to the possibility of infection, tumor, or a metabolic disorder.

2. Foreign bodies associated with significant injury/wounding must be sent to pathology

Note: Bullets must always be given to security and must be passed directly from person to person, see RII Chain of Custody, Forensic Specimen Removal, Handling, and Documentation Policy).
Note: A foreign body that has been discovered and removed from a patient and has been determined to be an unintentional event (e.g., retained surgical sponge) must be submitted to the Pathology department for examination.

3. Tissues/materials including skin and breast tissue from reduction mammoplasties must always be sent to pathology as well as most prosthetic devices shall be sent to Pathology. The tissues/materials listed below, which need not be sent to pathology other than at the surgeon’s discretion.

1. Normal skin, adipose tissue, mucosa, cartilage and bone removed during plastic surgical procedures for non-neoplastic disease.
2. Liposuction fat removed for cosmetic reasons.
3. Plastic implants (e.g. ports) from body parts other than breast.
4. Foreign bodies, other than those associated with significant injury/wounding (note that bullets must always be given to security and must be passed directly from person to person, see RH Chain of Custody, Forensic Specimen Removal, Handling, and Documentation Policy).

Note also that a foreign body that has been discovered and removed from a patient and has been determined to be an unintentional event (e.g., retained surgical sponge) must be submitted to the Pathology department for examination.

5. Scars excised during re-operation for non-malignant disease.
6. Orthopedic hardware.
7. Arthroscopic debridement(s).
8. Bone, synovium and soft tissue from joint replacements affected by osteoarthritis or rheumatoid arthritis, removed during reconstructive procedures.
9. Meniscal, bunionectomy, sesamoid bones and hammertoes.
10. Intervertebral disc material.
11. Ribs and other normal tissues removed for exposure in non-malignant disease.
12. Teeth.
13. Tumours and fingernails.
14. Thrombi, emboli, atheromatous plaque and aneurysm contents.
15. Unused portions of veins utilized in bypass operation.
17. Forehead from children.
18. Bone fragments, fracture fragments.
19. Debrided necrotic skin.

VI. Additional Considerations:

Large surgical specimens, which do not fit in the formalin filled specimen containers, should be placed in a large specimen container and transported immediately to the Surgical Pathology refrigerator.
Surgical Specimens that are too large for the Surgical Pathology refrigerator (e.g. amputated limbs) will be brought to the morgue for refrigeration. The completed requisition form should be left in the Surgical Pathology Department.

The use of suction cannisters as specimen containers should be avoided. The use of red bags should be avoided.

*Subject to IRB approval, any specimens may be collected for Research purposes by arrangement between the researcher and the surgeon (or Institutional Tissue Bank).*

**VII. PROCEDURE for processing Clinical Specimens to Laboratories:**

1. When the circulating nurse is informed that a clinical specimen is obtained, the circulating nurse will verify the specimen description and intended laboratory studies with a verbal READ BACK.
2. The circulating nurse will prepare the specimen container with a patient label.
3. The circulating nurse will prepare the appropriate lab slip (e.g. Downtime Request) indicating the intended lab studies.
4. The circulating nurse or designee will send all stat clinical specimens immediately to their relevant destinations.
5. The circulating nurse or designee will enter all clinical specimen information in the Clinical Specimen log and send the clinical specimen(s) with Downtime forms via the pneumatic tube to the relevant clinical laboratory. In the event of downtime of the pneumatic tube system, all clinical specimens will be hand carried immediately to their relevant destinations by the OR Assistant. The circulating nurse or designee will notify the OR Assistant to transport the specimen immediately.
6. The circulating nurse will document clinical specimens on the Nursing Intra-operative Record.

References:


A. Guidelines for Surgical Pathology Specimen Submission

1. Lifespan Surgical Pathology Requisition, University Dermatology Foundation Requisition, and Ereq for some outreach customer should be used (with the exception of consults).

2. Requisition required information*: 
   a) Patient’s full name*
   b) Date of birth*
   c) Physicians full name*
   d) Procedure date*
   e) Type of procedure (biopsy, excision, re-excision, other etc.)*
   f) Site and side (location specimen was removed from)*
   g) Additional information:
      Patient's address
      Patient’s history and diagnosis
      Name(s) of any additional physicians requiring copies of the final report

3. Specimen container label requirements*: (this information must match requisition. When questions arise as to whether the site/site on container is a match to the requisition, the accessioner should contact the Lead PA to verify the match.
   a) Patient’s full name*
   b) Date of birth*
   c) Site and side (location specimen was removed from)*
   d) All containers must have a matching specimen on requisition form*

B. Specimen Receipt

(For policy on Rhode Island Hospital OR handoff of specimens – see appendix (OR Policy on Sending Specimens to Surgical Pathology). When specimens are received improperly labeled or without the appropriate Surgical Pathology Request Form (DLM020/Y82), they should not be accessioned and appropriate efforts should be taken to contact the operating room, procedure room, or the physician's office to notify the submitting physician of the problem and have him/her begin efforts to correct it. If the physician or his/her representative is not in the hospital the Pathology secretaries will telephone the office to inform them that:

1. A letter will be faxed along with a copy of their patient’s requisition and a specimen identification verification form to correct a problem (see Requisition Return letter).

   Should the verification forms to correct the identified issue, not be received by 3:00 pm, the staff member who identified the problem should copy the requisition and continue with the process of verifying in writing the corrective action. The requisition and specimen containers should be given to the accessioner to process. The accessioner will indicate in the Final Diagnosis “DO NOT SIGN OUT UNTIL SPECIMEN VERIFICATION IS RECEIVED”. The specimen will then be
accessioned and processed by prosector. Once the corrective action has been received the accessioner will notify the pathologist who is assigned to the case and the diagnosis text “DO NOT SIGN OUT UNTIL SPECIMEN VERIFICATION IS RECEIVED” will be deleted. Reporting will continue as always.

2. A courier will be sent to their office along with the specimen container, the requisition and a specimen identification verification form to correct the problem (see Specimen container and requisition return letter).

Accession personnel will then document the problem (deficiency) and resolution of the problem in CoPath and if appropriate (see deficiency and incident chart) in a departmental and/or hospital incident report and/or near miss reporting (see chart). The problem should always be corrected directly by the physician or his/her designate and not by laboratory personnel. Laboratory personnel should never assume the responsibility of identifying a specimen. To assure the highest quality of patient care, the detailed Specimen Rejection Policy (in the Administrative Manual Section of this binder) will be rigorously enforced.
LIFESPAN AMC DEPARTMENT OF PATHOLOGY
CONFIRMATION OF SPECIMEN IDENTIFICATION

Patient's Name ____________________________________________________
Medical Record No. _______________ Patient's Location/Room No. _______
Type of Specimen ___________________________________________________
Collection Date ___________ Time ___________

Verification of Specimen Identity:
I am able to identify this specimen as originating from the above named patient because:
(list physical identifying characteristics of specimen below)

and I ACCEPT FULL RESPONSIBILITY FOR THE ASSIGNMENT OF THIS SPECIMEN TO THIS PATIENT, and I ACCEPT THE RESPONSIBILITY FOR ANY RESULTING UNTOWARD EFFECTS TO THE PATIENT AND ANY LIABILITIES, THEREFROM. The Laboratory will file a Patient Incident Report with the Hospital's Department of Quality Assurance & Risk Management Utilization Review, and the requesting physician will be notified of this incident.

Name/Title/Department of Certifying Person (please print legibly)
________________________________________ ______________________
Signature of Certifying Person __________________ Date __________________
Dear Dr. ______________________,

We are returning to your office a Surgical Pathology Requisition because the following problems were encountered upon arrival of the specimen and requisition:

- The specimen container label does not have a patient's date of birth
- The specimen container label does not indicate the type of specimen and/or site or side (circle relevant missing data)
- The specimen container label indicates the type of specimen and/or site or side is different than the requisition information. Container label indicates the specimen is: ________________________________________________________________

The requisition is missing the following information:

- Patient's date of birth
- Date of procedure
- Type of procedure (biopsy, excision, fine needle aspirate, etc.)
- Type of specimen (site and side)

We are unable to process this/these specimens until the problem(s) is corrected. Please make corrections as noted above to the requisition we have faxed. Complete the specimen confirmation form and return it with the corrected requisition via the fax to 401-444-0955. We will then promptly process your patient's specimen(s).

Thank you for your cooperation.

Sincerely,
SPECIMEN CONTAINER AND REQUISITION RETURN LETTER –
LETTER TO BE SENT ALONG WITH CONTAINER, REQUISITION AND SPECIMEN IDENTIFICATION VERIFICATION FORM VIA PATHOLOGY PERSONNEL OR BY COURIER:

DATE: ____________________

Submitting Clinician Name: __________________________________
Address:                                __________________________________
__________________________________

Dear Dr. ______________________,

We are returning to your office ___ specimen container(s) and associated paperwork because the following problems were encountered:

☐ The specimen container label does not have a patient's full name
☐ The specimen container label has a different name than the paperwork/requisition
☐ There are multiple specimen containers and they are not labeled with sites and sides to match the paperwork/requisition

We are unable to process this/these specimens until this problem is corrected. Please make corrections as noted above to the container labels. Complete the specimen confirmation form and return the container(s), specimen confirmation form and requisition to the courier who delivered it. He/she will return it to us promptly and processing will begin.

Thank you for your cooperation.

Sincerely,

Murray Resnick, M.D., Ph.D.
Director, Surgical Pathology
Lifespan AMC
**ANATOMIC PATHOLOGY INCIDENT REPORT**

<table>
<thead>
<tr>
<th>Type of Incident</th>
<th>Patient Impact</th>
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<tbody>
<tr>
<td>☐ Extraneous Tissue Found in Specimen</td>
<td>☐ Pathology report issued on incorrect patient</td>
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<tr>
<td>☐ Incorrect Patient Registered</td>
<td>☐ Delay in pathology result reporting</td>
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<tr>
<td>☐ Incorrect Patient Accessioned</td>
<td>☐ Delay in billing</td>
</tr>
<tr>
<td>☐ Mismatched Required Patient Info on Container and Requisition</td>
<td>☐ Incorrect patient billed</td>
</tr>
<tr>
<td>☐ No Specimen in Container</td>
<td>☐ DEFICIENCY ENTERED IN COPATH</td>
</tr>
<tr>
<td>☐ Patients Incorrectly Merged in CoPath System</td>
<td>☐ AMENDMENT TO PATHOLOGY REPORT REQUIRED</td>
</tr>
<tr>
<td>☐ QNS</td>
<td>CHECK IF TO BE ENTERED IN SAFETY NET:</td>
</tr>
<tr>
<td>☐ Site/Side on Final Report Amended</td>
<td>☐ EVENT (incident reached a pt.)</td>
</tr>
<tr>
<td>☐ Slides Mislabelled</td>
<td>☐ NEAR MISS (incident entirely prevented from reaching pt.)</td>
</tr>
<tr>
<td>☐ Slides Not Labelled</td>
<td>☐ NON-PATIENT EVENT (med. event not involving specific pts.)</td>
</tr>
<tr>
<td>☐ Specimen Did Not Survive Processing</td>
<td>☐ UNSAFE CONDITIONS (situation may cause a future event)</td>
</tr>
<tr>
<td>☐ Specimen Lost by Pathology</td>
<td></td>
</tr>
<tr>
<td>☐ Specimen Not Labelled</td>
<td></td>
</tr>
<tr>
<td>☐ Specimen Submitted With Incorrect Name on Requisition and Container</td>
<td></td>
</tr>
<tr>
<td>☐ Miscellaneous</td>
<td></td>
</tr>
</tbody>
</table>

**AFFILIATE (circle):** RIH   TMH

**ANATOMIC PATHOLOGY SPECIMEN #(s):** ______________________________

**Patient Name(s):** ___________________________   MR#: ________

**Patient Name:** ___________________________   MR#: ________

**Clinician:** ___________________________   **Pathologist:** ___________________________

**DESCRIPTION OF INCIDENT (Attach Request forms, working drafts, specimen id forms etc):**

_________________________________________________________________________________________________________________

_________________________________________________________________________________________________________________

_________________________________________________________________________________________________________________

_________________________________________________________________________________________________________________

**RESOLUTION:**

_________________________________________________________________________________________________________________

_________________________________________________________________________________________________________________

<table>
<thead>
<tr>
<th>Reported by:</th>
<th>Supervisor Notified:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature</td>
<td>Date</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Director Notified:</th>
<th>Reviewed at Surg. Path Meeting:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature</td>
<td>Date (see Minutes)</td>
</tr>
</tbody>
</table>

| Date / Initials Entered: | |

**CHECK IF TO BE ENTERED IN SAFETY NET: Date / Initials Entered: _________________________**
2.3 SPECIMEN ACCESSIONING

Specimen Accessioning

1. A surgical pathology number is assigned and labels are automatically generated. A label is affixed to the requisition and on all specimen containers. On occasion patients will have more than one operative procedure performed. If the procedures are performed in a single "trip" to the operating room, all specimens received on the patient are given the same surgical pathology number.

2. The number of specimens for a case is noted if there is more than one specimen received. Each specimen is identified with a letter (e.g., specimen A right cheek biopsy; specimen B left cheek biopsy).

3. Any discrepancies of specimen identification noted by the resident, pathology assistant or secretary are clarified promptly. Contact the staff pathologist and/or clinician if there are any questions. Unlabeled specimens are managed using the Specimen Rejection Policy (Laboratory Administrative Manual policy 1.7).

4. Consults: Cases from other institutions
   a) The Miriam and Rhode Island Hospitals: Cases are not re-accessioned and retain the affiliate accession number unless the consultation is requested by an AMC physician who is caring for the patient. In this case, specimen is re-accessioned as MO or RO consult.
   b) All other institutions: Cases consisting of glass slides or blocks are accessioned as MO or RO. Cases with fresh tissue are accessioned as MS or RS.

5. Consults
   a) Slides with reports that arrive from outside institutions, other pathologists, private physicians etc. who are requesting a second opinion from Rhode Island Hospital or The Miriam Hospital pathologists will be accessioned as consults and handled as such.
      1. Letter of request should indicate if case is requested by a pathologist from the outside hospital (Consult Agency) or if it is requested by RH/TMH staff physician (Consult Staff) or if it is requested by the patient (Consult, w/slides). If case arrives without a letter and/or report call the submitting hospital pathology department for a report or a working draft.
      2. Consult form (see attached) is completed by secretary/clerk and faxed to Registration for the patient to be registered into the hospital data base. For the date of service use "procedure date", or "collection date" on the submitting hospital pathology report, unless it is more than 2 weeks from...
the date we receive it. If more than 2 weeks we use the date case is accessioned. For an agency consult use the pathologist who will perform the consult for the submitting physician (this will be corrected during accessioning).

3. Check with registrar to see if patient has been registered then accession the case (following standard accessioning procedure), making sure to check that the encounter date matches the date you gave registration for the procedure date. Accession the case as a consult (RO).
   a. Client: check ADT data to assure that the client is the outside institution.
   b. Part type for cases requested by an outside pathologist is “Consult Agency”; Part type for cases requested by a RIH/TMH physician is “Consult staff”; consult requested by patient is “Consult w/slides”. All cases submitted from outside are to be accessioned as one part type if they are from the same date of service (date the surgical or cytologic procedure was performed) even if they are labeled from the outside institution as separate case numbers. Only accession as a separate part if the slides are from different dates of service.
   c. Description portion of part type: Do not delete the description already there just add to it - # of slides/blocks & slide/block #s, hospital name and specimen part (e.g. Consult/Staff Physician/4 slides “SP11-455”/Memorial Hospital/Thyroid).
   d. Submitting physician, If Agency Billing, use pathologist from submitting hospital; if Staff Consult, use the staff physician’s name. If our pathologists name is in as the submitting physician correct it at this time.
   e. Clinical history: if provided on report from outside institution type it in the RIH or TMH consult Clinical History.
   f. Gross description: use quick text as follows: Quick text “C1” is to be used for one single consult; “C1A” is to be used for two sets of slides with one date of service; “C2” I to be used for two sets of slides with two different dates of service (Copy as needed for 3 or more).

Examples of gross description are listed below:
   i. C1 – “Received from Kent County Hospital, Rhode Island are 7 slides labelled KS06-12 and an identifying Surgical Pathology report; date of service – 1/2/06.”
   ii. C1A – “Received from Kent County Hospital, Rhode Island are 7 slides labeled KS06-12 and an identifying Surgical Pathology Report; date of service – 12/06 and 19 slides labeled KS06-15 and an identifying Surgical Pathology Report.”
   iii. C2 –
      a. “Received from Kent County Hospital, Rhode Island are 7 slides labeled KS06-12 and an identifying Surgical Pathology Report; date of service– 1/2/06.
      b. Received from Kent County Hospital, Rhode Island are 19 slides labeled KS06-15 and an identifying Surgical Pathology Report; date of service – 1/5/06.

4. Assign case to the pathologist as requested in letter and send to their worklist.

5. Label all slides with case number using blank white labels and place on trays.
6. Scan all materials into Copath as “Consult”.
7. Give slides and materials to pathologist for review.
CONSULT FOR REGISTRATION

PATIENT NAME: __________________________________________

Last                                  First                      MI

DOB: _______________          SEX: ____________

PATIENT ADDRESS: _______________________________________

_________________________________________________________________

PATIENT TELEPHONE: _______________________________________

BILL (Circle one):               HOSPITAL           PATIENT INSURANCE

INSURANCE: ____________________________

DATE OF PROCEDURE: _______________________

ORDERING CLINICIAN/HOSPITAL: _______________

FOR PATHOLOGY ONLY
CONSULT TYPE: ____________________________
## SURGICAL PATHOLOGY REQUEST

**LIFESPAN AMC DEPT. OF PATHOLOGY**

- **RHODE ISLAND HOSPITAL**  
  593 Eddy Street, Providence, RI 02903  
  Phone 401-444-5160  Fax 401-444-4377

- **THE MIRIAM HOSPITAL**  
  164 Summit Avenue, Providence, RI 02906  
  Phone 401-793-4245  Fax 401-274-5154

If preprinted patient plate is not used the following is required: Name, Address, DOB, Sex, Ins. Carrier and ID No., Phone No.

### PLEASE WRITE LEGIBLY AND FILL OUT COMPLETELY

<table>
<thead>
<tr>
<th>Procedure Date: / /</th>
<th>Received in SP: / /</th>
</tr>
</thead>
</table>

History (include pertinent physical, radiologic & lab. findings, isolation precautions, prior chemo/radiation therapy and special requests):

Preoperative Diagnosis:  
Postoperative Diagnosis (if different):

### Procedure:

- [ ] Biopsy (Specify Type: [ ] Excisional  [ ] Incisional  [ ] Endoscopic  [ ] Needle  [ ] Other )
- [ ] Resection (specify): _________________  
- [ ] Other (specify):

### Specimen (specific site):

- A. __________________________________________  
- B. __________________________________________  
- C. __________________________________________  
- D. __________________________________________  
- E. __________________________________________  
- F. __________________________________________  
- G. __________________________________________  
- H. __________________________________________

**Submitting Surgeon/Physician**

Print full name

**Additional Copies To:** (print full name) (if not Lifespan physician, please write address & Medical License #)

**Submitting Surgeon/Physician Signature**

Both Copies to Surgical Pathology Dept.

SHADED AREAS TO BE COMPLETED BY PATHOLOGY

---

Revised 4/1/02  
Cost Center 2965
2.4 ROUTINE GROSS EXAMINATION, DESCRIPTION AND TISSUE SUBMISSION

General Procedures

1. Universal Precautions are in effect when handling all specimens. Under no circumstances should requisitions which have been in contact with blood, specimens or fixatives be brought or sent to the Clean Areas.

2. Specimens should be divided based on sample size and type as follows:

   a) Biopsy Specimens:
      1) Small specimens (usually < 0.5 cm in maximal dimension) which can be effectively processed using a biopsy tissue processing program. These are identified by TAN cassettes at RIH and PINK cassettes at TMH. These specimens typically include endoscopic biopsies, needle biopsy, and small skin biopsy. Label as RS (last 2 digits of current year) - # at RIH. Label as MS (last 2 digits of current year) - # at TMH.

   b) Rush Biopsy Specimens:
      1) Needle or endoscopic biopsies which are urgently required for patient management. These can be rapid processed during the day if received by 9:00 AM in the Histology Laboratory. TAN cassettes at RIH and PINK cassettes at TMH are employed and the samples are hand carried to the Histology Laboratory. Label as RS (last 2 digits of current year)-# at RIH and MS (last 2 digits of current year)-# at TMH.

   c) Routine Specimens:
      1) Larger specimens including larger excisional biopsies such as breast biopsies as well as definitive resection specimens which will not be adequately processed using a biopsy tissue processing program as well as other non-urgent specimens e.g. atheromas, thrombi, etc. Such samples are placed WHITE cassettes at RIH and YELLOW at TMH. Label as RS (last 2 digits of current year)-# at RIH and MS (last 2 digits of current year)-# at TMH.

   c) Bone Marrow Biopsies:
      These are sent to the Special Hematology Laboratory for B5 post fixation and decalcification. They are identified by TAN cassettes at both RIH and TMH. Label as RH (last 2 digits of current year) - # at RIH and MH (last 2 digits of current year) - # at TMH.
e) Decalcification Specimens:

1) Specimens with sufficient calcium content to complicate the preparation of tissue sections are placed in GREEN cassettes at RIH and TMH. Decalcification is ordered as a procedure in the Histology module of CoPath for each block requiring decalcification (see CoPath Procedure Manual). Label as RS (last 2 digits of current year)-# at RIH. Label as MS (last 2 digits of current year)-# at TMH.

3. The RTAS Digital Dictation System can be used to dictate reports as per detailed procedure in the RTAS manual. Be certain there is no noise in the background. Begin the RTAS dictation for all cases with the surgical number, the patient's name, as identified on the specimen labels, and how the specimen was received (i.e., unfixed, in formalin, etc.). When describing the specimen, be as concise as possible and use the most specific terms or description possible. If an organ or tissue is identifiable on sight, call it by its name; i.e. do not call a gallbladder an "erythematous saccular tissue fragment." Include in the description measurable quantities such as size, weight, color, consistency, distance from surgical margins, etc. Specimens submitted in separately labeled parts should be described under separate letter headings (e.g. Labeled “-A. Small intestine”, received in formalin are etc.).

4. Indicate whether residual tissue remains using the following jar codes at the end of each specimen description:
   - jar zero J0 all tissue submitted
   - jar one J1 residual tissue in small biopsy container (5-200 cc)
   - jar two J2 residual tissue in medium size round container (200-500 cc)
   - jar three J3 residual tissue in large container or refrigerator

5. Specialized tissue processing techniques should be included in the gross description:
   - decalcification
   - special fixatives for light microscopy, i.e. B5
   - electron microscopy
   - flow cytometry
   - immunofluorescence
   - frozen
6. Specimens should be sectioned in a thoughtful manner. The first cut through a specimen generally bisects the lesion and should provide clear orientation of the lesion to the rest of the specimen. If multiple cuts through the tissue are required, they should be made at regular intervals, parallel to each other and in such a fashion that the specimen can be reconstructed. Sections should be taken to correctly diagnose the lesion and to determine its extent, severity, relationship to surgical margins, as per detailed, specimen specific protocols. In lymph node dissections for malignant disease, all identified nodes should be processed for histologic examination.

7. Tissue sections should be taken to preserve as much of the architecture of a specimen as possible (i.e., parallel to cut surfaces), demonstrate the junction between the lesion and normal tissue, and document the extent of the lesion. In the case of neoplasms this may include any of the following: depth of invasion, invasion of adjacent structures, involvement of surgical margins, document the status of grossly normal tissues other than the main lesion.

8. Blocks should be trimmed thin enough (2-3 mm) to allow for adequate fixation and proper processing. Wrap small or fragmented specimens in a single sheet of lens paper then place in a cassette. All sutures and staples must be removed from tissue submitted in cassettes. All tissue blocks are entered into CoPath per detailed CoPath procedures.

9. Overnight fixation of large specimens by floating them in a container of formalin generally improves the quality of histologic sections. Residents and pathology assistants should use their judgment in deciding when overnight fixation is appropriate and consult with a staff pathologist if there are any questions. Approximately ten times the volume of the specimen is an appropriate amount of formalin for fixation.

10. The best way of evaluating margins depends on the type of lesion, its location, and the anatomy of the specimen (refer to detailed specimen specific protocols)

11. Label each cassette with the case number and when more than one cassette is used, the letter and subnumber for each block. Write legibly using a Tissue Tech marker. Cassettes are additionally labeled with letters of the alphabet for each specimen and subnumbers where appropriate, beginning with 1; i.e., A1, A2, etc. Frozen section material should be identified in the gross description and the residua of each frozen section must be submitted in a separate cassette and designated at frozen section residua in the gross description.

12. In cases where there are several specimens and/or cassettes, it is useful to dictate a summary at the end of your gross description and list clearly each cassette letter and what it represents as specified in specific specimen protocols (Appendix A). Specimen diagrams illustrating how tissue sections are taken should be used as needed.

13. GMS and AFB stains should be ordered for all specimens from immunocompromised patients or for specimens with granulomatous disease.

14. Sutures and/or staples should be removed from tissue before cassetting.

15. Cassettes should be allowed to fix in abundant warm formalin prior to transport to the Histology Laboratory.

16. Gross specimens are retained for a minimum of 2 weeks after case sign out. Unassigned case lists are generated biweekly and are distributed to Pathologist’s Assistants responsible for the Surgical Pathology Suite who are responsible for reviewing these lists to assure that all specimens have been dictated in a timely manner.
2.5 SMALL SPECIMENS FOR MICROSCOPIC EXAMINATION

<table>
<thead>
<tr>
<th>Prepared by</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Revised</td>
<td></td>
</tr>
<tr>
<td>Reviewed</td>
<td></td>
</tr>
</tbody>
</table>

Small Specimens for Microscopic Examination

1. Describe:
   - How the specimen is labeled
   - Fixative
   - Number of pieces (1-4 or multiple if more than 4)
   - Size of specimen or range for maximal sizes for fragments or aggregate measurement
   - Color
   - Consistency
   - Lesions/abnormalities if present
   - Sections submitted or jar code if a single section is submitted

2. Examples:
   - Labeled A, antrum, received in formalin are 3 tan soft tissue fragments measuring from 0.1 to 0.3 cm in maximal dimension. J0.
   - Labeled TURP, received in formalin are multiple tan pink tissue fragments weighing 12 g and measuring 5.0 x 3.0 x 1.0, labeled A1-A4. J1.

3. Special biopsies; order the indicated special stains or levels in CoPath
   - Liver biopsy for non-neoplastic disease:
     - Adult-Reticulin, trichrome, iron
     - Pediatric-Above plus PAS with and without diastase
   - Temporal artery biopsy:
     - Elastic stain
   - Nerve biopsy:
     - Submit unfixed to Neuropathology Laboratory (x43246)
   - Muscle biopsy:
     - Submit unfixed to Neuropathology Laboratory (x43246)
   - Kidney biopsy:
     - Submit a portion unfixed to Immunohistochemistry Laboratory when appropriate or place in immunofluorescence transport media (obtained from the Immunohistochemistry Laboratory at RIH x44734)
Place a portion in glutaraldehyde (obtained from the EM Laboratory x44374) when appropriate.

Place the remainder in kidney biopsy fixative (obtained from the Immunohistochemistry Laboratory at RIH x44734).

4. Small biopsies should be marked with hematoxylin prior to cassetting and should be wrapped in tissue or foam pads to prevent loss during tissue processing.

5. For needle biopsies, each well-defined core should be submitted in a separate cassette. If more than 3 cores are received, up to three cores may be placed in each cassette. If the needle biopsy consists of non-discrete fragments, it may be submitted in a single cassette.
Other Specimens for Microscopic Examination

1. Use detailed organ and tissue specific protocols in this manual for the following specimens:

   - Amputations
   - Appendix
   - Bladder resection
   - Bone, femoral head and knee
   - Breast, excisional biopsy and resection
   - Esophagus resection
   - Eye enucleation
   - Fallopian tube
   - Gallbladder
   - Head and neck: ear, jaw, tongue, maxilla, salivary gland, radical neck, larynx, excision
   - Intestine, resection and polypectomy
   - Kidney excision
   - Liver excision
   - Lung excision
   - Ovary
   - Penis
   - Pancreas
   - Prostate, transurethral and radical excision
   - Sentinel lymph nodes
   - Skin, punch and shave biopsy and excision
   - Spleen excision
   - Stomach excision
   - Testis excision
   - Thyroid excision
   - Uterus, cone biopsy and excision
   - Vulva excision

2. For other specimens follow the guidelines for the description of small specimens

3. Examples:

   Labeled gallbladder, received unfixed is a gallbladder measuring 5 cm from the fundus to the cystic duct by 3 cm in diameter. The serosal surface is smooth and glistening. On opening, it contains bile and 3 stones measuring from 0.4 to 1.0 cm. The mucosa is velvety and without lesions. The wall measuring 0.2 cm in maximal thickness. J1.

   Labeled right knee contents, received unfixed are fragments of bone and soft tissue aggregating to 7 x 6 x 5 cm. A tibial plateau is recognizable with focal eburnation. No other lesions are noted. Submitted after decalcification. J2.
Tissue Removal at Operation

As indicated in the Rhode Island Hospital Surgical Services Policy and in the Staff Association Bylaws (adopted August 15, 2002), section entitled Rules and Regulations, item 10: “The staff member of record in charge of a patient is responsible for seeing that all tissues, with the exception of teeth, removed at operation or for study, shall be sent to the Hospital pathologist who shall make examination as he/she may consider necessary to arrive at a pathological diagnosis and sign his/her report. Teeth with an unusual clinical appearance, soft tissue, and bone removed concurrently with teeth are excluded from this exemption and should be submitted for pathological examination.”

As indicated in the Miriam Hospital Surgical Services Policy and all tissue removed at operation will be sent to the hospital pathologist for examination

Specimens for Gross Examination Only

Describe as above for specimens according to the approved Gross Only List below. If the specimen is unusual for type or the history does not conform to the Gross Only List requirements, submit tissue sections as described above. The gross description should conclude with “gross only” and the appropriate jar code.
**New Gross Only List for RIH and TMH Effective 2/14/2010**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Aneurysm Thrombus and Atherosclerotic Plaque</td>
<td>Arthroscopic Shavings</td>
</tr>
<tr>
<td>Bone Fragments from Reconstructive Procedures</td>
<td>Articular Fragments from Arthrodeses</td>
</tr>
<tr>
<td>Graft Declotting Specimens</td>
<td>Segments of Skin Used for Grafting</td>
</tr>
<tr>
<td>Bunion, Hammertoes and Hallux Valgus</td>
<td>Cutaneous Scars</td>
</tr>
<tr>
<td>Carotid Atherosclerotic Plaque</td>
<td>Portions of Normal Bone</td>
</tr>
<tr>
<td>Fingernails and Toenails</td>
<td>Muscles Perceived to be Normal, e.g. Strabismus Surgery</td>
</tr>
<tr>
<td>Foreign Bodies and Material</td>
<td></td>
</tr>
<tr>
<td>Foreskin, &lt;6 months old</td>
<td></td>
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<tr>
<td>Hydrocele Sacs</td>
<td></td>
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<tr>
<td>Liposuction Specimens</td>
<td></td>
</tr>
<tr>
<td>Intervertebral Discs from Patients with No History of Cancer: If No History is Given, Submit Tissue</td>
<td></td>
</tr>
<tr>
<td>Lenses/Cataracts</td>
<td></td>
</tr>
<tr>
<td>Normal Skin, Cartilage and Bone from Nasoseptal and Sinus Procedures</td>
<td>Soft Tissue Should Be Submitted for Microscopic Examination</td>
</tr>
<tr>
<td>Ribs from Non-Malignant Thoracotomies or Nephrectomies</td>
<td></td>
</tr>
<tr>
<td>Scar Tissue Excised for Cosmetic Reasons with No History of Cancer</td>
<td></td>
</tr>
<tr>
<td>Stones; Send for Analysis When Appropriate</td>
<td></td>
</tr>
<tr>
<td>Supernumerary Digits</td>
<td></td>
</tr>
<tr>
<td>Teeth: Count and Describe</td>
<td></td>
</tr>
<tr>
<td>Tonsils and Adenoids from Patients Less Than 16 Years Old *</td>
<td></td>
</tr>
<tr>
<td>Traumatic Amputations and Repairs</td>
<td></td>
</tr>
</tbody>
</table>

*Tonsil cases received from SNEC will still continue to get microscopic examination that is they are to be grossed and submitted to Histology. THEY ARE NOT TO BE CONSIDERED AS GROSS ONLY CASES.*
2.7 SPECIMEN PROCESSING GUIDELINES

Specimen Processing Guidelines

1. When surgical specimens are delivered to the Surgical Pathology Suite on the 3rd floor of the Bridge Bldg., the accessioners are responsible for comparing the requisition for each specimen to the specimen container/containers to ensure that the patients’ names, dates of birth, types of specimens submitted and sites of procedure agree. For specimens generated in the O.R., an Addressograph label for each patient is attached to chain of command sheets. The type of specimen and site/side of procedure are recorded to the right of the Addressograph by an O.R. attendant/circulator and initialed by him/her. These sheets accompany the specimens to the Pathology Suite. While the attendant waits, the accessioners check the requisitions and specimen containers. If all agree, each is marked with a check, the chain of command sheet is time-stamped and initialed by the accessioner and the paperwork is placed in a ring binder. If a discrepancy is encountered, the specimen is returned to the O.R. for correction, with the discrepancy listed on the chain of command sheet, and is processed in the above-described manner upon its return to the Suite once the correction has been made.

2. The accessioners then enter the specimens into CoPath, which assigns an accession number to each specimen. The accession numbers are written on the requisitions and corresponding specimen containers. The requisitions are attached to the containers by elastic bands or are placed in plastic specimen bags along with the container/containers. The specimens are then placed on a counter in the Pathology Suite for the prosectors to access. The specimens are grouped by specimen type – Large, Routines, Biopsies, Derms, Priority Derms, Newport Hospital cases and Rush cases.

3. The prosectors take the specimens from the counter to their respective grossing stations for processing. The prosectors enter the accession numbers into CoPath, which calls up the cases on the computer monitors. The number of cassettes the prosector wishes to print for a particular case is entered into CoPath along with any special protocols that may be required. The prosector clicks on “Engrave”, and the cassettes for that case are printed on one of the two ShurMark cassette labelers. The type of specimen being grossed drives the color of the cassettes being engraved. RIH routine cases are assigned white cassettes, RIH biopsies - tan cassettes, RIH decals – green cassettes, Dorms – orange cassettes, NH routines – blue cassettes and NH biopsies – lilac cassettes. Only the cassettes for the particular specimen being processed are printed. At no time, are cassettes for multiple cases printed, i.e. “batching”. The prosector then retrieves the cassettes from the labeler and returns to his/her grossing station. It is the responsibility of the prosector to ensure that the accession number on the cassettes matches the accession number of the specimen being processed. Cassettes for specimens with multiple parts may be printed simultaneously. However, only the cassettes for the particular part being addressed are placed on the prosector’s cutting board. All cassettes for the remaining parts are placed on the grossing station to either side of the cutting board and accessed when necessary.
4. The prosector then dictates a gross description for the specimen, beginning each dictation with the surgical number, the patient’s name and the type of specimen, as indicated on the requisition, along with site and side, if applicable. The tissue is then placed into the corresponding cassette/cassettes, uncut, bisected, trisected, serially sectioned, etc. For large cases, a section code is dictated at the end of the gross description. The cassettes are covered and placed in a metal rack in a plastic container filled with formalin at the prosector’s side. The number of pieces placed in each cassette is entered into CoPath in the Histology section, and the case is saved in CoPath. The prosector is then free to move on to the next case.

5. When the entire specimen is submitted, the empty specimen containers, or J0’s, are placed in a plastic bucket. The following morning, the diener places all the J0’s in a plastic bag labeled with the previous day’s date and transports them to the Autopsy Suite where they are stored for a period of two weeks before being discarded. The specimen containers with residual tissue, referred to as J1’s or J2’s depending upon their size, are stored in a room in the Pathology Suite for a period of one month after sign-out.

6. At approximately 2:00 P.M. each afternoon, a histo tech comes to the Pathology Suite and collects the metal racks containing the tissue cassettes from each prosector. The cassettes are then reconciled with an accession log by the histo tech. It is this person’s responsibility to ensure that all of the blocks on the accession log are accounted for in the metal racks. Once this is accomplished, the histo tech takes the blocks to the Histology lab on the 12th floor of the APC Bldg. to be loaded on the tissue processor.

7. Any cases grossed after 2:00 P.M. are loaded onto the tissue processor by one of the prosectors. The blocks from each prosector are placed in the tissue processor racks at the end of the day and taken to the Histology lab. The racks are placed in the tissue processor by the prosector at approximately 7:30 P.M.
2.8 TISSUE AND CASSETTING

TISSUE AND CASSETTING

1. Tissue submitted should not exceed 2 mm in thickness. Sections that are too thick will not process properly. This will result in a delay of at least 24 hours requiring the specimen to be reprocessed and often producing sections of inferior quality. The resident/pathologist assigned to the case will be notified of this delay on the QA sheet.

2. Small tissue samples, less than 5 mm in diameter, may shrink up to 50%, causing loss of tissue during processing. These specimens must be wrapped in lens paper or sandwiched between blue sponges prior to processing.

COLOR CODED CASSETTES

<table>
<thead>
<tr>
<th>RIH SPECIMENS</th>
<th>MIRIAM SPECIMENS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tan Biopsies</td>
<td>Pink Biopsies</td>
</tr>
<tr>
<td>White Routines</td>
<td>Yellow Routines</td>
</tr>
<tr>
<td>Green Decals</td>
<td>Aqua Decals</td>
</tr>
<tr>
<td>Gold Dehys</td>
<td>Blue Autopsies</td>
</tr>
<tr>
<td>Orange Derms</td>
<td></td>
</tr>
<tr>
<td>Yellow Autopsies</td>
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3. Routine specimens should be entered on the routine log and placed in white cassettes. Indicate if there are any rush cases to alert the technologist.

4. Biopsies – Biopsies received after 5 pm will be the responsibility of the prosector or resident to cassette and put on the tissue processor.

5. Brief decals should be placed in the appropriately labeled formalin container. All specimens for decal must be fixed for a minimum of 2 hours prior to decalcification.

6. Bone decals should be placed in green cassettes. Place them in formalin with the routine specimens. These will be decalcified in the main lab. Designate “DECAL” on log.

7. Cell blocks from Histology and Cytology should be placed in white cassettes.

8. Autopsies – must be delivered to the laboratory prior to 3:30 pm to go on the processor that evening. Please note that the processors are always full on weekends with surgicals so autopsies are not processed on Fridays.

9. Whole eyes – submit in formalin to the Neuropathology Lab for special handling.
10. Uric Acid – all specimens for uric acid must be placed directly into 100% ethyl alcohol. Submit to the Histopathology Lab in the OR suite with a designation on the container and prosection sheet that the specimen is in 100% alcohol.

LOG SHEETS

Do not enter routine specimens on the biopsy log sheet even if the specimen is small and needs to be processed as a biopsy.

Do not process any tissue without a log sheet indicating the number of blocks and their designations. Do not log in a number (for pending tissue) unless you let the Accession clerk know in advance.
2.9 CASSETTES/SPECIMEN PROCESSING

Prepared by

Revised

Reviewed

Reviewed

CASSETTES/SPECIMEN PROCESSING PROTOCOL

1. When processing surgical specimens, only the cassettes for the particular specimen being addressed are to be printed. **At no time, are cassettes for multiple cases to be printed, i.e. “batching”.**

2. Cassettes for specimens with multiple parts may be printed simultaneously. However, only the cassettes for the particular part being addressed are to be on the prosector’s cutting board. All cassettes for the remaining parts are to be placed on the grossing station to either side of the cutting board and accessed when necessary.

These measures are mandated to greatly reduce, if not entirely eliminate, the possibility of tissue being placed in the incorrect cassettes. Anyone found to be violating this procedure will receive an immediate written warning for the first offense, a final written warning for a second offense and termination upon a third offense.
Engraver Directions

All cases must be accessioned into CoPath before a cassette can be engraved.

As protocol, blocks are entered through the Histology Data Entry/Edit window.

On the Specimen tab, pick a block protocol. Then run the protocol or;

Use the Histology tab and enter blocks, either way will work.

On the Histology tab is a button <SAVE/ENGRAVE>. Click this button to engrave cassettes.

Request Cassette Label screen will appear see below.

The case information about will appear. Recheck your cassette entry.
Under the header REQUESTED an <N> will initially appear. This indicates you have not requested a print yet.

Hit the OK button and a <Y> will appear indicating you have approved the cassette label and the cassette will print to the designated engraver.

At this junction, all ORANGE cassettes will go only to engraver between grossing stations 1 and 2; White, Tan and Yellow will be directed to the engraver near grossing station 3. If at any time you need to reprint a cassette, go to the SAVE/ENGRAVE screen and the previously ordered cassettes will appear. Using the left mouse button and the <CTRL> key on your keyboard, hi-light the cassette to be reprinted and push <OK>.

To add additional cassettes to a case, follow protocol by entering them into CoPath, hit <SAVE/ENGRAVE> and the screen above will appear with the new cassette hi-lighted with a <N> under the requested field, hit <OK> and a new cassette will print.

White Cassettes used for Routine cases, non biopsies
Orange Cassettes used for Derms
Tan cassettes are for routine, biopsy cases
Yellow for autopsies

There is no change in the cassettes colors nor specimen classes
### IMAGE CAPTURING, LABELLING, STORAGE, AND DISTRIBUTION

#### POLICY:

All surgical and autopsy pathology images that have been captured on a digital camera are to be labeled, stored, and if requested, distributed in the following manner:

**NETWORK DRIVE:**

Residents, fellows, and pathologists must have access to the I Network Drive” [PathImages$ on 'lsfile01' (I:)].

**FOLDERS:**

Two folders are available in the I drive for this purpose:
- IMAGES - SURGICAL PATHOLOGY
- IMAGES - AUTOPSY PATHOLOGY

**SUBFOLDER:**

A subfolder for each accessioned case that has photographs must be made in the appropriate I drive (e.g., I:/IMAGES - SURGICAL PATHOLOGY/RA06-021). For surgicals, the case number should have a total of 10 digits including the hyphen (e.g., RS06-01234). Use “0” to fill in the case number. Autopsies must have a total of 8 digits e.g., RA06-024)
FILES - INDIVIDUAL PHOTOGRAPHS

All photographs for the case must then be filed within the subfolder. The individual photographs must be labeled with:

Case number (including specific part A, B, C, etc. for surgical cases)

Name of the organ photographed

Example for a gross image of an appendix (part A) on case RS06-123 “RS06-00123A Appendix”.

Example for microscopic image of Hodgkin Lymphoma case shown at Tumor Board. RS06-00022B Mediastinal lymph node, Reed-Sternberg cell

3. Specify description when appropriate.

For autopsies, the labeling of the individual photographs is the case number followed by the block and then the organ name.

ENTERING FLAG IN COPATH FOR PHOTOGRAPHS THAT ARE AVAILABLE

In COPATH - enter the retrieval flag “Photograph(s), microscopic” or Photographs, gross” (see below). In the comment line enter the letter (of the part for a surgical case or organ for an autopsy). If the case is signed out you will need to go through “post-signout edit” to enter this information. These flags will allow searches to locate any cases with photographs on file. If the photographs are sent in report form (see G) to a physician, please indicate this in the comment as follows (e.g.. Part A – included in report to Dr. ….).
PHOTOGRAPHS TO BE INCLUDED IN REPORT FORM AND DISTRIBUTED

1. When photograph is to be included in printed form to the requesting or additional physicians indicate this in both the Retrieval Flag field (see section F) and as a Diagnosis Comment (IMG).

2. Open template available in I drive filed as “Image – Template” (see p. 231)

3. Type in specimen #, patient name, medical record number and any comments.

4. Click in first text box then click <Insert>, <picture>, <from file>, locate your picture in the Images file drive and click on <Insert>.

5. Click in the text box under the picture and type in description (e.g., A. Gallbladder, and any other info you would like as part of the legend).

6. Click in any unused text boxes and press delete.

7. Save file as discussed in section E.

8. Print on color printer and place in basket labeled “Photographs for Physicians” in Surgical Pathology Office.

9. Secretarial staff will mail photographs with physician’s copy of the full report.
Microscopic image and diagram, if present, are a symbolic representation of the key findings of this case. The site(s) designated on the organ diagram are based upon clinical information provided and do not necessarily indicate the specific location from where the biopsy was taken. The image and diagram are not intended to replace a complete reading of the final report.
### 3.0 ORGAN AND TISSUE SPECIFIC PROTOCOLS

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A. Amputation for Bone Tumor

1. Gross Examination

   a) All bone cases are to be photographed; consult with the surgeon if necessary for proper orientation of the specimen

   b) Review of the roentgenographs taken before amputation

   c) Measure the length and circumference (including a measure of the circumference at the level of the tumor if this is apparent or known)

   d) Determine the presence, position and dimensions of biopsy sites

   e) Search for the major lymph node groups, identify, and place in separate containers

   f) Cut a cross section of the proximal bone margin with a band saw. Ink surgical margins and take sections of the peripheral margins of resection, i.e., muscle, nerve, etc.

   g) Dissect out all the soft tissues (down to the periosteum) around the involved bone with a scalpel, forceps and scissors. Review the clinical and roentgenographic findings before proceeding. If there is any indication (from the roentgenograms or at the time of dissection) of soft tissue extension by the tumor, dissect around this area and keep it in continuity with the bone. If, from the roentgenograms, the tumor does not seem to involve the joint, cut through it; if it does, leave the joint intact and make a cross section with the band saw through the adjacent non-involved bone, approximately 5-10 cm from the joint. If a previous incision site is present, take a sample for histology at this time, along the entire course of the incision.

   h) Cut longitudinally the bone specimen thus obtained with a band saw. In most cases, a section dividing the specimen into an anterior and a posterior half is preferable; in others, sagittal, lateralized or even oblique cuts are recommended. The type of bone involved and the location of the tumor as seen roentgenographically will determine which plane of section will give the most information.

   i) Cut parallel sections with the band saw, producing slices about 5 mm thick. Use a saw guide for this purpose. Make additional cuts of the remaining bone pieces if indicated.

   j) Quickly dissect the soft tissues that had been peeled off the involved bone; cut sagittally with the band saw all major bones that were left in this portion of the specimen and examine carefully for other foci of tumor or other lesions. Open the major joints and examine them.

   k) Place thin sections of tumor both in routine decal and formic acid (for better cytologic detail). If the tumor is soft, place representative section in B5.

   l) Use either a diagram to include in the final report to identify the sites of the sections taken.

2. Gross Description and Tissue Sampling
Describe:

a) Type of amputation; side of extremity.

b) Length and circumference of extremity, including circumference at level of tumor.

c) Presence, position and dimensions of biopsy sites.

d) Tumor characteristics.

e) Location: bone involved; diaphysis, metaphysis, epiphysis?, medulla, cortex or periosteum?, epiphyseal line apparent? (if so, is the tumor crossing it?), does the tumor involve articular cartilage and joint cavity?, does it extend into soft tissue?, is the periosteum elevated by tumor? (if so, to what extent?) invaded by tumor?, if previous incision present, is there evidence of tumor extension along it?

f) Features of tumor: size, shape, color, borders, consistency; does it appear to be bone forming, cartilaginous, fibrous or myxoid? (cystic changes, hemorrhage or necrosis).

g) Distance of tumor to osseous margin of resection

h) Appearance of bone away from tumor; satellite lesions?

i) Appearance of remaining extremity if any abnormality is noted (if not, so state); skin, subcutaneous fat, muscles, major vessels and nerves, other bones, joints

j) Appearance and approximate number of lymph nodes found

Sample:

a) Tumor: Four sections or more depending on size and extent. A minimum number of sections is one for each centimeter of maximum tumor size. All grossly dissimilar areas should be sampled. Whenever possible, sections should be taken to include the periphery of the tumor and adjacent cortex, medulla, epiphyseal line, articular cartilage, periosteum and soft tissue.

b) Previous incision site (is present) taken all along its course.

c) Section from grossly non-involved bone.

d) Osseous margin of resection

e) Any abnormal-looking areas elsewhere in bone, soft tissues or skin.
3. Microscopic Diagnosis

Bone: Right/left leg/arm, amputation:

Dx
B. **Amputation: Leg for Non-neoplastic Condition**

1. **Gross Examination**
   
   a) Dissect major neurovascular bundles
   
   b) Above the knee amputation: femoral, popliteal, posterior tibial, anterior tibial
   
   c) Below the knee amputation: Anterior tibial, posterior tibial
   
   d) Note type of amputation and give measurements
   
   e) Note presence of gangrene or ulcers giving location and extent of injury
   
   f) Does ulceration involve underlying bone?
   
   g) Is tissue at the margin of resection grossly normal?
   
   h) Note appearance of vessels, i.e., degree of atherosclerotic change and sites of greatest stenosis/occlusion/thrombosis
   
   i) Note appearance of subcutis, muscle

2. **Gross Description and Tissue Sampling**

   a) Received unfixed is an above-the-knee (or below-the-knee, etc.) amputation. Its overall measurement is: x x x cm. The skin of the (ankle/dorsum of foot/toes/etc.) is (dark gray/purple, etc.). This area measures x x cm and shows a x cm ulcer (or no ulcer) in the (center/periphery). The artery (popliteal/posterior tibia/other major vessels) is % occluded with (yellow/tan/red/etc.), slightly friable material. No other lesions are identified. Labeled: A1, proximal margin; A2, ulcer/necrosis; A3, vessels; A4 bone for decalcification; J3.

3. **Microscopic Diagnosis**

   Right/left leg/arm, amputation:
   
   - Dx
C. **Amputation: Extremity for Soft Tissue Tumor**

1. **Gross Examination**
   a) All amputations for soft tissue and bone tumors are to be photographed
   b) Discuss the case with the surgeon and learn the correct orientation and anatomic landmarks of the specimen is necessary
   c) Measure the length and circumference (including a measurement of the circumference at the level of the tumor)
   d) Determine the presence, position and dimensions of biopsy sites
   e) Search for the major lymph node groups, identify and place in separate container
   f) Cut through the skin and carefully dissect the subcutaneous fat, muscles and major arteries, veins and nerves around the tumor, avoid cutting through the latter. Use an anatomy atlas as a guide if necessary. Try to determine as accurately as possible the relationship of the tumor with the following structures: skin, subcutaneous fat, specific muscles, arteries, veins and nerves, periosteum and bone. Mark some of the major anatomic landmarks with tags if indicated
   g) As soon as all the margins of the tumor have been determined and inked, carefully divide the tumor with a large knife. Continue the dissection with the forceps, scissors and scalpel to determine the tumor relationship with the structures previously mentioned. Carefully photograph the specimen. Place several pieces from different areas of the tumor in B5 and formalin, fix and trim to place in cassettes
   h) Sample tumor for EM and hold; send for tumor bank and cytogenetics as appropriate
   i) Place the entire specimen in a large pan containing formalin, cover with a towel, fix overnight; cut parallel slices with a large, sharp knife. Take roentgenograms if pertinent. Use a diagram to be included in the report to identify the sites of the sections taken
   j) Quickly dissect the soft tissues from the rest of the extremity, looking for other foci of tumor or other lesions
   k) Cut the major bones of the extremities longitudinally with a band saw as necessary. Make one of the sections through the area of bone closest to the soft tissue tumor. Examined for tumor extension or other lesions
   l) Open the major joints and examine them

2. **Gross Description and Tissue Sampling**
   Describe:
   a) Type of amputation; side of extremity
   b) Length and circumference of extremity, including circumference at level of tumor
   c) Presence, position and dimensions of biopsy sites
d) If previous incision present, is there evidence of tumor extension along it?

e) Size (three dimensions), shape, color, borders (encapsulated?, pushing?, infiltrating?), consistency, secondary changes (cysts, necrosis?, hemorrhage?)

f) Presence of myxoid changes, foci of calcification, cartilage or bone

g) Shortest distance of tumor from margin of resection

h) Appearance of remaining extremity if abnormal (if not, so state); skin,, subcutaneous fat, muscles, major vessels and nerves, bone (tumor invasion?, osteoporosis?, bone marrow?), joints (osteoarthritis?)

i) Appearance and approximate number of lymph nodes found

Sample:

a) Tumor: Four sections or more depending on size and extent. All grossly dissimilar areas should be sampled. Whenever possible, sections should be taken to include the periphery of the tumor and adjacent fat, muscle, skin, periosteum, vessels, and/or nerves. A minimum of one section for each centimeter of maximum tumor size should be taken

b) Previous incision sites (if present) taken all along its course

c) Lymph nodes

d) Margins of resection: subcutaneous fat and muscle (plus skin and/or bone if indicated)

3. Microscopic Diagnosis

Right/left leg/arm, amputation:

- Dx
D. Appendix

1. Gross Examination
   a) Measure length and greatest dimension and bisect the tip longitudinally
   b) Look for exudate, perforation, or other lesions
   c) Bisect the tip longitudinally and serially cross-section the remainder looking for fecaliths, masses, etc.

2. Gross Description and Tissue Sampling
   a) Save a cross-section from the proximal margin and the middle as well as longitudinal section from the tip for standard sections as per diagram (see below).

3. Microscopic Diagnosis
   Appendix, excision:
   - Dx.
E. Bladder Resection

A radical cystectomy is typically performed. In males, this is usually accompanied by removal of the prostate and seminal vesicles (cystoprostatectomy). The entire length of the urethra may also be excised (cysto-urethrectomy).

1. Gross Examination

   a) Knowledge of the location of the tumor should guide the dissection technique.

   b) Paint the entire external surface (including the prostate, if present) with ink.

   c) Before the bladder is opened, the location of the tumor is determined by looking up prior biopsy specimen or Lifelink. It is very important to avoid cutting through the tumor when opening the bladder. If its location is unknown, or if it is in the usual location near the trigone, the bladder can be opened with scissors in an Y-shape along the anterior wall, starting from the urethral opening. Both resected ureters should also be opened longitudinally. (The mucosa surface should not be touched because it is delicate and is easily denuded). The specimen is pinned to cork and fixed overnight before sectioning.

   *Note: Urethral margin should be submitted perpendicularly.

   Alternatively:

   After the urethral and ureteral margins of resection and lymph nodes are sampled, the specimen is inflated with formalin. After overnight fixation it is bisected into anterior/posterior or right/left halves. The ureters are opened longitudinally.

   Prostate and seminal vesicles are serially sectioned at 3-4 mm intervals from the posterior surface, leaving these structures attached to the bladder.

2. Gross Description and Tissue Sampling

   Labeled ___, received (unfixed/in formalin) is a urinary bladder, segments of both ureters, (prostate and seminal vesicles). The bladder measures x x cm. The dome of the bladder is covered by yellow adipose tissue. The specimen is (opened anteriorly through the urethra/ bivalved). A x cm tumor is present in the (trigone/right/left/anterior/ posterior /wall/dome). It is (exophytic/ulcerated/depressed) and on section it extends cm into the bladder wall. (Note: If the tumor is grossly not apparent, describe the abnormal areas without using the term tumor.) The surrounding bladder mucosa is (edematous/hemorrhagic/unremarkable). The segments of ureter measure cm on the right and cm on the left. They are both grossly (free of tumor/ involved by tumor). The prostate measuring x x cm and on section the surfaces are yellow-tan, rubbery, firm and focally nodular. It grossly (appears/does not appear) involved by tumor. The seminal vesicles each measure x x cm and area filled with cloudy gray fluid and (appear/do not appear) grossly involved by tumor. _ (number) lymph nodes are present in the attached fibroadipose tissue and grossly (appear/do not appear) involved by tumor.

   Labeled:
   A1-A3 tumor (including junction with normal mucosa, deepest point of invasion, and deep margin)
   A4 trigone
   A5 bladder neck
   A6 anterior wall
   A7 posterior wall
   A8 dome
   A9 right wall
A10 left wall
A11 urethral margin
A12 right ureteral margin
A13 left ureteral margin
A14-A? - if present: diverticula, lymph nodes,

**For male:** right prostate (4 cassettes), left prostate (4 cassettes), right seminal vesicle (one section), left seminal vesicle (one section),

**For female:** one representative section from the vaginal mucosa and any gross lesions will be submitted.

3. Microscopic Diagnosis
   Bladder, radical cystectomy
F. Bone, Femoral Head or Total Knee Replacement

1. Gross Examination
   a) Examine articular and cut surfaces
   b) Measure diameter and thickness
   c) Hold the specimen securely in a vise and cut through the center of the articular surface (fovea) with a saw

2. Gross Description and Tissue Sampling
   a) Make a parallel cut about 2-3 mm from the first cut while holding the specimen in the same position for permanent sections. Sample any grossly suspicious areas microscopically.
   b) Examine a cut section of the slice. Make parallel cuts through remaining pieces, if indicated, looking for evidence of osteophytic lipping at the periphery, synovial hypertrophy, eburnation (loss of cartilage), subchondral cysts, tumor masses, etc.

Labeled _____, received (unfixed/in formalin) is a _____ measuring x x cm. The articular surface is eburnated. On sectioning, ___ focal lesions are identified. Labeled A1 after acid decal. J2.

Labeled _____, received (unfixed/in formalin) are fragments of bone and soft tissue measuring x x cm. The tibial plateau is identifiable and shows focal eburnation. _____ focal lesions are identified. Labeled A1 after acid decal. J2.

3. Microscopic Diagnosis

Bone, right/left hip/knee, excision:
   - Dx
G. Breast Excisional Biopsy or Lumpectomy

Document the time the specimen is placed in formalin and calculate the cold ischemic time as the interval between the time received and the time formalin is added. Lastly, the time the specimen is removed from formalin must also be documented. This time is 10:00 P.M. on the same day. The gross dictation may begin with, "Placed in formalin at (time on date), with a cold ischemic time of (duration), and removed from formalin at 10:00 P.M. (on date), is a ...

1. Gross Examination
   a) Check in COPATH/Lifelinks for any prior Pathology reports.
   b) Measure and ink the margins of the excisional biopsy specimen prior to sectioning, if this has not been done by surgeon. Maintain specimen orientation with different colored inks as appropriate.
   c) OR Consultation – In most cases with a clinically suspicious gross or mammographic breast lesion, the pathologist will be consulted to evaluate the fresh, unfixed specimen and to process the tissue appropriately. A notation documenting what was done with fresh tissue received for consultation should be made on the FS/IOC form.
   d) In cases with Sentinel lymph nodes, follow the separate RIH and TMH procedures for intraoperative lymph node evaluation and histologic evaluation. Conform to institutional Radiation Safety Policies.

2. Gross Description and Tissue Sampling
   a) Describe the dimensions and consistency of the specimen, appearance of cut sections: fibrosis, cysts (size, number, content), calcification, tumor masses (size in three dimensions, color, borders, consistency, necrosis relationship of tumor to margin).
   b) For needle localizations, describe calcifications is present on specimen radiograph or absence of identifiable calcifications. Specify blocks from area(s) of calcifications.
   c) If a lesion is grossly identified state distance(s) from each of the margins.

Submit sections as follows:

1) For lesions grossly typical of fibroadenomas (and supported by prior pathology), 3 sections of tumor + sections of adjacent parenchyma

2) For lesions grossly suspicious and identifiable lesion, 6 sections minimum including adjacent margins of resection. Specify relationship of each section to a resection margin. Section(s) of all margins must be included.

3) Identify biopsy site (needle tract/biopsy cavity) and submit section(s) of the same.

4) For specimens with no grossly suspicious lesions, 5 sections minimum (if atypical ductal hyperplasia or intraductal carcinoma is identified microscopically, all parenchymal breast tissue must be examined microscopically). At the time of
5) Submit section of skin if present
6) For gross gynecomastia, 3 sections minimum

Format for dictation:

Labeled _____, received (unfixed/in formalin) is a --x --x cm segment of fibroadipose tissue. The resection margins are marked as follows: ______. Multiple cross-sections show (a well-circumscribed mass; nodular, firm areas, etc.) with/without (few/many)(color) cysts, ranging in diameter from __ to ___ cm and containing (yellow/viscous/hemorrhagic) fluid. The mass/lesion/suspicious area measures --- x --- x cm, is (yellow/tan/white, etc., give an accurate description of the lesion) and is (measure distance to each margin) away from the margin/s. Biopsy site corresponding the prior needle tract/excision identified. Labeled A1, inferior; A2, superior; A3, medial; A4, lateral; A5, posterior, etc. J2.

3. Microscopic Diagnosis for Carcinoma
H. Breast, Mastectomy

Document the time the specimen is placed in formalin and calculate the cold ischemic time as the interval between the time received and the time formalin is added. Lastly, the time the specimen is removed from formalin must also be documented. This time is 10:00 P.M. on the same day. The gross dictation may begin with, "Placed in formalin at (time on date), with a cold ischemic time of (duration), and removed from formalin at 10:00 P.M. (on date), is a ...".

1. Gross Examination
   a) Orient the specimen; use the axillary fat as a marker for the lateral side and the surgical section of the muscle as a marker for the upper side. Place the specimen on the cutting board, posterior side up, with its most inferior point toward the dissector. Mark the deep margin with ink.
   b) Measure the breast, the skin ellipse, the nipple, and the axillary tail. Measure any incisions/scars/lesions and note their location.
   c) Remove axillary tail and dissect lymph nodes and submit the lymph nodes in entirety.
   d) Serially section the breast at 0.5 cm intervals from the deep margin. Not cysts, mass lesions, biopsy cavities and their location and relation to the margins of resection. Adequately sample the grossly identified lesion and the biopsy cavity (at least 3-5 sections). Inspect carefully the other quadrants and describe additional lesions if any stating the quadrant in which found and distance from the index lesion. Submit 1-2 section of grossly identified additional lesions. If no lesion found submit 2 sections of breast parenchyma from each quadrant. Submit sections of nipple/areola and skin scar as well as any additional abnormal areas.
   e) In cases with Sentinel lymph nodes, follow the separate RIH and TMH procedures for intraoperative lymph node evaluation and histologic evaluation. Conform to institutional Radiation Safety Policies

2. Gross Description and Tissue Sampling

Labeled ___, received (unfixed/in formalin) is a (right/left) breast and attached axillary tail. It is covered on one surface by an ellipse of (color) skin measuring x x cm. The nipple is (mobile/retracted/fissured/ulcerated). The skin surface is (indurated/reddened/unremarkable) and contains a recent surgical scar (or sutured incision) measuring _ cm in the _ quadrant. Multiple serial sections through the breast parenchyma show a (firm/hard/gritty/irregular/round/gray-white/focally necrotic) tumor measuring x x cm located in the _ quadrant in the area of a previous biopsy site. The tumor (does/does not) retract the overlying skin and (is _ cm from/involves) the deep resection margin. The surrounding breast parenchyma is yellow-white and (focally cystic/nodular/unremarkable). The axillary fat pad contains multiple lymph nodes, ranging in diameter from _ to _ cm.

Labeled:A1 nipple
   A2-4 previous biopsy site or tumor
   A5 deep margin
   A6 skin incision
   A7-9 other breast quadrants
   A10 lymph nodes

3. Microscopic Diagnosis
I. **Esophagectomy**

1. **Gross Examination**
   
a) After marking the soft tissue resection margins with ink, the specimen should be opened longitudinally avoiding cutting through the tumor, if possible. If gastric cardia is included, continue to cut along the greater curvature. Lay down the specimen on a cork board, mucosal side up and fix overnight in a formalin container. The cork board is placed with the specimen on the underside.

2. **Gross Description and Tissue Sampling**
   
a) Length and diameter or circumference of specimen; proximal stomach included? (if so, indicate length along lesser and greater curvature); include thickness measurements for esophagus and stomach.

b) Tumor: size, appearance (fungating?, rolled edges?, ulcerated?); does it involve entire organ circumferentially?, depth of invasion; extension into stomach and adjacent organs?, distance from both lines of resection and from cardias, if present.

c) Mucosa: appearance of non-neoplastic mucosa; recognizable esophageal mucosa distal to tumor?, evidence of Barrett’s esophagus? (if so, length of the segment and appearance of mucosa); lumen dilated proximal to tumor?

d) Wall: thickened?, varices?

e) Stomach, if present: features of cardioesophageal junction and gastric mucosa

f) Lymph nodes: number found, size of largest; grossly involved by tumor?
   
   Labeled ________, received (unfixed/in formalin) is _________.

   A1-4 Tumor; four longitudinal sections, one including portion of non-neoplastic mucosa proximal to tumor and another a portion distal to tumor and deep margin of resection

   A5-6 Non-neoplastic esophageal mucosa

   A7 Gastroesophageal junction if present

   A8 Proximal line of resection

   A9 Distal line of resection

   A10 Lymph nodes

g) All post chemo- or radiotherapy treatment esophageal resections should be examined prior to fixation for areas suspicious for tumor ulceration. Those suspicious areas should be blocked out and submitted. If none are observed, please contact the attending pathologists in the Suite, the GI Pathology Fellow, or any other attending to review the specimen prior to fixation.
3. Microscopic Diagnosis
J. Eye Enucleation

1. Gross Examination
   a) Fix the intact ocular globe in formalin for 24 hours before sectioning; it is not advisable to open the eye, to cut windows into the sclera, or to inject fixative into the vitreous.
   b) Wash in running tap water for 1 or more hours and, optionally, place in 60% ethyl alcohol for a few more hours.
   c) Review the summary of the clinical history and the results of the ophthalmologic examination prior to sectioning.
   d) Measure anteroposterior, horizontal, and vertical dimensions of the globe, length of the optic nerve, and horizontal dimensions of the cornea.
   e) Look for sites of accidental or surgical injuries.
   f) Transilluminate the globe before opening it. A substage microscope lamp in a darkened room is satisfactory. Rotate the globe over the light source; if abnormal shadows are detected, mark them on the sclera with an indelible pencil.
   g) Examination of the globe with a x7 objective of a dissecting microscope can be carried out to detect minute lesions.
   h) If intraocular foreign bodies or retinoblastoma is suspected, take a roentgenogram of the globe before it is opened.
   i) If choroidal malignant melanoma is suspected, sample at least one of the vortex veins from each of the four quadrants (see accompanying drawing).
   j) Open the eye with a sharp razor blade by holding the globe with the left hand, cornea down against the cutting block and the blade between the thumb and middle finger of the right hand. Open the eye with a sawing motion from back to front. The plane of section should begin adjacent to the optic nerve and end through the periphery of the cornea. The plane of section is dependent on whether a lesion has been detected in the previous steps. If it has not, cut the globe along a horizontal plane, using as surface landmarks the superior and inferior oblique insertions and the long postciliary vein (see accompanying drawing). If a lesion has been found, modify the plane of section so that the lesion will be included in the slab.
   k) Examine the interior of the globe.
   l) Place the eye flat on its cut surface and make a second plane of section, parallel to the first, again passing from back to front.
   m) Examine carefully the ~8 mm disc-shaped slab thus obtained, which should contain the cornea, pupil, lens, and optic nerve. Take regular and Polaroid photographs or photocopies, if indicated.

2. Gross Description and Tissue Sampling
   a) Size of the globe; anteroposterior, horizontal, and vertical dimensions.
b) Length of optic nerve

c) Horizontal and vertical dimensions of cornea

d) Anterior segment: surgical incisions? corneal opacification? iris abnormalities? lens present?

e) Transillumination findings

f) Corneal thickness; anterior chamber depth; configuration of anterior chamber angle

g) Condition of iris, ciliary body, and lens

h) Condition of choroid, retina, vitreous body, and optic disc

i) If tumor present: location, size, color, edges, consistency, presence of hemorrhage or necrosis, ocular structures involved, extension into optic nerve.

Labeled _____, received ___________ (unfixed/in formalin) is ________________.

Labeled:
A1-3 Tumor with eye slab
A4 Any (other) abnormal areas
A5 For tumors, particularly retinoblastoma: cross section of surgical margin of optic nerve.
A6 In suspected malignant melanoma: sample from at least one of the vortex veins from each of four quadrants.

3. Microscopic Diagnosis

   Right/left eye, enucleation:
   -dx
K. **Fallopian Tube, Excision**

1. **Gross Examination**
   
   a) Fix the specimen before sectioning. If the tubes are attached to the uterus they should be fixed in that position.
   
   b) Measure the length and greatest diameter.
   
   c) If the tube is relatively normal in size, serially section at 5-mm intervals and examine. Make the cuts incomplete so that the pieces remain attached by the serosa.
   
   d) If the tube is obviously enlarged, make one complete longitudinal section, followed by parallel sections.

2. **Gross Description and Tissue Sampling**
   
   a) Length and greatest diameter
   
   b) Serosa: fibrin? hemorrhage? fibrous adhesions to ovary and other organs?
   
   c) Wall: abnormally thick? ruptured?
   
   d) Mucosa: atrophic? hyperplastic? appearance of fimbriated end; inverted?
   
   e) Lumen: patent? dilated? content; diameter if abnormally large.
   
   f) Masses: size, appearance, invasion
   
   g) Cysts in parovarian region: diameter, thickness of wall, content; sessile or pedunculated?
   
   h) In cases of suspected ectopic pregnancy: embryo or placenta identified? amount of hemorrhage; rupture?

Labeled _______, received _____ (unfixed/in formalin) is ______________________.

Labeled.

1. For incidental tubes without gross abnormalities: three cross sections of each tube, taken from the proximal, mid, and distal portions, submitted in the same cassette (see accompanying drawing).

2. For tubes with suspected ectopic pregnancy: submit any tissue with gross appearance of products of conception. If none is grossly identified, submit several sections from the wall in the area of hemorrhage as well as several from the intraluminal clot. If products of conception are not identified microscopically, submit additional sections.

3. For tubes with other lesions: as many as needed to adequately examine any abnormal areas. If tumor is present, at least three sections must be taken to include grossly uninvolved mucosa.
Microscopic Diagnosis

Fallopian tube, left/right, excision:
- dx
L. **Gallbladder Cholecystectomy**

1. **Gross Examination**

   Length and greatest diameter of gallbladder.
   
   a) Serosa: thickened fibrous adhesions, fibrin
   
   b) Wall: thickened (if so, focally of diffusely), hemorrhage?
   
   c) Mucosa: color, appearance, ulcerated, hyperplastic, cholesterosis
   
   d) Cystic duct: dilated impacted with stones, lymph nodes present, size and appearance
   
   e) Approximate volume, color and consistency of bile
   
   f) Stones: approximate number, shape and size range: color and appearance on cross-section; type of stone (see accompanying table)
   
   g) If tumor present: location, distance from fundus and neck, size: polypoid? ulcerated?, infiltrative?, serosal involvement?

2. **Gross Description and Tissue Sampling**

   a) Labeled gallbladder, received (unfixed/in formalin) is a gallbladder measuring cm from the fundus to the cystic duct and cm in diameter.
   
   b) The serosal surface is ________.
   
   c) On opening, the mucosa is _____ and the wall thickness is cm.
   
   d) Stones measuring up to cm are present.

   Labeled A1. J1. (Single tissue block includes cystic duct margin and section from fundus. If any focal lesions are present, these must be sampled in additional cassettes.)

3. **Microscopic Diagnosis**

   **Gallbladder, excision:**
   
   - Dx
M. Head and Neck, Jaw Resection, Glossectomy, Hemiglossectomy

1. Gross Examination
   a) Fix the whole specimen in formalin overnight
   b) Paint the surgical margins with ink
   c) For bone tumors: make multiple parallel sections through the bone and soft tissue with a band saw, fix further in formalin and decalcify
   d) For mucosal or soft tissue tumors: separate soft tissue from the mandible with blunt dissection or a scalpel
   e) Take photographs
   f) Diagram the specimen and identify the site of the sections to be taken. These specimens are usually complex and require diagrams and careful gross descriptions to explain the specimen. A clean copy needs to be included in the final report.
   g) Reconstruction of specimen for re-orientation is often necessary. Never cut specimens into pieces
   h) Consult a senior resident or an attending pathologist when you have questions. Also consult with the surgeon to establish proper margins if necessary
   i) If the specimen includes a radical neck dissection, process according to instructions for "lymph node dissection-radical neck"

2. Gross Description and Tissue Sampling
   a) Type of resection (partial or total) and side; overall size of specimen, specify size of bone if present and overall dimensions of mucosa and soft tissue
   b) Tumor: size (3 dimension is preferred) color, appearance (exophytic, etc.), edges, bone invaded?
   c) Non-neoplastic mucosa: leukoplakia or multifocality?
   d) Bone: appearance on cross-sections
   e) Teeth: number and appearance

Labeled ________, received (unfixed/in formalin) is ____________________.

Labeled:
   A1-3 Tumor: three sections minimum
   A4 Non-neoplastic mucosa
   A5-8 Mucosal surgical margins (indicate how sections were taken on diagram)
   A9 Soft tissue surgical margins
   A12 Bone surgical margins after acid decal
   A15 Mandibular nerve (surgical margins)
   A18 Bone if grossly involved or suspicious

3. Microscopic Diagnosis
N. Head and Neck, Larynx

Three types of laryngectomy are performed: hemi-, supraglottic and total. Hemilaryngectomy (also called partial vertical laryngectomy) consists of dividing the thyroid cartilage in the midline and resecting in the continuity the thyroid cartilage along with the corresponding true and false vocal cords and ventricle. Supraglottic laryngectomy (also called partial horizontal laryngectomy) consists of excising the upper half of the larynx horizontally through the ventricle. Total laryngectomy consists of removal of the entire larynx, including upper laryngeal rings.

1. Gross Examination

   a) Separate the larynx from the radical neck dissection if accompanied by the latter.

   b) In total or supraglottic laryngectomy specimens, open the larynx along the posterior midline and keep it open with wooden applicator sticks or by pinning to a cork board

   c) Photograph all laryngectomies

   d) Fix overnight in formalin

   e) Remove the hyoid bone, thyroid cartilage and cricoid cartilage, trying to keep the soft tissue as a single piece even if the bone and cartilage need to be fragmented in the process. Alternatively, the entire specimen can be decalcified after removal of the hyoid bone and attached soft tissue and/or thyroid gland and fixed in a formic acid decal solution for 4-5 days before cutting.

   f) Take two photographs or diagram the specimen and identify the sites of the sections to be taken.

   g) Paint the surgical margins (lingual, pharyngeal and tracheal) with India ink.

   h) Orient as to superoinferior and anteroposterior axis

   i) Section the whole specimen longitudinally in parallel slices

   j) Handle the radical neck dissection according to instructions for “lymph node dissection-radical neck”

2. Gross Description and Tissue Sampling

   a) Type of laryngectomy: total, hemi-, supraglottic; presence of pyriform sinus, hyoid bone, tracheal rings, thyroid and organs from neck dissection. Measure overall size of larynx and soft tissue; measure portion of thyroid if included

   b) Tumor characteristics: location (glottic, supraglottic, infraglottic or transglottic?), side involved (wholly unilateral or encroaching upon or crossing the midline?), size, pattern of growth (exophytic or endophytic?), ulceration, depth of invasion, presence of extra laryngeal spread, features of non-neoplastic mucosa (especially in true vocal cords). Give 3 dimensions of tumor.
c) For glottic tumors: length of cord involved, involvement of anterior or posterior
commissures, extension to ventricle, and degree of subglottic extension as
measured from the superior border of the true cord.

d) For supraglottic tumors: if the hyoid bone is attached, is the tumor supra- or
infrahyoid? Does it involve the false cords, aryepiglottic folds, pyriform sinus (if
present), or pre-epiglottic space?

e) If thyroid is included: weight, measurement and appearance. Invaded by glands
or prelaryngeal (delphian) node present?, is there a tracheostomy? If so, is there
any evidence of tumor involvement?

Labeled ___, received (unfixed/in formalin) is a larynx, (right/left or entire thyroid)
and (number) tracheal rings. The specimen has been (previously opened by
surgeon) opened along the posterior wall. The (right/left) vocal cord is thickened
and distorted by a (gray-white/hemorrhagic/friable/exophytic/ulcerated) tumor ,
x x cm. The tumor (involves/does not involve) the entire part of the (right/left)
cord and (does/does not) extend through the midline to the opposite side. The
tumor (does/does not) involve the (epiglottic/pyriform sinuses) and (does/does
not) extend to aryepiglottic fold. On section, it (does/does not) extend through the
laryngeal wall and (does/does not) involve the underlying cartilage. The (right/left/
both) lobe of the thyroid weighs g. and is (red/brown/firm/nodular/finely lobu-
lated) and (is/is not) involved with tumor. The remainder of the laryngeal mucosa,
including the lower tracheal and superior, oropharyngeal margins of resection are
(unremarkable/focally hemorrhagic/free of tumor). (number) lymph nodes are
identified. A (right/left/superior inferior) parathyroid gland is identified.

Labeled:
A1-3 Tumor
A4 Anterior commissure
A5 Opposite vocal cord
A6 Trachea resection margin
A7-8 Right and left pharyngeal resection margins
A9 Epiglottis
A10 Thyroid
A11 Thyroid cartilage – decal
A13 Parathyroid
A14 Lymph node
A15 Cricoid cartilage
3. **Microscopic Diagnosis**

Larynx, excision:
- Dx
O. Head and Neck, Nasal Cavity and or Maxillectomy for Tumor

1. Gross Examination
   a) Fix the specimen in formalin overnight
   b) Paint the surgical margins with ink
   c) Take surgical margins (anterior, posterior, external and superior); cut the specimen with the band saw in parallel slides 0.5 cm thick. Fix them overnight
   d) Take photographs (and roentgenograms if indicated).
   e) Take two Polaroid photographs or diagram specimen and identify the site of the sections to be taken.

2. Gross Description and Tissue Sampling
   a) Extent of resection
   b) Presence of following structures: hard palate; superior, medial and inferior turbinates; medial and lateral pterygoid plate of sphenoid bone; air cells of ethmoid; bony floor or orbit; orbital contents; zygoma, masseter, temporalis, external and internal pterygoid muscles
   c) Tumor characteristics: location, extent, size; limited to the maxillary sinus?, arising from superior, medial, lateral, anterior, posterior or inferior part of sinus?, extending into infratemporal fossa, nasal cavity, ethmoid cells, or any other aforementioned structures?, presence of tumor at surgical margins?

3. Sections
   Tumor: minimum of three sections
   Surgical margins (Indicate on diagram)

Note: These are complex specimens that should be processed in conjunction with a staff pathologist and/or surgeon to obtain necessary margins.

4. Microscopic Diagnosis
P. Head and Neck Pathology, Ear-Temporal Bone Resection

1. Gross Description
   a) Review roentgenograms if available and obtain roentgenograms of the specimens if facilities are available.
   b) Orient the specimen as to anteroposterior, superoinferior and mediolateral planes. Call surgeon to help with orientation if necessary.
   c) Mark the margins with ink.
   d) Section longitudinally in two halves or in parallel cross-sections, depending on location and size of tumor; photograph tumor.

2. Gross Description and Tissue Sampling
   a) Type of resection: subtotal or total
   b) Tumor: size, gross features and location: external ear, auditory canal, middle ear. If in the canal, does it involve the outer cartilaginous third or the inner osseous two thirds?
   c) Location within the canal: floor, walls, roof, circumferential. Invasion anteriorly toward the parotid gland?, superiorly toward the cranial cavity?
   d) Status of tympanic membrane
   e) Parotid gland (if present): invaded by tumor?
      Labeled ________, received (unfixed/in formalin) is ________.

3. Sections
   Tumor: in its entirety, unless it’s massive, then sample surgical margins Parotid gland, if present. Other sections as necessary (ear canal, skin, bone, etc.)
Q. Head and Neck, Radical Neck Dissection

The standard radical neck dissection includes removal of cervical lymph nodes, sternocleidomastoid muscle, internal jugular vein, spinal accessory nerve and submaxillary gland; the tail of the parotid is sometimes also included.

In the modified radical neck dissection (also known as functional or Bocca neck dissection), the sternocleidomastoid muscle, spinal accessory nerve, and internal jugular vein are spared.

The extended radical neck dissection includes, in addition to the structures removed in the standard operation, the excision of retropharyngeal, paratracheal, parotid, suboccipital and/or upper mediastinal lymph nodes.

In the regional (partial or selective) neck dissection, only the station of lymph nodes thought to represent the first metastatic station is removed.

The instructions following are devised for standard radical neck dissections and need to be modified for the other three. Because of the lack of anatomic landmarks in the modified and regional procedures, the labeling of the lymph nodes according to groups needs to be done by the surgeon. The same applies to the extra lymph node groups removed in the extended operation.

1. Gross Examination
   a) Orient the specimen and divide it into submaxillary gland, platysma (usually is not present), sternocleidomastoid muscle, internal jugular vein and node-containing fat.
   b) Divide the lymph nodes into five levels depending on whether they are on the upper or lower portion of the specimen and on their relationship with the jugular vein (level 1- submandibular and submental regions, level 2- upper jugular, level 3- mid jugular, level 4- lower jugular, level 5- posterior triangle); rarely level 6 will be included (anterior compartment between level 1 and sternum) or level for (upper mediastinal). Remove all muscle tissue from fat before looking for nodes.

2. Gross Description and Tissue Sampling
   a) Site and type of primary neoplasm (see specific instructions) if included; measure overall neck specimen and submandibular gland (if present).
   b) Length of sternocleidomastoid muscle.
   c) Jugular vein included?, length?, invaded by tumor?
   d) Presence of tumor in lymph nodes (capsular invasion, size, necrosis, matted nodes), submaxillary gland, soft tissue or muscle.

Labeled (right/left) radical neck dissection, received (fresh/in formalin) is a neck dissection measuring x x x cm. It includes a x x cm submandibular gland, a x x cm portion of parotid gland, a x x cm portion of the sternocleidomastoid muscle, a x x cm portion of internal jugular vein and attached fibroadipose tissue. Sections through the submandibular and parotid glands show tan, lobulated, unremarkable __ (or fibrotic/atrophic) parenchyma. The
sterno-cleidomastoid muscle is (grossly unremarkable/involved by tumor). The internal jugular vein is (unremarkable/free of tumor/thrombosed/involved by tumor). The lymph nodes present in the surrounding adipose tissue range in diameter from cm to cm and (are/are not) involved by tumor.

Labeled:
A1 Submandibular (or submaxillary) gland
A2,3 Level 1 Lymph nodes
A4,5 Level 2 Lymph nodes
A6,7 Level 3 Lymph nodes
A8,9 Level 4 Lymph nodes
A10,11 Level 5 Lymph nodes
A12 Tumor in jugular vein or any other structure if present
A13 Parotid tissue, if found

3. Microscopic Diagnosis

Lymph node, ______, excision:
- Dx

Submandibular gland, left/right, excision:
- Dx

Soft tissue, right/left sternocleidomastoid muscle, partial excision:
- Dx

External jugular vein, right/left, excision:
- Dx
R. Head and Neck, Salivary Gland

1. Gross Examination
   a) Paint surgical margins with India ink unless the gland is removed for an inflammatory process.
   b) Bisect in the fresh state and fix overnight or process fresh, depending on size of specimen.
   c) Cut parallel sections; photograph all primary excisions.
   d) Look for intraparotid and periparotid lymph nodes and for major nerves in total parotidectomy specimens.
   e) If the specimen includes a radical neck dissection, process according to instruction for Lymph node dissection-radical neck.

2. Gross Description and Tissue Sampling
   a) Type of specimen: parotid lobectomy, total parotidectomy without facial nerve, total submandibulectomy; side of operation.
   b) Tumor: size, location, shape, color, distance from closest margin. Solitary or multiple, cystic or solid encapsulated, circumscribed, or poorly defined, hemorrhage or necrosis, extraglandular extension?
   c) Appearance of non-neoplastic gland, ducts (Dilated), fibrosis and stones.
   d) Appearance of intraparotid and other lymph nodes.

   Labeled ____________, received (unfixed/in formalin) is a lobe of parotid. The specimen measures x x cm. The cut surfaces show a well-circumscribed, gray-white, firm nodule measuring x x cm. The nodule appears to compress the adjacent salivary gland tissue. Elsewhere the parotid shows tan, lobulated tissue.

   Labeled:
   A1-5 Tumor with margins of resection
   A6 Non-neoplastic gland
   A7- Lymph nodes if present

3. Microscopic Diagnosis

   Salivary gland, right/left parotid/submandibular, excision:
   - Dx
S. Intestine, Polypectomy

1. Gross Examination
   
   a) The base/stalk usually looks gray-white and smooth whereas the rest of the polyp is red and somewhat shaggy
   
   b) Cut perpendicular to the mucosal surface to make sections 3-4 mm thick, which would show the mucosal surface and submucosa
2. Gross Description and Tissue Sampling

Labeled _______ received (unfixed/in formalin) is a polypoid tissue fragment measuring cm. A cauterized base/stalk is identifiable. The specimen is serially sectioned through the base/stalk. Labeled A1-  . J0.
T. **Intestine, Segmental Resection, Non-neoplastic**

1. **Gross Examination**
   a) Open specimen longitudinally
   b) Look for mesenteric lymph nodes. If no incidental tumor is present, only random larger lymph nodes need be submitted. Optional – lymph nodes may be searched for in the fixed specimen.
   c) Submit sections of the lesion and both resection margins (the latter if appropriate) fresh for histology. Optional: more detailed analysis may be performed following fixation.
   d) Pin specimen to cork after removal of the bulk of mesenteric fat and fix in formalin. Optional: Mesentery may be kept attached to the bowel to evaluate topographic relationships.
   e) Take additional sections of the fixed lesion if the microscopic slides of sections taken from the fresh specimen do not provide sufficient information or show poor orientation.
   f) Recommend taking a longitudinal strip of the lesion and bowel and submitted in tot in several blocks.
   g) For IBD cases sequential sections should be taken at 10cm intervals and from every unusual raised, polypoid or depressed areas. Tissue should be submitted from normal appearing mucosa to document skip lesions.
   h) For polyposis specimens any polyps suspicious for invasive cancer as well as all polyps over 1cm in size should be sampled. Otherwise one section per quadrant (4 sections per colectomy) should be sampled. Lymph node dissection should be performed.

2. **Gross Description and Tissue Sampling**
   a) Length and circumference
   b) Serosa: adhesions
   c) Mesenteric fat and lymph nodes
      1) Mucosal surface; color, hemorrhage, ulceration, edema, diverticula
      2) Bowel wall: thickness, perforation, fistulas

Labeled _____, received (unfixed/in formalin) is a ___ cm segment of (small/large) bowel. The serosal surface is purple-red and (smooth/glistening/dull/dusky/hemorrhagic). A fibrinous exudate covers part of the serosa. The bowel wall is (edematous/unremarkable/thickened) to a maximum of ___ cm. The lumen contains (foul smelling/watery/mucoid/hemorrhagic) material. There is a (sharp/gradual) demarcation between hemorrhagic (or abnormal) and normal mucosa. The resection margins (appear/do not appear) viable and the obvious necrosis extends to within ___ cm of the closest margin resection margin. Foci of hemorrhage are also present in the attached mesentery. Section of mesentery vessels reveal (thrombi/no thrombi or atherosclerotic plaque resulting in a ___% obstruction of the arterial lumen).

Labeled:
A1 Proximal margin
A2 Distal margin
A3-5  Lesions (for chronic inflammatory bowel disease, submit at least 1 section per 10 cm of resection specimen)
A6  Mesentery/lymph node. Lesion: 2 sections, at least
U. Intestine (large or small) or Rectum, Segmental Resection, Neoplastic

1. Gross Examination
   a) Tumor location should be specified as to whether it’s in the right (cecum, ascending), transverse, left or sigmoid colon, rectum or small intestine. Tumors within the non-peritonealized distal portion and by definition all tumors within 16cm of the anal verge are rectal. For rectal tumors, the location of the tumor is relative to peritoneal reflection.

   b) When present the radial margin should be inked fresh. For rectal tumors, ink the soft tissue margin beneath palpable tumor.

   c) Open specimen longitudinally with scissors. Avoid cutting through the tumor by using your index finger placed inside the lumen to palpate for the tumor.

   d) Identify all mesenteric nodes. Divide nodes into those subjacent to the tumor, proximal to tumor and distal to tumor. If a mesenteric apex can be identified, submit nodes from it separately. All grossly negative lymph nodes should be submitted entirely. If it is a large specimen lymph nodes must be designated as regional and non-regional. If fewer than 10 lymph nodes are identified a second search should be made. If available, fat may be post-fixed in Bouins to facilitate the process.

   e) Site within colorectum. In the case of rectal cancer, state the distance of the most distal point of the anterior peritoneal reflection from the distal margin and the length of the tumor above and below the reflection. State, if possible, the quadrant showing the site of deepest tumor invasion (anterior, right lateral, posterior, and left lateral) and estimate the proportion of the circumference that is involved (multiples of 10%).

   f) Appearance of mesorectal excision in the case of rectal cancer (complete when invested by shiny fascia and with only minor breaches <5 mm across, nearly complete but with breaches in fascia greater than 5 mm, incomplete with breaches extending to the muscularis propria).

   g) Tumor: size, distance from margins, exophytic, ulcerated, color, depth of invasion. Submit at least 3 sections from the tumor, including tumor/normal mucosa interface and the deepest point of penetration.

   h) Non-tumoral mucosa and bowel wall appearance. Submit polyps and all unusual areas.

Labeled ______, received (unfixed/in formalin) is a _cm segment of colon and attached portion of mesenteric fat. The serosal surface over the colon is retracted over a _cm area. On opening, a fungating/exophytic/polypoid/ulcerated/ sessile/ circumferential) tumor measuring _ x _ x _ cm is noted. On sectioning, it appears to extend to the serosal surface but not into the pericolic fat. The tumor is _cm from the proximal and _ cm from the distal resection margins. There are (number of) pedunculated polypoid in the portion proximal to the tumor; the largest polyp is _ cm. In the pericolic fat, multiple lymph nodes, ranging in diameter from _ cm to _ cm are present.

Labeled:
A1 Proximal margin (specify as perpendicular or circumferential; circumferential preferred if tumor is located within 2 cm of the margin)
A2 Distal margin (specify as perpendicular or circumferential; circumferential preferred if tumor is located within 2 cm of the margin)
A3-5 Tumor
A6 Non-neoplastic mucosa
A7 Lymph nodes

i) All post chemo- or radiotherapy treatment rectal resections should be examined prior to fixation for areas suspicious for tumor ulceration. Those suspicious areas should be blocked out and submitted. If none are observed, please contact the attending pathologists in the Suite, the GI Pathology Fellow, or any other attending to review the specimen prior to fixation.

Microscopic Diagnosis
V.  Kidney, Neoplastic

1. Gross Examination:

a. Radical nephrectomy (including the kidney, most of the ureter, and renal vessels, perinephric fat, and surrounding Gerota’s fascia. An adrenal gland may be present (exam carefully)

a) Weighed and size (with fat)
b) Examine hilum to identify the ureter, renal vein and artery (tumor involvement of the renal vein is typically obvious. It looks like a smooth – surfaced projection extending out from the hilum, or may be a plug of tumor in the lumen, or the tumor may invade into the vessel wall.).
c) Examine Gerota’s fascia (very thin membrane (fascia) surrounding perirenal fat, the kidney and the adrenal gland. If any areas are suspicious for tumor they are inked selectively, but this is rarely seen)
d) Look for perirenal lymph nodes (typically, lymph node is note found).
e) Take sections of resection margins (artery, vein and ureter, look for sutures) then open longitudinally (starting at the side opposite the hilum and bivalving the kidney), and open calyces, pelvis and ureter.

Additional cuts are made as necessary to assess the parenchyma.
f) If tumor is limited to the kidney, you may remove the fat and ink the capsule over tumor with India ink.
g) For pediatric tumor cases, do not remove capsule and fat.

Section with capsule intact and weigh the entire specimen.

b) Partial nephrectomy:

a) Be sure major vessels and ureter is not present
b) Resection margins are inked
c) The specimen is serially sectioned
d) The distance of the tumor from the cute renal resection margin is recorded
e) 3-5 sections, demonstrate the relationship of the tumor to the resection margin as well as to the deep (perirenal fat) margin.

2. Gross Description and Tissue Sampling for radical nephrectomy:

Labeled _____, received (unfixed/in formalin) is a (right/left) kidney with attached segment of ureter, surrounding perirenal fat and adrenal gland. It weighs g and measures x x cm. Sections show a x x cm round, circumscribed tumor in (the upper/the lower) pole. The cut surface of the tumor varies from (bright yellow to brown-gray, with foci of hemorrhage and necrosis). The tumor (does/does not) grossly involve the renal vein and pelvis. The remainder of the renal parenchyma is (unremarkable). The tumor (does/does not) involve the perirenal fat. The adrenal gland is normal in configuration, weighs g, and measures x x cm. The cortex is (smooth/nodular) and (bright yellow, atrophic or any nodules).

Labeled:
A1-A3 Tumor with capsule or pelvis, tumor with adjacent normal kidney
A4 Uninvolved kidney
A5 Ureter margin
A6 Artery/vein margin
A7 Adrenal
A8 Lymph node
3. Microscopic Diagnosis
   Kidney, pelvis/ureter, radical nephrectomy:
W. Kidney, Non-neoplastic

1. Gross Examination
   a) Measure and weigh organ after removing capsule and fat.
   b) Cut longitudinally and open calyceal system, pelvis and ureter.

2. Gross Description and Tissue Sampling
   a) Dimensions, amount of pericapsular tissue
   b) External surface appearance; smooth, scarred, cyst
   c) Cortex: color, width
   d) Medulla: color, width
   e) Pelvis: appearance of lining; dilatation of calyces or not, presence of stones (number, location, shape, size, submit for chemical analysis)
   f) Renal vessels
      Labeled _______, received (unfixed/in saline/in formalin) and consists of a (right/left) kidney with attached segment of ureter, surrounding perirenal fat and adrenal gland. It weighs g and measures x x cm. The capsular surface is (color) and (smooth/finely/coarsely granular) (with/without) scars (which do/do not extend into the medulla). The cortex (is/is not) (irregularly/uniformly) narrowed, is (color) and averages cm in thickness. The corticomedullary junction is (distinct/indistinct). The medullary striations are (absent/blurred/retained). The calyces and renal pelvis are normal in size and contour and free of mucosal lesions. The renal arteries and vein are unremarkable. The ureter is thin-walled, non-dilated, free of tumor and patent. J3.

Labeled: A1-3 Parenchyma including renal pelvis
        A4 Ureter
        A5 Vascular margins

3. Transplant nephrectomy:
   a) Weight and size of the kidney; length and diameter of any vessels at the hilum
   b) The vessels are examined for thrombosis, intimal proliferation, and atherosclerotic plaques
   c) The description includes: kidney color, thickness of cortex, shape of calyces and papillae (normal or blunted), state of the pelvis, ureter, and vessels, presence of infarcts (size and location), hemorrhage or necrosis.
d) Four cassettes are submitted: including cortex, medulla, hilar vessels, ureter and focal lesion.

Note: If the transplant has failed 6 months or more after transplantations, or if there is significant proteinuria and recurrence of the patient's original disease is suspected, it may be appropriate to save tissue for EM and immunofluorescence studies.
X. Liver, Partial Excision

1. Gross Examination
   a) Weigh and measure.
   b) Ink the surgical margin.
   c) Cut serial 0.5-1 cm sections either parallel or perpendicular to the surgical margin depending upon tumor’s proximity to the margin.

2. Gross Description and Tissue Sampling
   a) Weight, color, capsule
   b) Tumor: size, color, circumscription, number, relationship to margin, vascular involvement (at least 4 sections of tumor as well as sections of tumor at relevant margins).
   c) Parenchyma: consistency, smooth, fatty, cirrhotic (size of nodules) (at least 2 sections)

Labeled _____, received (unfixed/in formalin) is a partial hepatectomy specimen measuring _ cm and weighing _ g. The hepatic parenchyma appears ____. The capsule _____ and measures _ cm. The margins of resection are inked and the specimen is serially sectioned. ___ mass lesions are present measuring _ cm and extending to within __ of the ____ surgical margin

Labeled:
A1-5 Tumor with margins of resection
A6-7 Non-neoplastic liver

2. Microscopic Diagnosis

Liver, partial/total resection:
Y. Lung Resection, Non-neoplastic

1. Gross Examination
   a) Note: Cultures from lesions suspected of being infectious should be done in the OR if possible.
   b) Weigh the specimen.
   c) Inject with formalin through the main bronchus, tie off or clamp the bronchus, fix overnight and serially section at 1 cm intervals through the hilum with a sharp knife.
   d) For lungs with tuberculosis and other contagious diseases (proved or suspected); fix in formalin for 48 hours; keep the specimen in the same container while dissecting and cutting the sections; send the contaminated instruments for sterilization; carefully wrap the contaminated material in a plastic bag and place in a scrap bucket.
   e) If a rib was submitted as part of the thoracotomy, examine it grossly and if normal do not submit sections.

2. Gross Description and Tissue Sampling
   a) Weight of specimen and type of resection (pneumonectomy, lobectomy, wedge resection).
   b) If lobectomy or wedge, then how long is margin?, is it stapled?
   c) Pleura: thickness; fibrosis?, fibrin?, parietal pleura present? (identified by presence of subserosal fat).
   d) Bronchi: mucosa, lumen (diameter and content).
   e) Parenchyma: appearance; if localized lesion is present; appearance; lobe and, if possible, bronchopulmonary segment in which located; relationships to bronchi, vessels, pleura and lymph nodes.
   f) Lymph nodes: number, size, appearance, and location.

Labeled __________, received (unfixed/in formalin) is a lobectomy specimen measuring __ cm and weighing __ g. The pleural surface is ___. On sectioning, the parenchyma appears ___. ______ mass lesions are present measuring __ cm and extending to within __ cm of the _____ surgical margin.

Labeled: 

A1-3 Lesion
3. Microscopic Diagnosis

Lung, right/left upper/middle/lower lobe, excision:
- Dx
Z. Lung Resection, Neoplastic

1. Gross Description
   a) Weigh the specimen
   b) Inject with formalin through the main bronchus, tie off or clamp the bronchus, fix overnight and serially section at 1 cm intervals through the hilum with a sharp knife.
   c) For lungs with tuberculosis and other contagious diseases (proved or suspected): fix in formalin for 48 hours; keep the specimen in the same container while dissecting and cutting the sections; send the contaminated instruments for sterilization; carefully wrap the contaminated material in a plastic bag and place in a scrap bucket.
   d) If a rib is submitted as part of the thoracotomy, examine it grossly. Sections need not be taken.

2. Gross Description and Tissue Sampling
   a) Weight of specimen and type of resection (pneumonectomy, lobectomy, wedge resection).
   b) If lobectomy or wedge, then how long is margin, is it stapled?
   c) Pleura: thickness; fibrosis?, fibrin?, parietal pleura present? (identified by presence of subserosal fat).
   d) Bronchi: mucosa, lumen (diameter and content)
   e) Parenchyma: appearance; if localized lesion is present: appearance; lobe and, if possible, bronchopulmonary segment in which located; relationships to bronchi, vessels, pleura and lymph nodes.
   f) Tumor: size, location, relation to bronchi and pleura, (how far away from resection margin), color, presence of anthracotic pigment, areas of necrosis, mucin, hemorrhage, cavitation.
   g) Regional lymph nodes: appearance and number, and location.
   h) Relation of tumor to pleura and bronchi margin (distance).

Labeled _____, received (unfixed/in formalin) is a g., x x cm lobe of white area retracts the pleural surface on the (medial/lateral/superior/inferior) aspect over an area of x cm. An emphysematous bleb cm in diameter is also present in the apical area. The remainder of the pleura is glistening and transparent with multiple areas of black, anthracotic discoloration. Lymphatic vessels appear (dilated/normal). The lung (after being inflated with formalin) is sectioned along its longitudinal axis. There is poorly circumscribed gray-white and focally necrotic tumor in the periphery of the (upper/lateral/medial/inferior) portion of the lobe measuring x x cm. It (involves/does not appear) to correspond to a segmental bronchus, pleura.***The remainder of the lung parenchyma is focally consolidated and hemorrhagic (or is well aerated and does not have other gross lesions). The bronchial resection margin is smooth and (does/does not) appear involved with tumor. (number) hilar and (number) peribronchial lymph nodes, ranging from cm to cm in diameter are present. The major pulmonary vessels
are (grossly unremarkable/obstructed by recent thromboembolus/grossly involved by tumor).

Labeled:
- **A1** Bronchial margin (full cross-section)
- **A2-4** Tumor, including pleura
- **A5** Non-neoplastic lung, including any abnormal areas
- **A6,7** Lymph nodes, if possible, separate hilar, peribronchial, segmental nodes into separate cassettes.

3. **Microscopic Diagnosis**
   - Lung, r/l, excision:
AA. Lymph Node Biopsy

1. Specimen Protocol

This protocol applies to lymph nodes (LN) that are biopsied for the evaluation of lymphoproliferative diseases or for non-lymphoproliferative diseases but not for the examination of regional LN dissection specimens (e.g., axillary or neck dissections).

2. Examination at Intraoperative Consultation (IOC) With or Without Frozen Section (FS)

   a. For the evaluation of lymphoma.

      1) If the biopsy is performed for the evaluation of lymphoma, the sole purpose of the IOC is to determine whether or not the biopsy tissue provided is sufficient for diagnosis. Gross examination, sometimes augmented by touch preparation evaluation, is often sufficient for this determination. FS should be avoided in order to preserve the tissue for permanent sections, flow cytometry (FC), and other ancillary studies.

      2) If the biopsy tissue provided is scanty (< 1.0 cc.) or if a FS must be performed to determine the histopathology, request more tissue from the surgeon before FS is performed. If no additional tissue is forthcoming and the tissue is homogeneous, divide the specimen, if size permits, between FS and permanent sections and do not submit tissue for FC. If additional tissue is received, triage it between permanent sections, FC, and other ancillary studies.

      3) If the biopsy tissue is abundant, a FS may be performed but is always discouraged. Submit tissue for FC (0.5 cc. of tissue is necessary) and other studies (such as, cytogenetics and tumor bank).

   b. For the evaluation of metastatic disease (no suspicion of lymphoma).

   1) If there is no additional tissue available, a FS may be performed. If the tissue is homogeneous and size permit, divide the specimen between FS and permanent sections.

3. Pertinent Clinical History

   Clinical history is sometimes essential in making a specific lymphoma diagnosis. At IOC or before reaching a final diagnosis, the pathologist is encouraged to obtain all available clinical history (prior diagnosis of lymphoma, extent of lymphadenopathy, presence of organomegaly, hematological findings, symptoms, prior immunological deficiency including HIV status, knowledge of pertinent infections (H. pylori, EBV, CMV, HTLV-1, HHV-8).}

4. Gross Description and Specimen Sampling

   Tumor size (state size range, smallest to largest mass) and shape of specimen
Characteristics of any focal lesions

Tissue sections for lymphoma evaluation

If the lymph node is received unfixed and the tissue is abundant, submit tissue for FC, cytogenics, and tumor bank. If the tissue is scanty, submit all tissue for permanent sections.

Serially section the LN at 2 mm. intervals parallel to the long axis in order to maximize the architectural assessment. Submit all small LNs and fragments and at least three representative sections of large LNs (or one section per cm. after the first three). The first section should be submitted on the day of receipt, and all other sections should be submitted after 24 hours of formalin fixation. State the fixative used per each block in the block summary.

If the LN is being evaluated for metastatic disease, record the number of LNs. Submit all small LNs and fragments and at least three representative sections of large LNs (or one section per one cm. after the first three). State whether or not the LNs are sectioned so that an accurate count can be obtained for final diagnosis.

5. Final Diagnosis and Prognostic Features Sign-Out Checklist

a. Anatomic location of lymph node (defined by surgeon), e.g., Lymph node, left cervical

b. Specimen type, e.g., biopsy, incisional biopsy, lymphadenectomy, staging laparotomy, etc.

c. If the diagnosis is lymphoma, the tumor should be classified as per the 2001 WHO Classification of Haematopoietic and Lymphoid Tissue

Final Diagnosis (an example format)

“Lymph node, specific anatomic site, biopsy or excision:
Diagnosis (WHO classification)”

d. If the diagnosis is metastatic disease

1) Number of LNs with metastases versus the number examined

2) Number of metastatic deposits

3) Size (greatest diameter) of largest metastatic deposits

4) Presence or absence of extranodal extension

5) Final Diagnosis (an example format)

“Lymph nodes, specific anatomic site (sentinel #), excision:
- Metastatic carcinoma (1 of 3) (1.5 cm. in greatest dimension with no extranodal extension)”

e. Integrate all of the known clinical, histopathological, immunological (IHC and FC), molecular, and cytogenetic results into the surgical pathology report, either in the initial report or by issuing amended or addendum reports.
f. The presence or absence of LN involvement by lymphoma is indicated in the lymphoma stage that is assigned by the oncologist.

g. If the diagnosis is not lymphoma or metastatic disease, provide as specific a diagnosis within the categories of lymphadenitis or lymphadenopathy as clinically useful, e.g. angiofollicular lymphadenopathy (Castleman's disease), non-necrotizing granulomata (sarcoidal type), etc.
BB. Ovary

1. Gross Examination

   Measure the organ. Weigh it if it is obviously abnormal. If the specimen is received fresh:

   a) Normal-sized or nearly normal-sized organ: bivalve along the greatest dimension including the hilus and fix for several hours

   b) Enlarged organ: make several parallel cuts and fix for several hours

2. Gross Description and Tissue Sampling

   a) Size and shape: weigh if enlarged


   c) Cut section: character of cortex, medulla, and hilus; cysts (size and content); corpus luteum? Calcification? Hemorrhage?

   d) Tumors: size; external appearance: smooth or papillary? Solid or cystic? Content of cystic masses; hemorrhage, necrosis or calcification?

   e) Photograph all interesting specimens

   f) Sections

   1.) For incidental oophorectomies: one sagittal section of each entire ovary labeled as to side, e.g. "A1, A2"

   2.) For cysts: up to three sections of cyst wall (particularly from areas with papillary appearance) labeled as "A1,2,3"

   3.) For tumors:

      (a) Cystic ovarian tumor: Observe the quality of the cyst fluid, (mucoid, viscous, clear amber, etc.). The presence of solid or papillary areas within the cysts, whether it is unilocular, multilocular or has tumor on the ovarian surfaces. Concentrate sampling on solid or papillary areas as they are more likely to show malignant tumor. For low malignant potential tumors, sample 1 section per cm of diameter, always including sections of the ovarian surface showing its relationship to the tumor. Where wall is thin, 2 or 3 sections may fit in one cassette. Always try to find residual ovary which may be grossly visible in the cyst wall, e.g., small follicle cysts or yellow nodules.
(b) Solid ovarian tumors: if small, note location, i.e., cortical, medullary or hilar, describe cut surface (homogeneous, nodular, variegated). Note the presence of necrosis, hemorrhage or calcification. Section at several-millimeter intervals and sample all areas of differing gross appearance or texture. If cysts are present, sample them as well. For germ cell tumors, sample 1 section for each cm of greatest dimension.

(c) Dermoid cysts: wash with water to remove sebum and hair. Look for the knob on the wall (so called dermal mammilla or process) and take at least one section from this area and one or two representative sections of the cyst wall. Sample in addition, any areas of wall thickening.

(d) For large ovarian carcinomas 8 cassettes is usually sufficient (min. 5)

3. Microscopic Diagnosis
   Ovary, r/l, excision
CC. Pancreas, Resection

1. Gross Examination

   a) Dissect lymph nodes fresh and divide them according to illustrated groups.

   b) Ink the bile duct surgical margin, all soft tissue margins in the retroperitoneum and pancreatic tail surgical margin.

   c) Open the stomach along the lesser curvature continuing into the duodenum opposite the ampulla of Vater.

   d) Demonstrate the relationships at the ampulla of Vater by opening it and following the pancreatic and bile ducts into the pancreas.

   e) The pancreatic parenchyma can be sectioned longitudinally cutting from tail toward head so that the pancreas is divided into 2 anterior and posterior halves.

   f) The specimen may be pinned to cork and fixed overnight before sectioning. Place a pad of formalin-soaked paper towels (not gauze) in between the cut leaves of the pancreas so that they fix adequately. If you are fixing it overnight first sample tumor for EM and hold; send for tumor bank and cytogenetics as appropriate.

2. Gross Description and Tissue Sampling

   a) Organs present in specimen and their dimensions: weight of spleen.

   b) Tumor characteristics: involvement of ampulla, duodenal mucosa, stomach, common bile duct, pancreatic duct, and pancreas; size, shape (papillary?, flat?, ulcerated?), color and consistency; if tumor is in the ampulla: intra-ampullary, periampullary, or mixed?

   c) Common bile duct, main pancreatic duct and accessory pancreatic duct: location and relationship with each other; dilated?, stones?, tumor?.

   d) Pancreas: Tumor invasion?, atrophy?, fibrosis?, ductal dilatation?.

   e) Spleen: tumor invasion?, other features

   The pancreas measures \( x \times x \) cm and weights (optional) \( g \). It is light pinkish-tan, lobular and cuts with (normal) resistance. The parenchyma is free of hemorrhage, fat necrosis, fibrosis and calculi. Tumor (is/is not) present. It is of a ____ color, (circumscribed/infiltrative) and ____ consistency and is located in the (head/body/tail). The tumor measures approximately ____cm (mention if you can see the tumor arising within the duct if possible). The pancreatic duct appears of normal caliber (or dilated) and is free of calculi. The common bile duct measures ____cm in length and ____cm in diameter. It appears (grossly unremarkable, if involved by tumor describe further). Peripancreatic lymph nodes measuring up to ____ cm are identified and (none/number) appear grossly involved by tumor.

Labeled: A1 Gastric margin
        A2 Duodenal margin
        A3 Common bile and pancreatic duct margins
        A4 Pancreatic tail margin
A5-A8  Anterior, posterior, superior and inferior soft tissue margins
A9-13  Tumor (at least one section per cm of tumor)
A14-AX Lymph nodes

3. Microscopic Diagnosis
   Pancreas, excision:
DD. **Parathyroid, Resection (Parathyroidectomy)**

Prior to the advent of parathyroid imaging techniques and intraoperative parathyroid hormone assays, for most patients with primary hyperparathyroidism due to parathyroid adenoma, the abnormal gland was removed in its entirety and the remaining glands were biopsied to confirm that they were normal. Currently, only the adenomatous gland is removed. If parathyroid hormone levels fall to normal, no further surgery is performed.

1. **Gross examination**

   **Adenoma**
   a) Record weight and dimensions of specimen
   b) Ink surface of gland if there is any suspicion of parathyroid carcinoma. (capsular fibrosis, adherence to adjacent tissue, etc.)
   c) Prepare multiple cross sections, record their color and consistencies and submit one representative cross section per centimeter of tumor diameter
   d) If biopsies of other glands are obtained, record their weights and dimensions. Since multiple biopsies are usually performed, it is critical to record their anatomic sites as indicated by the surgeon. Generally, these biopsies should each be submitted individually in separately labeled cassettes.

   **Carcinoma**
   a) Submit at least one section per each cm of tumor diameter. It is critical to include the inked margins so that soft tissue invasion can be assessed. If contiguous thyroid tissue is also submitted with tumor, sections should include both tumor and adjacent tumor.

   **Hyperplasia**
   b) Record weights and dimensions of each specimen. For lesions measuring up to 1 cm in diameter, one section per gland should suffice for histological examination. For larger specimens, submit one section per cm. Since multiple specimens are usually obtained, it is critical to record their anatomic sites, as indicated by the surgeon.

   **Adenoma**

   Labeled ________, received (unfixed, in formalin) is the (left, right, upper, lower) parathyroid weighing _______ g and measuring __ x __ x __ cm. The capsule is (thin and delicate/fibrotic) and the capsular surface is (smooth, irregular, nodular). The capsular surface is (is not inked). On section, the parenchyma is (pink-tan, tan-brown), (soft, firm) and appears (homogeneous, cystic, fibrotic). Representative sections are submitted in cassettes A1 to A3.
Hyperplasia (or other glands)

Labeled _______, received (unfixed, in formalin) is the (left, right, upper, lower) parathyroid gland weighing ___ g and measuring ___ x ___ x ___ cm. The tissue is (yellow-tan, tan) and (soft firm). Areas of cyst formation are (present/absent). Fibrosis is (present/absent). The specimen is submitted in toto or representatively) for histological examination in cassettes A1 to A____.
EE. Penis

1. Specimen protocol
   a. Amputation of the penis is almost always performed for the resection of invasive squamous cell carcinoma.
   
   b. In some cases, the specimen may be accompanied by inguinal lymph nodes dissections, which should be processed according to the specific protocol for these dissections elsewhere in this manual.

2. Gross Description and Specimen Sampling
   a. Record the dimension of the specimen (length and circumference) and the foreskin (length, width, and thickness).
   
   b. Tumors usually affect the glans and coronal sulcus. Describe the principal lesion and any satellite lesions [location, size, color, growth pattern (fungating, papillary, verrucous, ulcerated), consistency (friable, soft, hard, rubbery), contour (well defined, infiltrating), and the distance from the proximal surgical margin].
   
   c. Open the urethra along its ventral aspect where it is closest to the skin. Then, deepen the cut to bisect the specimen. Record the depth of tumor invasion and its involvement of foreskin, frenulum, glans, meatus, corpora cavernosa, corpus spongiosum, and urethra.
   
   d. Fix the specimen in sufficient formalin overnight and submit tissue sections the next day to document:
      1) The deepest extent of invasion (submit three tissue sections of tumor);
      2) The tumor’s relationship to adjacent structures and to the proximal surgical margin (submit two or more tissue sections, including skin, corpora, and urethra); and
      3) Tissue sections of satellite lesions or any grossly suspicious areas.

3. Final Diagnosis and Prognostic Features Sign-Out Checklist
   a. Tumor type: Squamous cell carcinoma; others are rarely encountered
   
   b. Tumor grade: Well, moderately, or poorly differentiated
   
   c. Structures invaded: In-situ, subepithelial tissue, corpus spongiosum, corpus cavernosum, urethra, or prostate gland
   
   d. Surgical margins status: Involved or not involved
e. Lymph node status: Number of lymph nodes involved vs. number evaluated; dimension of largest metastasis; presence of extranodal extension; bilaterality of lymph nodes
FF. Prostate, Radical Prostatectomy

1. Gross Examination

Includes the prostate, seminal vesicles, vas deferens, urethra and occasionally lymph nodes. Weigh the specimen, measure the gland the seminal vesicles and vasa deferentia. Differentially ink the posterior surface, right half, and left half of the gland. Ink the rim of tissue at the bladder neck / proximal urothelial margin a separate color. In robot-assisted procedures there is extensive cautery artifact at the proximal margin and the anatomy can be distorted. Inserting a probe into the prostatic urethra may be helpful. Allow the specimen to fix in a large volume of formalin overnight.

Amputate the apex (~ 4 mm), section the apex serially and submit perpendicular margins on edge. Submit cross sections of the right and left vasa deferentia and seminal vesicles (the first cross section should be immediately adjacent to the prostate gland). Amputate the proximal margin and adjacent prostatic tissue. Submit the proximal margin and adjacent prostatic capsular margin on edge. Submit a perpendicular section of the base of the gland on the right and left of the proximal margin. Serially section the remainder of the gland and describe the findings. For grossly apparent tumor submit the tumor and adjacent inked capsular margin entirely. Submit every other complete cross section of uninvolved prostate. In cases where the tumor is not grossly apparent, submit every other complete cross section. Store the remaining tissue in formalin so that laterality can be re-established in the event that additional tissue needs to be submitted.

For submitted lymph nodes or lymph node dissections submit every identified lymph node for histologic study.

2. Gross Description and Tissue Sampling Labeled:

A1 Apical margin, right (perpendicular)
A2 Apical margin, left (perpendicular)
A3 Proximal urethral / bladder neck margin (perpendicular)
A4 Right seminal vesicle/vas deferens
A5 Left seminal vesicle/vas deferens
A6 Right high prostate, adj. to proximal margin
A7 Left high prostate, adj. to proximal margin
A8 Right low prostate, anterior
A9 Right low prostate, posterior
A10 Left low prostate, anterior
A11 Left low prostate, posterior
A12 Right mid prostate, anterior
A13 Right mid prostate, posterior
A14 Left mid prostate, anterior
A15 Left mid prostate
A16 Right mid prostate, anterior
A17 Right mid prostate, posterior
A18 Left mid prostate, anterior
A19 Left mid prostate, posterior
A20 Right high prostate, anterior
A21 Right high prostate, posterior
A22 Left high prostate, anterior
A23 Left high prostate, posterior

3. Microscopic Diagnosis

Prostate, radical prostatectomy:
GG. Prostate, Transurethral Resection

1. Gross Examination
   a) Weigh the specimen.
   b) Examine all fragments carefully. Carcinoma of the prostate is often yellow and/or hard.
   c) Submit all suspicious fragments.

2. Gross Description and Tissue Sampling
   a) Specimens < 10 g: submit all tissue.
   b) Specimens > 10 g: submit 3 cassettes plus 1 additional cassette for each additional 10 g of tissue.

3. Microscopic Diagnosis

   Prostate, transurethral resection:
   - Dx
HH. Sentinel Lymph Node Biopsy

1. Specimen Protocol
   a) This protocol applies to specimens that are designated as “sentinel lymph nodes” (SLN) by surgeon and that are typically related to the staging of breast cancer and melanoma patients. The lymph nodes (LN) may be described further as “hot, blue” or “hot, non-blue” that indicates the means of their detection. These descriptors should be included in the Gross Examination specimen label, e.g., “Labeled as, ‘Right Axillary Sentinel Lymph Node #1 (Hot Blue).’” These specimens are radioactive, but the amount and type of radiation present represent minimal risk to personnel. In conformance with ALARA policy (“as low as reasonably achievable”), tissue handling should be minimized.
   b) When an excision specimen is included with the SLN, it is also typically radioactive, and ALARA policy should be followed with minimal specimen handling time.

2. Gross Description and Specimen Sampling
   a) Size and shape of specimen
   b) Characteristics of any focal lesions
   c) All LNs should be bisected to prepare touch preparation for Intraoperative Consultation evaluation. Subsequently, those that > 0.5 cm. in thickness should be serially sectioned at 2 mm. intervals. The number of LNs is recorded, and each LN is submitted completely in designated cassette(s) and submitted on the day of receipt unless additional fixation time is needed.
   d) Immunohistochemistry (IHC) studies are used routinely for melanoma staging (melan-A or HMB-45) and may also be used for breast carcinoma staging (pancytokeratin), when the nature of microscopic cell clusters requires clarification. IHC studies should be routinely applied in eval. of SLNs, axillary LNs in cases of invasive lobular carcinoma

3. Final Diagnosis and Prognostic Features Sign-Out Checklist
   a) Anatomic location of LN (defined by surgeon)
   b) Number of LNs with metastases versus the number examined
   c) Number of metastatic deposits
   d) Size (greatest diameter) of largest metastatic deposit
   e) Whether or not IHC is used to id or define the metastases (indicated in TNM stage)
   f) Presence or absence of extranodal extension
   g) Final Diagnosis (an example format)
   “Lymph node, anatomic site (sentinel #), excision:
   - Metastatic carcinoma (number of LNs involved, e.g. 1 of 1) (number of metastatic deposits and size, e.g., 2 metastatic deposits, 0.5 cm. in greatest dimension, without extranodal extension)”
II. Skin, Excisional Biopsy

1. Gross Examination
   a) Pigmented nevi, seborrheic keratoses, and other benign skin conditions (as well as small basal cell carcinoma) are usually removed with narrow margins, and the size of the specimen mainly depends on the size of the lesion.
   b) Fix well before processing.
   c) Paint margins with ink to maintain orientation if present.

2. Gross Description and Tissue Sampling
   a) Size and shape of specimen; features of surface; lesion present?, size, color, other features; margin grossly involved?.
   b) Characteristics of lesion: size, shape, color or colors, configuration, elevated or depressed?, ulceration?, types of margins (sharp or ill-defined?, flat or elevated?); distance from margins of resection; satellite nodules?
   c) If specimen transected, description of appearance of cross-section.

Sections:
1) For specimens measuring 3 mm or less. Submit entirely without cutting
2) For specimens measuring between 4 and 6 mm in width (see accompanying drawing B under “Skin-Excision for Malignant Tumor”): Cut through the center and submit both halves.
3) For specimens with a width of 7 mm or more: cut into 2-3 mm slices. If the clinician has provided orientation with a suture, maintain orientation by nicking through the epidermis superficially along one side with a scalpel. Do not submit more than two pieces in one block.

3. Microscopic Diagnosis

Skin, ________, excision biopsy:
- Dx
JJ.  Skin, Wide Excision for Malignant Melanoma:

Gross Examination

a)  Note the specimen and margin orientation provided by the OR on the requisition sheet.

b)  Ink the specimen using two separate colored inks, each ink covering one half of the specimen, extend the ink to the edges of the epidermis.

c)  Measure the specimen and accurately describe the lesion (color/configuration/borders/ulceration etc.) on the skin surface. Note if there is a scar from prior surgery. Write down the measurements of the lesion/scar. Describe the location of the lesion/scar and relationships as well as distance to various margins.

Fix well before processing.

Submission of sections:

a)  Submit sections after adequate fixation (4-6 hours or overnight).

b)  Serially section the specimen from one end to other and submit entirely if only 6 cassettes generated. Mention in the summary of sections the laterality/location of each slice submitted (for example: “sections submitted from lateral to medial end of the specimen A1 being the most lateral end of the specimen and A6 being the most medial end of the specimen” etc.).

c)  If specimen is large and cannot be submitted entirely within 6 cassettes, block out the lesional area and serially section the blocked portion and submit it entirely again mentioning the laterality/location of each slice as described above. Submit the two tips in separate cassette specifying their laterality/orientation. Randomly submit slices from the rest of the specimen again specifying the margins/location they represent.
KK. Skin, Punch Biopsy

1. Gross Examination
   a) Size of specimen.
   b) Number of fragments.
   c) Features of surface.

2. Gross Description and Tissue Sampling
   a) If width is 3 mm or less, submit in toto without cutting.
   b) If width is 4 mm or more, cut in parallel slices, about 2-3 mm thick, and submit all for histology. Do not submit more than two pieces in one block.
   c) Make sure all sections are requested to be ORIENTED ON EDGE as an embedding log comment.

3. Microscopic Diagnosis
   Skin, _____, punch biopsy:
   - Dx
1. Gross Examination
   a) Size of specimen.
   b) Number of fragments.
   c) Features of surface
2. Gross Description and Tissue Sampling
   a) If width is 3 mm or less, submit in toto without cutting
   b) If width is 4 mm or more, cut in parallel slices, about 2-3 mm thick, and submit all for histology. Do not submit more than two pieces in one block.
   c) Make sure all sections are requested to be ORIENTED ON EDGE as an embedding log comment.
3. Microscopic Diagnosis
   Skin, __________, shave biopsy:
   - Dx
**MM. Splenectomy**

1. **Specimen Protocol**

   This protocol applies to splenectomy specimens that are being evaluated for hematopoietic disorders, primarily lymphomas and leukemias, and non-hematopoietic lesions and conditions.

2. **Gross Description and Specimen Sampling**

   a) Weigh and measure the spleen in three dimensions. Describe the integrity and quality of the capsule. If hilar lymph nodes or accessory spleens are present, report their number and size in greatest dimension, and submit a representative tissue section of each.

   b) Step-section the spleen at 0.3 to 0.5 cm. intervals transversely and describe the quality of the malphigian corpuscles and red pulp. Describe the distribution and characteristics of all focal lesions. Quantify all lesions that are 0.5 cm. or larger in diameter from staging laparotomies for Hodgkin lymphoma and submit representative tissue sections (2 mm in thickness) of each lesion after overnight fixation in formalin.

   c) If lymphoma or leukemia is suspected or if the malphigian corpuscle architecture is effaced, submit tissue for flow cytometry and other ancillary studies as necessary (at least 0.5 cc. of tissue is necessary for flow cytometry). Submit additional tissue sections after B5 fixation.

   d) For all other spleens, including those post-trauma, submit three tissue sections, one from each pole that includes the capsule and one from the hilum.

3. **Pertinent Clinical History**

   Clinical history is sometimes essential in making a specific lymphoma or leukemia diagnosis. At IOC or before reaching a final diagnosis, the pathologist is encouraged to obtain all available clinical history (prior diagnosis of lymphoma or leukemia, extent of lymphadenopathy, presence of organomegaly, hematological findings, symptoms, prior immunological deficiency including HIV status, knowledge of pertinent infections (H. pylori, EBV, HTLV-1).

4. **Final Diagnosis and Prognostic Features Sign-Out Checklist**

5. If splenectomy is performed for Hodgkin lymphoma staging, quantifying the number of macroscopic lesions is important (greater than four lesions has been shown to have prognostic importance). Report the number of these lesions in the Final Diagnosis Comments.

6. If the diagnosis is lymphoma or leukemia, the tumor should be classified as per the 2001 WHO Classification of Haematopoietic and Lymphoid Tissue

   Final Diagnosis (an example format)

   "Spleen, splenectomy:
   - Diagnosis (WHO classification)

   Accessory spleen, splenic hilum, splenectomy:
   - Diagnosis

   Lymph node, hilar, splenectomy:
   - Diagnosis"

   a) Integrate all of the known clinical, histopathological, immunological (ICH and FC), molecular, and cytogenetic into the surgical pathology report, either in the initial report or by issuing amended or addendum reports.
b) The presence or absence of splenic involvement is indicated in the stage that is assigned by the oncologist.
NN. Stomach, Resection, Neoplastic

1. Gross Examination
   a) Specimen is opened along its greater curvature, or the lesser curvature when the tumor is located in the greater curvature.
   b) Before fixation, paint all surgical margins with India ink. Also paint serosa adjacent to tumor.
   c) Pin the stomach on cork board, fix overnight and make a diagram of the specimen to illustrate section sites.
   d) Dissect lymph node group according to diagram specifying those that are near the tumor and remove the omentum.

2. Gross Description and Tissue Sampling
   a) Type of resection (total or sub-total), length of greater and lesser curvatures and duodenal cuff.
   b) Tumor location, size (including thickness), fungating, ulcerated spreading. Is serosa involved? Take at least three sections of tumor including tumor/normal interface, deepest point of penetration and relationship to visceral peritoneum.
   c) Extension into duodenum.
   d) Distance from both margins of resection.
   e) Appearance of non-neoplastic mucosa.

Labeled _____, received (unfixed/in formalin) is a segment of stomach measuring cm along the greater curvature and cm along the lesser curvature. An attached cm segment of omentum is present along the greater curvature and cm along the lesser curvature. On opening, a (fungating/exophytic/ulcerated/infiltrative) tumor is present in the (anterior/posterior wall/greater/lesser curvature). It measures x x cm and is cm from the proximal and cm from the distal resection margins. Sections show extension into the gastric wall to a depth of cm. The remainder of the gastric mucosa shows (normal/atrophic) folds. (Describe any other lesions, i.e., small polyp and submit sections). Lymph nodes are present in the attached adipose tissue; they range from cm to cm and (are/are not) grossly involved by tumor.

Labeled:
A1, A2 Proximal resection margin
A3, A4 Distal resection margin
A5, A6 Tumor (including margins)
A7, A8 Random sections
3. Microscopic Diagnosis
   Stomach, partial/total gastrectomy:
OO. Stomach, Resection, Non-neoplastic

1. Gross Examination
   a) Examine specimen in the fresh state
   b) Open the specimen along the greater curvature (unless the lesion is in this location; if it is, open the specimen along the lesser curvature).
   c) Dissect the lymph node groups and remove the omentum
   d) Look carefully for small mucosal erosions and irregularities and for intramural or subserosal nodules.
   e) Pin the stomach on a cork board and fix overnight in formalin before sectioning.

2. Gross Description and Tissue Sampling
   a) Type of resection; length of greater curvature, lesser curvature and duodenal cuff
   b) Ulcer characteristics: location, size, depth of penetration, shape and color of edges, flat or elevated?, converging folds?; presence of large vessels and/or perforation at ulcer base; appearance of serosa (if the clinical/radiographic diagnosis is peptic ulcer, but no ulcer is identified in the specimen, contact the surgeon to find out whether the ulcer was not resected. Record this information as part of the gross dictation)
   c) Appearance of uninvolved mucosa: atrophy, edema, hemorrhage, etc.

Labeled ____, received (unfixed/in formalin) is a segment of stomach measuring x x cm along the lesser curvature and _ cm along the greater curvature. The distal line of resection includes the pylorus/a cuff of duodenum) measuring cm. The serosal surface is (smooth/glistening/perforated/hemorrhagic). The specimen is opened along the (lesser/greater) curvature. Situated on the (anterior/posterior wall/greater/lesser curvature) is a (sharply demarcated/poorly circumscribed/punched out) ulcer, _ cm in diameter. The ulcer is located _ cm from the distal ____ and _ cm from the proximal resection margins. The ulcer edges are (sharp/raised/undetermined); the wall along the ulcer is _ (indurated) and the base contains (yellow/red) fibrinous material. The rugal folds radiate from the ulcer. The remainder of the gastric mucosa elsewhere is unremarkable.

Labeled:
A1, A2  Ulcer
A3  Proximal margins
A4  Distal margins
A5, A6  Random sections of stomach mucosa

3. Microscopic Diagnosis

Stomach, partial excision:- Dx
Gross Examination

II. Testis, Radical Orchiectomy

1. Gross Examination

   a) Weigh and measure the specimen. Open the tunica vaginalis (a sac that surrounds the front and sides of the testis and extends upward over the spermatic cord). Cut the testicle longitudinally along the anterior border. The testis is bisected parallel to and through the epididymis. Additional cuts can be made parallel to this plane.

2. Gross Description and Tissue Sampling

   a) Weight and size of specimen (three dimensions of the testis and epididymis

   b) Length and diameter of spermatic cord.

   c) Tumor: size, color, consistency, border (circumscribed vs invasive), homogeneity or lack of it, cysts, necrosis, hemorrhage, extension (to tunica albuginea, tunica vaginalis, epididymis, cord or other structures).

   d) Non-neoplastic testicle: atrophic, nodules, scars, calcification.

Tumor:

Submit in toto unless more than 6 blocks are required, in which case submit at least 6 blocks unless tumor is more than 6 cm in diameter, in which case submit at least 1 section per 1 cm of maximum tumor diameter.

Being sure to demonstrate tunica albuginea over the tumor and uninvolved testis adjacent to the tumor (where vascular invasion and intratubular germ cell tumor are most likely to be found), and section of the relationship to the epididymis. Sample all the grossly different types of tumor.

Sample of dictation:
Received, labeled with ___ is a ___ gram orchiectomy specimen that includes testis (_X_ cm), epididymis (_cm in length x _cm in diameter). There is a _ x _ cm tan-white, firm, circumscribed- mass with focal areas of (hemorrhage and necrosis and cystic spaces) within the testis. The tumor does not grossly extending into the tunica albuginea or into the epididymis. The remainder of the testicular parenchyma is brown-tan, and grossly normal tubules are present. The spermatic cord consists of vas deferens, arteries and veins, and is grossly unremarkable.

Sections:

A 1-6 (or more sections) tumor (including different area and cystic area)
A 7 tumor with epididymis
A8 tumor with Tunica vaginalis
A9 any other lesions
A10 Hilus
A11 Spermatic cord resection margin
A12 spermatic cord, midsection
A13 spermatic cord, peritesticular section
A14 uninvolved adjacent testis
A15 All lymph nodes (if any)

Microscopic Diagnosis

Testis, r/l, radical orchiectomy:
Specimen Protocol

This protocol applies to the excision of the thymus gland for the Diagnosis of thymoma. In some instances, other disease processes may be found: thymic hyperplasia, thymic cysts, germ cell tumor, or lymphomas (particularly, Hodgkin lymphoma, diffuse large B-cell lymphoma, and precursor T-lymphoblastic lymphoma). When lymphomas or germ cell tumors are suspected, refer to the sections in this manual where they are considered.

Pertinent Clinical History

Clinical history is sometimes helpful in the evaluation of tumors of the thymus and should be sought in all cases (e.g., pleural effusions, myasthenia gravis, pure red cell aplasia, prior diagnosis of carcinomas that may be metastatic, hematological findings, tumor marker serology).

Gross Description and Specimen Sampling

a) Size, shape, and weight of specimen (normal thymus weighs 30 g. or less). If the specimen is intact, the surface should be inked.

b) Describe the color, consistency (uniform, nodular, fibrous bands, cystic, gritty), the presence of an intact or incomplete capsule, the presence of adherent adjacent tissue, the presence of necrosis or hemorrhage, and the proportion of adipose tissue vs. thymic tissue.

c) Submit three tissue sections or one section for each cm. of the lesion’s diameter, one section of uninvolved thymus gland, and representative sections of lymph nodes, pericardium, and/or pleura

d) Submit tissue sections to document the margin status for staging purposes, i.e. of the capsule or specimen surface that includes adipose tissue, adherent tissues, and/or adjacent parenchymal tissue.

e) Immunohistochemistry (IHC) studies are essential for documenting the nature of the lesion: primary vs. metastatic tumor, lymphoma, germ cell tumor. An appropriate panel of antibodies should be selected following the review of routine microscopic slides. The following IHC antibodies are useful for the purpose of thymoma diagnosis: pancytokeratin, CD5 (usually expressed by thymic epithelium), CD20, CD3, CD1a, and nTdT, (residual thymocytes express CD3, CD1a, and nTdT).

Final Diagnosis and Prognostic Features Sign-Out Checklist

a) Type of thymoma or thymic carcinoma; use classification scheme outlined in Rosai J, Rosai and Ackerman’s Surgical Pathology, 9 ed., pg. 477, emphasizing the Bernatz classification and/or the Muller-Hermelink classification that is most appropriate and providing the corresponding WHO type parenthetically.

Final Diagnosis (an example format)

“Thymus gland, anterior mediastinum, excision/biopsy:—
- Thymoma, spindle cell or medullary type (type A, WHO classification)”
Tumor size in greatest dimension

Extent of encapsulation: complete, partial, or not encapsulated

Extent of invasion:
   a) Invasion into capsule
   b) Invasion into adjacent adipose tissue and/or pleura
   c) Invasion into mediastinal structures or organs: pericardium, lung, great vessels

9. Margin status: Involved or uninvolved

10. Presence or absence of metastases
RR. Thyroid, Resection (Lobectomy or Thyroidectomy)

1. Gross Examination
   a) Record dimensions and weight of specimen
   b) Search for parathyroids and perithyroidal lymph nodes
   c) Ink surfaces
   d) Prepare serial cross sections of each lobe and longitudinal sections of isthmus and pyramidal lobe (if present)
   e) If no lesions are found, then serially section the specimen.

2. Gross Description and Tissue Sampling
   a) If a frozen section is performed, the site and laterality of the frozen section should be specified in the frozen section diagnosis (e.g., right upper lobe nodule, right lower lobe nodule, etc.).
   b) Note abnormalities on cut surfaces; smooth vs. nodular, color, number and size of nodules, whether nodules are solid/cystic/calcified/hemorrhagic/fibrotic/necrotic encapsulated.

   Sections:
   1) For diffuse and/or inflammatory lesions: three sections from each lobe and one from isthmus.
   2) For a solitary encapsulated nodule measuring up to 5 cm: sections should be taken from the entire circumference; take one additional section for each additional centimeter in diameter. Sections should include the tumor capsule and adjacent thyroid tissue. For lesions that are close to the thyroid capsule (inked), include the resection margin.
   3) For multinodular thyroid glands; one section of each nodule (up to 5 nodules), including rim and adjacent normal gland; more than one section for larger nodules.
   4) For papillary carcinoma: block the majority of the tumor bearing lobe and submit 3 representative sections of the contralateral lobe if there are no abnormalities. Sections should include inked resection margins. If the specimen is a lobectomy, sections from the isthmus (resection margin) should be included.
   5) For carcinomas other than papillary; same as for “4” (papillary).
   6) For cases of familial medullary thyroid carcinoma or C-cell hyperplasia, cross sections of each lobe should be submitted in their entirety for histological examination.
7) For all cases: submit parathyroid glands and perithyroidal lymph nodes if found on gross inspection.

(Nodular hyperplasia/Goiter)

Labeled _____, received (unfixed/in formalin) is a (right/left/entire) thyroid weighing _g. and measuring _x_ _x_ _cm. The capsule is (thin and delicate/fibrotic) and the capsular surface is nodular. Sections show multiple (red-tan, glistening) nodules of various sizes, ranging from _cm to _ cm in diameter. Areas of fibrosis, cystic degeneration and calcification (are/are not) present. Representative sections are submitted as A1-6 (random sections of nodules).

(Thyroiditis)

Labeled ____, received (unfixed/in formalin) is a (lobe/entire gland) weighing _g., and measuring _x_ _x_ _cm. The capsule is (thin/delicate/smooth/fibrotic). Sections show homogeneous, firm, pale brown and red surfaces. Labeled A1-6.

(Neoplasm)

Labeled _____, received (unfixed/in formalin) is a (lobe/entire gland) weighing _g., and measuring _x_ _x_ _cm. The capsule is (thin/delicate/smooth/fibrotic). Sections show an encapsulated (or well-circumscribed but not encapsulated or non-encapsulated), mass, measuring _x_ _x_ cm with (tan/translucent/yellow/firm/soft) cut surfaces. The tumor (extends, does not extend) beyond the thyroid capsule. The surrounding thyroid parenchyma is (finely lobulated/unremarkable/nodular). The specimen is photographed.

Labeled:
  A1-6   Nodule and thyroid/capsule
  A7     Isthmus
  A8-10  contralateral lobe (if present)

3. Microscopic Diagnosis

   Thyroid, excision
SS. Uterus, Cervical Cone Biopsy

1. Gross Examination
   a) Ideally, the specimen should be received intact, in the fresh state, and with a suture or other material identifying the 12:00 position.
   b) Open the specimen by inserting a sharp pointed scissors into the cervical canal and cutting longitudinally along the 12:00 position. If the specimen has not been oriented as to position, open at any site.
   c) Pin on a cork board with the mucosal side up and fix in formalin for several hours.
   d) Paint the entire stroma surgical margin with India ink, taking special care that the epithelial side of the margins is well stained along its entire length.
   e) Cut the entire cervix by making parallel sections, 2-3 mm apart, along with plane of the endocervical canal starting at the 12:00 position and moving clockwise. Sections should be taken in such a way that the epithelium (including the squamocolumnar junction) is present in each section.

2. Gross Description and Tissue Sampling
   a) Size (diameter and depth) and shape of cone; complete and intact, or fragments?
   b) Epithelium: color, presence of irregularities, erosions, healed or recent lacerations, masses (size, shape, location), cysts
      Sections:
      (1) All of the tissue must be submitted.
      (2) If the cone has been oriented to the 12:00 position, serially section and identify the separate quadrants, i.e., 12:00-3:00, 3:00-6:00, 6:00-9:00, 9:00-12:00.
      (3) Label as “A1, A2, A3, A4”, etc.

3. Microscopic Diagnosis
   Uterus, cervix, cone biopsy:
TT. Modification For Cervical Dysplasia/Carcinoma

Uterus - Modification For Cervical Dysplasia

Submit the entire cervix clockwise as a cone biopsy, including the transformation zone. The ectocervical or vaginal margin should also be included in these sections. DO NOT submit separate lower uterine segment sections.

Uterus - Modification For Invasive Cervical Carcinoma (Radical Hysterectomy)

An adequate gross description is essential. Describe the gross location, appearance and three dimensional size of the tumor. Bisect the cervix, if it has not already be done. How deep does the tumor penetrate into the cervical stroma? Does the tumor extend to the lower uterine segment or endometrial cavity? Does it involve the parametrium (paracervical soft tissue) bilaterally? Accurate measurements of the stretched out vaginal cuff and bilateral parametrium must be in the gross description!

For small tumors, submit the tumor and adjacent vaginal cuff as a cone. With a wide grossly normal vaginal cuff, anterior and posterior cuff shave margins (one cassette each) are preferred.

With larger tumors, adjacent sections may be needed to document the full depth of invasion into the cervical stroma. This should be explicitly stated in the block list. ONLY if the majority of the tumor is higher in the endocervical canal, additional sections should be taken to evaluate the depth of invasion and extension to the lower uterine segment.

Separately labelled cassettes of the left and right parametrial soft tissue are always submitted.

Uterus, excision
UU. **Uterus - Modification For Endometrial Hyperplasia & Carcinoma**

Describe the location (fundus, entire cavity or lower uterine segment) and size of the endometrial lesion, as well as the gross extent of myometrial invasion (superficial, one third, one half, more than half etc.). Note the presence or absence of gross tumor extension to the lower uterine segment and/or endocervical canal.

Full thickness sections are submitted as follows:

1. Anterior cervix, including the transformation zone
2. Posterior cervix, including the transformation zone
3. Anterior lower uterine segment*
4. Posterior lower uterine segment*
5-7. Anterior endomyometrium (this will include tumor, of course)
8-10. Posterior endomyometrium (this will include tumor, of course)

*Sections of the cervix and lower uterine segment are contiguous.

**ALL UTERINE SECTIONS ARE FULL THICKNESS.**

If the uterine wall is too thick to fit in one cassette, a cross-section should be bisected and submitted in two cassettes (i.e. 6-7) and this should be noted. Full thickness sections are required to accurately measure the depth of myometrial invasion. It is not necessary to specifically mention which sections of endomyometrium contain tumor!

**Microscopic Diagnosis**

**Uterus, excision:**

(ENDOMETRIUM)
VV. Uterus, Hysterectomy, Non-neoplastic

1. Gross Examination
   a) Identify as uterus and cervix – note if there is a vaginal cuff or attached parametria (radical hysterectomy).
   b) Weigh.
   c) Take the following measurements:
      1) Top of the fundus to endocervix
      2) Cornu to cornu
      3) Thickness of uterine corpus
      4) Length of cervix and diameter of cervical os
      5) Vaginal cuff, if present – anterior and posterior lengths
   d) Identify anterior and posterior by the following clues:
      1) The ligament of the ovary is posterior to the isthmus of the fallopian tube.
      2) The level of peritoneal reflection is lower on the posterior aspect of the uterus.
      3) The round ligament is anterior.
   e) If the uterus has not been previously opened, open it laterally at 3 and 9 o’clock from the cervix to the cornu. Make an “X” on the anterior serosal surface for orientation.
   f) Fix well before sectioning (overnight for cancer cases, several hours for small, benign uteri)
   g) Make parallel longitudinal sections each half, about 1 cm apart, stopping short of completing them at the superior end (in order to keep them together) and carefully examine each surface.
   h) Make at least one cross-section of every leiomyoma present and examine carefully; larger myomas need additional cuts.
   i) If tubes and/or ovaries accompany the specimen, follow instructions for these organs.

2. Gross Description and Tissue Sampling
   a) Type of hysterectomy: total?, radical?, with salpingo-oophorectomy?
   b) Measurements: external measurements – as noted above
   c) Shape of uterus: deformed?, subserosal bulges?
d) Myometrium: thickness, abnormalities.

e) Endometrium: appearance; thickness; polyp? (size, shape); cysts?, size of endometrial cavity (length, maximum width and thickness)

f) Cervix: appearance of ectocervix, squamocolumnar junction, endocervical canal; erosions?, polyp?, cysts?

g) Leiomyomas: number, location (subserosal, intramural, submucosal); size; sessile or pedunculated, hemorrhage, necrosis or calcification, ulceration of overlying endometrium

Sections:

1) Cervix: one section from anterior half and one from posterior half, submit polyps in entirety if not of large size. Labeled “A1, A2”.

2) Corpus: two sections (anterior and posterior) taken close to fundus and including endometrium, good portion of myometrium and, if thickness permits, serosa; additional sections from any grossly abnormal areas, submit endometrial polyp in its entirety if they are not of large size. Label “A3, A4”, etc.

3) Leiomyomas: if no suspicious areas are seen (hemorrhage, necrosis, edema, etc.) then sampling of two tumors is sufficient. Sections of myometrium, around the tumors will suffice for routine myometrial sections. Label “A5, A6”.

4) Four to six sections total are sufficient for most routine hysterectomy specimens.

Labeled __. received (unfixed/in formalin) is a uterus and cervix. The uterus measures x x cm and weighs g. The cervix measures x x cm. The serosal surface (is smooth and glistening/ has a few fibrous adhesions). The ectocervix is (smooth and glistening). The cervical os is (irregular, multiparous) and measures _ cm. The uterus is distorted by multiple round leiomyomas ranging in size from _ cm to _ cm. They have whorled, tan-white cut surfaces without evidence of hemorrhage, softening or necrosis. Areas of undistorted myometrium measure _ cm in thickness. The endometrial cavity measures _ x _ cm in thickness. The myometrium is tan and uniform. The right and left fallopian tubes measure _ x _ cm and _ x _ cm, respectively. The outer surfaces are smooth and glistening. The fimbriae are delicate. Serial cross-sections reveal the tubes to be patent and unremarkable. The right and left ovaries measure _ x _ cm and _ x _ cm, respectively. The outer surfaces are glistening and slightly nodular. The cut surfaces reveal (numerous corpora albicantia/a few small clear fluid-filled cysts/corpus luteum/hemorrhagic corpus luteum).

Labeled:

A1  Anterior cervix
A2  Posterior cervix
A3  Anterior endo- and myometrium
A4  Posterior endo- and myometrium
A5  Leiomyoma #1
A6  Leiomyoma #2
A7  Right ovary
A8  Right fallopian tube
A9  Left ovary
A10 Left fallopian tube

NOTE: If ovaries are small, right and left ovary and fallopian tube can be submitted together in one cassette for each side.
3. Microscopic Diagnosis

Uterus, cervix, excision:
- Dx

Uterus, endometrium, excision:
- Dx

Uterus, myometrium, excision:
- Dx

Uterus, serosa, excision:
- Dx

Fallopian tube, right and left, excision:
- Dx

Ovary, right and left, excision:

Leiomyoma(s) - Myomectomy

Describe the number of tissue fragments, size range or aggregate size and weight. Describe the cut surface.

Submit one section of each leiomyoma, with additional sections of large leiomyomas or areas of discoloration and softening.

LYMPH NODES (Axillary, Inguinal, Pelvic, Peri-Aortic)

Submit all nodes in their entirety. Dissect away excess fat.
Vulva - Excisions And Vulvectomies (+/- Nodes)

Orient the specimen! What type of specimen is it - wide excision, hemivulvectomy, anterior or posterior vulvectomy, total vulvectomy? Are the nodes attached or separate? Measure the size of the skin and underlying soft tissue. Consult the attending pathologist on any vulvectomy.

Examine the skin for any visible lesion. Note the location, size and appearance of any visible tumor. Ink the lateral and deep margins of resection. Multiple inks can be used to indicate specific margins. Is there gross invasion? Are there other lesions present - discoloration, pigmentation, leukoplakia? Measure the gross distance of tumor from each of the 4 major margins - lateral, medial (or right and left), superior and inferior.

Nodes should be dissected from the adipose tissue. This is most easily done with the fresh tissue. Submit all nodes in toto.

A drawing of the vulvectomy should be made to indicate the location of sections. This will be filed with the report. See example on next page. Trim sections as thin as possible and fix in breast fixative (alcoholic formalin).

Submit the following sections:
- At least 3 blocks of tumor, including any close margin(s)
- Sections of other lesions or abnormalities
- All margins of resection; shave margins of the entire specimen are preferred when a distinct gross tumor is not apparent and for all cases of VIN III
- Random section(s) of normal skin
- Inguinal nodes, if present

Sentinel Lymph Node(s) are submitted in their entirety in green cassettes. Bisect or trisect large nodes; they may need more than 1 cassette. If a node grossly contains tumor, submit in a white cassette (levels NOT needed).
4.0 ELECTRON MICROSCOPY

Electron Microscopy

Tissue should be sampled immediately to preserve ultrastructural detail; accordingly, sample for EM before doing any other histologic sampling. Use a fresh scalpel blade to cut tissue samples. Place a few drops of glutaraldehyde on a paraffin sheet (dental wax) and cut the tissue into 1 mm fragments. Then carefully place in vial with glutaraldehyde and refrigerate. Tissue may be held in the gross room refrigerator pending review of the H&E histology and sent for processing if it is then indicated together with the proper requisition.
4.1 FLOW CYTOMETRY

Flow Cytometry

Notify the Special Hematology Laboratory (x48342). Place the tissue on saline-soaked gauze. The tissue may be held in saline or tissue culture media if it is received after 5 p.m. or on the weekend and has to be held overnight. (This is in refrigerator by operating room entrance to Davol Suite.)
### 4.2 MICROBIOLOGIC CULTURES

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**Microbiologic Cultures**

Ideally, cultures are taken by the surgeon in the OR under sterile conditions. If it is necessary to culture specimens in the gross room, use a sterile forceps and blade to remove a tissue sample from the interior of a contaminated specimen and send specimens to the Microbiology Laboratory as soon as possible after they have been properly identified with the patient’s name and surgical pathology number. If a specimen cannot be sent immediately, place it in the refrigerator. Specify the cultures desired on the requisition.
B5 Fixation for Bone Marrow Biopsies

1. Add small vial of formaldehyde (6 cc) to B5 cup (60 cc) immediately before adding tissue, this forms the working B5 solution.

2. Add tissue and fix in working B5 solution for approximately 2 hours. Be careful not to use or place any metal objects, needles, forceps, etc., in the B5 solution as this forms precipitates.

3. Tissue is submitted to the histology lab in B5 solution.
### 4.4 IMMUNOHISTOCHEMISTRY

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**Immunohistochemistry**

Immunoperoxidase stains are ordered electronically through CoPath (see CoPath Manual). Upon order receipt, immunohistochemistry personnel will generate blank procedure reports with appropriate antibodies and send these to the responsible pathologists work list for signout. Immunohistochemistry procedure reports usually specify positive, negative, or equivocal results with detailed interpretations in the Comment field of the main report.
4.5 IMMUNOFLUORESCENCE

Instructions for Biopsy submission for immunofluorescent processing

1. Place specimen on saline-moistened gauze or place in immunofluorescent media. Make sure the specimen has been double-bagged.

2. Label with patient’s first & last name, site & side of specimen and date of Must specify on requisition form, "FOR IMMUNOFLUORESCENCE" “DO NOT PLACE IN FORMALIN”, with clinical history.

3. Deliver immediately, to Surgical Pathology Suite in Bridge Bldg (3rd Floor). If no one is available to receive specimen, please page on-call pathology resident.
4.6 FIXATION FOR SPECIMENS THAT REQUIRE IHC TESTING

Fixation for Specimens That Require IHC Testing Including Breast Needle and Excisional Biopsies.

*The radiology department has been requested to write the time of the biopsy on the requisition slip.

1. When a time is written on the requisition you are to note that time at the end of your gross description, (e.g.) received in pathology, state time and date.

2. If no time is written on the requisition, please use the procedure time and date it was received in pathology, this can be found on the histology tab.

3. At RIH, core biopsies received before 3:00pm will be loaded on the biopsies machine, referred to as Eve. Cores received after 3:00pm will be loaded on the routine machine by the prosectors referred to as VIP (Daily except Friday)

4. Fridays, late biopsies will be loaded by the prosectors on the processor referred to as Eve

5. A time should also be recorded for all excisional breast biopsies. Please use the procedure time and date it was received. FOLLOWING THESE DIRECTIONS WILL ENSURE THE PROPER FIXATION TIME IN FORMALIN OF 6 HOUR MINIMUM AND 48 HOURS MAXIMUM.
Sectioning Prostate Needle Biopsies

1. After the initial trimming of the biopsy block the first section off the ribbon to be taken will be a blank on a blue slide. The first H&E level taken will be the next adjacent section after the blank. The next adjacent section after the first H&E level will be the second blank on a blue slide.

2. The next adjacent section after the second blank will be discarded. The next adjacent section after the discarded section will be the third blank section on a blue slide. The next adjacent section after the third blank section will be the second H&E level. The next adjacent section after the second H&E level will be the fourth blank section.

3. The next two adjacent sections after the fourth blank section will be discarded. The next adjacent section after the discarded sections will be the fifth blank section. The next adjacent section after the fifth blank section will be the third H&E level. The next adjacent section after the third H&E level will be the sixth blank section on a blue slide.

4. The blank slides will be stored for possible future IHC staining.
### 4.8 RIH INTRAOPERATIVE CONSULTATION AND FROZEN SECTION

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**INTRAOPERATIVE CONSULTATION AND FROZEN SECTION**

**A. Purpose and Availability**

1. Intraoperative consultations and frozen sections are intended to assist the surgeon in case management and to identify tissue which should be processed for special procedures (see Section VII below). A departmental call schedule for staff and residents on Surgical Pathology is distributed monthly. Frozen sections between 8:00 AM and 5:00 PM at RIH are the responsibility of the Staff Pathologist (and resident) on daily call. Late frozen sections (after 5:00 PM or before 8:00 AM at RIH) are the responsibility of the Staff Pathologist (and resident) on night/weekend call. There is an intercom system for communication between the operating rooms and the Bridge Building Surgical Suite at RIH and a phone can also be used to call individual ORs at RIH.

**B. Procedure**

1. OR will deliver the labeled specimen(s), Intraoperative Consultation/Frozen Section Request Form (see Specimen Rejection Policy) (also see page 36A) and a second loose label. The loose label should be initialed upon receipt, time stamped, write the letter of the specimen, and give the label back to OR Assistant. Time of specimen receipt should be recorded on the request form (time stamp machine), and case accessioned into CoPath.

2. The clinical question and/or issues which need to be addressed are first assessed by examination of the form and consultation with the surgeon if necessary.

3. The CoPath system should be checked for prior biopsy samples or cytological specimens, and representative slides should be available and reviewed, if needed, for interpretation of the frozen sections.

4. Slides should be labeled with case number (if the case has already been accessioned, the patient’s last name and first initial, the date of birth and with the number of frozen section (FS1, FS2, FS3, etc.).

5. After gross examination, touch preparations may be made and stained with H&E. Slides should be labeled in the same manner as a slide for a frozen section. Touch preparations are routinely requested by some surgeons for evaluation of sentinel lymph nodes in cases of breast carcinoma (see below).
6. For frozen section examination, tissue is frozen in a pellet of OCT compound on a "chuck", in a thermostatically regulated bath or in the freezing rack of the cryostat. (Some brain and spinal cord lesions may be frozen using liquid nitrogen.) Touch preparations can be prepared by touching a dry slide to blood free, freshly cut tissue surfaces and fixed immediately in 95% alcohol (for H&E stain) or air (for Diff-Quik stain). For tumors which may not shed cells easily, crush or scrape preparations should be made using a second glass slide to exfoliate cells or fine needle aspiration. When multiple chucks are in the cryostat at one time, the resident or PA should write the case number and frozen section number on the OCT pellet adherent to the chuck once the slides have been cut. Place the chuck in the originally labelled container or placed in a container labelled with a copath generated label in the cryostat.

7. Tissue sections are cut at 5-10 microns on a cryostat, fixed in alcohol or formalin and stained with hematoxylin and eosin. All jars should be labelled with the name of the reagent. Reagent labels should be clearly visible. Staining reagents are changed every Monday and alcohols and water are changed daily.

30 seconds 95% alcohol  
5 dips in water  
30 sec in hematoxylin  
5 dips in water  
10 dips in ammonia water  
5 dips in 50% ethanol  
5 dips in 95% ethanol  
5 dips in eosin  
5 dips in 95% ethanol  
5 dips in 100% ethanol  
5 dips in 100% ethanol  
5 dips in xylene

8. When multiple frozen section specimens on different patients arrive in the Surgical Pathology Suite at the same time, they are to be accessioned and processed in the order in which they are received. As each case is accessioned, the Intraoperative Consultation/Frozen Section Request Forms are to be placed on the counter along the back wall of the suite behind the multi-headed microscope. As the frozen section slides are completed, they are to be placed on a paper towel and left on top of the corresponding Intraoperative Consultation/Frozen Section Request Form. If the number of frozen sections received at one time is too great to allow for an acceptable turn-around time, the attending pathologist is to call an additional PA and if necessary a second attending pathologist for assistance. The attending pathologist MUST check the frozen section slides against the corresponding Intraoperative Consultation/Frozen Section Request Form to ensure that the correct patient's slides are being read.
9. Diagnoses are written on an Intraoperative Consultation/Frozen Section Request Form and are verbally relayed to the surgeon. In reporting a frozen section, the pathologist should indicate his/her name, the name of the patient, and the result of the frozen section examination. If the surgeon is unable to speak to the pathologist directly, the result may be given to the circulating nurse and the pathologist should ask the nurse or surgeon to repeat the diagnosis to ensure that the diagnosis has been transmitted accurately. Once the attending has rendered a diagnosis to the surgeon or circulating nurse, permanent slide labels, with the information previously hand-written on the slides, are to be affixed to the slides. The completed frozen section slides are to be immediately placed in a slide tray located on the counter towards the front of the suite away from the multi-headed microscope, in order to avoid the possibility of inadvertently reading slides from a previously completed case. At the end of each day, all completed frozen section slides are to be taken to the Pathology office on APC 12 by a laboratory clerk. Each morning, any completed frozen section slides from cases received after normal working hours are likewise to be taken to the Pathology office on APC 12 by a laboratory clerk. A copy of the frozen section form is filed in the frozen section/gross room.

10. Time of reporting of frozen section result must be recorded on frozen section form by the pathologist and recorded in the associated QA review (see QA Review).

11. Gross descriptions including how the specimen arrived (i.e. size and number of pieces, presence of localization wire, pins, etc.) and relevant clinical information is recorded on the Intraoperative Consultation/Frozen Section Request Form. All of these data should become part of the final report.

12. The frozen section residue is to be placed in a tissue cassette labelled with the appropriate accession number, 2D bar code, part type and frozen section designator. The frozen section residue is then submitted for permanent sections along with any additional sections submitted for permanents.

13. IOC and FS diagnoses are dictated under a separate heading specified as “IOC” or IOC with FS”. IOC with touch preps are designated as IOCs, not as IOCs with FS. Diagnoses are dictated as: “Site-dx by pathologist/resident initials” (e.g. Lymph node-metastatic carcinoma by JQP). Specify the FS by the relevant # if it is so designated and by the corresponding part designation (e.g. A, B, C, etc.).

14. All frozen section slides are to be delivered to the signout area in the histology lab. The slides will be added to the folder containing the permanent slides prior to delivery to the pathologist.

15. IRB approved protocols may use samples from operative specimens under the supervision of the pathologist, provided that the diagnosis is not compromised. If in doubt, keep tissue for diagnosis.

16. QA Diagnosis review must be performed on 100% of Frozen Sections by the primary pathologist assigned to the surgical pathology case (see QA section of manual)
4.9 TMH INTRAOPERATIVE CONSULTATION AND FROZEN SECTION

A. Purpose and Availability

1. Intraoperative consultations and frozen sections are intended to assist the surgeon in case management and to identify tissue which should be processed for special procedures (see Section VII below). A departmental call schedule for staff and residents on Surgical Pathology is distributed monthly. Frozen sections between 7:30 AM and 5 PM at TMH are the responsibility of the Staff Pathologist (and resident) on daily call. Late frozen sections (after 5:00 PM or before 7:30 AM at TMH) are the responsibility of the Staff Pathologist (and resident) on night/weekend call.

B. Procedure

1. OR will deliver the labeled specimen(s), Intraoperative Consultation/Frozen Section Request Form (see Specimen Rejection Policy) and a second loose label. The loose label should be initialed upon receipt, time stamped, write the letter of the specimen, and give the label back to OR Assistant. Time of specimen receipt should be recorded on the request form (time stamp machine), and case accessioned into CoPath.

2. The clinical question and/or issues which need to be addressed are first assessed by examination of the form and consultation with the surgeon if necessary.

3. The CoPath system should be checked for prior biopsy samples or cytological specimens, and representative slides should be available and reviewed, if needed, for interpretation of the frozen sections.

4. Slides should be labeled with case number (if the case has already been accessioned, the patient’s last name and first initial, the date of birth and with the number of frozen section (FS1, FS2, FS3, etc.).

5. After gross examination, touch preparations may be made and stained with H&E. Slides should be labeled in the same manner as a slide for a frozen section. Touch preparations are routinely requested by some surgeons for evaluation of sentinel lymph nodes in cases of breast carcinoma (see below).
6. For frozen section examination, tissue is frozen in a pellet of OCT compound on a "chuck", in a thermostatically regulated bath or in the freezing rack of the cryostat. (Some brain and spinal cord lesions may be frozen using liquid nitrogen.) Touch preparations can be prepared by touching a dry slide to blood free, freshly cut tissue surfaces and fixed immediately in 95% alcohol (for H&E stain) or air (for Diff-Quik stain). For tumors which may not shed cells easily, crush or scrape preparations should be made using a second glass slide to exfoliate cells or fine needle aspiration. When multiple chucks are in the cryostat at one time, the resident or PA should write the case number and frozen section number on the OCT pellet adherent to the chuck once the slides have been cut. Place the chuck in the originally labelled container or placed in a container labelled with a copath generate label in the cryostat.

7. Tissue sections are cut at 5-10 microns on a cryostat, fixed in alcohol or formalin and stained with hematoxylin and eosin. All jars should be labelled with the name of the reagent. Reagent labels should be clearly visible. Staining reagent are changed every Monday and changed during the week as necessary.

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   5 dips in water
   30 sec in hematoxylin
   5 dips in water
   10 dips in ammonia water
   5 dips in 50% ethanol
   5 dips in 95% ethanol
   5 dips in eosin
   5 dips in 95% ethanol
   5 dips in 100% ethanol
   5 dips in 100% ethanol
   5 dips in xylene

8. When multiple frozen section specimens on different patients arrive in the Surgical Pathology Suite at the same time, they are to be accessioned and processed in the order in which they are received. As each case is accessioned, the Intraoperative Consultation/Frozen Section Request Forms are to be placed on the counter along the back wall of the suite behind the multi-headed microscope. As the frozen section slides are completed, they are to be placed on a paper towel and left on top of the corresponding Intraoperative Consultation/Frozen Section Request Form. If the number of frozen sections received at one time is too great to allow for an acceptable turn-around time, the attending pathologist is to call an additional PA and if necessary a second attending pathologist for assistance. The attending pathologist MUST check the frozen section slides against the corresponding Intraoperative Consultation/Frozen Section Request Form to ensure that the correct patient's slides are being read.
9. Diagnoses are written on an Intraoperative Consultation/Frozen Section Request Form and are verbally relayed to the surgeon. In reporting a frozen section, the pathologist should indicate his/her name, the name of the patient, and the result of the frozen section examination. If the surgeon is unable to speak to the pathologist directly, the result may be given to the circulating nurse and the pathologist should ask the nurse or surgeon to repeat the diagnosis to ensure that the diagnosis has been transmitted accurately. Once the attending has rendered a diagnosis to the surgeon or circulating nurse, permanent slide labels, with the information previously hand-written on the slides, are to be affixed to the slides.

10. Time of reporting of frozen section result must be recorded on frozen section form by the pathologist and recorded in the associated QA review (see QA Review).

11. Gross descriptions including how the specimen arrived (i.e. size and number of pieces, presence of localization wire, pins, etc.) and relevant clinical information is recorded on the Intraoperative Consultation/Frozen Section Request Form. All of these data should become part of the final report.

12. The frozen section residue is to be placed in a tissue cassette labelled with the appropriate accession number, 2D bar code, part type and frozen section designator. The frozen section residue is then submitted for permanent sections along with any additional sections submitted for permanents.

13. IOC and FS diagnoses are dictated under a separate heading specified as “IOC” or IOC with FS”. IOC with touch preps are designated as IOCs, not as IOCs with FS. Diagnoses are dictated as: “Site-dx by pathologist/resident initials” (e.g. Lymph node-metastatic carcinoma by JQP). Specify the FS by the relevant # if it is so designated and by the corresponding part designation (e.g. A, B, C, etc.).

14. All frozen section slides will remain in the cutting room. The pathologist signing out the case will request delivery off the slides to their office to be reviewed with the permanent slides.

15. IRB approved protocols may use samples from operative specimens under the supervision of the pathologist, provided that the diagnosis is not compromised. If in doubt, keep tissue for diagnosis.

16. QA Diagnosis review must be performed on 100% of Frozen Sections by the primary pathologist assigned to the surgical pathology case (see QA section of manual)
### 4.10 RUSH BIOPSY SPECIMENS

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Rush Biopsy Specimens

It is the policy of the Pathology Department at RIH/TMH to expedite the interpretation of surgical pathology specimens as rapidly as possible. Excluding weekends the typical turnaround time of over 90% of small biopsy specimens is 24 hours from specimen accession in the pathology suite to the issuing of a final diagnosis. This includes overnight processing of the specimen, sectioning, staining and interpretation by a pathologist. The minority of cases which require special histochemical, immunohistochemical and molecular testing or interdepartmental consultation will usually be signed out within an additional 2-4 days.

We are well aware of the fact that for certain specimens a more expedited processing and interpretation may be required. Examples of such situations would include; mediastinal mass in a patient with SVC, infection in an immunocompromised host, vertebral collapse due to a mass lesion etc. If there is a clinical indication to expedite the processing and reading of a biopsy specimen please specify such on the requisition form. If the biopsy is performed on Friday or over the weekend, page the pathology resident on-call. Please discuss with the on-call resident when and where the biopsy will take place and clarify how the specimen will be transported to the Pathology Department and the name and contact information of the physician to whom the results should be communicated.
JOINT REPLACEMENT FROZEN SECTION PROTOCOL

Pathologists

1. Scan section at low power
2. Count at least 10HPF at 40X
3. Do not count PMN’s in fibrin or within vessels
4. A positive for increased PMN’s is 5 or more PMN’s per each HPF in 5 or more HPF
5. If frozen section is negative but permanent is positive (or vise versa) please call surgeon
Result Reporting

A. The working draft will include the results of prior cytology and surgical pathology reports. These materials should be reviewed as appropriate together with current surgical biopsies or resection specimens. The accession numbers of these cases should be referenced in the final report, if relevant to the diagnosis. If concurrent cytological specimens are available, reference to these cases should be made in the ‘Comment’ section.

B. All diagnoses are in the format:

Anatomic site, procedure:
- Diagnosis

C. The diagnosis uses sentence style capitalization and is in 10 point Arial. The diagnosis is separated from the site and procedure by a line break, a tab, and a hyphen mark as follows:

Appendix, excision:
- Carcinoid tumor, margin free, see Comment
  - Acute appendicitis

Diagnoses should be concise, additional important information should be included under the diagnosis Comment Section (e.g. An incidental carcinoid tumor is present measuring 0.2 cm in maximal diameter. No vascular invasion is identified. No lymph nodes are identified.). This includes additional descriptive information and patient management recommendations and information about continuing case work up. Special procedures should be reported under the Procedure/Addendum Section (see above). The Microscopic Description Section should only be used under unusual circumstances since it is not visible in working draft mode for prior cases.

C. Amendments are used to correct demographic information and/or diagnostic information. The comment section of the amendment must clearly identify the nature of all changes to
the report (e.g. for changing the diagnosis from “Malignant tumor” to “Malignant melanoma” after immunohistochemistry results are available, the comment would read “Immunohistochemistry permits a more specific diagnosis”). PRIOR TO MAKING ANY AMENDMENT TO ANY CASE – A COPY OF THE ENTIRE REPORT MUST BE PRINTED AND GIVEN TO THE LEAD SECRETARY FOR FILING IN THE AMENDED CASE BINDER. THIS REPORT WILL SERVE AS A PERMANENT COPY OF THE REPORT AS IT APPEARED PRIOR TO AMENDMENT AS IT WILL NO LONGER BE AVAILABLE ON THE SYSTEM.

D. Any discrepancies between the results of frozen permanent sections should be addressed in the ‘Comment’ field.

F. An Addendum is used to add information regarding special studies or outside consultations. If the information generated in this addendum changes the diagnosis then an amendment is also made. If there is a discrepancy in the results between the special studies and the surgical pathology report the two pathologists involved and the department chair will review the case and come to a consensus about the diagnosis.

G. Reporting of immunohistochemical studies to provide diagnostic predictive information independent of other histopathologic findings (e.g. hormone receptor in breast carcinoma, HER2 and EGFR) should include the following information.
   a. The type of specimen fixation and processing
   b. The antibody clone and general form of the detection system used
   c. Criteria used to determine a positive vs. negative result, and/or scoring system
5.1 REPORT DISTRIBUTION

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Report Distribution

1. Physicians Copies are automatically generated with address pages and should be stuffed in envelopes and mailed the same day. Hospital physicians should be separated from outside physicians and enveloped placed in a separate pile for in house mailing rather than stamped mailing.

2. Medical Records Copies are automatically generated and printed directly in Medical Records for placement in the charts and distribution to the Cancer Registry for Staging forms.

3. Departmental Copies are no longer maintained. Electronic signature of all reports has made this unnecessary. All reports are available on the CoPath system. In addition reports are available in Medical Records and the Physicians Office. Reports that are to be amended will be printed prior to amendment and will be maintained in the department in a binder marked “Amended Reports”. An additional binder marked “External Reports” will be maintained for copies of outside reports related to our Surgicals, Cytologies and Autopsies.

4. Physicians who have requested all reports to be faxed receive these automatically in addition to the hard copy that is mailed. In some instances the hard copy is omitted (upon request by the physician).
Communication and Documentation of New Malignancies in Surgical Pathology

1. Principle

All diagnoses of new malignancies rendered by surgical pathology will be communicated directly to the submitting physician.

2. Background

In order to verify that all diagnoses of new malignancies are received by the submitting physician, in addition to hard copies and faxed reports, the clinician will be directly contacted by the pathologist responsible for the case. This does not apply to basal and squamous cell carcinomas of the skin. Ductal carcinoma in-situ of the breast as well as high grade dysplasias of the gastrointestinal tract are to be considered in the category of new malignancies.

3. Policy

When a new diagnosis of malignancy is rendered it is the responsibility of the staff pathologist issuing the diagnosis to promptly contact the submitting physician whose name appears on the pathology requisition form (or within the CoPath or LifeLinks system). A fellow or resident may also contact the submitting physician under the direction of the staff pathologist signing out the report. Direct communication of these results by telephone, pager or in-person is required. If the submitting physician is not reachable after reasonable efforts are made to contact him/her, the results may be reported to a physician assistant, personal secretary or nurse. It should be made clear to the person receiving the message that the findings are to be relayed to the submitting physician. The name of the person receiving this message should be recorded. There should be documentation of date and time of such special notification (to be included in the pathology report). If the submitting physician is not reachable after reasonable efforts are made to contact him/her, the results will be sent to the physician by registered mail and a confirmation of receipt of this letter will be maintained in the Department of Pathology.
5.3 Communication and Documentation of Significant or Unexpected Surgical Pathology Findings

Communication and Documentation of “Significant” or “Unexpected” Surgical Pathology Findings.

1. Principle
   All clinically significant or unexpected surgical pathology findings will be communicated directly to the submitting physician.

2. Background
   Certain surgical pathology diagnoses may be considered particularly significant or unexpected. Such diagnoses may include: malignancy in an uncommon location or specimen type (e.g., hernia sac, intervertebral disk material, tonsil, etc.), absence of chorionic villi when clinically expected (potential ectopic pregnancy), change of a frozen section diagnosis after review of permanent sections, temporal artery biopsies (positive or negative) and/or mycobacterial, fungal or other significant infectious organisms identified on special stains. Also included in this category would be the diagnosis of an unsuspected malignancy such as gastric cancer in an endoscopically normal appearing gastric biopsy, gallbladder cancer in a routine cholecystectomy etc.

3. Policy
   When a significant or unexpected diagnosis is rendered it is the responsibility of the staff pathologist issuing the diagnosis to promptly contact the submitting physician whose name appears on the pathology requisition form (or within the CoPath or LifeLinks system). A fellow or resident may also contact the submitting physician under the responsibility of the staff pathologist signing out the report. Direct communication of these results by telephone, pager or in-person is required. If the submitting physician is not reachable after reasonable efforts are made to contact him/her, the results may be reported to a physician assistant, personal secretary or nurse. It should be made clear to the person receiving the message that the findings are to be relayed to the submitting physician. The name of the person receiving this message should be recorded. There should be documentation of date and time of such special notification (to be included in the pathology report).
5.4 REQUESTS FOR SLIDES/REPORTS

Request for Slides/Reports

Clinician/Patient Inquiries

Determine who inquirer is. Only a clinician (with Lifespan privileges) or their designee can obtain information regarding a case, unless they state they are treating the patient. If clinician is a relation of the patient and is not the clinician of record, information cannot be released. Patients should always be referred to their surgeon/clinician.

Never offer information that is not pertinent to the case. Never give information on a case that is not signed out- if a clinician needs information on an unsigned case, refer him/her to appropriate pathologist. Always let pathologist know what inquiry is about before sending someone or transferring a call. Ask pathologist if slides and a copy of report are needed for review. All inquiries are handled promptly and courteously. No client should leave the Department or phone without appropriate information or referral to appropriate place.

N.B. If case has not been signed out, information that may be released to inquirer includes:
Whether case has been accessioned/date.
Pathologist assigned to the case.
Approximate expected date of completion (if able to determine).
If the inquirer asks to speak to a pathologist-relay necessary information regarding case to the pathologist and refer inquirer appropriately.

1. Phone Calls

Phone inquiries from the Attendings, Medical Staff, Pathologists, Histology and patients are handled by the Secretaries. Complete information (fax slips, or telephone message pads) is necessary. If uncertain of the spelling of a name, please ask for it. Using the Inquiry Feature (page 13) determine status of the case requested. If case is signed out, caller faxed no verbal reports may have report.

2. In Person Inquiries

In person inquiries from Attendings, Medical Staff, Pathologists, Histology, and patients are handled by Secretary referring those cases you are unable to handle to Supervisor. Clinician requesting information must have full name of patient and either date of procedure or date of birth of the patient. Clinicians are not allowed to review screen until it has been determined that the case is signed out. Once it is determined that the case has been signed out, print out report for them.
5.5 FAXING TO CLINICIANS OFFICES

Faxing to Clinicians Offices

On Request:

When a clinician’s office requests a diagnosis via telephone, the report is faxed to the office. This enables the clinician to have the entire written report rather than a portion of it and avoid a possible miscommunication of the report via phone. Reports are faxed on requested "signed out" reports throughout the day by Secretaries as soon as request is made.

When clinician's office phones for diagnosis and FAX is to be sent, the following questions are to be asked and completed on a FAX transmittal memo:

- Clinician’s Name, FAX number, office number, person calling
- Patient’s full name and DOB
- Type of specimen and date of procedure

Secretary will then use the Inquiry feature to check the status of the report. If report is signed out, let the caller know the report will be FAXed.

Automatic Scheduled Faxing:

In addition to individual requests for faxing of reports – the majority of physicians have automatic faxing of all their reports on a schedule (5 times a day) throughout the day (see individual physician’s address in CoPath and Report Chute Manager for listings). Following signout of the report the report is automatically added to various distribution batches including a hard copy to physician and a fax batch. Some physicians when set to receive autofaxing have requested hard copies be omitted.
5.6 SLIDE SEND OUTS/RETURN

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Slide Send Outs/Returns

Secretaries will take appropriate information over the phone or in person and prepare materials for send out/return. All requests must be handled in a timely manner (no more than 2 work days). Unusual requests, problems, or complaints are to be brought to the Lead Secretary or Manager’s attention immediately.

Send Outs

When a request for slide(s) or block(s) for send out is received by the Surgical Pathology Office, secretaries complete a Lifespan AMC – Requisition for Anatomic Pathology Material, print the final report and pull the slides or block. Secretaries request that a pathologist review slides as well as report prior to send out. All Surgical Pathology slides and blocks requested by clinicians/patients for second (outside) opinions must be reviewed by a pathologist who was not responsible for the initial diagnosis. Each case is reviewed with respect to the parameters listed below. The data derived from this analysis are to be entered into the COPATH QA Diagnosis Review Module by the reviewing pathologist. Any discrepancies are to be brought to the attention of the signout pathologist and to the Pathologist-in-Chief by the reviewing pathologist. Amended reports are prepared prior to case sendout. If differences in opinion cannot be reconciled, the case may be sent to an additional pathologist/consultant for his/her opinion. When slides have been returned to secretaries by pathologist, secretaries are to check the QA Diagnosis Review field to assure it has been entered in CoPath. If it is not entered and info is written on External Consult Log Form secretaries will enter it and place a check mark next to the written QA. If already entered again a check mark is placed next to the written QA on the form. If not on the form – return everything to the pathologist for QA information. Secretaries enter Slide Send Out in CoPath (completing all fields). Print letter to requestor (automatically generated by CoPath), package materials requested, our final report, and send by UPS or courier.

If a request is received for blocks, and the slides are either already out or requested as well, ask “is this for patient treatment/therapy?” If the request is for patient therapy/treatment, notify Histology Manager and release the blocks. If not for patient therapy/treatment, blocks are generally not sent out at the same time as slides, in order to preserve materials for that case. However, always check with Manager for direction in this matter.

Tissue prosthesis requested by the surgeon or patient is handled in same manner as slides. However, reports are not given to the patient with the specimen. When specimen/prosthesis is given to clinician or patient, fixative is removed. A “Material Release” form is given to the patient (or clinician) to be signed prior to the release of the
specimen. Tissue/jars are maintained for three weeks following signout; however check to see if the material requested is still available. If it has not been three weeks since signout inform the diener to retain the specimen and notify you when it is available for sendout.

Returns

In cases where an extradepartmental consultation is sought or cases reviewed extradepartmentally for any reason, the consultant’s opinion is reviewed by the responsible attending pathologist. All materials should be returned to the Surgical Pathology Office who will check the materials back into CoPath in the Slide Send Out module (Return Complete). A copy of the original report and the consult report will be given to the pathologist for review. Pathologist must write an addendum with either a concurrence of his/her diagnosis or a statement that the second opinion disagreed (in which case a third pathologist from our institution should be consulted). In addition, QA Diagnosis Review – Slides Returned must be completed by pathologist. The consultant’s report is then returned to the Surgical Pathology Office to be filed in a binder labeled “Outside Consults”.
5.7 SLIDES/BLOCKS NOT RETURNED

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Slides/Blocks Not Returned

1. Policy

   a. CoPath is set to automatically generate a monthly letter to all institutions/physicians who have not returned slides and blocks within 30 days of sendout (excluding legal cases and those sent to Protocol Office).

   b. After 90 days with no response or return of slides/blocks (note date of slide sendout on the letters generated each month) from the institution/person listed on the slide send out letter:

      1) Check the department’s slide file to assure that slides have not been returned. If blocks were sent – check with Histology to assure they did not receive the material directly.

      2) If slides/blocks were returned change status in CoPath – Slide Send Out field.

      3) If slides/blocks have not been returned, compile a list with the patient’s name, DOB and the MS/RS, MH/RH case number.

      4) Call the phone number listed in Slide Sendout of the institution that the materials were sent to and remind them to return slides/blocks. Ask for their fax number and fax the list of overdue materials.

   c. If institution indicates that slides/blocks were returned ask the method of transportation (if appropriate get a tracking number and followup).

   d. If slides/blocks are still at the institution ask for them to be returned.

   e. If slides are deemed "lost" order recuts for our files.
### 5.7 Slides/Blocks Not Returned

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   4) Call the phone number listed in Slide Sendout of the institution that the materials were sent to and remind them to return slides/blocks. Ask for their fax number and fax the list of overdue materials.

   If institution indicates that slides/blocks were returned ask the method of transportation (if appropriate get a tracking number and followup).

   If slides/blocks are still at the institution ask for them to be returned.

   If slides are deemed “lost” order recuts for our files.
**LIFESPAN AMC – REQUISITION FOR ANATOMIC PATHOLOGY MATERIAL**

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<td>Request taken by:</td>
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<tr>
<td>Patient Name:</td>
<td>__________________________________________________________________</td>
<td></td>
</tr>
<tr>
<td>DOB:</td>
<td>__________</td>
<td>MRN(s)</td>
</tr>
<tr>
<td>Specimen Type(s):</td>
<td>___________________________________________________________</td>
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</tr>
<tr>
<td>Accession No(s):</td>
<td>___________________________________________________________</td>
<td></td>
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<tr>
<td>Requested by:</td>
<td>___________________________________________________________</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>Affiliation</td>
<td>Phone no.</td>
</tr>
</tbody>
</table>

**Case Material Sent to:**

| Physician/Other: | ___________________________________________________________ |
| Institution/Address: | ________________________________________________________ |
| Telephone No.: | _________________________________ |

Reason for Sending Materials (Please circle/write in): *(All Legal Cases to be referred to Lead Secretary)*

| Patient Therapy | __________ | 2nd Opinion | __________ | Other: | __________ |

If slides are out, blocks can only be sent if for patient therapy (see Lead Secretary).

**Materials Reviewed by Pathologist:**

| Initials: | __________ | Date: | ________________ |
| QA Result: | ________________ |
| QA Comment (if any): | ________________ |

**Materials Sent**

| Slide(s): | ___________________________________________________________ |
| Block(s): | ___________________________________________________________ |
| Report(s): | ___________________________________________________________ |

Date Sent/Picked Up: ________________ Means of Transportation: __________________________

Printed Name and Signature of Courier/Patient/Phys. Office Picking up Materials:

(If picked up – ID required) __________________________________________________________________
5/23/2014

Dear Sir/Madam:

This letter is a follow-up to reminders that we are requesting the return of our department's surgical pathology slides. It has been longer than 90 days since we sent our patient ________________________ slides/blocks labeled ________________________ to your institution.

We have not yet received those slides/blocks and would like to ask if you would check your files one last time. If the materials were sent to another institution or to the patient please contact a secretary in our department at 401-793-4245 to give us additional information.

Thank you for your cooperation in helping to maintain our patient's materials.

Sincerely,

Lifespan Academic Medical Center
Department of Pathology
### 5.9 SYNOPTIC WORKSHEETS

<p>| LIF AMPULLA OF VATER: Ampullectomy, Pancreaticoduodenectomy (Whipple Resection) | -2011 |
| LIF ANUS: Abdominoperineal Resection | -2011 |
| LIF APPENDIX: Resection (Appendectomy w/wo Right Hemicolectomy) | -2011 |
| LIF BREAST: Ductal Carcinoma In Situ (DCIS), Complete Excision and Mastectomy | -2010 |
| LIF BREAST: Invasive Carcinoma (Complete Excision and Mastectomy) | -2011 |
| LIF COLON AND RECTUM NET: Resection, Including Transanal Disk Excision of Rectal Neoplasms | -2011 |
| LIF COLON AND RECTUM: Excisional Biopsy (Polypectomy) | -2011 |
| LIF COLON AND RECTUM: Resection, Including Transanal Disk Excision of Rectal Neoplasms | -2011 |
| LIF DISTAL EXTRAHEPATIC BILE DUCTS: Local or Segmental Resection, Pancreaticoduodenectomy | -2011 |
| LIF ENDOMETRIUM: Hysterectomy, With/Without Other Organs/Tissues | 2011 |
| LIF ESOPHAGUS: Endoscopic Resection, Esophagectomy, or Esophagogastronomy | 2011 |
| LIF FALLOPIAN TUBE: Unilateral Salpingectomy, Salpingo-ooophorectomy, Hysterec w/ Salpingo-oop | 2011 |
| LIF GALLBLADDER: Resection/Cholecystectomy | -2011 |
| LIF GASTROINTESTINAL STROMAL TUMOR (GIST): Resection | -2011 |
| LIF HEPATOBLASTOMA (PEDIATRIC LIVER): Resection | 2011 |
| LIF HEPATOCELLULAR CARCINOMA: Hepatic Resection | -2011 |
| LIF INTRAHEPATIC BILE DUCTS: Resection | 2011 |
| LIF KIDNEY: Biopsy | 2011 |
| LIF KIDNEY: Nephrectomy, Partial or Radical | -2011 |
| LIF KIDNEY: Resection for Pediatric Renal Tumor | -2011 |
| LIF LARYNX (SUPRAGLOTTIS, GLOTTIS, SUBGLOTTIS): Incisional Biopsy, Excisional Biop, Res | -2011 |
| LIF LIP AND ORAL CAVITY: Incisional Biopsy, Excisional Biopsy, Resection | -2011 |
| LIF LUNG: Resection | -2011 |
| LIF MELANOMA OF THE SKIN: Biopsy, Excision, Re-Excision | 2011 |
| LIF NASAL CAVITY AND PARANASAL SINUSES: Incisional Biopsy, Excisional Biopsy, Resection | 2011 |
| LIF OVARY: Oophorectomy, Salpingo-ooophorectomy, Subtotal Oophorectomy | -2011 |
| LIF PANCREAS (ENDOCRINE): Resection | -2011 |
| LIF PANCREAS (EXOCRINE): Resection | -2011 |
| LIF PERIHILAR BILE DUCTS: Local or Segmental, Hilar Resection with or w/o Hepatic Resection | 2011 |
| LIF PHARYNX (OROPHARYNX, HYPOPHARYNX, NASOPHARYNX): Inc Biopsy, Excisional Biopsy, Resection | -2010 |
| LIF PROSTATE GLAND: Needle Biopsy | 2011 |
| LIF PROSTATE GLAND: Radical Prostatectomy | -2011v1 |
| LIF PROSTATE GLAND: TUR, Enucleation Specimen | -2011 |
| LIF RENAL PELVIS: Resection/Nephroureterectomy, Partial or Complete | -2011 |
| LIF SALIVARY MAJOR GLANDS: Resection | -2011 |</p>
<table>
<thead>
<tr>
<th>Organ</th>
<th>Procedures</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small Intestine and Ampulla Net</td>
<td>Segmental Resection, Ampullectomy, Pancreaticoduodenectomy</td>
<td>2011</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>Segmental Resection, Pancreaticoduodenectomy (Whipple Resection)</td>
<td>2011</td>
</tr>
<tr>
<td>Squamous Cell Carcinoma of the Skin</td>
<td>Biopsy, Excision, Re-excision, Lymphadenectomy</td>
<td>2011</td>
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<td>Stomach</td>
<td>Local Resection, Gastrectomy</td>
<td>2011</td>
</tr>
<tr>
<td>Testis</td>
<td>Radical Orchiectomy</td>
<td>2011</td>
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<tr>
<td>Testis</td>
<td>Retroperitoneal Lymphadenectomy</td>
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<tr>
<td>Thyroid</td>
<td>Resection</td>
<td>2011</td>
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<td>Ureter, Renal Pelvis</td>
<td>Biopsy</td>
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<tr>
<td>Ureter</td>
<td>Resection</td>
<td>2011</td>
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<tr>
<td>Urinary Bladder</td>
<td>Biopsy and Transurethral Resection of Bladder Tumor (TURBT)</td>
<td>2010</td>
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<tr>
<td>Urinary Bladder</td>
<td>Cystectomy, Part, Total or Rad, Anterior Exenteration</td>
<td>2011</td>
</tr>
<tr>
<td>Uterine Cervix</td>
<td>Excision (Cone/LEEP)</td>
<td>2011</td>
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<tr>
<td>Uterine Cervix</td>
<td>Trachelectomy, Hysterectomy, Pelvic Exenteration</td>
<td>2011</td>
</tr>
<tr>
<td>Vulva</td>
<td>Excisional Biopsy/Resection</td>
<td>2011</td>
</tr>
</tbody>
</table>
A. Principle:

Special requests are performed on certain types of tissue in the laboratory. Special stains are performed by individual technicians on a rotating schedule. Basic procedures must be followed by each tech to ensure uniform results.

B. Preorder:

Standard special requests are performed on the following tissue

Kidney needle biopsy: Embedded by the tech responsible for cutting the biopsy
15 consecutive sections are cut on transplant biopsies*
30 consecutive sections are cut on all others*

*(Technique note: Face block until tissue is exposed – take section and check microscopically for glomeruli. If OK, continue cutting. If no glomeruli, try second block if available.)

H&E x 4 on appropriately spaced sections (e.g., 1st, 5th, 10th, 15th)
PAS x 4
Trichrome Green
Jones’ Methenamine Silver

Kidney wedge biopsy: H&E x 2
PAS
Trichrome Green

Liver biopsy: H&E
Reticulum
Trichrome Blue
Iron

Bone Marrow and biopsy: H&E x 1

Prostate biopsy: Levels x 3
Breast biopsy: Levels x 4

Stomach biopsy: Helico

Sentinel nodes for melanoma: H&E, levels x 5, Blanks x 10 on Plus slides. 25-30 microns between each level/blank. Take 2 blanks between each H&E, preferably from the same ribbon.

Sentinel nodes other than melanoma: H&E, levels x 5, 25-30 microns between each slide.

**Urate Crystals:** Specimens which are suspicious for uric acid crystals (gout) must not be placed in any aqueous solutions such as formalin. This dissolves the crystals. The submitting physician must place the specimen in 100% ETOH or, if received fresh, the PA must place the specimen in ETOH. The specimen is then brought to the Main Histology Lab where it is hand processed using the following procedure:

- 100% ETOH – at least 1 hour
- Xylene – 2 changes, 1 hour each
- Paraffin – 2 changes, 1 hour each

**Special stain requests:** All special stains will be placed on Poly-L-Lysine coated slides to prevent the tissue from falling off. The special stain log will be generated at 5:30 and 10:00 am each day and these requests will also be cut by the special stain tech. All handwritten requests placed in the wall folder by 10 am will be completed the same day. Any requests which come into the lab after 10 am will be considered on an individual basis and completed as quickly as possible.

**Preparing Poly-L-Lysine Slides:** Poly-L-Lysine which is commercially available, is order from Sigma, #P-89206. Store the solution in refrigerator. Fill large staining racks with clean, yellow, dry slides. Dilute Poly-L-Lysine solution 1:10 with distilled water. Immerse slides in room temperature diluted Poly-L-Lysine until coated. Dry the slides in the oven. Store slides at room temperature. Do not exceed 900 slides per batch. This diluted solution is stable for 3 months. Do not mix old and new solutions of diluted Poly-L-Lysine.

**Special stain delivery:** Deliver special stains to the ordering pathologists as soon as the stains on an entire case are completed.
6.1 PROCEDURE FOR DECALCIFICATION

A. Principle:

In order to obtain satisfactory microscopic slides, tissue containing calcium must be chemically treated before processing.

B. Procedure:

1. When cassettes are received from the prosector in the suite, the frozen section tech will fill out a decal sheet (including surgical number, number of cassettes, block designations and date received) and place all green (RIH) cassettes in a separate formalin container.

2. The frozen section tech will bring these cassettes and the decal sheet up to the main lab (APC 12). Transfer the cassettes to the container containing decal solution under the hood in the special stain room. Place the decal sheet next to this container. The special stain tech will follow the same procedure for aqua (TMH) cassettes.

3. The decal tech will transfer all information from the decal sheet to the decal log book daily. In addition, date in and out of decal will also be recorded. The decal tech will check the tissue in each cassette daily until the tissue is suitable for cutting by feel. This requires judgement gained through experience. The decal tech will wash the cassettes in running water for 15 minutes and place them in formalin. The decal tech will place them on the processor for loading with the routine work.

4. The following working day, once the decals have been signed-out, the sign-out tech will complete the information in the decal log book – date signed out and the pathologist the case was assigned to. Billing for decals will be recorded in the log book.
All renal biopsies, including transplant biopsies, will be sent to Dr. Stillman at the Beth Israel Hospital for processing. All kidney biopsies from the Miriam Hospital will be accessioned there. The specimens will be sent to RIH on saline soaked gauze, along with a copy of the requisition and a send out form, via a stat courier run. The RIH and TMH biopsies will be processed at RIH as follows:

**Accessioners:**
- a) Accession specimen using party type Kidney Bx./Send Out (Abbr. KB)
- b) Assign case to Dr. Murray Resnick
- c) Complete send out form
- d) Give specimen, requisition and send out form, along with send out kit (kit prepared and stored in the specimen refrigerator) to prosector.

**Prosectors:**
- a) The prosector will examine the cores microscopically to determine which cores contain the greatest number of glomeruli. The core with the greatest number will be placed in the formalin container, included in the kit, for light microscopy. The core with the second greatest number of glomeruli will be placed in Michel's medium for immuno, and the third core will be placed in Gluteraldehyde for EM. The prosector will ensure that all containers are labeled with the patient’s name, DOB and case number.
- b) Go to the Histology Data/Entry screen, (do not put blocks in CoPath), go to the Text tab and click on Gross Description and then Edit Text. On the toolbar, there will be an image of a running man. Click on this icon, and when the window opens, in the search field type in KSOB, hit Search and then OK. The template for the kidney gross description will drop in and you need only to fill in the measurements.
- c) The prosector will then package the specimens. All 3 containers will be placed in the Biohazard bag, which is included in the kit, and seal the bag. A copy of the working draft, including the gross description, will be printed by the prosector. This, along with a copy of the requisition and the send out form, will
be placed in the outside pocket of the bag. If needed, paper towels should be placed in the box to prevent shifting. Containers are leak proof, but only if the caps are put back on securely.

d) The prosector will bring the kit to the Surgical Pathology Office, M-F up till 3:00 PM. If after office hours, the specimen will be refrigerated in the Suite until the next working day.

e) The exception to the above procedure includes those renal biopsies labeled as "RUSH" by the nephrologist. The vast majority of these will be transplant biopsies. For rush cases, the prosector will order a biopsy block in CoPath and run the protocol for "Rush Kidney Biopsy". Two H&E's, two PAS's and six unstained slides will be automatically generated. The core selected for light microscopy will be submitted in this block. If the specimens are received in the Suite in the AM, (by 11:00), they will be processed rapidly so that the initial slides can be reviewed that afternoon. If they are received after 11:00 AM, they will be processed overnight, and the slides will be reviewed the following morning. If the specimen arrives Friday PM, the on-call pathologist should contact the nephrologist. If the nephrologist is willing to delay review until Monday AM, the case should be processed accordingly. If the nephrologist requests a Friday PM or Saturday AM review, the on-call pathologist should contact the lab for processing and coordinate with the nephrologist when the case will be reviewed. For the cases that arrive during the week, Dr. Resnick is to be notified by Histology when the slides are ready for review. If Dr. Resnick is unavailable, Dr. Mangray should be notified. If neither Dr. Resnick nor Dr. Mangray is available, the responsibility then goes to the RIH pathologist who is reading biopsies that day. For weekend cases, the on-call pathologist will be notified. In all cases, the slides will be reviewed with the nephrologists. Once the case has been reviewed, the all of the slides and the paraffin block will be sent to Dr. Stillman at the BI, along with the IF and EM tissue that will be stored in the specimen refrigerator in the Surgical Suite.

Surgical Pathology Office

a) The office will log on to the UPS web site, and using the Beth Israel's UPS account number, will order a pick-up of the specimen. A secretary will then deliver the specimen to the UPS box in the mailroom.

b) Secretaries will enter the case in Slide Send Out with full information about what is being sent and where.

c) When the completed surgical report is faxed from the Beth Israel to Pathology at RIH, the secretaries will fax the report to the submitting and additional physicians and then type the full report into the CoPath case and under the Final Diagnosis text. Use Quick Text "KTBI" which will read "This diagnosis
was performed by Dr. Isaac Stillman, Beth Israel Deaconess Hospital (case # ).
Original report faxed to submitting and additional physicians and scanned into CoPath.∗ The report will be added to Dr. Resnick’s worklist.
d) A copy of the Beth Israel report is to be given to Rose Tavares.
Secretaries to enter transaction into slide send out and scan this form into CoPath record

Date: ___________

RENTAL PATHOLOGY SEND OUT FORM

To: Isaac E. Stillman, M.D. From: Murray B. Resnick, M.D., Ph. D.
Department of Pathology Lifespan c/o Rhode Island Hospital
BIDMC East Campus 1st Flr. Pathology 593 Eddy Street, APC12-110
330 Brookline Avenue Providence, RI 02903
Boston, MA 02215

Phone: 617-667-5959 Phone: 401-444-4380
Lab Phone: 617-667-4335 or 4344 Lab: 401-444-6391 (Lois DeCosta)

VIA: SAL COURIER – SAME DAY DELIVERY

BRING COMPLETED FORM AND BOX WITH SPECIMENS TO APC11 SPECIMEN SENDOUT

NEPHROLOGIST TO CONTACT: ____________________________ Phone: ___________

PATIENT NAME: _________________________________________________________________
Last                                               First                                   MI
DOB: _____________________ CASE NUMBER: ____________________________

PROCEDURE: _______ □ SURGICAL REQUEST FORM      □ WORKING DRAFT ATTACHED

DIRECT INVOICES TO:
MARILYN MCCALLISTER
ADMINISTRATIVE DIRECTOR
LIFESPAN AMC
C/O RHODE ISLAND HOSPITAL
593 EDDY STREET, APC12-108
PROVIDENCE, RI 02903
EMAIL: MMCALLISTER@LIFESPAN.ORG

PLEASE FAX THE PATHOLOGY REPORT(S) TO: 401-444-4377

PLEASE RETURN SLIDES AND CD WITH THE IF AND EM IMAGES ALONG WITH PRINTED PATHOLOGY REPORT TO:
RHODE ISLAND HOSPITAL
SURGICAL PATHOLOGY OFFICE
ATTN: LOIS DECOSTA
APC12-114
593 EDDY STREET
PROVIDENCE, RI 02903
PROTOCOL FOR SUBMISSION OF STONES/CALCULI

A. Principle:

1. Kidney stones submitted with no other type of surgical pathology specimen should be submitted on a standard laboratory requisition rather than a surgical pathology requisition.
   a) Submit a standard laboratory requisition indicating that this is a “calculi for analysis”.
   b) Specimen will be sent to the Laboratory Specimen Receiving window.
   c) Specimen receiving will enter the specimen into Soft and forward to Specimen Sendout.
   d) Specimen will be sent to Quest for analysis.
   e) Results will be forwarded directly to the physician.

2. Kidney stones submitted with additional surgical pathology tissue should be submitted on a Surgical Pathology requisition along with the other tissue (each listed individually)
   a) Submit on a Surgical Pathology requisition listing each specimen including calculi separately.
   b) Send to Surgical Pathology
   c) Surgical Pathology will accession the case in CoPath and indicate that the calculi portion of the order was sent to Quest for analysis.
   d) Specimen should be given to Specimen Send out to be sent to Quest for analysis.
   e) Results from Quest will be sent directly to the physician.
   f) CoPath case will be signed out with diagnosis for the portion of the case worked up in Surgical Pathology. The calculi part will be signed out as - Sent to Quest for analysis - results submitted by Quest to physician directly
MUSCLE AND NERVE BIOPSY PROTOCOL FOR NEUROPATHOLOGY LABORATORY

24 HR NOTICE MUST BE GIVEN FOR ALL BIOPSY PROCEDURES!!

It is essential that the Neuropath lab be notified in advance to ensure proper handling of the specimen and/or specimens. Page the Neuropathology technician at 350-5590, or call the Neuropathology laboratory at 444-3246. Refer to the list of contact people at the bottom of this page if the Neuropathology technician cannot be reached. A requisition for the patient should be filled-out with the following information: patient name, date of birth, social security number, complete address, insurance information, name of hospital where patient had biopsy performed name of physician performing biopsy and body site of biopsy.

A. Specimen Requirements:

1. MUSCLE…..1-3 SQUARE CENTIMETERS OF TISSUE
2. NERVE…..1-2 CENTIMETERS IN LENGTH OF TISSUE

At the time of biopsy the muscle and/or nerve should be loosely wrapped in gauze dampened with saline. DO NOT IMMERSE MUSCLE and/or NERVE IN SALINE!!!! Place the gauze wrapped specimen in a dry container; place this container on crushed ice and immediately deliver to the Neuropathology Laboratory at Rhode Island Hospital, 593 Eddy Street, APC Building, floor 12, room 211 Providence RI. If the biopsy procedure is done within Rhode Island Hospital the Neuropathology technician or contact person will obtain specimen when paged/called.

B. Rhode Island Hospital Neuropathology Laboratory Contacts:

Nancy Heath, Neuropathology Technician    Pager 350-5590  Phone (401) 444-3246
Dr. Ed Stoppa, pager (401) 544-9952
Dr. John Donohue, pager (401) 350-5622
Dr. Suzanne DelaMonte, pager (401) 350-8994
Fellows Office 444-8524
ELECTRON MICROSCOPY

AMC Director: Murray Resnick, M.D., Ph.D. Phone Ext. 4-5154 Pager: 350-1799
AMC Manager: Rosemarie Tavares Phone Ext. 4-8523 Pager: 350-5741
Contact: Grant Jolly Phone Ext. 4-4378

Location: RIH, APC 12-211 Phone Ext. 4-4374

Lab Hours: 7:30 a.m. - 4:00 p.m., Monday-Friday; Laboratory closed weekends and holidays.

1. Specimens: Specimens for E.M. examinations must be sent to Surgical Pathology, TMH/MAIN-2 or RIH/APC-12 as soon as possible after excision with an attached Surgical Pathology Request Form containing patient’s name, address, sex, age, date of birth, hospital number, tissue source, name of physician; attach to specimen container. It is stored in the Surgical Suite refrigerator (Davol 2), in the Morgue and in the EM Lab, APC12-211. At The Miriam Hospital it is stored in the Pathology Lab refrigerator in the Cutting Room on the second floor. Outside users can obtain fresh fixative daily during regular working hours. Refrigerate if there is a delay in delivery to Surgical Pathology (weekend, night etc.) It must be kept refrigerated and is stable for 1 year. Outside physicians’ offices and hospitals can obtain the fixative during regular working hours, 7:30 a.m. - 4:00 p.m., and weekdays.

2. Reports: Reports may be obtained through the Surgical Pathology Office, TMH ext. 3-4245 or RIH ext. 4-5160.
PROCEDURE FOR PROCESSING WHOLE EYE SPECIMENS

Use the eye worksheet for the following procedure.

1. Fix in buffered formalin for 24 hours.
2. The neuropathologist will prosect by cutting the eye slightly off center just in front of the optic nerve.
3. Place the specimen in a Mega cassette and continue with processing.
4. After embedding, section six levels of the block – find the level with the optic nerve.
5. Stain with H&E and give slides to the Neuropathologist.
<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
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<tbody>
<tr>
<td>Adopted</td>
<td></td>
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<tr>
<td>Revised</td>
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PROTOCOL FOR THE TISSUE BANK
TISSUE PROCUREMENT SERVICE

PRINCIPAL INVESTIGATOR: Evgeny Yakirevich, M.D, D.Sc

A. OBJECTIVES:

1. To accomplish the collection of human research materials within Lifespan Academic Medical Center in an efficient and ethical manner, protecting the patient’s right to privacy and uninterrupted clinical care.

2. To assure that researchers will have a reliable and adequate supply of optimally procured human tissue and all documentation needed for proper interpretation of experimental results.

B. BACKGROUND:

Lifespan Academic Medical Center is a major medical center in New England where major surgical procedures are carried out daily. In many cases after the pathological evaluation of the surgical specimens substantial quantities of tissue including tumor tissue remain unused. These samples are of great potential value in conducting a variety of research studies. The proposed Tissue Procurement Service will serve as a centralized facility in this regard. The Tissue Procurement Service will serve to optimize specimen collection while protecting the patients’ interests. For investigators the Procurement Service will assure that laboratories are regularly supplied with samples of high quality, which meet the specific needs of each laboratory.

C. SIGNIFICANCE:

While it is possible that currently research investigators at Lifespan Academic Medical Center have devised limited facilities to store fresh tissue samples a centralized program for collection, storage and distribution has several advantages. Material can be collected and evaluated for research suitability by trained personnel (Technicians, Pathologists and Nurses) and equitably distributed among investigators. The material can be collected and prepared to suit individual requirements of investigators and collection and distribution centrally documented. This program assures that the patient’s rights are protected and relieves investigators of the burden both in time and money of individual and separate procurement each time a specimen is to be obtained. Since pathologists evaluate all the specimens, proper diagnostic procedures are followed thereby assuring the patients quality care and the investigators of properly diagnosed research materials.
D. PATIENT ELIGIBILITY:

All patients undergoing clinically indicated diagnostic, therapeutic, or surgical procedures at Lifespan Academic Medical Center are potential donors of research material when tissue removed exceeds the amount needed for completion of pathologic or other clinical examinations. The tissue for collection includes left over fresh, frozen, or formalin fixed pathology or autopsy specimens, blood, urine, or other body fluids. These donations are covered under the standard Lifespan consent form and do not require a separate consent form. Any procedure to obtain body tissues or fluids for research purposes only, i.e. in the absence of any clinically indicated procedure, must be covered by a separate IRB approved protocol and informed consent form.

E. PROCEDURE FOR TISSUE PROCUREMENT:

1. Investigators requiring human tissues for research complete a Specimen Request Form (Appendix 1), giving specific information on the type of specimen required, minimum size of sample and special handling (sterile collection, quick-freezing in liquid nitrogen, OCT embedded sample, formalin-fixed sample, or stabilizing media). The investigator must provide a brief summary of his/her research, documentation of IRB approval and safety/universal precautions training in order to obtain specimens for research purposes. The request is submitted to the TPS director who then contacts the investigator to confirm the request, discuss the projected availability of material and the exact method of collection. The project director is available for consultation at any time. The completed request is reviewed by the project director and the Lifespan Tissue Utilization Committee.

2. From the completed specimen request form the Tissue Bank technician (or Senior Research Assistant in technician’s absence) initiates a tissue procurement request file that is maintained in a computerized database and as a hard copy that is kept in the Pathology Department. The request is cross-indexed by tissue type and director so that material can be efficiently and systematically distributed to as many investigators as possible according to the individualized requirements of each researcher. Specimens are rotated in an equitable manner to assure all approved projects receive material unless specific priorities are directed by the Lifespan Tissue utilization committee.

3. In order to assure that specimens available for tissue banking are as fresh as possible, the Tissue Procurement Service research technician will assume the responsibility for collection of fresh tissue samples with the help of the grossing staff (Residents and Pathologist Assistants) from all routine specimens. Since the specimens come fresh immediately after they are removed from the patients from the operating rooms, to the grossing room area located in the surgical suite, the tissue quality is virtually guaranteed in virtually every case. Specimens requiring even faster processing and on an urgent basis by the surgeon and/or the research investigator will be processed forthwith by the Tissue
4. Bank research technician within minutes of the specimen being excised after determining excess tissue is available. In every instance a pathologist (typically a resident in pathology) will help in obtaining the sample thereby ensuring that none of the diagnostic requirements are compromised while obtaining the specimen for banking. Where sterile techniques are required the specimen will be handled under a sterile hood located in the Tissue Bank facility located in the Rhode Island Hospital Bridge Building, 3rd floor. The Tissue Procurement Service staff will deliver the stored specimen samples to the investigators/research labs after their requests are processed. In the event that such requests come from an outside institution/investigators, the specimens will be sent via express mail service and or messenger service. Packaging and shipping arrangements will be made by the Tissue Procurement Service.

5. In cases of autopsy, the Tissue Procurement Service research technician will assume the responsibility of obtaining fresh tissue samples with the help of the prosector staff (Residents) when the samples can be obtained within 12 hours of death.

6. Feedback on specimen quality is encouraged as is modification of the request once the project commences to ensure that the material provided best meets the needs of the individual researcher.

7. Researchers may request a clinical abstract of the patient’s history with an accompanying pathology report. To ensure confidentiality all the specimens will be assigned a code designation, and patient identifying information will be removed from these reports. Researchers will only be provided relevant clinical pathological details without any patient identification data. In order to ensure that the diagnostic information is not compromised, two records will be maintained by the Department of Pathology—one will contain the patient identifying information as well as the code designation and will be kept in the Pathology Administrative Office, the second will contain the code designation and the tissue detail in order to facilitate tracing specimens as necessary for diagnostic use and will be kept in the Tissue Bank. This will ensure that the Tissue Bank staff have no access to patient related information.

F. RISKS:

Since residual materials after diagnostic study are used or samples are obtained at the same time routine procedures are done, the patient has no additional risk related to research collection. The patient’s privacy, in accordance with the National Cancer Institute Privacy Act, is maintained at all times.
G. CONSENT:

Patients signing the routine consent form for diagnostic or therapeutic procedures agree that the hospital may dispose of excess tissues, which are removed in their accustomed manner which at Lifespan has included making them available for approved research projects. Any procedure to obtain body tissue or fluids in excess of amount needed for diagnostic purposes or any procedure performed solely for the purposes of research (not clinically indicated) requires a separate IRB approved protocol and consent form.

H. FACILITIES:

Office and laboratory as well as storage space is located at the Rhode Island Hospital, Bridge Building, 3rd floor, and Aldrich Building, 6th floor. Office space is used for data and billing preparation, record keeping and administration. The laboratory space is used for specimen aliquot making, centrifuging of blood for sera or plasma separation, and other tumor preparations under a laminar flow hood. Counter space is used for shipment preparations. Storage space is provided for the large volume of specimen and shipping containers used. Major storage equipment includes 2 Revco freezers, a tabletop centrifuge and a Laminar flow hood.

I. PERSONNEL AND FUNDING:

In addition to the project director the Tissue Procurement Service will have a full time research technician with a background in histological techniques and tissue handling.

J. CHARGE-BACK SYSTEM:

The charge-back system has been developed to partially recover the costs of specimen provision from individual users’ grants and contracts. Briefly the system functions as follows:

1. Investigators requiring human research materials are provided with a Specimen Request Form by the Tissue Procurement Service research technician. This form includes sections for funding designation and approval by the individual’s laboratory head for debiting of the fund.

2. The research technician prepares billing input documents on a monthly basis from tissue procurement statistics and submits it to the departmental research coordinator who, in turn, bills the investigators. Internal investigators approve and submit their invoice to Research Finance for processing. External investigators provide direct payment.
3. Processing fees will be based on arbitrarily defined Work Level units which in turn is based on the effort associated with specimen collection and distribution. Work level 1 unit represents blood, urine, and other body fluids; level 2 represents tissues. Assignment of the levels will be made by the Tissue Procurement Service director.

4. The processing fee schedule will be reviewed and revised periodically by the Tissue Bank Director depending on operational costs and to ensure that the service operates on a non-profit basis.

**ADDENDUM #1:** See attached protocol for procedures on “Tissue Sample Preparation and Storage”.

**ADDENDUM #2:** See attached protocol for collection of salivary gland tissue, serum, saliva.

“Combined Efforts for Collecting Salivary Gland Neoplasms, Salivary Gland Consortium/Biorepository through the NIDCR-NIH” (consortium with MD Anderson Cancer Center, Houston, Texas)

NOTE: The Lifespan Tissue Bank is not utilizing the attached protocol and is only responsible for submitting residual salivary gland tissue to the MD Anderson Cancer Center for their study referenced above. The Lifespan Tissue Bank follows a separate approved protocol for the collection of residual tissue which does not require obtaining separate patient consent but rather consent through the Lifespan “Acknowledgement of Consent for Surgical or Other Procedure” form which includes consent of the use of residual tissue for research purposes.
Autopsy Standard Precautions

1. All personnel should follow full standard precautions, to include double gloving. Personnel should be restricted. A “clean” person should be utilized to record findings.

2. The autopsy, whether limited to the head only or complete, should be conducted with limited exposure to the organs. It is important to try to contain all body fluids either by placing the body in a plastic well or containing fluid in a sink. At the completion of the autopsy, 1 N NaOH (approximately 1 gallon) should be added to the fluids and let stand for one hour.

3. The safest method for removal of the brain would be via a manual hand saw. However, if a Styker saw is used, it is essential to use a vacuum attachment and to work within a plastic bag or under a sheet of plastic.

4. Tissue for histologic sections should be placed in a phenol-saturated formalin 100 ml) for 72 hours and then placed in formic acid for one hour before placing in formalin.

5. At the conclusion of the autopsy, the body should be washed with detergent and then washed with a phenolic disinfectant.

6. The table should be cleaned with 1 N NaOH and allowed to set for 1 hour before washing thoroughly with soap. Instrumentation should follow this same procedure.

7. All gloves, gowns, goggles, masks and disposables should be placed in a red biohazard bag for incineration.

8. All tissue should be clearly marked as “Biohazardous” before submitting for tissue processing.

9. Morticians and mortuary workers should be warned of possible hazards posed by the tissues associated with CJD. They should also be aware of the disinfection methods.
Precautions To Be Used When Handling Specimens In The Frozen Section Suite

Receipt and transport of all specimens should be done by one assigned person who is properly gloved and gowned. The specimen should be accessioned in a designated area of the laboratory to be considered a contaminated work area. All clean areas in the frozen section suite must not be touched with contaminated gloves or other contaminated supplies. All areas that are contaminated should be specifically marked with contamination stickers. These areas must not be touched without wearing gloves and appropriate protective wear.

FROZEN SECTIONS
  Gloves
  Gown
  Mask (when using Freeze Spray) and glasses or full face shield

BIOPSY CASSETTING
  Gloves
  Gown

BONE MARROW
  Gloves
  Gown
  Face Shield

BODY FLUIDS FOR CELL BLOCK
  Gloves
  Gown
  Face Shield
  (It is advisable that this procedure be performed in a totally enclosed centrifuge or under a biohazard hood).

All contaminated laboratory bench surfaces must be cleaned and decontaminated with 10% bleach or a commercial surface disinfectant. Bleach solution or commercial products must be available in each area where potentially infectious specimens are handled.

Cryostats without formalin fumigation systems will be decontaminated at regularly scheduled intervals with bleach at the time of defrosting. Cryostats with formalin fumigation systems may be decontaminated on demand in addition to regularly scheduled intervals.
All protective clothing must be removed prior to leaving the contaminated work area, to avoid contamination of clean surfaces.

All other procedures pertaining to the disposal and handling of potentially infectious material should be followed and are available in the Safety manual.
CJD (Creutzfeldt Jakob Disease) Precautions

1. Creutzfeldt Jakob Disease (CJD) is a transmissible spongiform encephalopathy (TSE). TSE’s are infectious, progressive, neurological degenerative disorders caused by a class of pathogens known as prions. Prions are smaller than viruses and contain no nucleic acid. The incubation period may be short (after transplantation of infected tissue), or more commonly than, as long as 30-40 years.

2. Prions are extremely resistant to almost all forms of disinfection and sterilization. Tissues known to be infectious are:
   - Brain tissue
   - CSF
   - Thymus gland
   - Dura mater
   - Eye (corneal tissue)
   - Pituitary gland
   - Spinal cord

3. It is not clear if blood or other tissues are capable of transmitting the disease, therefore, Standard Precautions must be used

4. Only sodium hydroxide and steam sterilization as described below are considered effective in inactivating the infectious agent.

5. Disinfection of Surfaces:
   a) Sodium hydroxide
      (1) 1N (normal) sodium hydroxide for 60 minutes before cleaning; rinse 3 times.

6. Sterilization:
   a) Autoclave
      (1) 134°C for 18 minutes in a pre-vacuum sterilizer
      (2) 132°C for 60 minutes in a gravity sterilizer
      (3) Disinfect as above then autoclave in gravity sterilizer at 121°C for 60 minutes
7. Special Considerations for Operating Room, Autopsy Room and Pathology
   a) Restrict access to only those necessary for the procedure
   b) All staff entering needs full protective attire and double gloves. All attire must be disposable, red bagged and incinerated
   c) Use only manual saws to decrease splatter and aerosolization
   d) Liquids, including suctioned material and RINSE WATER from surgery or autopsy must NOT be poured down a hopper. The autopsy table drain should be plugged and water collected in a container. A solidifier must be added and the container red-bagged and incinerated.
   e) Use disposable equipment and instruments whenever possible.
   f) Wipe reusable instruments carefully to remove tissue – **DO NOT WASH** before sending for sterilization. Equipment must be able to tolerate steam sterilization. ETO (gas) is ineffective in inactivating the pathogen. After decontamination in the sterilizer, wash and inspect instruments and proceed with usual sterilization procedures.
   g) Decontaminate all surfaces and non-critical items with 1N sodium 60 minutes. Rinse thoroughly with water and then proceed with routine cleaning and disinfection.
   h) Clearly label all specimens CJD. A formalin-formic acid procedure is required for inactivating the pathogen in tissue samples (see attached).

8. Discharge Plan:
   a) If a patient is transferred to any other institution, notify the receiving institution of suspected CJD. The manager/designee should notify the mortuary of CJD precautions when a patient dies.
XYLENE, FORMALIN, BIOLOGICAL WASTE DISPOSAL, AND SPILL CLEAN-UP
(Issued 11/00 by G. Gilmore, Safety Manager, RIH)

A. Regulated Waste:
- Liquids or semi-liquid blood or other potentially infectious (OPIM)
- Body fluids (sperm, vaginal secretions, cerebrospinal fluid, synovial, pleural fluid, pericardial, peritoneal, amniotic, saliva in dental procedures, any body fluid that is visibly contaminated with blood
- Unfixed tissue or organs from humans
- HIV containing cell or tissue culture, and HIV or HBV containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV
- Contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed; items that have dried blood or OPIM and are capable of releasing these materials during handling; contaminated sharps; and biological and microbial waste containing blood or OPIM.

B. Red Bag Waste: DOUBLE BAGGED
- All solid regulated waste (listed above) except sharps should be placed in double lined red biohazard bags.
- Containers should remain closed while not in use (dumping waste into container).
- When full carefully box.
- Call ESD for removal.
- Waste is incinerated.

C. Autoclaved Waste:
- All pathogenic organisms.
  - All recombinant DNA work.
  - Once autoclaved, place in red bag for incineration.

D. Chemical Disinfection:
- Continuous cultures of established cell lines (unless human or non-human primate - autoclave).
  - Small quantities of blood (< 1 pint diluted to final dilution if 1/10 with bleach).
  - Small spills.
E. **Sharps:** Objects that may cause physical damage as well as be contaminated with potentially infectious materials. BIOSYSTEM containers are the only acceptable sharps containers.
   - Needles (syringe attached/ syringes alone).
   - Broken glass.
   - Razor/scalpel blades
   - Glass Pasteur pipets
   - Glass capillary tubes
   - Glass slides/cover slips
   - Glass vials/tubes of blood/blood products/OPIM

F. **Sharps Containers:**
   - Only boxes from BIOSYSTEMS are accepted at RIH/TMH.
   - Weekly service is scheduled; if box is over 3/4 full, call ESD for immediate pick-up and replacement.
   - If more boxes are needed, call ESD for BIOSYSTEMS service.
   - ALL above sharps are approved for disposal in needle boxes.

G. **Regular Trash:**
   - Waste that is not saturated with blood or OPIM
   - Dried materials may be thrown in regular trash.
   - NO SHARPS regardless of contamination.
   - Materials used to disinfect spilled blood or OPIM.
   - Clean, unbroken medical glassware.

H. **Chemical Bottles:**
   - Empty chemical bottles should be tripled rinsed and disposed of through regular trash.
     *Never pick up broken glass with fingers/hands. Use forceps.*

**NO CHEMICAL CAN BE POURED DOWN THE DRAIN.** All chemicals must be properly labeled, stored and disposed of following the guidelines below:
- Satellite accumulation area must be designated prior to generation of chemical waste.
- Be sure containers are compatible with waste (use original containers or similar)
- All containers must be labeled with a hazardous waste label (provided by Safety - x45060)
- Each hazardous waste label must contain the following information:
  - All hazardous constituents (no formulas or abbreviations)
  - The chemical’s associated hazards (flammable, combustible, poison, carcinogen, corrosive, etc)
  - The date the container becomes full and ready for pickup.
- Hazardous waste containers must remain closed at all times during storage, except when waste is being added. Do not store under the hood unless being used.
- All hazardous waste containers must be stored in secondary containment bins (provided by Safety - x45060)
- Incompatible wastes MUST be separated.
- Once the container becomes full, date, ensure label is filled out properly, and *call Safety for removal. Containers must be removed from satellite area within 3 days.

*Waste in pathology labs on APC 12 is removed daily by ESD*
I. Procedure for Spill Cleanup

1. Purpose:

   To familiarize lab personnel with the best methods for handling accidental chemical spills in a safe and effective manner. The following instructions may be found in the red & white RIH RESPONSE GUIDE posted in the laboratory.

   1. Isolate the spill area.

   2. Identify the spill. MSDS sheets are located in the Main Lab and in F.S. Suite

   3. If the spill is large, dial 45111 and give location and nature of the spill. Have the MSD available to response team.

   4. If the spill is small, use the following equipment:

      ABSORBENT PILLOWS

      1. In main lab beneath center windows

      2. Special stain room in cabinet beneath the sink

      3. F.S. Suite on the counter near the hood.

      CLEAN-UP KITS

      5. Special stain room - near control slide file

      6. Processor room - on floor to right of door

      7. F.S. Suite on the counter near the hood.

      Clean-up kits contain agents for acid, caustic, flammable and mercury spills.

      Each kit also contains instructions for use.

      After the Safety Officer confirms or authorizes the area is safe, ask Environmental Services to wash the spill area.

      All exposed personnel should be checked by Employee Health (M-F 7:30-4:30) or the Emergency Room.

      Complete a spill incident report.

All spills must be reported to the Safety Office (8357) and any materials used to pick up a spill must be treated as hazardous waste.
SAFETY POLICY FOR XYLENE HANDLING

A. Principle:

To ensure the safety of the personnel using xylene.

B. Monitoring:

1. Yearly monitoring is performed by an outside environmental agency.
2. If limits exceed OSHA standards affected employees will be retested immediately and again 4-6 weeks thereafter.
3. If limits are still high after retesting the Safety Committee will investigate the cause and recommend viable solutions to the laboratory
4. Copies of all results will be given to the employee
5. OSHA permissible exposure for Xylene vapor is: Long term (8 hours) – 100 ppm
6. NIOSH permissible exposure limit for Xylene vapor is: Short term (15 min) – 150 ppm (There is no OSHA short-term exposure limit)

C. Handling:

Protective eyewear is recommended

Use in a well-ventilated area of under a hood

D. Disposal:

1. Waste Xylene must be placed in appropriately labeled gallon containers and then in secondary containers for daily pick-up by Housekeeping.
2. A chemical waste form be filled out and accompany the waste daily.
Section 1 - Chemical Product and Company Identification

MSDS Name:
Xylenes, mixed isomers with ethylbenzene (Flash Point 26.1°C / 79°F; PG III)

Catalog Numbers:
HC790/IOAL

Synonyms:
Dimethylbenzene, Methyltoluene.

Company Identification:
Fisher Diagnostics
Fisher Scientific Company LLC
8365 Valley Pike
Middletown, VA 22645-0307

Company Phone Number:
(800) 525-0494

Emergency Phone Number:
(800) 525-0494

CHEMTREC Phone Number, US:
(800) 424-9300

CHEMTREC Phone Number, Europe:
(202) 463-7816

Section 2 - Composition, Information on Ingredients

<table>
<thead>
<tr>
<th>CAS#</th>
<th>Chemical Name:</th>
<th>Percent</th>
<th>EMERGENCY TELEPHONE NUMBERS</th>
<th>HAZARD SYMBOLES</th>
<th>RISK PHRASES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1330-20-7</td>
<td>Xylenes (o-, m-, p- isomers)</td>
<td>96</td>
<td>215-535-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100-41-4</td>
<td>Ethylbenzene</td>
<td>4</td>
<td>202-848-4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section 3 - Hazards Identification

EMERGENCY OVERVIEW

Appearance: Clear, colorless liquid

Warning! Flammable liquid and vapor. Causes eye, skin, and respiratory tract irritation. Aspiration hazard if swallowed. Can enter lungs and cause damage. May be harmful if absorbed through skin or if inhaled. May cause central nervous system depression.

Target Organs: Central nervous system, Respiratory system, Eyes, Skin

Potential Health Effects:
Eye:
Splashes of xylene in human eyes generally cause transient superficial injury.

Skin:
May be harmful if absorbed through the skin. Xylene contact causes defatting of the skin with irritation, dryness, and cracking. Blistering may occur, particularly if exposure to concentrated xylene is prolonged and the exposed area of skin is occluded.

Ingestion:
Aspiration hazard. May cause irritation of the digestive tract. May cause central nervous system depression, characterized by excitement, followed by headache, dizziness, drowsiness, and nausea. Advanced stages may cause collapse, unconsciousness, coma and possible death due to respiratory failure. Aspiration of material into the lungs may cause chemical pneumonitis, which may be fatal.

Inhalation:
Causes respiratory tract irritation. Irritation may lead to chemical pneumonitis and pulmonary edema. Odor thresholds ranging from 0.07 to 40 ppm have been reported for xylene. Inhalation overexposure may lead to central nervous system depression, producing effects such as dizziness, headache, confusion, incoordination, nausea, weakness, and loss of consciousness. Extreme exposures may cause other CNS effects including death.

Chronic:
Chronic exposure to xylene may cause defatting dermatitis, reversible eye damage, dyspnea (labored breathing), confusion, dizziness, apprehension, memory loss, headache, tremors, weakness, anorexia, nausea, ringing in the ears, irritability, thirst, mild changes in liver function, kidney impairment, anemia, and hyperplasia, but not destruction, of the bone marrow.

Section 4 - First Aid Measures

Eyes:
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical aid.

Skin:
In case of contact, flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical aid if irritation develops and persists. Wash clothing before reuse.

Ingestion:
Potential for aspiration if swallowed. Get medical aid immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If vomiting occurs naturally, have victim lean forward.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid.

Notes to Physician:
Treat symptomatically and supportively.
Section 5 - Fire Fighting Measures

General Information:
As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. Use water spray to keep fire-exposed containers cool. Flammable liquid and vapor. Vapors may form an explosive mixture with air. Vapors are heavier than air and may travel to a source of ignition and flash back. Vapors can spread along the ground and collect in low or confined areas. This liquid floats on water and may travel to a source of ignition and spread fire. May accumulate static electricity.

Extinguishing Media:
Water may be ineffective. This material is lighter than water and insoluble in water. The fire could easily be spread by the use of water in an area where the water cannot be contained. Use water spray, dry chemical, carbon dioxide, or appropriate foam.

Autoignition Temperature:
527°C (980.62°F)

Explosion Limits:
Lower: 1.1%  Upper: 7.0%

Flash Point:
26-63.2°C

NFPA Rating:
(estimated) Health: 2, Flammability: 3, Instability: 0

Section 6 - Accidental Release Measures

General Information:
Use proper personal protective equipment as indicated in Section 8.

Spills/Leaks:
Absorb spill with inert material (e.g. vermiculite, sand or earth), then place in suitable container. Remove all sources of ignition. Use a spark-proof tool. Provide ventilation. A vapor suppressing foam may be used to reduce vapors. Water spray may reduce vapor but may not prevent ignition in closed spaces. U.S. regulations require reporting spills and releases to soil, water and air in excess of reportable quantities. This material creates a fire hazard because it floats on water. If possible, try to contain floating material.

Section 7 - Handling and Storage

Handling:
Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Ground and bond containers when transferring material. Avoid contact with eyes, skin, and clothing. Empty containers retain product residue (liquid and/or vapor), and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose empty containers to heat, sparks or open flames. Use only with adequate ventilation. Keep away from heat, sparks and flame. Avoid breathing vapor or mist.

Storage:
Keep away from sources of ignition. Keep container closed when not in use. Keep from contact with oxidizing materials. Store in a cool, dry, well-ventilated area away from incompatible substances.
Section 8 - Exposure Controls, Personal Protection

Engineering Controls:
Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits. Ventilation fans and other electrical service must be non-sparking and have an explosion-proof design.

Exposure Limits

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>NIOSH</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xylenes (o-, m-, p- isomers)</td>
<td>100 ppm TWA; 150 ppm STEL</td>
<td>None listed</td>
<td>100 ppm TWA; 435 mg/m³ TWA</td>
</tr>
<tr>
<td>Ethylbenzene</td>
<td>100 ppm TWA; 125 ppm STEL</td>
<td>100 ppm TWA; 435 mg/m³ TWA</td>
<td>100 ppm TWA; 435 mg/m³ TWA</td>
</tr>
</tbody>
</table>

OSHA Vacated PELs
- Xylenes (o-, m-, p- isomers): 100 ppm TWA; 435 mg/m³ TWA
- Ethylbenzene: 100 ppm TWA; 435 mg/m³ TWA

Personal Protective Equipment

Eyes:
Wear chemical splash goggles.

Skin:
Wear appropriate gloves to prevent skin exposure.

Clothing:
Wear appropriate protective clothing to prevent skin exposure.

Respirators:
Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Section 9 - Physical and Chemical Properties

Physical State: Liquid
Color: Clear, colorless
Odor: Aromatic odor
pH: Not applicable
Vapor Pressure: 8.29 mm Hg @ 25°C
Vapor Density: 3.68 (air=1)
Evaporation Rate: 0.7 (butyl acetate=1)
Viscosity: <32.6 SUS
Boiling Point: 136 - 140°C
Freezing/Melting Point: -34°C
Decomposition Temperature: No information found
Solubility in water: Insoluble.
Material Safety Data Sheet
Xylenes, mixed isomers with ethylbenzene (Flash Point 28.1°C / 79°F; PG III)

Specific Gravity/Density: 0.865 (water=1)
Molecular Formula: C8H10
Molecular Weight: 106.17

Section 10 - Stability and Reactivity

Chemical Stability:
Stable under normal temperatures and pressures.

Conditions to Avoid:
High temperatures, ignition sources

Incompatibilities with Other Materials
Strong oxidizing agents, nitric acid

Hazardous Decomposition Products
Carbon monoxide, carbon dioxide

Hazardous Polymerization
Will not occur.

Section 11 - Toxicological Information

RTECS:
CAS# 1330-20-7: Z2E2100000
CAS# 100-41-4: DAD7000000

LD50/LC50:
CAS# 1330-20-7:
Draize test, rabbit, eye: 87 mg Mild
Draize test, rabbit, eye: 5 mg/24H Severe
Draize test, rabbit, skin: 100% Moderate
Draize test, rabbit, skin: 500 mg/24H Moderate
Inhalation, rat: LC50 = 5000 ppm/4H
Oral, mouse: LD50 = 2119 mg/kg
Oral, rat: LD50 = 4300 mg/kg
Skin, rabbit: LD50 = ~1700 mg/kg.
CAS# 100-41-4:
Draize test, rabbit, eye: 500 mg Severe
Inhalation, mouse: LC50 = 35500 mg/m3/2H
Inhalation, rat: LC50 = 55000 mg/m3/2H
Oral, rat: LD50 = 3500 mg/kg
Oral, rat: LD50 = 5000 mg/kg
Skin, rabbit: LD50 = 17800 uL/kg.

Carcinogenicity:
CAS# 1330-20-7: Not listed as a carcinogen by ACGIH, IARC, NTP, or CA Prop 65.
CAS# 100-41-4
ACGIH: A3 - Confirmed Animal Carcinogen with Unknown Relevance to Humans
California: carcinogen, initial date 6/11/04
NTP: Not listed
IARC: Group 2B carcinogen
Xylenes, mixed isomers with ethylbenzene (Flash Point 25.1°C / 77°F; PG III)

Epidemiology:
176 workers were exposed to 21 ppm of xylene for 7 years. Subjective symptoms such as anxiety, forgetfulness, inability to concentrate and dizziness were reported. Xylenes accounted for >70% of the total exposure. Liver & kidney effects were not reported.

Teratogenicity:
No increased incidence of birth defects was reported in a study of lab workers exposed to xylene during early pregnancy. Exposure to other solvents and chemicals also occurred. An increased incidence of spontaneous abortions was reported. Animal information suggests that xylene is not teratogenic or embryotoxic at exposure levels that are not harmful to the mother.

Reproductive:
An increase in menstrual disorders has been reported in women exposed to organic solvents such as benzene, toluene, and xylenes. It is not possible to attribute these effects to xylenes in particular.

Mutagenicity:
Xylene does not appear to be a mutagen.

Neurotoxicity:
Xylene may be ototoxic (damages hearing or enhances sensitivity to noise) in chronic occupational exposures, probably from a neurotoxic mechanism.

Other:
See actual entry in RTECS for complete information.

Section 12 - Ecological Information

Ecotoxicity:
Fish: Rainbow trout; LC50 = 13.5 mg/L; 96 Hr; Unspecified
Fish: Goldfish; LD50 = 13 mg/L; 24 Hr; Unspecified
Fish: Fathead Minnow; LC50 = 4.1 mg/L; 1 Hr; Static bioassay

Acute and long-term toxicity to fish and invertebrates: LD50 for goldfish is 13 mg/L/24 Hr.

Cas13330-20-7:
LC50(96Hr); Rainbow trout = 8.05 mg/L; Static condition;
LC50(96Hr); Fathead Minnow = 16.1 mg/L; flow-through condition;
LC50(96Hr); Bluegill = 16.1 mg/L; flow-through condition;
EC50 (24 Hr); Water flea = 3.92 mg/L; flow-through condition;
EC50 (24 Hr); Photobacterium phosphoreum = 0.0084 mg/L; Microtox test.

Environmental:
In air, xylenes degrade by reacting with photochemically produced hydroxyl radicals. In soil it will volatilize and leach into groundwater. Little bioconcentration is expected.

Physical:
ATMOSPHERIC FATE: According to a model of gas/particle partitioning of semivolatile organic compounds in the atmosphere, xylene, which has an experimental vapor pressure of 7.98 mm Hg at 25 deg C, will exist solely as a vapor in the ambient atmosphere. Vapor-phase xylene is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the atmospheric lifetime of xylene is about 14-26 hours. Ambient levels of xylene are detected in the atmosphere due to large emissions of this compound.

Other:
No information found.
Section 13 - Disposal Considerations

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Part 261. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

RCRA P Series Wastes
None of the components are on this list.

RCRA U Series Wastes
CAS# 1330-20-7: waste number U239 (Ignitable waste, Toxic waste).

Section 14 - Transport Information

<table>
<thead>
<tr>
<th>US DOT</th>
<th>Canadian TDG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper Shipping Name:</td>
<td>XYLENES</td>
</tr>
<tr>
<td>Hazard Class:</td>
<td>3</td>
</tr>
<tr>
<td>UN Number:</td>
<td>UN1307</td>
</tr>
<tr>
<td>Packing Group:</td>
<td>III</td>
</tr>
</tbody>
</table>

USA RQ: CAS# 1330-20-7: 100 lb final RQ; 45.4 kg final RQ
USA RQ: CAS# 100-41-4: 1000 lb final RQ; 454 kg final RQ

Section 15 - Regulatory Information

European/International Regulations

European Labelling in Accordance with EC Directives:
Hazard Symbols: XN
Risk Phrases: R 10: Flammable
R 20/21: Harmful by inhalation and in contact with skin.
R 35/36: Irritating to eyes and skin.
Safety Phrases: S 25: Avoid contact with eyes.

WGK (Water Danger/Protection)
Not available

United Kingdom Occupational Exposure Limits
Not available

United Kingdom Maximum Exposure Limits
Not available

Canadian DSL/NDSL
CAS# 1330-20-7 is listed on Canada's DSL List.
CAS# 100-41-4 is listed on Canada's DSL List.
Xylenes, mixed isomers with ethylbenzene (Flash Point 26.1°C / 79°F; PG III)

Canadian WHMIS Classifications
This product has a WHMIS classification of B2, D2B, D2A. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all of the information required by those regulations.

Canadian Ingredient Disclosure List
CAS# 1330-20-7 is not listed on the Canadian Ingredient Disclosure List.
CAS# 100-41-4 is listed on the Canadian Ingredient Disclosure List.

US Federal
TSCA
CAS# 1330-20-7 is listed on the TSCA Inventory.
CAS# 100-41-4 is listed on the TSCA Inventory.

Health and Safety Reporting List
CAS# 100-41-4. Effective 6/19/87, Sunset 6/19/97

Chemical Test Rules
TSCA Section 12b
None of the components are on this list.

TSCA Significant New Use Rule (SNUR)
None of the components are on this list.

CERCLA Hazardous Substances and corresponding RQs
CAS# 1330-20-7: 100 lb final RQ, 45.4 kg final RQ
CAS# 100-41-4: 1000 lb final RQ, 454 kg final RQ

SARA Section 302 Extremely Hazardous Substances
None of the components are on this list.

SARA Hazard Categories
CAS# 1330-20-7: immediate, delayed, fire.
CAS# 100-41-4: immediate, delayed, fire.

SARA Section 313
This material contains Xylenes (o-, m-, p- isomers) (CAS# 1330-20-7, 96%), which is subject to the reporting requirements of Section 313 of SARA Title III and 40 CFR Part 372.
This material contains Ethylbenzene (CAS# 100-41-4, 4%), which is subject to the reporting requirements of Section 313 of SARA Title III and 40 CFR Part 372.

Clean Air Act - Hazardous Air Pollutants (HAPs)
CAS# 1330-20-7 is listed as a hazardous air pollutant (HAP).
CAS# 100-41-4 is listed as a hazardous air pollutant (HAP).

Clean Air Act - Class 1 Ozone Depleters
None of the components are on this list.

Clean Air Act - Class 2 Ozone Depleters
None of the components are on this list.

Clean Water Act - Hazardous Substances
CAS# 1330-20-7 is listed as a Hazardous Substance under the CWA.
CAS# 100-41-4 is listed as a Hazardous Substance under the CWA.

Clean Water Act - Priority Pollutants
CAS# 100-41-4 is listed as a Priority Pollutant under the CWA.
Material Safety Data Sheet
Xylenes, mixed isomers with ethylbenzene (Flash Point 26.1°C / 79°F; PG III)

Clean Water Act - Toxic Pollutants
CAS# 106-41-4 is listed as a Toxic Pollutant under the CWA.

OSHA - Highly Hazardous
None of the components are on this list.

OSHA - Specifically Regulated Chemicals
None of the components are on this list.

US State
State Right to Know
Xylenes (o-, m-, p- isomers) can be found on the following state Right-to-Know lists: California, New Jersey, Pennsylvania, Minnesota, Massachusetts.

California
Ethylbenzene can be found on the following state Right-to-Know lists: California, New Jersey, Pennsylvania, Minnesota, Massachusetts.

California Prop 65
WARNING: This product contains Ethylbenzene, a chemical known to the State of California to cause cancer.

California No Significant Risk Level
None of the components are on this list.
None of the components are on this list.

Section 16 - Other Information

Color information has been
MSDS Creation Date: June 22, 1999
Revision Date: July 20, 2009

This MSDS is intended for review and guidance in the receipt, storage, handling, use and disposal of product purchased from us, and for no other purpose. Use this product only as directed and in accordance with applicable instructions and warnings provided with the product. Please consult your institution’s policies regarding use of this product. If you have obtained this MSDS other than in connection with the supply of this product from us, this MSDS should be consulted for general information only, and should not be relied upon for any purpose. As with the use of all hazardous materials, you should in all instances follow the guidance of the MSDS provided or available with the specific product purchased.
SAFETY POLICY FOR HANDLING FORMALIN

A. Principle:
   To ensure the safety of the personnel using formalin solutions.

B. Monitoring:
   1. Yearly monitoring is performed by an outside environmental agency.
   2. If limits exceed OSHA standards affected employees will be retested immediately and again 4-6 weeks thereafter.
   3. If limits are still high after retesting the Safety Committee will investigate the cause and recommend viable solutions to the laboratory.
   4. Copies of all results will be given to the employee.
   5. OSHA permissible exposure limit for Formaldehyde vapor is:
      a) Short term (15 minutes) – 2.0 ppm
      b) Long term (8 hours) – 0.75 ppm

C. Handling:
   1. Protective eyewear is recommended.
   2. Use in a well-ventilated area or under a hood.

D. Disposal:
   1. Waste Formalin must be placed in appropriately labeled gallon containers and then in secondary containers for daily pick-up by Housekeeping.
   2. A chemical waste form be filled out and accompany the waste daily.
1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Protocol™ 10% Neutral Buffered Formalin
Synonyms: No information available.
Recommended Use: In vitro diagnostic

Company: Fisher Diagnostics
A Division of Fisher Scientific Company, LLC
A Part of Thermo Fisher Scientific, Inc.
9365 Valley Pike
Middletown, VA 22645-1905
Tel: (800) 526-0494

Emergency Telephone Number
Chemtrec US: (800) 424-9300
Chemtrec EU: (202) 493-7910

2. HAZARDS IDENTIFICATION

WARNING!

Emergency Overview
Cancer hazard. May cause eye, skin, and respiratory tract irritation. May cause an allergic skin reaction.

Appearance: Colorless
Physical State: Liquid
Odor: Characteristic formaldehyde

Target Organs: Central nervous system (CNS), Skin, Liver, Kidney, spleen, Blood

Potential Health Effects:

Acute Effects:

Principle Routes of Exposure:

Eyes: May cause irritation.
Skin: May cause irritation. May be harmful in contact with skin. May produce an allergic reaction.
Inhalation: May cause irritation of respiratory tract. May be harmful if inhaled.
Ingestion: May be harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
Chronic Effects: May cause cancer. Tumorigenic effects have been reported in experimental animals. Experiments have shown reproductive toxicity effects on laboratory animals. May cause adverse liver effects. May cause adverse kidney effects. Repeated contact may cause allergic reactions in very susceptible persons.

See Section 11 for additional toxicological information.

Aggravated Medical Conditions: Central nervous system disorders. Gastrointestinal tract. Pre-existing eye disorders. Skin disorders.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No.</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>&gt; 90</td>
</tr>
<tr>
<td>Sodium acid phosphate</td>
<td>7651-50-7</td>
<td>&lt; 1.0</td>
</tr>
<tr>
<td>Sodium phosphate dibasic</td>
<td>7556-79-4</td>
<td>&lt; 1.0</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>3.5 - 4.0</td>
</tr>
<tr>
<td>Methyl alcohol</td>
<td>67-56-1</td>
<td>1.0 - 2.0</td>
</tr>
</tbody>
</table>

### 4. FIRST AID MEASURES

- **Eye Contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.
- **Skin Contact:** Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention.
- **Inhalation:** Move to fresh air. If breathing is difficult, give oxygen. Get medical attention immediately if symptoms occur.
- **Ingestion:** Do not induce vomiting. Obtain medical attention.
- **Notes to Physician:** Treat symptomatically.

### 5. FIRE-FIGHTING MEASURES

- **Flash Point:** > 93.3°C / 199.9°F
- **Method:** No information available.
- **Autoignition Temperature:** No information available.
- **Explosion Limits:**
  - Upper: No data available
  - Lower: No data available
- **Suitable Extinguishing Media:** Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
- **Unsuitable Extinguishing Media:** No information available.
- **Hazardous Combustion Products:** No information available.
- **Sensitivity to mechanical impact:** No information available.
- **Sensitivity to static discharge:** No information available.
Specific Hazards Arising from the Chemical
Thermal decomposition can lead to release of irritating gases and vapors. Keep product and empty container away from heat and sources of ignition.

Protective Equipment and Precautions for Firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA
Health 2 Flammability 1 Instability 0 Physical hazards N/A

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions
Use personal protective equipment. Ensure adequate ventilation. Remove all sources of ignition. Avoid contact with skin, eyes and clothing.

Environmental Precautions
Should not be released into the environment.

Methods for Containment and Clean Up
Remove all sources of ignition. Soak up with inert absorbent material. Keep in suitable and closed containers for disposal.

7. HANDLING AND STORAGE

Handling
Use only under a chemical fume hood. Wear personal protective equipment. Keep away from open flames, hot surfaces and sources of ignition. Do not breathe vapors or spray mist. Do not get in eyes, on skin, or on clothing.

Storage
Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat and sources of ignition.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Measures
Use only under a chemical fume hood. Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location.

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH STEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>Ceiling: 0.5 ppm</td>
<td>(Vacated) TWA: 3 ppm (Vacated) STEL: 10 ppm</td>
<td>TWA: 0.2 ppm (Vacated) Ceiling: 0.1 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methyl alcohol</td>
<td>TWA: 250 ppm STEL: 250 ppm Skin</td>
<td>(Vacated) TWA: 200 ppm (Vacated) STEL: 325 mg/m³</td>
<td>TWA: 250 ppm STEL: 250 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Quebec</th>
<th>Mexico OEL (TWA)</th>
<th>Ontario TWA/STEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>Ceiling: 3 mg/m³ Ceiling: 3 ppm</td>
<td>Peak: 3 mg/m³ Peak: 3 ppm</td>
<td>STEL: 1.8 ppm OEL: 1.5 ppm</td>
</tr>
</tbody>
</table>
Buffered Formalin

<table>
<thead>
<tr>
<th>Component</th>
<th>Quebec</th>
<th>Mexico OEL (TWA)</th>
<th>Ontario TWA/EC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methanal</td>
<td>TWA: 280 ppm</td>
<td>TWA: 280 ppm</td>
<td>TWA: 280 ppm</td>
</tr>
<tr>
<td></td>
<td>STEL: 550 ppm</td>
<td>STEL: 250 ppm</td>
<td>STEL: 325 ppm</td>
</tr>
<tr>
<td></td>
<td>Skin: 14 mg/m³</td>
<td>STEL: 35 mg/m³</td>
<td>STEL: 35 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Skin</td>
<td>STEL: 35 mg/m³</td>
<td>STEL: 35 mg/m³</td>
</tr>
</tbody>
</table>

**MOSH IDLH: Immediately Dangerous to Life or Health**

**Personal Protective Equipment**

- **Eye/face Protection**: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA’s eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.
- **Skin and body protection**: Wear appropriate protective gloves and clothing to prevent skin exposure.
- **Respiratory Protection**: Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Physical State**: Liquid
- **Appearance**: Colorless
- **Odor**: Characteristic formaldehyde
- **Odor Threshold**: No information available.
- **pH**: 6.9 - 7.1
- **Vapor Pressure**: No information available.
- **Vapor Density**: No information available.
- **Viscosity**: No information available.
- **Boiling Point/Range**: 102°C / 215.6°F
- **Melting Point/Range**: No information available.
- **Decomposition Temperature °C**: > 333°C / 669.9°F
- **Flash Point**: No information available.
- **Evaporation Rate**: No data available.
- **Specific Gravity**: 1.0
- **Solubility**: No information available.
- **Log Pow**: No data available

### 10. STABILITY AND REACTIVITY

- **Stability**: Stable under normal conditions.
- **Conditions to Avoid**: Incompatible products. Heat, flames and sparks.
- **Incompatible Materials**: Strong oxidizing agents
- **Hazardous Decomposition Products**: Thermal decomposition can lead to release of irritating gases and vapors
- **Hazardous Polymerization**: Hazardous polymerization does not occur
- **Hazardous Reactions**: None under normal processing.

### 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity**
Product Information

No acute toxicity information is available for this product

Component Information

<table>
<thead>
<tr>
<th>Component</th>
<th>LD50 Oral</th>
<th>LD50 Dermal</th>
<th>LC50 Inhalation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>4 mL/kg (Rat)</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
<tr>
<td>Sodium acetate</td>
<td>1500 mg/kg (Rat)</td>
<td>500 mg/kg (Rabbit)</td>
<td>Not listed</td>
</tr>
<tr>
<td>Sodium phosphate</td>
<td>1.7 mg/kg (Rat)</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
<tr>
<td>Methyl alcohol</td>
<td>5628 mg/kg (Rat)</td>
<td>15690 mg/kg (Rabbit)</td>
<td>0.004 ppm (Rat)</td>
</tr>
</tbody>
</table>

Irritation

No information available.

Toxicologically Synergistic

No information available.

Chronic Toxicity

Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen.

<table>
<thead>
<tr>
<th>Component</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
<th>Mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>A2</td>
<td>Group 1</td>
<td>Reasonably Anticipated</td>
<td>X</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

ACGIH: (American Conference of Governmental Industrial Hygienists)
A1 - Known Human Carcinogen
A2 - Possibly Human Carcinogen
A3 - Animal Carcinogen
IARC: (International Agency for Research on Cancer)
Group 1 - Carcinogenic to Humans
Group 2A - Probable Carcinogenic to Humans
Group 2B - Possibly Carcinogenic to Humans
NTP: (National Toxicity Program)
Known - Known Carcinogen
Reasonably Anticipated - Reasonably Anticipated to be a Human Carcinogen

Sensitization
May cause sensitization by skin contact

Mutagenic Effects
Mutagenic effects have occurred in humans.

Reproductive Effects
Experiments have shown reproductive toxicity effects on laboratory animals.

Developmental Effects
Developmental effects have occurred in experimental animals.

Teratogenicity
Teratogenic effects have occurred in experimental animals.

Other Adverse Effects
See actual entry in RTECS for complete information.

Endocrine Disruptor Information
No information available
12. ECOLOGICAL INFORMATION

Ecotoxicity

<table>
<thead>
<tr>
<th>Component</th>
<th>Freshwater Algae</th>
<th>Freshwater Fish</th>
<th>Microtox</th>
<th>Water Flea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>Not listed</td>
<td>Listed</td>
<td>Not listed</td>
<td>Listed</td>
</tr>
<tr>
<td>Methyl alcohol</td>
<td>Not listed</td>
<td>Listed</td>
<td>Not listed</td>
<td>Listed</td>
</tr>
</tbody>
</table>

Persistence and Degradability: No information available

Bioaccumulation/Accumulation: No information available

Mobility

<table>
<thead>
<tr>
<th>Component</th>
<th>log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>0.38</td>
</tr>
<tr>
<td>Methyl alcohol</td>
<td>0.74</td>
</tr>
</tbody>
</table>

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods: Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

<table>
<thead>
<tr>
<th>Component</th>
<th>RCRA - U Series Wastes</th>
<th>RCRA - P Series Wastes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde - 50-00-0</td>
<td>U02</td>
<td>-</td>
</tr>
<tr>
<td>Methyl alcohol - 67-56-1</td>
<td>U54</td>
<td>-</td>
</tr>
</tbody>
</table>

14. TRANSPORT INFORMATION

DOT

<table>
<thead>
<tr>
<th>UN-No</th>
<th>Proper Shipping Name</th>
<th>Hazard Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN3334</td>
<td>AVIATION REGULATED LIQUID, N.O.S.</td>
<td>9</td>
</tr>
</tbody>
</table>

TDG

<table>
<thead>
<tr>
<th>UN-No</th>
<th>Proper Shipping Name</th>
<th>Hazard Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN3334</td>
<td>AVIATION REGULATED LIQUID, N.O.S.</td>
<td>9</td>
</tr>
</tbody>
</table>

IATA
14. TRANSPORT INFORMATION

UN-No. 3334
Proper Shipping Name. AVIATION REGULATED LIQUID, N.O.S.
Hazard Class. 9

IMDG/IMO. Not regulated

15. REGULATORY INFORMATION

International Inventories

<table>
<thead>
<tr>
<th>Component</th>
<th>TSCA</th>
<th>DSL</th>
<th>NDSL</th>
<th>EINECS</th>
<th>ELINCS</th>
<th>NLP</th>
<th>PICCS</th>
<th>ENCS</th>
<th>AICS</th>
<th>CHINA</th>
<th>RECL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>X</td>
<td>X</td>
<td>-</td>
<td>231-79-2</td>
<td>-</td>
<td>X</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Sodium acid phosphate</td>
<td>X</td>
<td>X</td>
<td>-</td>
<td>231-449-2</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>KE-31577 X</td>
</tr>
<tr>
<td>Sodium phosphate dibasic</td>
<td>X</td>
<td>X</td>
<td>-</td>
<td>231-449-7</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>KE-12544 X</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>X</td>
<td>X</td>
<td>-</td>
<td>260-000-8</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>KE-17078 X</td>
</tr>
<tr>
<td>Methyl alcohol</td>
<td>X</td>
<td>X</td>
<td>-</td>
<td>260-555-6</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>KE-23193 X</td>
</tr>
</tbody>
</table>

Legend:
X - Listed
E - Indicates a substance that is the subject of a Section 5(e) Consent order under TSCA.
F - Indicates a substance that is the subject of a Section 5(f)(2) Rule under TSCA.
N - Indicates a polymeric substance containing no free-radical initiator in its inventory name but is considered to cover the designated polymers made with any free-radical initiator regardless of the amount used.
P - Indicates a commercial PMN substance.
R - Indicates a substance that is the subject of a Section 6 risk management rule under TSCA.
S - Indicates a substance that is identified in a proposed or final Significant New Use Rule.
T - Indicates a substance that is the subject of a Section 4 test rule under TSCA.
XII - Indicates a substance exempt from reporting under the Inventory Update Rule, i.e. Partial Updating of the TSCA Inventory Data Base Production and Sale Reports (40 CFR Part 710).
Y1 - Indicates an exempt polymer that has a molecular weight of 1,000 or greater.
Y2 - Indicates an exempt polymer that is a polymer and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

U.S. Federal Regulations

TSCA 12(b) Not applicable

SARA 313

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>Weight %</th>
<th>SARA 313 - Threshold Values %</th>
</tr>
</thead>
</table>

Page 7 / 10
Thermo Fisher Scientific - Protocoll™ 10% Neutral Buffered Formalin

<table>
<thead>
<tr>
<th>Component</th>
<th>CWA - Hazardous Substances</th>
<th>CWA - Reportable Quantities</th>
<th>CWA - Toxic Pollutants</th>
<th>CWA - Priority Pollutants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>X</td>
<td>500 lb</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Methyl alcohol</td>
<td></td>
<td>100 lb</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**SARA 311/312 Hazardous Categorization**

- Acute Health Hazard: No
- Chronic Health Hazard: No
- Fire Hazard: Yes
- Sudden Release of Pressure Hazard: No
- Reactive Hazard: No

**Clean Water Act**

<table>
<thead>
<tr>
<th>Component</th>
<th>RAPS Data</th>
<th>Class 1 Ozone Depletors</th>
<th>Class 2 Ozone Depletors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methyl alcohol</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Clean Air Act**

<table>
<thead>
<tr>
<th>Component</th>
<th>Specifically Regulated Chemicals</th>
<th>Highly Hazardous Chemicals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>0.5 ppm Action Level</td>
<td>100 lb</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>3 ppm TWA</td>
<td>10 ppm STEL</td>
</tr>
<tr>
<td>Methyl alcohol</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**OSHA**

**CERCLA**

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (40 CFR 302)

<table>
<thead>
<tr>
<th>Component</th>
<th>Hazardous Substance Rels</th>
<th>CERCLA Rels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium phosphate dibasic</td>
<td>5000 lb</td>
<td>-</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>100 lb</td>
<td>100 lb</td>
</tr>
<tr>
<td>Methyl alcohol</td>
<td>5000 lb</td>
<td>-</td>
</tr>
</tbody>
</table>

**California Proposition 65**

This product contains the following Proposition 65 chemicals:

<table>
<thead>
<tr>
<th>Component</th>
<th>CA Prop. 65</th>
<th>Prop. 65 NARR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>Carcinogen</td>
<td>40 mg/l/day</td>
</tr>
<tr>
<td>Methyl alcohol</td>
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**State Right-to-Know**

<table>
<thead>
<tr>
<th>Component</th>
<th>Massachusetts</th>
<th>New Jersey</th>
<th>Pennsylvania</th>
<th>Illinois</th>
<th>Rhode Island</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium phosphate dibasic</td>
<td>X</td>
<td>X</td>
<td>A</td>
<td>-</td>
<td></td>
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</table>
Buffered Formalin

<table>
<thead>
<tr>
<th>Component</th>
<th>Massachusetts</th>
<th>New Jersey</th>
<th>Pennsylvania</th>
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</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Methylenecyanurate</td>
<td>X</td>
<td>X</td>
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**U.S. Department of Transportation**
- Reportable Quantity (RQ): Y
- DOT Marine Pollutant: N
- DOT Severe Marine Pollutant: N

**U.S. Department of Homeland Security**
This product contains the following DHS chemicals:

<table>
<thead>
<tr>
<th>Component</th>
<th>DHS Chemical Facility Anti-Terrorism Standard</th>
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<tbody>
<tr>
<td>Sodium acid phosphate</td>
<td>2000 lbs STQ</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>1125 lbs STQ (solution)</td>
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</table>

**Other International Regulations**
- **Mexico** - Grade 1, Slight risk, Grade 1
- **Canada**

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.

**WHMIS Hazard Class**
- D2A Very toxic materials
- D2B Toxic materials

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**16. OTHER INFORMATION**

Prepared By: Regulatory Affairs  
Thermo Fisher Scientific  
Tel: (412) 496-8929

Creation Date: 22-Feb-2010  
Print Date: 22-Feb-2010  
Revision Summary: "***", and red text indicates revision
Disclaimer
The information provided on this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of MSDS
7.6 POLICY FOR RADIATION TISSUE SAMPLING

<table>
<thead>
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<tbody>
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<td>Revised</td>
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<tr>
<td>Reviewed</td>
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<tr>
<td>Reviewed</td>
<td></td>
</tr>
</tbody>
</table>

POLICY FOR RADIATION TISSUE SAMPLING
Surgical Pathology Procedures
For Handling Specimens Containing Radioactive Material

1. Specimens from Patients Undergoing Diagnostic Nuclear Medicine Testing
   There are no special precautions necessary for samples taken from patients undergoing
diagnostic Nuclear Medicine procedures such as bone scans, PET scans, cardiac stress
tests, etc. Specimens shall be obtained observing "standard precautions". Disposal of
samples may be made via the appropriate "Biohazard" waste stream. Excreta from these
patients may be disposed of in the sanitary sewerage system.

2. Sentinel Node Biopsy Procedure:
The amount of radioactive material used during a sentinel node procedure is small. These
tissue samples may be transported from the OR to the laboratory without radiological
precautions. Radiation dose to pathology personnel who handle the radioactive sentinel
node are minimal. Therefore, the histological specimen can be processed without delay.
Sentinal node specimens can be disposed of through ordinary medical waste disposal
methods.

3. Specimens from Patients Receiving Therapeutic Doses of Radioactive Material:
   No blood work, urinalysis, cultures or other lab tests should be taken unless cleared by
Radiation Safety. When obtaining patient specimens, use standard precautions. All
specimen containers will be labeled with "Radioactive Material" labels or tape. Once
analyzed, the specimen containers should be segregated from regular biological waste.
Radiation Safety must be called for proper disposal. Call 4-5961 after a surgical procedure
for Radiation Safety to monitor the waste and surgical instruments.

If tissue sample contains radioactive sources (e.g. prostate or lung tissue containing
implanted radioactive seeds) Radiation Safety should be contacted to take possession of
the radioactive seeds.

4. Death of a Patient:
   If a patient dies with a radioactive source or a therapeutic dose of radioactive material in
the body, the Radiation Safety officer and responsible physician must be notified. Before
the body can be removed to the morgue, a radioactive tag, indicating the source, amount
and activity must be attached to the body. The Radiation Safety Officer will supervise the
safe care and handling of the body. If the body is to be cremated, the Radiation Safety
Officer must be consulted.

7/9/09

GLD:sm
Section V
Department of Nursing
Radiation Safety Manual

Operating Procedures and Management of Patients with Radioactive Implants or Other Radiotherapeutic Agents

I. General Information
II. Personnel Monitoring
III. Nursing Procedures for Patients Administered Radioactivity
IV. Radioactive Patient Documentation, Tags, Labels, and Signs
V. Instructions for Physicians and Other Hospital Personnel in the Patient Care Area
VI. Precautions for Visitors
VII. Transportation of Patients with Internal Radiation Sources
VIII. Emergencies Related to the Clinical Condition of the Patient
IX. Radiation Incidents
X. Death of a Patient with a Radioactive Source (or Sources) in Place
XI. Treatment with Removable Encapsulated Sources
XII. Nursing Care of Patients with Sealed Sources (Cs-137, I-125, Ir-192, etc.)
XIII. Precautions for Patients Receiving Therapeutic Doses of Radioactive Iodine-131
XIV. Nursing Care of I-131 Patients
XV. Precautions for Patients Receiving Diagnostic Doses of Long-lived Isotopes
Section V
Department of Nursing
Radiation Safety Manual

Operating Procedures and Management of Patients with Radioactive Implants or Other Radiotherapeutic Agents

I. General Information

By applying the principles of radiation protection, nurses and other personnel can greatly reduce their exposure.

A. Factors Determining the Amount of Radiation Exposure an Individual Receives:

1. **Time**
   Minimizing the time spent near the patient will decrease the exposure to radiation. Plan patient care so that activities are accomplished in the shortest amount of time possible.

2. **Distance**
   The exposure rate falls off very rapidly with distance. In fact, as you double the distance, you decrease the exposure rate by a factor of four, according to the Inverse Square Law.

3. **Shielding**
   A properly designed shield should be used whenever the safety factor of time and distance cannot be employed. Lead aprons, however, do not offer significant protection against the radiation from sources of Cs-137. Contact Radiation Safety Officer for further information.

B. Radiation Exposure for Personnel on Patient Care Units

1. **Background Radiation**
   Background radiation is the natural radiation that everyone receives. Radiation is found in soil, ground waters, building materials and also comes from outer space in the form of cosmic rays. Radioactive materials such as potassium-40 are found in the human body. Background is typically 1 mrem/day to the average person.

2. **Radiation Levels in the Corridor Outside a Patient Room**
   The Radiation Safety staff measures the radiation levels in the corridor outside the rooms of patients receiving therapeutic doses of radioactivity. While the levels are minimal for visitors and staff who are not permanently in this location, it is prudent to assign patients who are over age 55 to adjoining rooms where they are continuously present.

3. **Maximum Permissible Doses**
The maximum permissible dose of radiation exposure allowed for non-pregnant hospital workers is mandated by the Radiation Control Agency.

Whole Body: 5,000 millirems/year (Total Effective Dose Equivalent)
Lens of the Eye: 15,000 millirems/year
All other organs: 50,000 millirems/year

The maximum permissible dose to embryo/fetus due to occupational exposure of pregnant women must not exceed 500 millirems.

The maximum permissible dose to any member of the public is 100 millirems/year (Total Effective Dose Equivalent).

C. Exposure rates at one meter for a number of radionuclides are given in Table I.

These are calculated from the specific gamma ray emission and the Inverse Square Law of a point source. They are accordingly somewhat higher than the expected measured rates since there is no allowance made for attenuation of the radiation or distribution of radioactivity in the body of the patient.

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>Half Life</th>
<th>Exposure Rate at 1 Meter per 100 mCi Unshielded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iridium-192</td>
<td>74 days</td>
<td>48 mR/100 mCi per hr.</td>
</tr>
<tr>
<td>Iodine-131</td>
<td>8 days</td>
<td>22 mR/100 mCi per hr.</td>
</tr>
<tr>
<td>Iodine-125</td>
<td>60 days</td>
<td>7 mR/100 mCi per hr.</td>
</tr>
<tr>
<td>Cesium-137</td>
<td>30 years</td>
<td>33 mR/100 mCi per hr.</td>
</tr>
</tbody>
</table>

II. Personnel Monitoring

A. Personnel Monitoring Policy

1. All full-time and part-time nursing personnel assigned to 8A are issued a permanent monitoring badge.

2. Nursing Department floats and certified nursing assistants (CNA) are generally not assigned to patients with radioactive sources in place. However, if this arrangement is necessary, dosimeters must be worn.
3. The nursing leadership person on the patient unit is responsible for seeing that float or agency persons and/or private duty nurses are familiar with Radiation Safety precautions.

4. Student nurses are not assigned to care for patients receiving therapeutic doses of ionizing radiation.

5. The badges are sent each quarter by the Radiation Safety Office. A permanent record of exposure levels is kept by the Radiation Safety Officer and a copy of the report of exposure is sent to the Clinical Coordinator. The Radiation Safety Office will investigate the circumstances involved for any individual who receives a quarterly exposure in excess of 900 millirems.

B. Dosimeters

The Radiation Safety Office provides pocket dosimeters (Fig. 2.) and a log book which is kept in designated areas on the nursing unit 8A. Staff not permanently assigned to the unit but who may need to enter the room of a patient who is radioactive will use a dosimeter to monitor and record their exposure. Following are the steps for proper use of a dosimeter.

1. In the logbook record your name, date and serial number of the dosimeter being used along with the initial reading.

2. Fasten dosimeter to clothing at waist level.

3. After use, take the final dosimeter reading and subtract from initial reading to calculate exposure. Enter this in the logbook.

4. The logbook provided on the unit must be completed by each individual using a dosimeter.

5. Loss of a dosimeter or its removal from the hospital is reported to the Radiation Safety Officer.

Other monitoring devices may be used at the discretion of the Radiation Safety Officer.

C. Radiation Exposure Notification

1. The Radiation Safety Officer must be notified immediately of any single dosimeter reading of 90 mR or more (being certain that the dosimeter was set to ZERO at the initial exposure).

2. Nursing personnel should not receive more than 100 mR in a seven day period as evidenced in the dosimeter log book. Each individual
should keep track of his/her cumulative reading for the previous seven
days.

3. Nursing personnel who inadvertently sustain a cumulative reading
greater than 100 mR in less than seven days may NOT be assigned to
care for patients with radioactive sources for a period to be determined
by the Radiation Safety Officer.

4. The Radiation Safety Officer will notify the Assistant Director of
Nursing on the unit of any additional or unusual limitations placed on
personnel in relation to their radiation exposure.

D. Procedure for Radiation Badge Service

1. Arrival of Badges (8A)
   a. Distribute badges on a day close to the date marked on the film
      packets.
   b. Collect the old badges.
   c. Check to make sure that all people are badged appropriately.
   d. Mark reply on form and list corrections to be made, if any.

2. Radiation Exposure Reports
   a. Post the report in an area accessible to all workers, preferably near
      all other regulatory documents, OR have on the report on file so
      that any monitored worker can inspect his or her exposure record.
      These reports must be kept on file for inspection.
   b. If there are any questions concerning exposure, they should be
      raised with the Radiation Safety Officer (4-5961)

3. Changes
   a. Deletions: Any worker who is no longer assigned to the
department should have his/her name removed from the badging
list as soon as possible. On the reply form that is enclosed with
each shipment of badges, write:

      DELETE - Worker's Name, Department, Account No., Badge No.

   b. Name Changes: List former name and present name. Give
      Department, Account No., Badge No.

   c. Additions: Complete this information and send to the Radiation
      Safety Office.
NAME (Please Print) ________________________

Social Security No. ________________________

Date of Birth ________________ Sex __________

Department ________________________ Ext. __________

Has employee been badge elsewhere? __________ If so, where? __________

Trained in Lab Protection Procedures Y ___ N ___ N/A ___

Forms can be obtained from the Radiation Safety Office, Ext. 4-5961.

III. Nursing Procedures for Patients Administered Radioactivity

A. Nursing personnel should perform their duties in an efficient manner being conscious of time and distance. Special instructions may be issued by the patient's physician or the Radiation Safety Officer. The informed care giver can lessen apprehension on the part of the patient.

B. The degree of exposure of personnel is determined largely by the distance from the source of radiation and the length of exposure (time). Therefore, all nurses who regularly care for patients being treated by radiation sources internally should perform their nursing care activities in the shortest amount of time possible. Work efficiently and quickly, give care essential to the comfort and well being of the patient until the source material is removed or the radiation precaution is no longer necessary.

C. Shielding (such as lead aprons) is of little value in protecting personnel against radiation exposure from cesium implants which are the most commonly seen on nursing units.

D. Patient care activities should be planned so that as much work as possible is carried out away from the patient's bedside.

E. Nursing personnel should not spend time visiting with a patient close by the bedside. Conversations with patients which take place from a point immediately inside the room door can be effective in minimizing the patient's feeling of isolation.

F. Personal services such as bathing, shaving, etc., are considered non-vital services for the radioactive patient. Patients are encouraged to care for
themselves and to be as self-sufficient as possible, thus avoiding close contact with personnel.

G. A nurse is to be assigned to no more than two (preferably one) patient with a radioactive source at any one time.

H. Nurses known or suspected to be pregnant are not assigned to care for patients with radioactive sources in place. It is the responsibility of the staff member herself to report a known or suspected pregnancy to the Nursing Care Coordinator and/or Assistant Director of Nursing.

IV. Radioactive Patient Documentation, Tags, Labels and Signs

A. Medical Record

A "Caution-Radioactive" sticker should be attached to the cover of the Medical Record by the Radiation Safety Office for each patient who is receiving a therapeutic dose of radiation by means of implants or internal dose.

B. Precautions Tag

"Caution-Radioactive" tags should be attached to the patient at all times (wrist tags) and to the door. Tags are attached to bed, stretcher or wheelchair when necessary to transport the patient away from the room. The nurse caring for the patient is responsible for tagging these items.

SPECIAL NOTE: The tag or written statement included in the patient's medical record shall:

1. Specify the radionuclide administered by the physician and the activity in milliCuries or mCi Equivalent at the time of administration.

2. Specify the radiation level at both 1 meter and in the corridor, the date, the time the determination was done and by whom.

3. If possible, specify the date on which precautions shall cease to be required.

V. Instructions for Physicians and Other Hospital Personnel In the Patient Care Area

A. Physicians

1. Any physician wearing a pocket dosimeter when visiting a patient must log it in and out in the book provided.

2. Physicians requesting a radiation badge should be referred to the Radiation Safety Officer.
B. **Dietary Personnel**

1. Dietary personnel may **not** enter the room of patients who have ionizing radiation sources in place.

2. The dietitian will be advised on the diet sheet by Unit Services Management that nursing personnel must serve and remove meal trays, which will be delivered outside the patient’s room.

C. **Laboratory Personnel**

Laboratory personnel **may** enter the patient’s room and perform routine tasks as usual unless the physician in charge or the Radiation Safety Officer issues special instructions on the Medical Record to the contrary. They will be issued a dosimeter with readings logged before and after visiting the patient. Laboratory personnel will obtain dosimeters from the Nursing Care Coordinator or a delegate on the Patient Care Unit.

D. **Housekeeping Personnel**

Housekeeping personnel **may not** enter the patient’s room unless the Radiation Safety Officer issues special instructions to the contrary. Such persons should be issued a dosimeter with reading logged before and after entering patient room. Dosimeter can be obtained as above from the Nursing Care Coordinator or delegate.

E. **Other Personnel**

Personnel not directly involved in patient care are restricted from patient rooms where a radioactive source is in place.

VI. **Precautions for Visitors**

Visitors are not allowed to visit in the patient room. They will remain at the door or at the limit marked by the Radiation Safety Office for the time prescribed by the Radiation Safety Office. Children are not encouraged to visit, particularly for extended periods of time.

VII. **Transportation of Patients with Internal Radiation Sources**

A. Following an operative procedure in which a radioactive implant is used, the patient is removed from the operating room and transported directly to the Patient Care Unit.

B. The patient is moved as quickly as practical by authorized transportation personnel from the Operating Room using an unoccupied elevator to the
patient unit or Radiation Oncology Department (for source localization films).

C. Transport of such patients off the Nursing Unit must be approved by the attending physician. The Radiation Safety Officer must be notified.

D. Transport personnel must wear a dosimeter and be instructed in the appropriate Radiation Safety procedures by the originating patient care area.

E. Transport personnel must be over age 18.

F. Under NO circumstances may such patients be transported on the first (Main) floor. An unoccupied elevator is to be used.

G. A radiation wristband must be attached to the patient's wrist and a radiation sticker on the chart folder.

H. A radiation precaution tag must be attached to the side rail of the stretcher, bed, or wheelchair when transporting a patient with a radioactive source in place.

I. The patient shall be delivered to a responsible individual. Patients are not to be left unattended in areas where other employees, patients, etc. could be inadvertently irradiated.

VIII. Emergencies Related to the Clinical Condition of the Patient

A. Emergency Procedures

In an emergency, the proper clinical management of a patient takes precedence over routine radiation safety precautions. In an acute emergency it is extremely unlikely that any staff member would receive a significant percentage of their annual maximum permissible dose. It is the responsibility of the nurse and physician in charge of the emergency to rotate staff so that no individual receives excessive exposure. For instance, a staff member would receive less than 50 mR standing one meter from a typical cesium patient for one hour with no shield. For Iodine-131, exposure would be comparable or less, for Iodine-125, the exposure would be negligible.

1. Only personnel absolutely essential to the welfare of the patient may enter the room.

2. Personnel needed for an emergency situation should obtain a dosimeter as soon as possible.

3. Only necessary equipment and supplies may be brought in to the radiation area.
4. The responsible physician should be notified to remove the implant if possible. (Most implants used are easily removable).

5. The Radiation Safety Officer must be called after the emergency incident so that the area and personnel may be monitored.

IX. Radiation Incidents

A. All incidents involving radioactive sources must be reported immediately to the Assistant Director of Nursing or delegate and the Radiation Safety Officer.

Some examples include:
1. Lost or broken radioactive sources.
2. Dosimeter readings of 50 mR or more.
4. Loss of radiation badge or dosimeter.
5. Suspected leakage from sources.
6. Other major deviations from routine.

X. Death of a Patient with a Radioactive Source in Place

A. Notify the Radiation Safety Officer.

B. Notify the responsible physician to remove the radioactive source.

C. Notify the Assistant Director of Nursing (or delegate) of the concerned unit.

D. If the radioactive source is to remain in the body, a mortuary tag must be clearly marked “Radioactive Body” before the body is removed to the morgue. The tag should indicate the source, amount and activity of the source. It is a rare event when a radioactive source is left in place.

E. The Radiation Safety Officer must supervise the safe care and handling of the body.

XI. Treatment with Removable Encapsulated Sources

A. Removable Sources Used Internally

With sealed sources there is no danger of radioactive contamination except if there is severe mechanical damage to the source. This is very unlikely. No special precautions need to be taken with regard to food, utensils, bedding or excreta except to be sure that no source is lost via these routes by accidental premature removal.
The problem to be considered is the amount of time the caregiver should be allowed to spend in patient care activities. This depends on the radiation exposure rates.

B. Determination of Exposure Rate at One Meter from Patient

Measurement of the exposure rate by a survey instrument will be performed by the Radiation Safety staff immediately after insertion of the radioactive source.

This exposure rate at a distance of one meter from the approximate center of the implant or from the organ with the greatest radioactivity shall be entered on the patient’s chart.

For all administrations of radioactive material, an appropriate entry shall be made in the patient’s clinical record by the Radiation Safety staff. This entry shall include the date of administration and the activity and identity of the radionuclide.

| XII. Nursing Care of Patients with Sealed Sources (Cs-137, I-125, Ir-192, etc.) |
|----------------------------------|-------------------------------|
| A. Introduction  
The length of time that caregivers may spend in caring for patients should be limited by the exposure they may receive. Accordingly, as soon as the radioactive implant has been inserted by the physician and the exposure rate determined, the responsible person (RSO or designee) shall attach the radioactivity labels to the patient’s chart and issue any special nursing instructions and limitations on visitors. |
| B. General Instructions  
1. Radioactive sources may be inserted in the Operating Room or in the patient’s room by the afterloading technique.  
2. It may not be known immediately exactly when the radioactive source is to be removed. An estimate, however, can generally be obtained from the physician.  
3. All patients treated with brachytherapy sources will be placed in a specially designated private room with private toilet.  
4. The following area has been designated for patients with sealed radioactive sources: 8A, Main Building  
Rooms on other units will be selected by the Radiation Safety Officer as required. |

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5. Patients placed in adjoining rooms to radioactive source patients should be over age 55 unless, of course, they are also receiving treatment with radioactive sources. The final decision regarding placement of patients in adjoining rooms is the responsibility of the RSO.

6. The physician notifies the charge nurse and the Unit Manager after the source is implanted. The Radiation Therapy Physicist or Dosimetrist is responsible for calling the RSO to monitor radiation levels stat.

7. The RSO will monitor radiation levels one meter from the patient and in the corridor outside the patient’s room. These measurements will be recorded in the patient’s survey form.

8. Radiation signs for the patient room door, the medical record, and the patient’s radiation wrist band are to be in place. Radiation Safety is responsible for posting signs.

9. If the radioactive source comes out of the patient before its scheduled removal, the assigned nurse, using long forceps held at arm’s length, places the source in the lead lined carrier which is in the patient’s room. The physician and the RSO are notified at this time.

NOTE: Radioactive material must not be handled over sinks or drains.

10. When radioactive sources are removed from the patient, the physician is responsible for notifying the nurse supervisor of its removal and for returning the material to the storage area. The nurse supervisor notifies the Unit Services Manager to call the RSO.

11. At the conclusion of the treatment, the RSO surveys to confirm that all sources have been removed from the patient and that no sources remain in the patient’s room or any other area that has been occupied by the patient. At this time, radiation signs will be removed.

12. The RSO is responsible for documenting in the medical record that the patient can be safely discharged according to radiation standards.

13. Nurses should spend only the minimum time necessary near an implant patient and must obtain and wear a radiation badge and dosimeter. In the event that a patient may require more than the minimum amount of care, the RSO shall be consulted regarding safe time limits and rotation of nursing personnel.

XIII. Precautions for Patients Receiving Therapeutic Doses of Radioactive I-131

A. Radioactive I-131 is given to the patient by mouth in the patient’s room and administered by an authorized physician.
B. All patients treated with radioactive I-131 will be placed in a specially designated private room preferably at the end of the hallway. Shielding must be used if there are patients in adjacent rooms.

C. Prior to the patient's admission, the room should be covered in plastic by the Housekeeping Department to facilitate easy decontamination. The Nuclear Medicine Department is responsible for notifying Housekeeping that an I-131 patient is to be admitted.

D. Plastic is applied by the Housekeeping Department to the floor, bedside table, door knobs, faucets, chair, mattress, and pillow and any other areas the patient is likely to touch.

E. All personnel who enter the room must sign the sheet to have thyroid bioassays performed subsequent to patient discharge.

F. Nursing personnel will follow radiation safety procedures. Gloves are worn while in the room and immediately removed upon leaving. The gloves will be put into the radioactive waste trash.

XIV. Nursing Care of I-131 Patients

I-131 patients receiving therapeutic amounts of I-131 will remain in their room until authorized by Radiation Safety to be discharged.

The following procedures are to be followed:

1. All nursing personnel caring for the patient are to have a post-count of the thyroid. Call Radiation Safety to schedule these (4-5961).
2. Pregnant personnel are NOT to care for the patient.
3. Wear a pocket dosimeter or radiation badge when caring for the patient and document the exposure.
4. Wear gloves when working in the patient's room. Take them off before leaving the room and place them in the radioactive waste bag. Wear a gown if you might be brushing against the patient. Dispose of all trash in the designated trash bag and linen in the linen bag located inside the room. All linen and trash is to remain in the room until removed by Radiation Safety.
5. The patient's sheets should be changed as required. Ask the patient to sit at some distance from the bed (greater than 6', if possible). Routine bed making and bathing is not required.
6. All meals are to be served by nursing personnel on disposable trays. Leave used trays in the patient's room in the radioactive waste bag.
7. The patient should use normal toilet facilities. Remind them to flush at least two times following use.
8. No blood work, urinalysis, cultures or other lab tests should be taken unless cleared by Radiation Safety.
9. Visitors are to remain outside the room. No children or pregnant women are to visit.
10. Lead aprons offer no protection against Cesium implants or radioactive Iodine-131.
11. A dismissal survey must be performed prior to discharge.
Emergency Procedures for I-131

Vomiting within 24 hours after oral administration, urinary or bowel incontinence or spillage may result in contamination. Prevent the spread if possible by covering with paper towels. Ask the patient to remain in bed until the spill is cleared up. Leave shoes at the door when leaving the room. Notify Radiation Safety at 4-5961 or Page Operator. If you suspect you are contaminated, remove contaminated clothing if possible.

XV. Precautions for Patients Receiving Diagnostic Doses of Long-Lived Isotopes

Patients, receiving less than 5 milllicuries of I-131 or receiving diagnostic doses of other radiomelides, do not typically present radiation hazards. Precautions for these patients are minimal. Standard (formerly Universal) Precautions must be used when caring for these patients and while handling any bodily fluids.

Patients who have received diagnostic studies in the Department of Nuclear Medicine contain small amounts of radiopharmaceuticals for varying times after treatment. Any body fluid will also be slightly radioactive. Since the potential hazard from viral or bacterial contamination is greater than that of any radiopharmaceuticals in body fluids, the policy for handling items contaminated with body fluids from these patients will be the same as that presently established for the hospital, e.g., disposable items will be appropriately bagged and disposed of appropriately. Linens and similar items will be re-bagged and handled in the usual manner. As long as all persons handling these items use ordinary precautions, i.e., gloves, wash hands well after handling, etc., no hazard will be presented by the very small amounts of radioactive material which may be present.

Note: This policy applies only to diagnostic tests—not for radiopharmaceuticals given for therapeutic purposes.

In-patient charts will be labeled with the radiopharmaceutical and dose which has been administered. The purpose of these labels is to alert direct care providers that patients are potentially radioactive. The Radiation Safety Office (444 5961) must be contacted prior to lengthy operative or interventional radiology procedures that require close contact with the patient for extended time periods.

1. The Nuclear Medicine technologist who administers the radiopharmaceutical will fill out the Nuclear Medicine precautions label with patient name, patient number, radiopharmaceutical administered dose, date and time of administration, and expiration date of precautions.

2. The label will be placed on the outside binder of the patient chart prior to the patient’s return to the nursing floor.

3. Radiation Safety Office, Ext. 45961, will be available for any and all questions pertaining to radioactive materials precautions. Radiation Safety will provide monitoring of staff if necessary.

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4. The nursing floor should remove the sticker after the expiration date and time.

5. If there are surgical procedures, Radiation safety will survey the waste and any surgical instruments that need to be re-used.

**XVI. Precautions for Patients Receiving Therapeutic Doses of Unsealed Radioactive Iodine-125**

A. Radioactive I-25 (Gliosite) is administered in the patient's room by an authorized physician.

B. All patients treated with unsealed radioactive I-125 will be placed in a specially designated private room.

C. Prior to the patient's admission, the room should be covered in plastic by the Housekeeping Department to facilitate easy decontamination. The Nuclear Medicine Department is responsible for notifying Housekeeping that a Gliosite I-125 patient is to be admitted.

D. Plastic is applied by the Housekeeping Department to the floor, mattress and pillow.

E. All personnel routinely caring for patients treated with I-125 should have thyroid bioassays performed subsequent to patient discharge.

F. Nursing personnel will follow radiation safety procedures. Gloves are worn while in the room and immediately removed upon leaving. The gloves will be put into the radioactive waste trash.

G. Only under exceptional circumstances are visitors allowed inside the room.

**XVII. Sentinel Node Biopsy Survey Procedure**

A meter survey will be performed and documented after each sentinel node biopsy.

A calibrated Geiger counter will be used to survey the locations listed in the table below. Before readings are taken, a background and a check source (located on the side of meter) reading will be obtained and entered on the chart. If any readings taken at the locations differ from the background reading, contact the Radiation Safety Office at 4-5961. Hold any contaminated material separate from other material, apply radioactive sticker and hold until surveyed by the Radiation Safety Office.

<table>
<thead>
<tr>
<th>Date</th>
<th>Initial</th>
<th>Background</th>
<th>Meter Check Reading</th>
<th>Table</th>
<th>Linen Trash</th>
<th>Floor</th>
<th>Instruments</th>
</tr>
</thead>
</table>

*Nursing Radiation Safety Manual* 15 *Revised 3/19/09*
XVIII. Nuclear Medicine Precautions

The hospital recently installed a sensitive radiation detector to monitor outgoing hospital waste. This is to prevent any radioactive waste from being sent to the landfill. Although this waste does not pose any hazards, it could potentially set off a sensitive radiation detector at the landfill, which could result in a fine for the hospital.

Nuclear Medicine now has a policy that for certain diagnostic tests, the patient’s chart will be labeled with a Radiation Precaution sticker (see below). Because any body fluids may be slightly radioactive, we would like the staff to isolate soiled items so we can monitor these items before they go into the hospital waste.

Because these patients are receiving a diagnostic (not therapeutic) dose of a radiopharmaceutical, they do not pose any radiation hazard to the staff. Only standard (formerly universal) precautions are required when caring for these patients and handling any contaminated items. There is also no significant risk to pregnant staff for being in close proximity to these patients.

![Nuclear Medicine Precautions](image)

**Isotope Chart**

<table>
<thead>
<tr>
<th>Isotope</th>
<th>Max. Activity (mCi)</th>
<th>Half Life</th>
<th>Label Expiration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ga-67</td>
<td>9</td>
<td>78 hours</td>
<td>8 days</td>
</tr>
<tr>
<td>Te-99m</td>
<td>40</td>
<td>6 hours</td>
<td>1 day</td>
</tr>
<tr>
<td>In-111</td>
<td>5</td>
<td>2.8 days</td>
<td>8 days</td>
</tr>
<tr>
<td>I-131</td>
<td>30</td>
<td>8 days</td>
<td>8 days</td>
</tr>
<tr>
<td>I-131</td>
<td>200</td>
<td>8 days</td>
<td>8 days</td>
</tr>
<tr>
<td>Tl-201</td>
<td>4</td>
<td>73 hours</td>
<td>8 days</td>
</tr>
</tbody>
</table>

*Nursing Radiation Safety Manual* 17 Revised 3/19/09
Guidelines for I-131 Therapy Patients

1. Personnel not directly involved in patient care are not to enter the room.
2. All staff, including physicians, must wear a dosimeter or radiation badge.
3. Pregnant or suspected pregnant female staff may not care for patient.
4. Visitation at door only.
5. No pregnant females or children under 18 years of age are allowed to visit the patient.
6. Foot coverings must be worn to enter this room.
7. Do not remove any items from this room unless monitored by the Radiation Safety staff.

Any questions, call 4-5961 or Page Operator at 4-5611
8.0 RECORDING OF SPECIMEN DEFICIENCIES AND INCIDENTS

Recording of Specimen Deficiencies and Incidents

Administrative Coordinator runs a monthly report of all deficiencies from the CoPath system and that information is shared at the monthly Surgical Pathology Meeting related to QA. Some deficiencies are also considered incidents as noted in the deficiency list.

When “No Clinical History, Preop, Postop” information is given on the requisition form and no frozen section performed a deficiency is noted in the CoPath system as seen on the Deficiency List. On a monthly basis a list of cases that were noted as deficient are reported to each surgeon.

Incidents are those deficiencies as noted in the Anatom ic Pathology Deficiencies and Incidents List below. Completed Incident Forms and attached copies of requisition forms, preliminary paper work, final reports, logs and any other relevant paperwork are to be submitted to either the Administrative Coordinator if related to clerical, secretarial, or pathologists issues or to Manager of Anatomic Pathology if related to cassettes or slides. Each incident that occurs is documented as to specific problem and resolution. Following review of Incident Form by Manager it is given to Director of Anatomic Pathology for review and signature. If the particular incident requires reporting in the Occurrence Reporting System of Lifespan the Surgical Pathology Secretary will be assigned by the Administrative Coordinator to do so. Anatomic Pathology Incident logs are maintained by Administrative Coordinator and Manager of Anatomic Pathology. The entries are discussed monthly at the Surgical Pathology Meeting when logs are collected by Director for QA purposes.
<table>
<thead>
<tr>
<th>Deficiency</th>
<th>CoPath Abbrev.</th>
<th>Area most likely to find deficiency</th>
<th>Dept. Incident Report</th>
<th>Near Miss Event</th>
<th>Non-Pt. Event</th>
<th>Unsafe Condition</th>
<th>Requires Amended Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>fixative inappropriate/specimen left out unfixed.</td>
<td>FI</td>
<td>Acc</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>slides received broken</td>
<td>SB</td>
<td>Acc</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>container/requisition contaminated</td>
<td>CRC</td>
<td>Acc</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>specimen did not survive processing</td>
<td>SSP</td>
<td>Histology</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no specimen in container</td>
<td>NSC</td>
<td>Gross Lab</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>extraneous tissue found in specimen</td>
<td>ET</td>
<td>Pathologist</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>specimen lost by Pathology</td>
<td>SLP</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>incorrect patient accessioned</td>
<td>IPA</td>
<td>Secretary</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>incorrect patient registered</td>
<td>IPR</td>
<td>Acc</td>
<td>Yes</td>
<td>Yes *</td>
<td>Yes *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>missing required patient information</td>
<td>MRP</td>
<td>Acc</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>slides mislabelled</td>
<td>SM</td>
<td>Acc</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>slides not labelled</td>
<td>SNL</td>
<td>Acc</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mismatched required patient information on container and requisition</td>
<td>MIS</td>
<td>Acc</td>
<td>Yes</td>
<td>Yes *</td>
<td>Yes *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>specimen submitted with incorrect name on requisition and container</td>
<td>SS</td>
<td>Acc</td>
<td>Yes</td>
<td>Yes *</td>
<td>Yes *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>site/side information missing or does not match</td>
<td>SID</td>
<td>Acc</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no clinical, pre-op, post-op history</td>
<td>NADA</td>
<td>Acc</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no requisition slip</td>
<td>NRS</td>
<td>Acc</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no ordering physician</td>
<td>NOP</td>
<td>Acc</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no procedure date</td>
<td>NPD</td>
<td>Acc</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LMP not provided</td>
<td>LMP</td>
<td>Acc</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>site/side on final report amended</td>
<td>ASF</td>
<td>Ordering Physician</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>patients incorrectly merged in CoPath system</td>
<td>PIM</td>
<td>Secretary</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>MISC</td>
<td>All</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* If error not identified prior to final report
MISSION STATEMENT

In its commitment to provide for and continuously improve the quality of its service to the patients of The Miriam and Rhode Island Hospitals, the Department of Pathology seeks to evaluate, monitor and improve upon its quality assurance activities on an ongoing basis. This evaluation will include the following:

- Integration of the QA program across laboratory service lines and throughout the department. Each employee will be trained in all aspects of the QA/QI plans as they relate to his/her job functions. Each service will seek to define these activities in relationship to their specific services and will strive to incorporate elements of the plan throughout their operation. The focal points will highlight staff education, improvement of laboratory processes, data collection, overall efficiencies and productivity.

- The QA program will be implemented through the biweekly Surgical Pathology Staff Meetings and the monthly QA meetings. Focus groups will be assembled to evaluate specific problems and specific issues.

- The Department of Pathology will seek to conduct interdepartmental QA activities in order to improve patient outcomes and to increase the quality of our services.

- The Department of Pathology will seek to develop lines of communication with other departments to increase cross disciplinary effectiveness, to serve as a resource to other laboratory service areas and to participate in all aspects of patient care as they relate to diagnostic testing and laboratory medicine services.

- The Department of Pathology will seek to evaluate its services with the primary goal of integrating its activities with the mission of Rhode Island Hospital as they relate to specific issues of patient care.
Outline of the QA/QI Plan

A. The goal of the plan is to insure that the highest possible standards for the delivery of pathology services are achieved and that those standards are incorporated into the fabric of our daily operations.

B. Objectives for 2013-2014

The continued evaluation of the quality of pathology services through the monitoring of major clinical indicators which are focused on diagnostic accuracy, timeliness of reporting, report content adequacy and completeness and clinico-pathological correlations.

The development of effective criteria for the identification of deficiencies in specimen requisitions (eg. absent pre-op and post-op diagnoses, lack of history) and the development of a plan to reduce the number of cases with these problems.

C. Plan Elements

1. Monitoring procedures to assess the effectiveness with which aspects of service are carried out.

2. Regular review of findings to identify deficiencies requiring systematic changes for correction.

3. Development and implementation of corrective action plans.

4. Assessment of effectiveness of actions.

D. Organization of QA Activities

1. Surgical Pathology has identified its scope of care which it will use to plan, monitor and evaluate activities.

   Specimens are obtained both from inpatients and outpatients and as outside consults. Work-up may include routine histological evaluation and/or special procedures (immunohistochemistry, molecular diagnostics, electron microscopy and immunofluorescence). Surgical Pathology is responsible for accurate and timely reporting of results. The staff provides consultations regarding test selection, test strategies and interpretation of findings.

2. The aspects of the services that are monitored are selected to insure that diagnoses are accurate, that they are delivered in a timely fashion and that they are effectively transmitted to clinicians.

3. Indicators were developed (and continue to be developed) through biweekly Surgical Pathology Staff Meetings and our monthly QA conferences. The major indicators focus on diagnostic accuracy, report content accuracy, review of tissue processing techniques and special procedures, and clinicopathological correlations.

E. Monitoring Process

1. Data collection. The department systematically monitors and collects data for the purpose of service/care evaluation. Data are collected monthly and are forwarded to the Pathologist-in-Chief and QA Director for data analysis, identification of specific patient-care issues and evaluation of the effectiveness of corrective actions.
2. Corrective action implementation. The Pathologist-in-Chief has the responsibility for implementing corrective actions. Corrective action plans will contain the following items:

- What is to be changed
- When and how the correction action will be implemented
- Individuals responsible for implementation
- Time interval set for reassessment
QUALITY ASSURANCE

1. **General Mechanisms of QA Monitoring for Surgical Pathology**
   a. **Random Reviews of Surgical Pathology Cases**

   A review of 5% of all cases selected at random. Slide materials and final reports are distributed on a rotational basis to the surgical pathologists. The results are reviewed, summarized by and are presented at the Quality Assurance Meeting. Each case is reviewed with respect to:

   - Diagnostic Accuracy
   - Completeness and accuracy of gross descriptions
   - Completeness and accuracy of staging information (if applicable)
   - Quality and accuracy of frozen section diagnoses
   - Quality of histological sections
   - Quality and appropriateness of special stains
   - Quality and appropriateness of special studies (electron microscopy, immunohistochemistry, molecular diagnostics)

   Specimen identification data provided on requisition

   - The results of the random sampling are entered into the COPATH module **(under QA Diagnosis Review)** and are reviewed on a regular basis by the Pathologist-in-Chief.
     The following system is used for entering data into COPATH:

     Q1 Total Agreement
     Q2 Minor disagreement/does not change diagnosis or affect patient care
     Q3 Defects in clarity with minimal effects on patient care
     Q4 Major defects with minimal effects on patient care
     Q5 Major defects that could affect care/treatment of patient

   - Any reports requiring corrections or additions are discussed with the appropriate pathologists and clinicians and amended reports are issued.
   - Individuals with a higher than usual proportion of inaccuracies are counseled.
   - Problems with staining quality or sectioning are discussed with the manager and/or supervisor of the histology laboratory and corrective measures are undertaken.
- Problems with specific special procedures are discussed with directors of appropriate laboratories.
- Problems with incomplete or inaccurate clinical information are recorded and a letter documenting the deficiency is sent to the appropriate clinical staff and the Surgeon-in-Chief.

b. Review of Cases for Second Opinions (Slides Sent- Interdepartmental Consult Reviews)

All cases requested for second (outside) opinions are reviewed by a pathologist who was not responsible for the initial diagnosis. Each case is reviewed with respect to the parameters listed in section 1.a. The data derived from this analysis are entered into the COPATH QA Module. Any discrepancies are brought to the attention of the original pathologist and to the Pathologist-in-Chief. Amended reports are prepared prior to case send out, and the revisions are indicated in the revised report. The following system is used for entering the data into COPATH:

Q1  Total Agreement
Q2  Minor disagreement/does not change diagnosis or affect patient care
Q3  Defects in clarity with minimal effects in patient care
Q4  Major defects with minimal effects in patient care
Q5  Major defects that could affect care/treatment of patient

If differences in opinion cannot be reconciled, the case may be sent to an additional consultant for his/her opinion.

c. Interdepartmental consultations are documented (Slides returned)

In cases in which extradepartmental consultation is sought or in cases where case has been reviewed extradepartmentally for any reason, the consultant's opinion is reviewed by the responsible attending pathologist. The consultant's report is scanned with the case record.
The following system is used for entering data into COPATH:

Q1 Total Agreement
Q2 Minor disagreement/does not change diagnosis or affect patient care
Q3 Defects in clarity with minimal effects in patient care
Q4 Major defects with minimal effects in patient care
Q5 Major defects that could affect care/treatment of patient

Q3 or lower, Vice Chief should be contacted.
When no agreement as difference Vice Chief should be contacted

d. Conference Reviews
i. Clinical Conferences
   Department members are responsible for case presentation at a large number of Interdepartmental conferences. A record is kept of all reviewed cases and any differences in diagnoses are recorded. If necessary, revised reports are issued as a result of the review.

ii. 2:00 PM Surgical Pathology Consensus Conference
   This conference is held at the multiheaded microscope room in the Bridge Building Surgical Pathology Suite at RIH. The conference is attended by the surgical pathology attending staff and residents. This conference also includes cases from The Miriam Hospital. The purposes of the conference include:
   - Presentation and discussion of diagnostic problems and cases of special interest.
   - Correlation of special studies to reach final diagnoses on current cases.
   - Presentation of follow-up information by staff and residents on current or past cases.

   Discussion of selected cases reviewed for QA:
   1. Cases in which there are discrepancies between previous and current biopsies.
   2. Cases in which there are discrepancies between cytological and histological diagnosis.
   3. Cases in which there are discrepancies between original and consultant diagnoses.
   4. Cases of special interest.
   5. Cases in which special procedures have been performed.

   Cases presented at this conference are entered in the COPATH system by the secretarial staff using the log from the conference indicating all attendees and that consensus was reached (Q1). For any cases in which there are discrepant diagnoses or consult reviews, the appropriate clinicians are contacted and a revised report is distributed.

e. Internal Consultations
   The Department documents all internal consultations.

   Action Criterion:
   When an intra departmental member has reviewed a case, the opinion of that pathologist is included in the comment field of the final diagnosis. ("This case has also been reviewed by Dr. Jones, who concurs with this interpretation"). When the case is reviewed with the entire staff at the 2:00 PM conference, the opinion of the group is included in the comment field of the final diagnosis. ("This case has been reviewed at the Departmental Surgical Pathology Conference..."
with agreement with the final diagnosis). All cases, which are reviewed at this conference (including cases that have been signed out previously), are entered as having been reviewed in the COPATH system. In some cases, the name of the consulting pathologist is included in the diagnostic report. If a second pathologist’s name is entered in Copath a report indicating that Internal Consultation occurred will be generated.

f. Analysis of Revised Diagnoses

All cases with revised diagnoses are collected, the reasons for revision are tabulated and are discussed with the responsible attending pathologist. Data are presented to the Pathologist-in-Chief in order to identify trends and opportunities for quality improvement.

g. Review of Prior or Concurrent Materials

Case numbers of prior and concurrent biopsies and cytological samples are included in the working drafts that are generated by the COPATH system. If relevant to the current biopsies, reference is made in the Comment field of the signout that prior materials have been reviewed and compared with the current materials. If there is a current (pending) cytology sample, reference to the case number (and result, if available) should also be included in the Comment field.

h. Prospective Case Reviews of Breast and Prostate Needle Biopsies and Positive Sentinel Node Biopsies for Metastatic Melanoma Measuring Less than 0.5 mm

All breast and prostate needle biopsies, benign and malignant, will be reviewed by both a primary pathologist and by a second pathologist. The second pathologist will indicate whether the diagnosis is benign or malignant. This information will be recorded in the comments section of the pathology report.

All positive sentinel lymph node cases for metastatic melanoma where the metastatic deposit is less than 0.5 mm or is visualized by IHC alone should be confirmed either by a second pathologist or reviewed at daily consensus signout. This information should be recorded as a comment.

2. Specifically Monitored Quality Indicators for Surgical Pathology (Presented at Departmental QA Meeting)

a. Diagnostic Accuracy, Report Content and Turnaround Time

Intraoperative consultations, including frozen sections and gross examinations are accurate.

All cases with intraoperative diagnoses are reviewed at the time of case signout for any discrepancies with the final diagnosis and are classified as follows:

- FS 1. Complete agreement
- FS 2. Deferred diagnosis
- FS 3. Discrepancy due to sampling with no significant impact on patient care
- FS 4. Discrepancy due to sampling with significant impact on patient care
- FS 5. Discrepancy due to interpretation with no significant impact on patient care
- FS 6. Discrepancy due to interpretation with significant impact on patient care

This system of reporting was modified in March, 2002, from a system that included the following categories:

- Q 1. Total Agreement
Q 2. Minor disagreement/does not change diagnosis or affect patient care  
Q 3. Defects in clarity with minimal effects on patient care  
Q 4. Major defects with minimal effects on patient care  
Q 5. Major defects that could affect care/treatment of patient  

**Action Criterion:** Cases in which there are discrepancies are brought to the attention of the Attending Pathologist responsible for the frozen section and to the Director of Quality Assurance and the Pathologist-in-Chief. The responsible Clinical Attending is notified of the discrepancy and a report that documents the discrepancy is prepared and kept on file within the department. Reasons for the discrepancies are also discussed in the final diagnostic report for the individual case. Cases in which there are discrepancies are also discussed at the daily 1:00 PM Surgical Pathology Staff Conference. A second mechanism for review of accuracy of frozen section diagnoses involves a monthly review of all intraoperative consultations based on a log generated from the COPATH system. Discrepancies are classified as outlined above (1-6).

**Action Criterion:** The action criterion is similar to that described above. Data are presented at the monthly QA meeting. Cases in which there were significant discrepancies are reviewed at the daily 1:00 PM Surgical Pathology Staff Conference. Recurring problems with specific specimen types are discussed at the Surgical Pathology Staff Conference, the weekly Surgical Pathology Meeting and at the Monthly Quality Assurance Meeting.

Recurring problems experienced by individual Attending Pathologists are discussed with the Director of Anatomic Pathology and corrective plan is undertaken.

ii  
**Intraoperative Consultations, including frozen sections and gross examinations, are signed out in a timely manner**

The time of receipt of intraoperative consultations is recorded on the Frozen Section Consultation Form at the time of specimen receipt in Pathology. The time at which the intraoperative consultation is completed is also recorded when the first specimen for that case is reported to the Operating Room.

Time for completion of consultations is calculated and the average frozen section turnaround time is recorded for the month.

**Action Criterion:** The average turnaround time is presented at the Quality Assurance Meeting. Unduly delayed intraoperative turnaround times are discussed with individual pathologists, reasons for delays are analyzed and a corrective plan is undertaken.

iii  
**Final Surgical Reports are signed out in a timely manner**

Average biopsy turnaround time is calculated monthly. Case turnaround time statistics (the interval from accessioning to final signout) are monitored by a weekly log, which generates data for individual pathologists. Lists of outstanding cases are provided to the responsible pathologists and to the Pathologist-in-Chief.

**Action Criterion:** Responsible pathologists are informed of unsigned out cases. Trends are monitored for follow-up action. Recurrent problems are discussed with the Director of Anatomic Pathology and a corrective plan is undertaken.
**Action Criterion:** When an intradepartmental member has reviewed a case, the opinion of that pathologist is included in the comment field of the final diagnosis. (“This case has also been reviewed by Dr. Jones who concerns with this interpretation”). When the case is reviewed with the entire staff at the 1:00 conference the opinion of the group is included in the comment field of the final diagnosis. (This case has been reviewed at the Departmental Surgical Pathology Conference with agreement with the final diagnosis). All cases which are reviewed at this conference (including cases that have been signed out previously) are entered as having been reviewed in the COPATH system. In some cases, the name of the consulting pathologist is included in the diagnostic report.

3. **Hospital QA Program (Procedure Review Committee)**

   All cases are reviewed at signout for the following parameters which are presented at the Invasive Procedure Committee Meeting. Data are entered into the COPATH system (in field called Retrieval Flags) using the following designations and are tabulated monthly. The following designations are used:
   
   C1  Clinical or pathological diagnosis discrepancy (includes preoperative/postoperative discrepancy and post-operative/pathological diagnosis discrepancy).
   
   C2  Positive margins

   This system was put into effect in July, 2002. It replaced the following system:
   
   CO  Default category for non-registered cases
   
   C1  Frozen section/permanent section discrepancies
   
   C2  Preoperative/postoperative diagnoses discrepancies
   
   C3  Postoperative/pathologic diagnoses discrepancies
   
   C4  Inadequate Surgical Pathology Requisitions
   
   C5  Positive surgical margins

4. **Additional QA Parameters**

   a. **The Surgical Pathology Report is accurate**

      This parameter is monitored by a random review of 5% of cases and by extensive review of cases in association with a large number of specialty conferences. In addition, all reports are monitored daily by the Pathologist-in-Chief for completeness and clarity.

      **Action Criterion:** If indicated, Surgical Pathology Reports are revised and clinicians are advised of the reasons for revision. Recurrent problems are discussed with the Pathologist-in-Chief and are presented at the Surgical Pathology Committee Meeting. A corrective plan is then undertaken.

   b. **The Surgical Pathology Report contains adequate information to guide patient care**

      This parameter is monitored by a random review of 5% case, by extensive review of cases presented in association with specialty conferences and by a daily review of all reports by the Pathologist-in-Chief. During the past 2 years the report format has undergone extensive revision based on a series of practice guidelines agreed upon by the members of the department in consultation with surgical colleagues representing different specialties. As a result, all reports now contain detailed information on staging parameters and also includes TNM classification.
Action Criterion: If indicated, Surgical Pathology reports are revised. Recurrent problems are discussed with the Pathologist-in-Chief and are presented at the Surgical Pathology Committee Meeting. A corrective plan is then undertaken.

c. **Special procedures are of good technical quality and are relevant to the diagnosis**

   This parameter is monitored through the 5% random review process (immunoperoxidase, immunofluorescence, electron microscopy and molecular diagnostics) with respect to technical quality and relevance to diagnosis. Final diagnoses together with addenda resulting from the special procedure are reviewed and the results are tabulated.

Action Criterion: Cases in which special procedures are not relevant to the final diagnosis are discussed with the attending pathologist responsible for the case. Cases in which the technical quality is poor are discussed with the physician and/or supervisor responsible for the particular special procedures. Recurrent problems are discussed with the QA Committee and with the Pathologist-in-Chief and a corrective plan is undertaken.

5. **Tissue Processing and Staining Techniques**

   a. **Histologic sections and special stains are of good quality and are delivered in a timely manner**

      This parameter is monitored by a variety of mechanisms, including:
      - Daily slide delivery time
      - Daily review to evaluate tissue orientation, section quality and quality of routine and special stains.
      - Weekly random case review which includes quality of histological sections, routine stains and special stains
      - Daily review of preparation of specimens by residents and PAs.

      Action Criterion: Problems with slide delivery time are discussed with Supervisor of Histology lab and Manager of Anatomic Pathology. Reasons for delays are ascertained and corrective actions are undertaken. Problems with slide and stain preparation are discussed directly with Supervisor of Histology Laboratory who subsequently documents the responsible histotechnologist. Correction actions are then undertaken.

      Tissue sections which are incorrectly processed are brought to the attention of the responsible resident or PA. Recurrent problems are discussed with Pathologist-in-Chief.

   b. **Histological levels and special stains are appropriately utilized**

      This parameter is monitored by a weekly review, which includes the issue of whether levels and special stains were appropriate.

      Action Criterion: Evidence of over – or under – utilization of special stains and levels is communicated to the individual pathologist and is reported to the staff as a whole. Individual pathologists are counseled as to the proper utilization of special stains and levels. Recurrent problems are discussed at Surgical Pathology Committee Meeting.

   c. **Specimens are accurately accessioned and labeled and are adequate for histological sectioning**

      During accessioning, cases of the same tissue type are given non-consecutive numbers. Cases in which tissue was lost during processing are documented by the Histology Lab.
Action Criterion: Cases in which specimens are lost during processing are reported immediately to the attending pathologist and to the Pathologist-in-Chief. This report documents the type of loss (e.g. no tissue in cassette after processing, tissue lost from block while cutting, etc.). Procedures are followed to find the tissue and the outcome is documented. The report of the final diagnosis indicates that “a specimen was lost during processing”.

6. Specimen Data Integrity Review

a. The specimen is correctly labeled with patient identification information

The label on the specimen container should include (1) patient name; (2) date of birth; (3) date of procedure; (4) source of specimen (site and side). Compliance is monitored by maintaining a record of specimens in which there are deficiencies in labeling of specimen containers. All such cases are entered into the Specimen/Requisition Deficiency log of COPATH. A record of deficiencies is compiled for monthly review.

Action Criterion: Individual cases are discussed with appropriate clinical attendings. Letters summarizing the deficiencies are sent to responsible physicians when appropriate and the cumulative records of these cases are tabulated periodically so that feedback can be provided to service chiefs.

b. The specimen requisition form is correctly filled out and includes relevant clinical information

Each specimen is accompanied by a requisition form, which should contain the following information:

The requisition form should be stamped with the patient identification plate. If this is not available, the patient’s name and date of birth should be handwritten in the provided space.

The tissue types should be indicated.

Age, sex and brief clinical history should be indicated in appropriate sections.

Specimen procurement date should be indicated in the appropriate box.

Prior therapy should be documented.

Action Criterion: If information necessary to accession a specimen is lacking, the accessioners obtain it by telephone. Deficiencies are entered into COPATH and are reviewed regularly. Letters noting deficiencies are sent to the responsible physicians when appropriate and a record of these cases is tabulated periodically so that feedback can be provided to Chiefs of Service.

c. The specimen is delivered to the department in an appropriate manner

Cases in which empty containers are received or in which a specimen described on requisition is not received are documented in Specimen/Requisition Deficiency option in COPATH. Those specimens that are unlabeled or are leaking are similarly documented.

If frozen sections are requested, the specimens must be delivered unfixed. When requesting a frozen section, the OR personnel should indicate the patient’s name, OR number and the name of the requesting surgeon. The OR personnel should indicate
whether the specimen will be sent directly to pathology or whether the presence of the pathologist is requested in the OR.

If surgeon will be requesting a frozen section outside of the regular working hours, he/she should contact the department with this information. During evening hours and on weekends, pathologist and resident are available by pager (contact page operator).

**Action Criterion:** When a specimen is sent to the department in an inappropriate manner, the responsible physicians or operating room supervisors will be contacted. The cumulative record of these cases will be tabulated periodically so that feedback can be provided to Chiefs of Services.

d. **System Data Integrity Review**
   
i. The specimen is accessioned properly into the COPATH system.
      
      This parameter is monitored through the generation of a case logs.

      **Action Criterion:** Documentations of errors are recorded and are corrected immediately. Accessioning errors are discussed at the Surgical Pathology Meeting. Individuals with higher than average error rates are counseled as to correct procedures.

   
   ii. **Case Sign Out is prompt**

      This parameter is monitored by the generation of unsigned out case lists which are distributed to all pathologists and to the Director of Anatomic Pathology.

      **Action Criterion:** Responsible pathologists are informed of their unsigned out cases. Individuals with higher than average turnaround times are counseled.
<table>
<thead>
<tr>
<th>Date</th>
<th>Pathologist</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special Stain</td>
<td>Grade 1(best) – 4</td>
<td>Comment</td>
</tr>
<tr>
<td>AFB</td>
<td></td>
<td></td>
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<tr>
<td>Alcian Blue</td>
<td></td>
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<tr>
<td>Congo Red</td>
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<tr>
<td>Copper</td>
<td></td>
<td></td>
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<tr>
<td>Elastic</td>
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<tr>
<td>GMS</td>
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<td>Gram</td>
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<td>Iron</td>
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<td></td>
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<tr>
<td>Jones</td>
<td></td>
<td></td>
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<tr>
<td>Mucicarmine</td>
<td></td>
<td></td>
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<tr>
<td>PAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reticulum</td>
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<td></td>
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<tr>
<td>Trichrome</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warthin-Starry</td>
<td></td>
<td></td>
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<tr>
<td>H Pylori</td>
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</tbody>
</table>

H & E Review
8.2 RETENTION POLICY

Retention Policy

Retention of Laboratory Records and Materials

The College of American Pathologists makes the following recommendations for the minimal requirements for the retention of laboratory records and materials. They meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88). The College of American Pathologists urges laboratories to retain records and/or materials for a longer period of time than specified when such would be appropriate for educational or quality improvement needs. Laboratories are encouraged to retain materials for a longer period of time when patient care needs so warrant. In particular, laboratories should consider retaining paraffin blocks, tissue slides, and tissue pathology reports for the same period of time, and possibly longer than the times indicated. Some state regulations may require retention of records and/or materials for a longer time period than that specified in the CLIA-88 regulations; therefore any applicable state laws should be reviewed carefully when individual laboratories develop their record retention policies.

<table>
<thead>
<tr>
<th>Material/Record</th>
<th>Period of Retention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgical Pathology</strong></td>
<td></td>
</tr>
<tr>
<td>Wet tissue</td>
<td>2 weeks after final report</td>
</tr>
<tr>
<td>Paraffin blocks including frozen section residue</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Slides</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Reports</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Accession log records</td>
<td>6 years</td>
</tr>
<tr>
<td>Maintenance records</td>
<td>5 years</td>
</tr>
<tr>
<td>Requisition slips</td>
<td>6 years</td>
</tr>
</tbody>
</table>

<p>| <strong>Cytology</strong>                    |                                      |
| Slides (negative-unsatisfactory) | 5 years                              |
| Slides (suspicious-positive)    | 5 years                              |
| Fine Needle Aspiration Slides   | 10 years                             |
| Reports                         | 10 years                             |
| Accession log records           | 5 years                              |
| Maintenance records             | 5 years                              |
| Requisition slips               | 6 years                              |</p>
<table>
<thead>
<tr>
<th>Autopsy Records</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Wet tissue report</td>
<td>3 months after final</td>
</tr>
<tr>
<td>Paraffin blocks</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Slides</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Reports</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Accession log records</td>
<td>6 years</td>
</tr>
<tr>
<td>Maintenance records</td>
<td>5 years</td>
</tr>
</tbody>
</table>
Departmental Policy

MEMORANDUM

DATE: January 27, 2004
TO: Kathy King
     Blanche Williams
FROM: Ronald A. DeLellis, M.D.
     Pathologist-in-Chief
RE: RETENTION OF ANATOMIC PATHOLOGY SLIDES/BLOCKS/REPORTS AT AMC

The following is a revision of the policy for retention of reports, slides, and blocks at both Rhode Island and The Miriam Hospitals.

Reports and Slides/Blocks

<table>
<thead>
<tr>
<th>Blocks</th>
<th>Wet Tissue</th>
<th>Slides</th>
<th>Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical</td>
<td>2 weeks</td>
<td>indefinitely*</td>
<td>indefinitely*</td>
</tr>
<tr>
<td>Indefinitely</td>
<td>after final report</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Autopsy</td>
<td>3 months</td>
<td>indefinitely*</td>
<td>indefinitely*</td>
</tr>
<tr>
<td>indefinitely</td>
<td>after final report</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cytopathology – Non Gyn FNA</td>
<td>N/A</td>
<td>10 years</td>
<td>10 years</td>
</tr>
<tr>
<td>Cytopathology – Non Gyn and Gyn</td>
<td>N/A</td>
<td>5 years</td>
<td>10 years</td>
</tr>
</tbody>
</table>

Maintenance Logs, Working Drafts, QC

Surgical, Autopsy, Cytopathology 5 years

Requisitions and Accession Logs

Surgical, Autopsy, Cytopathology 6 years

*Slides and reports for 1982 and older were disposed of – per policy signed by Dr. Thomas King in 2001.
8.3 EQUIPMENT MAINTENANCE

EQUIPMENT (CRYOSTAT, PROCESSOR, GLASSWARE) MAINTENANCE

A. Instructions for Loading Cassettes on the Tissue Processors
   1. Add cassettes to center processor (Leica) only. You may add cassettes up until 6:30 PM.
   2. Add cassettes to the basket in numerical order.
   3. Never use more than 2 basket covers at one time. If you need to use 3 baskets, place the uncovered basket under one with a cover.

B. Operating Instructions for the VIP LEICA ASP300

   To place tissue on the processor:
   
   If the processor is empty:
   1. Open the retort by turning the black knob ¼ turn clockwise.
   2. Place the basket(s) in the retort.
   3. Close retort and turn knob back.

   If there are cassettes on the processor,
   1. Press Pause
   2. Open the retort.
   3. Load cassettes.
   5. Press Continue

   To start the program:
   1. Go to the Favorite Programs menu
   2. Select the program you wish to start
   3. Check screen for end date and time.
   4. Press Yes

   To remove the processed tissue:
   1. Press Yes to drain the retort.
2. Open the retort and remove the baskets.
3. Wipe the inside of the retort and clean the sensors with gauze.
4. Begin a Wax Clean on the wax bath with the oldest date.
5. Once the Wax Clean has finished, select and run the Standard Cleaning Program.

C. Operating Instructions for the VIP 3000

The processor's screen guides you through all the steps - read the bright yellow message line.

To place tissue on the processor:

1. At select menu number, choose START PROCESS
2. At exchange marked solution, press EXIT
3. Select program number:       1- daily  2 - weekend. Press ENTER
4. Start mode will be 1 - delay. Press ENTER
5. At enter experiment number, press ENTER
6. At this point, double check the information on the screen to verify all the data - program number, start mode…etc.
7. Press START if everything is correct. Press EXIT to make corrections.

To remove processed tissue:

1. At process finished, press ENTER.
2. Press START to drain.
3. Slide bar to the left, unlatch the cover and remove the tissue.
4. Press START to clean.

D. Cryostat Cleaning and Maintenance

DAILY

1. Wipe out cryostats with 95% ETOH each morning.
2. Cryostats should be decontaminated with 10% Sodium Hypochlorite solution after cutting known infectious cases.
3. For the CM 1850 UV, activate UV for 15 minute cycle each morning and for 60 minute cycle after cutting known infectious cases.
4. Replace cryostat blades each morning.
5. Check temperatures and record.
6. Check for frost and defrost if there is any sign of frosting.
WEEKLY

1. Leica Cryostat - RIH and TMH
   Decontaminate with 10% sodium hypochlorite (tuberculocidal disinfectant) then wipe down with 95% ETOH. Check the waste bottles and empty if necessary.

E. Repairs and Reconditioning
RIH Biomedical Engineering x48779
TMH Biomedical Engineering x32340
Preventative maintenance is performed annually on all equipment. The scheduling and performance of these checks are done by the vendor or by the hospital’s biomedical engineering department.

E. Scale Calibration
1. Scales should be calibrated by bi-annually.

F. Instrument Sharpening
1. When instrumentation is deemed ineffectual to accurately perform its function. New or re-sharpened instrumentation must be put into use.
2. Instruments in need of re-sharpening shall be delivered to the operating room where they will ship the instrumentation out for service. The OR will call the diener when the instrumentation has been returned to the facility.

G. Glassware Washing Protocol
1. Principle:
   Glassware used for special stains in the Histology Lab must be checked periodically to ensure that there is no residual soap or ionic residue from hand or automatic dishwashing which would adversely affect staining results.
2. Procedure:
   a. Once glassware has been washed with Instruclenz, Prezyme or Buell Cleaner (used with automatic dishwasher) rinse thoroughly with tap water.
   b. For silver stains, rinse glassware once more with distilled water.
   c. Once a week, check the pH of the remaining water droplets with pH paper. Results should be between 6.0 and 7.0 @ 25°C. Tolerance limit: +/- 0.5 pH.
   d. Record the results on glassware check sheet.
3. Corrective Action
   a. If the results are unacceptable, re-rinse with tap water and retest.

H. Temperature Monitoring by Aeroscout Probes
1. Every day the lab manager and the lead pathologist assistant receive an e-mail containing the temperature summary report of the past 24 hours. This report documents the minimum, maximum and average temperature for each probe. It also contains the number of alerts that were sent via e-mail to the lab manager and the lead pathologist assistant that need corrective action.
2. Alerts are programmed to alarm when the temperature of a probe is +/- 1°C before going out of range.
3. Corrective actions for alerts that are truly out of range are documented in the Aeroscout system by the lab manager.

4. Every Friday the lab manager and the lead pathologist assistant receive an e-mail containing a report of all alerts that were detected that week.

5. The first work day of the month the lab manager runs a battery level report for all of the Aeroscout probes.

CRYOSTAT MAINTENANCE

<table>
<thead>
<tr>
<th>Month:</th>
<th>Year:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Initials</td>
</tr>
<tr>
<td>CM1850 UV</td>
<td></td>
</tr>
<tr>
<td>(Cryostat #1)</td>
<td></td>
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<tr>
<td>---------------</td>
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</tr>
<tr>
<td>Daily</td>
<td></td>
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<tr>
<td>1. Check</td>
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<tr>
<td>Temperature</td>
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<tr>
<td>2. Wipe Out</td>
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<tr>
<td>debris</td>
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<td>3. Clean with</td>
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<tr>
<td>95% ETOH</td>
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<td>4. Decontamin-</td>
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<td>ated with UV</td>
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<td>Weekly as</td>
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<tr>
<td>needed</td>
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<tr>
<td>1. Oil</td>
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<td>2. Decontami-</td>
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<td>nated with</td>
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<tr>
<td>10% Sodium</td>
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<tr>
<td>Hypochlorite</td>
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<tr>
<td>3. Check waste</td>
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<tr>
<td>bottle, empty</td>
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<tr>
<td>if necessary</td>
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<table>
<thead>
<tr>
<th>CM1850 (Cryostat #2)</th>
<th></th>
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<tbody>
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<td></td>
</tr>
<tr>
<td>1. Check</td>
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</tr>
<tr>
<td>Temperature</td>
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<td></td>
</tr>
<tr>
<td>2. Wipe Out</td>
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</tr>
<tr>
<td>debris</td>
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<tr>
<td>3. Clean with</td>
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<td>95% ETOH</td>
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<td>4. Decontaminated</td>
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<tr>
<td>with UV</td>
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<td>Weekly as needed</td>
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<tr>
<td>1. Oil</td>
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<td>2. Decontaminated</td>
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<td>with 10% Sodium</td>
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<tr>
<td>Hypochlorite</td>
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<tr>
<td>3. Check waste bottle</td>
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<tr>
<td>, empty if necessary</td>
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## TEMPERATURE QC

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<tr>
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<th>CM 1850</th>
<th>Refrigerator #1</th>
<th>Refrigerator #2</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

Acceptable Ranges:
- Cryostats: -20°C (+/-5)
- Refrigerators: 4°C (+/-5)
9.0 PRINTING REQUISITION AND CONTAINER LABELS DURING ACCESSIONING

<table>
<thead>
<tr>
<th>Prepared by</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Revised</td>
<td></td>
</tr>
<tr>
<td>Reviewed</td>
<td></td>
</tr>
<tr>
<td>Reviewed</td>
<td></td>
</tr>
</tbody>
</table>
Printing Requisition and Container Labels During Accessioning

If Requisition and container labels are set to print for a specimen class, the Print Labels check box appears on the Source tab in the Accession Entry/Edit activity for that specimen class.

When the Part Type is added to the case a check will display in the Print Label check box.
Two Requisition labels and a Container label for each part type will print to the printer built in Copath for the location when the case is saved. One requisition label will be placed on each of the two Requisition sheets associated with the case on the upper left side of the requisition over the area with the hospital address. The appropriate container label will be placed on each container – trying (if possible) not to cover any patient or specimen information. The labels print in reverse order. The container label for Part A prints followed by the rest of the parts. The Requisition labels are the last ones to print.

If additional parts are added after case is accessioned, only the labels for the added parts will print when the case is saved.

**Frozen Sections**

Accession the case, assigning the correct part sequence to the frozen section. If the frozen section is not Part A use the “Soft Tissue, nos” part type as a place holder for the parts that have not arrived from the OR.

Save the case. The requisition and container labels will be generated.

Generate another set of requisition and container labels using the Container Label Reprint function (see below for instructions).

Trim one requisition label to fit on a frozen section slide (over the green area) – do not trim off any of the patient name, case number or bar code. Place the label on the frozen section slide.
Handwrite the frozen section # on the slide, FS1, FS2, etc. The frozen slide will be relabeled with the appropriate slide label when the block is cut in Histology.

Place a “requisition” label on both copies of the Intraoperative Consultation form (on the upper left area of the form – not covering any important information). An extra requisition label will be left (hold this label until frozen sections are completed for the case – this extra label can be used for additional slide labels for the same frozen section/IOC.

Place the correct container label for the frozen section on the container holding the frozen tissue.

Follow this same procedure for each additional Intraoperative Consultation form that arrives on the case.

**Container Label Reprint**

Requisition and container labels can be reprinted using the Container Label Reprint activity.

- Browse for “Container Label Reprint. Select Run.

- Enter Case number in the Specimen # field.
• Select whether to reprint requisition or container labels and number of labels. Press OK.

• The Container Label Reprint window will display. Select the appropriate printer from the drop down menu.

• The Container Label Print window displays stating the labels have been printed successfully.
<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepared by</td>
<td></td>
</tr>
<tr>
<td>Revised</td>
<td></td>
</tr>
<tr>
<td>Reviewed</td>
<td></td>
</tr>
<tr>
<td>Reviewed</td>
<td></td>
</tr>
</tbody>
</table>
Histology Data Entry/Edit Material Matching

1. Open Histology Data Entry/Edit. Scan requisition or container barcode to select the case. Histology Data Entry/Edit will open to the Specimen Tab.

2. The Prosector/Resident will order the Protocols needed for the part type(S).

3. The protocols will be run by selecting the Run Protocol button.

4. When the Prosector has completed ordering on the case the information will be sent to the engraver using the Save/Engrave button on the Histology tab. All cassettes for the case will print.
5. The Prosector will select the Materials Scan Tab. The Requisition, parts and ordered blocks will display.

6. The Prosector will scan the Requisition, first container and block(s) associated with that container. Check mark will display next to the Requisition, part and block(s) that were scanned. The status of the block will change from Ordered to Grossed.
7. A warning will display if the container or block scanned does not match the case # of the requisition or the materials scanned do not match what has been ordered in Copath on the case.

8. The prosector will add the tissue to the block and click on the Histology tab to enter the number of pieces per block.

9. Repeat steps 5 through 8 until all parts and blocks have been processed.

10. When the case is completed click on Save/Next Specimen.

**Canceling blocks on a case**

1. When a block(s) that have been ordered by the prosector is not needed those blocks should not be scanned on the Materials Scan Tab. Upon saving the case a prompt will appear asking if the unscanned block(s) should be cancelled. Click on Cancel Blocks.
2. The block status will now be canceled on the Materials Scan Tab

Adding blocks to a case

3. If the pathologist deems that additional blocks must be submitted on a case, the prosector will go to the Histology Tab. The all block(s) will be shaded in gray once the blocks have been engraved.
4. Click on the block detail button and change the status of the cancelled blocks from cancelled to ordered. Click OK. The Stains updates window will display. Click OK.

5. This will make the canceled block available for processing and keep the blocks in the correct number sequence.

**Decal blocks**

6. Block status is ordered when block is added to the case.
7. Change to block status to “In Decal” for blocks that are being decalcified. Press OK. In Decal status will print on the Overdue Block report. This will alert the Histology tech that this block will not be available for the 3pm Embedding list.

8. When the case is completed click on Save/Next Specimen.

**Autopsy Cases**

Residents will place cassettes in deli container. If autopsy cassette are ordered before blocking the tissue and some of the cassettes remain unused, those cassettes must be cancelled. The resident will bring cassettes directly to Histology. When load cassettes into processor, the Histology tech will scan these cassettes into a batch.
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<th>9.2 SPECIMEN TRACKING ACTIVITY</th>
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<td>BUILD AN EMBEDDING LOG</td>
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Building an Embedding log at TMH

1. As the cases are grossed the cassettes are put in racks. Prior to courier runs the cassette will be scanned on to a tracking list using the Build TMH to RIH Embedding Log using the following steps.
2. Select the Specimen Tracking option
3. In the Select Tracking Station window, select the Build TMH to RIH Embedding Log, then press OK.

4. In the Tracking Station – Each day select Build TMH to RIH Embedding log, select New Batch option to create a new embedding batch. When the New Batch button is chosen, CoPathPlus presents a New Batch window including pre-set defaults for batch creation.

5. In the Open Tissue Batch window, press OK.
6. In the build Embedding log window, the system will display the batch being created. Make note of the batch number. Begin scanning the cassettes.

7. Monitor the screen for any errors displayed in a red window. Press the Acknowledge button to continue scanning. One example of an error is:

Scanned block does not match the Department for this batch.
8. Press the CLOSE button in the lower right section of screen. The system will prompt for verification of whether or not the batch should be closed. Select YES to close this batch and exit the tracking station activity.

9. After scanning all cassettes the Histology tech will run the Overdue Block Status report.

10. To Run the Overdue Block Status report:
   a. Select menu option File -> Browse Items - > Overdue Blocks Report
   b. Criteria – Select appropriate Histo Department(s)
   c. – Select individual Block Status = Ordered and Grossed
   d. – Minutes in Status = All
   e. Click OK

11. Check the report for any cassettes that are in the “Grossed” status. If there are cassette in the “Grossed” status on the report, find the cassettes and add cassette to the list.

12. In the Select Tracking Station window, select Build TMH to RIH Embedding log, then press OK.

13. In the Tracking Station –Build Embedding Log window, select Select Batch option to add to the embedding batch.
14. When the **Select Batch** button is chosen, CoPathPlus presents a Select Tissue Processing window.

15. Select the appropriate Batch number and press OK.
16. When the Tissue Batch Status window displays, Press YES to re-open batch.

17. Repeat steps 6-11, if needed.

18. The cassettes are transported to the Histology lab.
9.3 ALL CASSETTES RECEIVED IN THE RIH HISTOLOGY LAB FROM THE RIH SURGICAL SUITE

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All Cassettes Received in the RIH Histology Lab from the RIH Surgical Suite

The blocks will be brought from the Bridge Building Surgical Suite to the Histology Lab. The tech will select the Embedding Batch Edit/Compile Item, press Run.

The Select Tissue Processing Batch window will display. Select the appropriate batch number. Press OK.
The Edit tissue Processing Batch # window displays. Press the Select All button.

The blocks will be highlighted. Press the Verify button. Press the Save/Print button to print the Embedding Log for the batch.
Press CLOSE to exit report.
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Microtomy with Slide Labeling

1. Select the Specimen Tracking option
2. In the Select Tracking Station window, select the Microtomy w/slide Labeling option, and then press OK.

3. When the Microtomy w/slide Labeling window opens, scan the appropriate block.

4. The system will display the Histology information associated with scanned block. The system will automatically generate slide labels and place a check mark next to the stain(s).
5. When finish cutting first block, continue this process with additional blocks.
6. Press CLOSE to close window.

Reprint labels using Microtomy w/Slide Labeling

- Select the Microtomy w/Slide Labeling stacking station
- Scan in the block
- Highlight the stain to be reprinted. The gray check that displays before the stain will change to blue.
- The Save & Label Slides button will be activated. Press this button and the slides will print on the appropriate printer.

Add levels

Once the block is scanned in and the block information is displayed in the Microtomy w/Slide labeling window, select the Edit Case: button.
The Histology Data Entry/Edit window will display. Add the appropriate Stain/Process for the levels needed. Only one label will print for all the levels that were ordered. If extra labels are needed add a stain called LEVEL LABEL for the additional labels needed. Increase the count to the number of additional labels needed.

Blocks that need reprocessing when the tech originally cuts the block.

When the case needs to be reprocessed Press the Edit Case button.
The Histology Data Entry/Edit window will display. Add a Reprocess block stain to the appropriate block. Select the Save/Close button. This will bring you back to the original Microtomy window.

These blocks will be put on the next appropriate embedding batch for that site created that day.

Specimens requiring additional decalcification will need to be tracked using the Decalcification Tracking step. See Decal Tracking procedure for details.
9.5 SLIDE DELIVERY WITH MATCHING

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Slide Delivery with Matching

Select the Slide Delivery w Matching tracking step.

Scan the Requisition

Scan the Working Draft
Scan the H & E slides
Press Done with the Case

The Incomplete Materials Match window will display.
Press OK-Continue.
The tracking Station – Slide Delivery w Matching window will display.
Press Close.

If all of the materials for the case have been scanned, a box will display stating All Required items were scanned.
Press Done with this case.
Press Close.
### 9.6 PRINT LEICA CASSETTES

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To Print Leica Cassettes – Cassettes will not print if NiceWatch is not running.

Before you start the Engraver Manager, you must start NiceWatch.

To Start NiceWatch

**Double-Click the NiceWatch Icon**

Wait for the NiceWatch Manager to run.

Start **Engraver Manager** as Normal
**Leica Not Printing Cassettes:**

If the Leica is not printing the main reason will be that the NiceWatch program was started AFTER the cassettes were printed through the engraver manager. When this happens, NiceWatch can not pick-up the already created file and the following steps need to be taken.

1. Stop NiceWatch

2. Go to Explorer and find the c:\nplive\jobs folder

3. Find the existing file in the Jobs Folder
4. Copy the file to the **Logs** Folder

5. **Restart NiceWatch**

6. Place the file back in the **Jobs Folder**

7. Wait a minute or so and the Cassettes should start to print

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**Leica Not Printing Cassettes:**
If the Leica is not printing the main reason will be that the NiceWatch program was started AFTER the cassettes were printed through the engraver manager. When this happens, NiceWatch can not pick-up the already created file and the following steps need to be taken.

8. Stop NiceWatch

9. Go to Explorer and find the c:\nl\plive\jobs folder

10. Find the existing file in the Jobs Folder

11. Copy the file to the Logs Fold
12. Restart NiceWatch

13. Place the file back in the Jobs Folder

14. Wait a minute or so and the Cassettes should start to print