Histology / Frozen Section Pre-Inspection Checklist

Site: ___________________________________  MTS-__________________________________

Director: _______________________________   Contact: ________________________________

Personnel:
The Medical Director is responsible for the overall technical supervision and management of test site personnel including policies and procedures for:
   Performing, recording, and reporting tests __________
   Maintaining ongoing quality assurance program __________
   Supervision of testing __________

Does the Medical Director evaluate, verify, and document the following related to technical personnel:
   Education, experience, and training in test performance and reporting test results ______
   Sufficient numbers to cover the scope and complexity of the services provided ______

Pathologists:
   Medical license and certification as appropriate __________
   Current results, education, residency and Pathology/Histology training __________
   Documentation of CE activities __________
   Peer group review of cases at professional meetings __________
   Documentation of consult with other pathologists __________

Does the Histotech have appropriate training and certification? ______

Records:
Requisitions:
   Contain patient name, identification, or other method of patient identification __________
   Name and address or other suitable identifiers of person ordering test __________
   Date of specimen collection, and time if appropriate __________
   Source of specimen, if appropriate __________
   Type of test ordered __________
   Sex, and age or date of birth of patient __________
   Pertinent clinical information if appropriate __________

Test Record Systems:
   Consist of instrument printouts, worksheets, accession logs, etc __________
   Include:
      Patient Identifiers (2) __________
      Date and time (if appropriate) specimen received __________
      Reason for specimen rejection or limitation __________
Date of specimen testing
Identification of testing personnel (if appropriate)

Accession Logs:
  Date specimen collected
  Date specimen processed/stained
  Date slides reviewed
  Date reported and charted
  System to assure that slides are back from processing laboratory if sent off-site

Specimen Labeling:
  Adequate on tissues, blocks and slides
  Is there a system for labeling slides?
  Is there a system for tracking the levels of tissues and is it in writing?

Test Reports:
  Maintained permitting identification & retrieval
  Released to authorized personnel only
  Name and address of testing facility
  Patient name & identification
  Date reported
  Time reported (if appropriate)
  Specimen source & limitations (if appropriate)
  Test name test result, and units of measurement (if appropriate)
  Signature or initials of authorized personnel (electronic acceptable)
  Referral reports contain essential elements and duplicate copy retrieval
  Corrected reports
  Documentation of consultations

Record Retention:
  Blocks (2 years from date of examination)
  Tissues (Retain remnants of tissue specimens in an appropriate preserved state until the portions submitted for microscopic have been examined and diagnosed)
  Reports (10 years)
  QC/QA Documents (2 years)
  Slides (10 years from date of examination)
  Process to maintain records if the MTS ceases operation

Lot Numbers retained for:
  Formalin
  Xylene
  Stains
  Stain Control Slides

Quality Assurance:
Written Quality Assurance Plan includes policies and procedures that
  Monitor, evaluate, and review QC, PT, Biannual Verification and test results
  How to identify & correct problems
Establish & maintain accurate, reliable, & prompt results _________
Establish and maintain adequate and competent personnel _________
Establish and maintain the patient identification from collection to result _________
  Name of patient or patient identifier _________
  Case Number __________
  Sequence ID of tissue and cuts __________
  Maintain all slides including slide showing margins are clear _________

Quality Assurance Program must include mechanisms or systems to
  Establish specimen collection criteria, acceptance & rejection __________
  Notification of critical values (if appropriate) __________
  Problem identification & troubleshooting _________
  Evaluate correct test reporting systems _________
  Issue corrected reports when indicated _________
  Insure proper specimen labeling _________
  Insure confidentiality _________
  Provide client updates as appropriate _________

Documentation of remedial action for QA, QC, Personnel, PT problems, patient complaints _________

Facilities/Tour
  Laboratory Space _________
  Processing of tissue _________
  Cutting (frozen section) _________
  Staining and slide examination _________
  Disposition and storage of report, blocks, slides, etc. _________

Safety
  Hazardous and infectious waste plan _________ and pick-up _________
  Safety plan and MSDS _________
  Is buffered formalin prepared on-site? _________
  Is there a procedure and appropriate documentation for the disposal of xylene and formalin? _________
  If xylene and formalin are recycled, is there a procedure and appropriate documentation? _________
  Is exposure to xylene and formalin being monitored appropriately? _________
  Is each open automated tissue processor operated at least 5 feet from the storage of combustible materials and from the paraffin dispenser? _________
  Are microtome knives stored in original containers or by some other means to avoid personnel injury or equipment damage? _________
  Are infectious tissues and other contaminated materials disposed of with a minimum danger to professional, technical, and custodial personnel? _________
  Are there documented procedures for the special handling of tissues in the histology laboratory from cases in which Creutzfeldt-Jakob disease is suspected? _________
  Is there documented procedures for safe disposal of used slides and paraffin blocks? _________

Is there a system to track slides that are being sent for biannual verification? _________
Are criteria available for selecting slides for biannual review and is it in writing? _________
What does the pathologist do when there is a disagreement with the verifier? 

Policies for
Specimen collection
Handling
Acceptance

Policies for
Performing test
Recording test
Reporting tests
Record retention?

Records of consults
CE activities
Turnaround time expectations
Remedial actions?

Quality Control:
Written procedures available at worksite
Written criteria for and maintain documentation of (if applicable)
  Temperature-controlled spaces and equipment
  Preventative maintenance activities
  Equipment function checks
  Procedure calibrations
  Method/instrument procedures
  Distilled water or ionized water (0.2µ particulate filter)

Documentation of (if applicable)
Tissue Processor Preventive Maintenance:
  Inspection of reagent bottles checked for leaks or any type of wear
  Inspection of tissue processor retort chamber for cracks, leaks, or broken seals
  Inspection of tissue processor reagent lines for clogs, leaks, and possible wear
  Testing of tissue processor heaters & thermostats for proper temperature
  Testing of tissue processor’s pressurization pump for proper function
  Testing of tissue processor’s control panel for proper function
  Are the staining dishes labeled accordingly?
  When are changes made to the stains or reagents?
  Are these stain and reagent changes recorded and maintained?

Microtome Preventive Maintenance:
  Disassembling, inspecting, cleaning, and re-assembling specimen holder
  Disassembling, inspection, cleaning, and re-assembling blade holder
  Removing housing, inspecting and cleaning internal gears and components

Tissue Embedding Center Preventive Maintenance:
  Inspecting controls for proper function
  Test heaters to insure proper temperature in paraffin reservoir, holding tank, base mold warmer, hot work stage, forceps warmer’s, and paraffin dispenser
Test for proper function of refrigeration components

Paraffin Dispenser Preventive Maintenance:
- Test paraffin reservoir heater for proper function
- Test paraffin dispenser’s spout thermostat for proper function
- Clean paraffin dispenser’s spout of wax and dirt build up

Tape Coverslipper Preventive Maintenance:
- Re-sharpen film cutting blade
- Test all tape dispensing, slide, and slide rack sensors
- Inspect proper dispensing of Xylene onto microscope slides
- Inspect internal components, clean all components, and re-lubricate gears and chains

Glass Coverslipper Preventive Maintenance:
- Inspect and maintenance of basket container, storage rack, and adjusting dispenser stroke
- Clean vacuum pad and dispenser holder
- Replace fuse (as appropriate)

Automatic Stainer Preventive Maintenance:
- Inspect and test control panel for proper function
- Inspect plumbing for proper function regarding water supplied in and water drained
- Inspect and test robotic arm with regard to calibration and proper function
- Clean ventilation system and replace the carbon filters

Microwave Device Maintenance:
- Are microwave devices (if applicable) monitored at least annually to ensure that there is less than 5 mW/cm² leakage at a distance of 5 cm from the surface?
- Are microwave devices (if applicable) periodically monitored for temperature reproducibility?
- Are all containers used in microwave devices (if applicable) made from microwave-transparent material?
- Are microwave devices (if applicable) properly ventilated?

Hood Maintenance:
- Hood Function and Safety Checks (Air Exchange)
- Safety hood vaneometer (100 lfm)

Review stained tissue slides to determine if they are adequate (Slides must be of adequate technical quality to be diagnostically useful. Criteria to evaluate include adequate tissue fixation, thickness of sections, absence of interfering tissue folds and tears, and good staining technique. For hematoxylin and eosin and other routine stains, the patient slide serves as the internal control to ensure staining technique.)

Are positive controls run routinely on special stains, with reactivity results documented, and are they verified for acceptability before reporting results?
Are the following stains of high quality, and do they satisfactorily demonstrate (on each day of use), the tissue characteristics for which they were designed and is this documented? (This list is neither all-inclusive nor exclusive of other “special stains” used in a given histology laboratory. For Gram Stain, control slides must demonstrate both Gram-positive and Gram-negative organisms.)

- Acid fast organisms
- Iron
- Bacteria
- Elastic tissues
- Fungi or pneumocystis
- Mucin
- Connective tissue
- Myelin
- Nerve fibers
- Periodic acid Schiff (PAS)
- Glycogen
- Reticulin fibers
- Amyloid
- Methyl green-pyronine (MGP)

Documentation of reagents, solutions, culture media, controls, calibrators, standards, reference materials and other testing materials (if appropriate) __________

Are reagents and solutions properly labeled, as applicable and appropriate, with the following?

- Content and quantity, concentration or titer
- Storage requirements
- Date prepared or reconstituted by laboratory
- Expiration date

Are all reagents, controls, and solutions used within the expiration dates:__________

Documentation of Temperatures on:

Refer __________ Incubator __________

Cryostat __________ Paraffin Bath __________

Are cryostats with digital temperature readout verified with a NIST thermometer? __________

Documentation of preventative maintenance on microscope __________