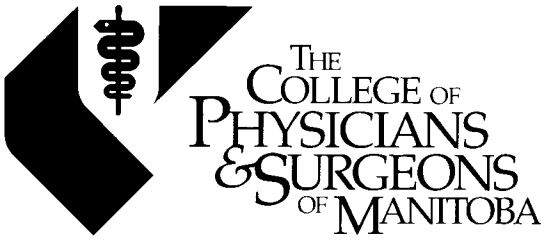

MANITOBA
LABORATORY STANDARDS

July 2014

INTRODUCTION

Pursuant to By-Law No. 3 of the College of Physicians and Surgeons of Manitoba, Council has established standards governing laboratory facilities, as follows:

Laboratory:

1. Quality Management Program
2. Manuals
3. Safety
4. Equipment
5. Anatomic Pathology
6. Clinical Biochemistry
7. Clinical Microbiology
8. Cytology
9. Hematopathology
10. Immunology
11. Semen Analysis
12. Transfusion Medicine
13. Urinalysis

Certain standards, namely Quality Management Program, Manuals, Safety and Equipment apply to all laboratory facilities. Whether the remaining standards are applicable to a facility depends on the type of work done in the facility.

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1.0 QUALITY MANAGEMENT PROGRAM

1.1 General

1.1.1 A facility must establish and maintain a quality management program[1] that:

1.1.1.1 defines:

1. the organizational structure[2].
2. policies[3].
3. procedures[4].
4. resources.
5. monitoring required for quality management.

1.1.1.2 at minimum, requires participation in formal external proficiency testing[5] programs for every test where an external proficiency testing program exists.

1.1.2 A facility must retain quality management program records on-site for at least two years.

1.2 Signage

1.2.1 A facility must post in the facility:

1.2.1.1 the facility director's name.

1.2.1.2 only current certificates of accreditation.

1.3 Personnel

1.3.1 A facility must:

1.3.1.1 employ only personnel with registration and licensure where registration and licensure are required by law for the individual's scope of practice.

1.3.1.2 employ only personnel with the education, training, competence and experience to perform procedures within the individual's job description.

1.3.1.3 provide personnel with readily available, current discipline specific reference material.

1.3.1.4 establish and maintain an annual program for maintenance of personnel competence, including:

1. educating personnel about the contents of policies and procedures relevant to the scope of their job description, and
2. where applicable, maintaining competence of analysts in microscopic evaluations.

1.4 Facility Director Review

1.4.1 The facility director must:

1.4.1.1 review and update the facility's quality management program documents at a minimum of every 2 years.

1.4.1.2 record the changes arising from the review and update policies and procedures as required.

1.4.1.3 inform facility personnel of the changes made as a result of the review.

1.5 Documentation

1.5.1 All facility policies and procedures must be in writing and available to personnel.

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[1] A Quality Management Program Manual is required by the Manuals Standard.

[2] Organizational Structure defines reporting relationships to include: functional, divisional, and matrix structures.

[3] Policy: A policy is a pre-determined course of action that establishes the rules and directives around core processes of the facility. A policy restricts negotiation and legitimizes decision making and actions. A policy is not intended to communicate operating procedures and is not a reiteration of laws and regulations.

[4] Procedure: A procedure is an informative process that provides protocols, routines, guidelines and methodologies.

[5] See also the Manuals Standard, Proficiency Testing (External and Internal) Manual.

2.0 MANUALS

2.1 General

2.1.1 Format of Manuals

2.1.1.1 A facility must format manuals to include:

1. a table of contents.
2. page headers with the following information:
   a) facility name.
   b) policy/procedure title.
   c) edition, effective and revision date.
   d) author.
   e) facility director approval.
3. a historical cover sheet.

2.1.2 Manual Availability

2.1.2.1 A facility must make each manual available to all personnel.

2.1.2.2 The Safety Manual must be available to personnel in hard copy format.

2.1.3 Manual Review

2.1.3.1 A facility director must review and update all manuals, at a minimum of every 2 years, and maintain a written record of the review of any changes made.[6] If a facility director delegates all the review, the facility director is responsible to sign off on all revisions and the annual review.

2.1.3.2 A facility must have all personnel sign to confirm review of all manuals and individual job descriptions every 2 years.

2.2 Required Manuals

A facility must establish and maintain the following manuals:

2.2.1 A Quality Management Program[7] Manual

2.2.1.1 The Quality Management Program Manual must include:

1. table of contents.
2. a description of the facility, ownership of the facility, operator of the facility, resources and main duties.
3. requirements for the physical facilities.
4. requirements for personnel education, training and competencies.
5. a quality mission/vision statement.
6. policies governing each of the following topics:
   a) compliance with *The Personal Health Information Act*[3]
   b) delegation of function.
   c) selection criteria for purchased external services and purchased controls and reagents.
   d) selection criteria for referral facilities.
   e) referral and tracking of specimens to another facility.
   f) quality assurance/quality control.
   g) retention times for specimens, documents[8] and quality assurance/quality control records.
   h) document control, as specified in the Operational Policies Manual.
   i) handling of complaints and remedial actions.
   j) internal audits.
   k) client satisfaction.
   l) risk management.
   m) handling ethical dilemmas.
   n) research and development (if applicable).

[6] See also the Quality Management Program Standard.
[7] See also the Quality Management Program Standard.
[3] See also the Operational Policies Manual.
[8] "Document" includes any information or instructions, including policy statements, text books, procedures, specifications, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software, drawings, plans and documents of external origin such as regulations, standards, or examination procedures.

7. An emergency preparedness plan. The emergency preparedness plan must include:
   a) definitions of all emergency codes.
   b) emergency contact information (e.g. fan out call list).
   c) directives for personnel regarding emergency preparedness, including any additional precautions required.

2.2.2 A Safety Manual

2.2.2.1 The Safety Manual must be site specific. For all facilities, the Safety Manual must establish and maintain policies and procedures governing:

1. general workplace safety and health.
2. routine practices.
3. waste management.
4. electrical safety.
5. fire safety.
6. eyewash safety.

2.2.2.2 If these topics are applicable to the specific facility, the Safety Manual must also have policies and procedures governing safety for:

1. hazardous materials.
2. carcinogens.
3. chemical hazards.
4. compressed gases and liquid nitrogen.
5. flammables.
6. laser and radiation safety.

2.2.2.3 General workplace safety and health policies and procedures must:

1. require competency based orientation training.[9]
2. require use of personal protective equipment where appropriate.
3. require that personnel secure hair (including beards).
4. identify suitable facility apparel.
5. prohibit food in technical work areas.
6. prohibit mouth pipetting.
7. include processes:
   a) to identify and resolve safety hazards.
   b) to document and investigate any incidents, accidents and adverse events.
   c) regarding incidents and work related injuries.
   d) regarding visitors in the facility.

2.2.2.4 Routine practices/infection control policies and procedures must include:

1. the use of personal protective equipment when handling blood and body fluids.
2. prevention of blood and body fluid exposure.
3. follow-up for potential exposure to tuberculosis or blood borne pathogens.
4. hand washing requirements.
5. use of alcohol based (minimum 70% alcohol) hand rubs.
6. FIT mask requirements.
7. sterile techniques.
8. daily disinfection of work surfaces.
9. the type and strength of decontamination solution must be expressed in percentage (bleach) or relative concentration (percept).
10. recognition and safe processing of potential bioterrorism agents.
11. biohazard sign posting requirements.

[9] See also the Personnel Policy Manual.

12. infection control, including the following mandatory practices:
    a) prohibiting preassembled blood collection holders with needles.
    b) using chairs (including phlebotomy chairs) and accessories with a material that may be decontaminated. Cloth chairs are unacceptable.
    c) if pillows are used, changing the pillow covers at least daily and whenever there are visible blood stains.
    d) changing table covers between patients, or disinfecting work surfaces.
    e) using biological safety cabinets/fume hoods in areas where there is handling of blood and organisms considered to be highly contagious by airborne routes.
    f) soaking all reusable glassware used for biologicals in a bleach (or equivalent solution) prior to cleaning.
    g) designating areas where personal protective equipment is required.
    h) prohibiting laboratory coats that are worn for patient testing from being worn elsewhere in the facility.

2.2.2.5 Waste management policies and procedures must include:

1. decontaminating and disposing contaminated waste, hazardous waste, chemical waste, and sharps.
2. trash containers with more than one scheduled quantity per kilogram of solid radioactive waste require labelling and storage for decay.

2.2.2.6 Electrical safety policies and procedures must include:

1. that new, modified, or repaired equipment is not put into use until a qualified person is satisfied that it is safe to use.
2. using approved extension cords.
3. checking all cords and plugs for frayed wires and repair where required.
4. locating all electrical receptacles, switches and controls so that they are not subject to liquid spills.
5. providing a clear access to switches, control devices and meters.
6. keeping multiple receptacle electrical adapters to a minimum.

2.2.2.7 Eyewash safety policies and procedures must include:

1. having eyewash stations available.
2. flushing eyewash stations weekly.
3. monitoring wall mounted eyewash stations for expiry dates regularly.

2.2.2.8 Fire safety policies and procedures must include:

1. having appropriate fire extinguishers.
2. annually documenting fire safety, fire extinguisher, fire drill and evacuation training for personnel.
3. having an evacuation plan which includes a process to assist those who are unable to evacuate without assistance.
4. emergency evacuation route posters visible in all patient and public areas.
5. clear and visible signage to indicate the location of the fire alarm pulls.
6. lit or photo phosphorescence exit signage.

2.2.2.9 Hazardous materials policies and procedures must include:

1. reporting and documenting hazardous material spills.
2. having chemical and biological spill kits readily available and establishing procedures for use of the kits.
3. monitoring expiration dates of chemicals and spill kits.
4. requiring personnel to certify in the transport of dangerous goods training program, if applicable.
5. required use of designated labels for Workplace Hazardous Material Information Systems controlled products.
6. having a master inventory list of hazardous materials.
7. maintaining current Material Safety Data Sheets (i.e. not greater than 3 years old).

2.2.2.10 Carcinogen safety policies and procedures must include:

1. storing and using carcinogens in a safe manner.
2. using only designated labels for all carcinogenic agents.
3. specifying:
    a) precautions to be taken to reduce risk of exposure.
    b) steps to be taken should exposure occur.

2.2.2.11 Chemical hazards policies and procedures must include:

1. educating personnel.
2. identifying the types of hazards (poisons, caustics, skin or eye irritants).
3. identifying precautions to be taken and instructions if an accident does occur.
4. storing strong acids and bases in Workplace Hazardous Material Information System approved containers in a secure location, and below counter level.
5. having acid, base and mercury spill kits readily available and establishing procedures for use of the kits, if applicable.
6. using acid/solvent bottle carriers for transportation of hazardous chemicals in excess of 500 millilitres (ml).
7. transporting all chemicals in accordance with the *Transportation of Dangerous Goods Act* and Regulations.
8. having Occupational Health and Safety monitor air for potentially harmful fumes (e.g.: formalin, xylene, etc.) at least annually. If safety limits are exceeded, extraction systems must be used.
9. providing a fume hood or chemical filtration unit for any procedures using volatile chemicals.

2.2.2.12 Compressed gas and liquid nitrogen policies and procedures must include:

1. identifying the contents of compressed gas cylinders.
2. using, storing and transporting compressed gas and liquid nitrogen.
3. providing appropriate safety devices for safe handling of compressed gases and liquid nitrogen.
4. equipping compressed gas cylinders with an approved functional valve system.
5. providing the quantity and spectrum of compressed gas appropriate for the requirements of the facility.
6. securing cylinders.
7. positioning compressed gas cylinders (e.g.: well away from open flames or other heat sources, and not in corridors or outside exhaust canopies).

2.2.2.13 Flammables policies and procedures must include:

1. storing highly volatile solvents (e.g. ether and pentane) in quantities greater than 500 millimeters in safety cans, unless purity requires glass storage.
2. storing flammables in quantities greater than 4.0 litres in safety cans and in flammable storage cabinets.
3. grounding large flammable containers.
4. performing and documenting an annual review of flammables.

2.2.2.14 Laser safety policies and procedures must include:

1. using laser equipment according to manufacturer specifications.
2. establishing appropriate safety measures for laser use.

2.2.2.15 Radiation safety policies and procedures must include:

1. compliance with the Atomic Energy Control Board license and regulations.
2. signage on rooms where radioactive materials are being used or stored to indicate the presence of radioactive materials.
3. appointing a radiation safety officer who is responsible for actively monitoring radiation safety.
4. providing radiation monitoring devices (i.e. thermo-luminescent dosimeters) for personnel in the appropriate areas of the facility.
5. performing radiation area surveys and wipe tests at least quarterly.
6. adhering to appropriate licenses and registrations for the use of radiopharmaceuticals.
7. requiring radiopharmaceutical shipments be delivered directly to the facility and not left unattended.

8. logging all shipments of radiopharmaceuticals by a facility tracking system.
9. shielding radiopharmaceutical handling, storage and decay areas to reduce scatter.
10. locking radiopharmaceutical storage and decay areas when not under the supervision of facility personnel.
11. documenting appropriate training for all personnel required to work with radioactive material.
12. transporting radioactive material according to the *Transportation of Dangerous Goods Act* and Regulations.

2.2.3 A Personnel Policy Manual

2.2.3.1 The Personnel Policy Manual must include policies governing:

1. a job description for each employee.
2. competency based orientation training requirements for each employee.
3. continuing education and maintenance of competence requirements for each employee.
4. records of personnel qualifications, registration and licensure.
5. annual competence appraisals for each employee.
6. workplace safety and health policies, including working alone, respectful workplace, discrimination, harassment and abuse in the workplace.
7. incidents, work related injuries and near miss reporting.
8. work schedule.
9. internet use.

2.2.4 An Operational Policy Manual

2.2.4.1 The Operational Policy Manual must include policies which govern:

1. document control:
   a) maintaining a historical coversheet to record major changes, additions or deletions.
   b) requiring all handwritten changes to be signed and dated by the person making the change and approved in writing by the facility director.
   c) ensuring that any posted material, procedural guideline or direction is current and in compliance with manual requirements.
   d) maintaining all quality control/quality assurance records and reports.
2. test management:
   a) using “in date” purchased controls and reagents.
   b) identifying and processing high priority specimens.
   c) handling “out of control” results.
   d) preventive and corrective actions.
   e) turnaround times and investigating non-conformities.
   f) identifying and correcting discrepancies in patient demographics.
   g) requisition and consultation requirements, including criteria for rejection.
   h) relevant clinical information, which may include:
      (i) the urgency of the examination.
      (ii) the date of referral.
      (iii) a history of all allergies.
3. required requisition information:
   a) patient first and last name.
   b) personal health identification number (PHIN).
   c) facility health record number or alternate number (e.g. RCMP, Canadian Forces, other provincial health numbers).
   d) current patient contact information (i.e. phone number, address).
   e) patient identifiers (correct patient/test) and site of specimen origin.
   f) date of birth.
   g) date of test (and time if applicable) and required test procedure.
   h) facility name.
   i) name and address of the physician/authorized healthcare provider, together with their contact details, in the event of a critical result.

4. patient management:
   a) notification of cancelled patient testing.
   b) identifying and correcting patient demographics.
   c) temporary patient identification.
   d) examinations with no patient clinical information available.
   e) record management for neonates who have not yet been issued a personal health identification number, including at least gender and the following demographics:
      (i) facility health record number (if out of province, provincial health number).
      (ii) date of birth and time of birth.
   f) post invasive procedure (patient management).
   g) use of restraints.
   h) referrals.
   i) consent issues:
      (i) informed consent for all invasive procedures (must include explanation, benefits, risks and alternatives).
      (ii) consent obtained by telephone.
      (iii) interpreters for patients who do not speak English (whenever possible).
      (iv) authorized substitute decision makers.
      (v) emergent situations: no substitute decision maker.
      (vi) refusal of examination.
5. report management:
   a) managing preliminary reports, including labelling, disclosure, and retention.
   b) reporting of results, including identification of any referral facility.
   c) amending reports, including notifying of the amendment.
   d) requiring the interpreting physician or designate to proof-read and sign.
   e) disclosing test results to patients.
   f) criteria for verbal reports, unsigned reports or reports not yet proof-read.
   g) including notifying a physician/healthcare provider of a critical result and record:
      (i) the date.
      (ii) time.
      (iii) staff member.
      (iv) person notified.
      (v) results conveyed.
      (vi) any difficulty in notification.
   h) call-back service examination requests (STAT list).
   i) identifying any statutory reporting requirements (e.g. Public Health, child abuse or sexual activity in patients 13 years of age or younger).
   j) traceability of the report to the patient.
6. compliance with *The Personal Health Information Act* must include:
   a) correcting of personal health information.
   b) transmitting personal health information via facsimile or other electronic means.
   c) record-use and disclosure.
   d) disposing of confidential information, including personal health information.
   e) security measures for electronic databases, computer screens, and transferring of personal health information.
   f) reporting of security breaches and corrective procedures.
7. incident management must include reporting and management of incidents and adverse events.

2.2.5 An Equipment and Maintenance Manual

"Equipment" includes processing equipment, consumables, computer hardware and software, information and analytical systems, whether specifically identified in this standard.

The Equipment and Maintenance Manual must be site specific and must include policies and procedures governing equipment maintenance, monitoring and records:

2.2.5.1 The Equipment and Maintenance Manual must include:

1. procedures:
   a) for safe handling, transporting, storing and use of equipment.
   b) for taking equipment out of service when found to be defective. Defective equipment must be clearly labelled as defective until it has been repaired.
   c) decontaminating equipment prior to it being serviced or removed from the facility.
   d) contingency planning to address failure of equipment.
   e) correctly updating the correction factors.
   f) defining tolerance limits for each procedure in the system.
2. maintenance procedures for:
   a) set-up and routine operation of equipment.
   b) minor troubleshooting and equipment repair.
   c) equipment maintenance to be scheduled and performed at least annually and more frequently if recommended by the manufacturer or required by the Quality Management Program.
   d) performing and documenting function checks to detect trends or malfunctions.
3. policies governing routine monitoring of all equipment as frequently as is required to ensure that the equipment is properly functioning and is being properly used. Monitoring must be performed by competent personnel and must be documented. Monitoring must include:
   a) at least daily, temperature documentation with certified thermometers that are calibrated against a traceable recognized reference standard.
   b) devices and alarm systems.
   c) water systems.
   d) calibration and quality control data as required.
4. requirements for record keeping must include recording and maintaining the following information respecting equipment:
   a) the name, model, serial number and date of purchase.
   b) manufacturer's instructions for equipment operation.
   c) equipment maintenance requirements include maintenance procedures, troubleshooting, breakdowns and repairs.
   d) a list of contact personnel and phone numbers for equipment maintenance support.
5. retention of the following records for the lifespan of the equipment plus two years:
   a) manufacturer's name, type of equipment, identification and serial number.
   b) manufacturer's contact information.
   c) date of receipt and date of commencement of service.
   d) condition when received.
   e) manufacturer's manuals.
   f) equipment performance records.
   g) maintenance records/equipment history log.
   h) copies of reports/certificate of all calibrations and verifications.
   i) adjustments.
   j) due date of next calibration/verification if in service.
6. for kits which have consumables and reagents, policies and procedures which include:
   a) using of kit procedures only as recommended by the manufacturer.
   b) where there are multiple components of a reagent kit:
      (i) using only components of reagent kits within the same kit lot number, unless specified by the manufacturer.
      (ii) checking whether there are different expiry dates for components within a kit.

7. for reference materials and reagents, policies and procedures which include:
   a) storing reference materials and reagents appropriately.
   b) monitoring expiry dates and using only reference materials and reagents which have not expired.
   c) an inventory control system for supplies and reagents.

2.2.5.2 A facility must have policies and procedures for the following types of equipment if this equipment is used in the specific facility:

1. autoclave policies and procedures must require:
   a) the autoclave be monitored with spore strips or ampoules weekly.
   b) monitoring the autoclave by temperature tape, thermograph or other means during each run.
   c) heat resistant gloves be available for use when loading and unloading the autoclave.
   d) disinfecting or containing specimens and sterilizing used media to minimize the hazard of an accident during transport to a remote incinerator.
2. automated stainer policies and procedures must require:
   a) the automated stainer be vented or located in a room with adequate ventilation.
   b) leveling to provide accurate staining.
   c) monitoring timing.
   d) documenting the quality of the stain.
3. balance policies and procedures must require:
   a) mounting balances on vibration-free benches in draft free areas.
   b) monitoring accuracy.
   c) using recognized standard weights for checking accuracy.
   d) maintaining weights (i.e. clean and not corroded).
4. biological safety cabinet policies and procedures must require:
   a) biological safety cabinets be certified on installation and then annually to ensure that filters are functioning properly and that airflow meets specifications.
   b) the use of biological safety cabinets be limited to work requiring biologically hazardous material.
   c) that the exhaust system for a vented biological safety cabinet is designed without connection to other systems, with proper sealing and with the exhaust vent in a safe location relative to the ventilation intake system.
   d) that the biological safety cabinet be located in a low traffic area or one in which the traffic can be controlled while in use at least 4 feet away from any supply air grilles (downward airflow).
   e) monitoring gauges daily.
   f) decontaminating the internal work surfaces daily.
   g) maintaining the biological safety cabinet interior free from clutter which may interfere with adequate airflow.
5. fume hoods policies and procedures must require:
   a) fume hoods be free from clutter which may interfere with adequate airflow.
   b) that it be located in a low traffic area, or one in which the traffic can be controlled while it is in use, and at least 4 feet away from any supply air grills (i.e.: downward airflow).
   c) annual certification that the fume hood filters are functioning properly and that airflow rates meet specifications.
6. centrifuge policies and procedures must require:
   a) centrifuges be decontaminated when handling spills and breakage.
   b) educating personnel on aerosol production and measures to control aerosol hazards.
   c) daily monitoring of operating speeds of all centrifuges.
   d) safety buckets be used if available.
   e) tubes be spun with caps on if safety buckets are not available.
   f) when replacing centrifuges, purchasing models with safety buckets.

7. computer policies and procedures must require:
   a) computers be upgraded with manufacturer's software.
   b) when computers or automated testing equipment are used for the collection, processing, recording, reporting, storage or retrieval of testing data, that:
      (i) computer software, including that built into equipment, is suitably validated as adequate for use in the facility.
      (ii) procedures are established and implemented for protecting the integrity of data at all times.
      (iii) computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of data.
      (iv) computer programs (including Laboratory Information Systems) are adequately protected to prevent access, alteration or destruction by unauthorized persons.
8. electrophoresis equipment policies and procedures must require that electrophoresis equipment be clean and maintained (electrodes and buffer tank intact, power supply electrodes fit snugly, no buildup of dried buffer).
9. electron microscope policies and procedures must require:
   a) calibrating electron microscopes for magnification after major maintenance.
   b) shielding to prevent irradiation of operators.
   c) monitoring radiation from the electron microscope.
10. film processing/photographic equipment policies and procedures must require:
   a) film processing/photographic equipment be replenished with film processing (developing) equipment reagents when serviced and repaired.
   b) fixed camera mountings that are level and secure.
11. flow cytometer policies and procedures must require:
   a) flow cytometers be used with appropriate particles to establish and monitor optimal signal intensity (peak/mean channel) and minimal variability (HPCV) on a daily basis or after any equipment or fluid changes.
   b) measuring and recording the laser input each day the equipment is used.
   c) daily monitoring of the colour compensation with freshly prepared samples stained with relevant fluorochromes or with plastic compensation beads.
   d) using either fluorescent particles of known molecules of equivalent soluble flurophores (MESF) value, or freshly stained samples under test-specific photomultiplier tube (PMT) settings to monitor the sensitivity of the equipment.
   e) monitoring the linearity of log amplifiers.
   f) verifying PMT settings using appropriate reference fluorescent particles or freshly stained cells before analyzing samples.
12. fluorescent microscope policies and procedures must require:
   a) using adequate barrier filters
   b) recording bulb hours used.
   c) shielding the fluorescent light source to protect personnel from direct light.
13. glassware and plastic policies and procedures must require:
   a) Class A glassware or the equivalent be used for precise accurate volumetric measurements.
   b) using only clean glassware and plastic that is in good condition, without watermarks or other residue, without chips or scratches which interfere with measurements, and with visible graduation marks.
   c) having adequate utilities (e.g. sinks, drains), an adequate supply of water of suitable quality, and sufficient space for glassware washing, drying and storage.

14. heating devices/incubator policies and procedures must require:
    a) using adequate barrier filters.
    b) monitoring temperatures/humidity for incubators, ovens and other heating devices.
    c) checking individual wells of thermocyclers for temperature accuracy before being placed in service and at least quarterly thereafter.
    d) checking anaerobic jars, glove boxes and chambers for adequate anaerobic conditions with each use.
    e) monitoring CO_2 levels for CO_2 incubators.
15. microscope policies and procedures must require:
    a) performing and documenting Koehler illumination.
16. microtome policies and procedures must require:
    a) microtome knives must be sharp, free of nicks and stored properly to avoid injury during handling.
    b) the microtome must be properly lubricated and without play in the advance mechanism.
    c) a procedure for decontamination of the microtome in the cryostat when an infective case is inadvertently sectioned (e.g.: tuberculosis).
17. paraffin bath policies and procedures must require:
    a) monitoring and recording the temperature of the paraffin bath daily.
    b) the temperature is suitable for the type of paraffin used.
    c) that the temperature tolerance limits be defined.
    d) the location of the paraffin bath be at least two meters away from open volatile solvents.
18. potenz hydrogen (pH) meter policies and procedures must require:
    a) calibrating and performing function checks.
    b) using high quality buffers (certified assay of content) for calibration.
19. pipette and pipetting device policies and procedures must require:
    a) segregating as to size and type of pipette.
    b) maintaining pipettes in good condition, without broken tips, blurred or lost markings which interfere with measurements.
    c) verifying the accuracy (Class A) of volumetric pipettes.
    d) monitoring of automatic/semi-automatic pipettors for calibration, accuracy and reproducibility before being placed in service, and subsequently calibrating:
        (i) every three months until the pipette has been proven to be reliable with two successive calibration procedures that required no adjustments to the pipette.
        (ii) every six months once calibration has been proven to be stable.
        (iii) after major service and/or repair.
        (iv) whenever necessary for troubleshooting.
20. radio assay equipment policies and procedures must require:
    a) radio assay equipment high voltage spectrophotometer be calibrated using calibrated reference standards (“peaking”) and compared to previous values.
    b) monitoring daily background counts at discriminator values (window) for the intended radioisotope prior to each use of the equipment.
    c) establishing a procedure for:
        (i) unacceptable background levels.
        (ii) counting times that are sufficiently long for statistical accuracy.
        (iii) performing recovery studies when setting up an assay.
21. refrigerator and freezer policies and procedures must require:
    a) monitoring refrigerators and freezers daily for temperature.
    b) defining temperature tolerance limits for temperature sensitive reagents.
    c) not storing temperature sensitive reagents in refrigerator and freezer doors or in self-defrosting refrigerators or freezers.
    d) using refrigerators and freezers only for laboratory supplies.
    e) having a freezer that is -70°C or colder and/or liquid nitrogen available for the preservation of viral antisera and stock virus cultures.

22. spectrophotometer policies and procedures must require:
    a) checking spectrophotometers for absorbance and photometric linearity with filters or standard solutions as required by the equipment manufacturer.
    b) if a procedure uses a calibration curve, verifying the curve after servicing or recalibration of the equipment.
23. thermometer policies and procedures must require:
    a) calibrating non-certified thermometers, including digital thermometers, against a traceable recognized reference standard before placing the thermometers into service and at least annually thereafter.
    b) checking thermometers for separated mercury/alcohol columns and gas bubbles.
24. tissue processor policies and procedures must require:
    a) changing tissue processor solutions as required by the manufacturer.
    b) adequately venting fumes from the tissue processor.
    c) appropriately alarming the tissue processor.

2.2.6 A Site Specific Specimen Collection/Hospital Ward Manual

2.2.6.1 The Site Specific Specimen Collection/Hospital Ward Manual must be developed in consultation with nursing (as appropriate). The Site Specific Specimen Collection/Hospital Ward Manual must include:

1. a list of tests done on-site.
2. a STAT list.
3. hours of operation.
4. call-back arrangements, if applicable.
5. a list of tests referred out and the name of the reference laboratory.
6. specimen shipping procedure.
7. a policy requiring requisitions be completed and specimens be labelled as a prerequisite to acceptance in the facility.
8. a specimen collection section, including:
    a) patient preparation and instructions (e.g.: fasting).
    b) instructions for completing the requisition and clinical information, if required.
    c) positive patient identification and labelling, using two unique identifiers (patient first name, patient last name, and unique identification number).
    d) specimen requirements (e.g.: volume, type of tube, fixative or preservative, storage, handling, timing and temperatures requirements).
    e) collection requirements (e.g.: order of draw, preservative, anticoagulant, transport media, use of topical anesthetic).
    f) criteria for specimen rejection.
    g) dedicated private space for the specimen collection.
9. a transfusion medicine section, if applicable.

2.2.7 A Laboratory Information System (LIS) Manual.

2.2.7.1 The Laboratory Information System Manual must include:

1. a list of personnel who have access to information and software security codes.
2. a list of contact personnel and phone numbers for system maintenance support.
3. a schedule for and location of back-up disks or tapes.
4. policies governing:
    a) requirements for LIS competency, training, orientation and evaluation for new personnel who will be required to use LIS, and for all personnel on updates or new versions.
    b) adequate technical support.
    c) validating of alterations to the LIS hardware or software by authorized personnel.
    d) controls to protect computer applications from unauthorized adjustments, tampering or destruction.
    e) changing passwords at least quarterly and confidentiality of passwords.
    f) who may use the LIS, and who may access or change patient information or application/configuration of data.
    g) periodic review and approval by the facility director of content and format of LIS-generated patient reports.

h) the archive retrieval system, which must include:
   (i) the ability to reproduce the original reported data including reference ranges originally provided for the examination flags, footnotes or interpretive comments.
   (ii) online retrieval of patient data and archived information, for designated periods of time based on clinical care or needs of individual facilities.
   (iii) controls to ensure that data storage media are properly labelled, stored and protected from damage and unauthorized use.

5. procedures:
   a) governing scheduled maintenance or other downtime, to include:
      (i) recovery of the LIS.
      (ii) replacement or updating of data files.
      (iii) notifying to users of interruption and restoration of service.
      (iv) maintaining written records of scheduled downtime, unscheduled downtime and the reasons for any failure and particulars of corrective action taken.
   b) specifying requirements for protecting confidentiality of patient results.
   c) governing personnel use of LIS, including:
      (i) routine log out of the LIS when not actively working on it.
      (ii) prohibiting use of another personnel member's log-in to perform work.
   d) ensuring data integrity after each back-up and each restoration of data files, including documenting particulars of corrective action taken.
   e) verifying and validating the LIS when first installed and after any alterations are made.
   f) comparing original input with all types of end user reports to detect errors in data transmission, processing or storage, whenever there has been a change to the LIS.
   g) ensuring that database tables and dictionaries are synchronized between the LIS and other interfaced systems.
   h) verifying computer generated calculations on patient results whenever there has been a change to the system.
   i) ensuring that results entered manually or by automated methods are reviewed and/or revised prior to final acceptance.
   j) approving any auto-verification procedures used for tests performed on an instrument.
   k) a reporting system that allows comments related to sample quality.
   l) governing documentation of other significant events that could affect clinical care.

2.2.8 A Proficiency Testing (External & Internal) Manual

2.2.8.1 The Proficiency Testing (External & Internal) Manual must include:

1. the requirement for participation in external proficiency testing for every test where a program exists[10].
2. lists of external proficiency testing provider(s).
3. a schedule of external and internal proficiency testing.
4. a policy governing corrective actions to be taken where results of performance testing are unsatisfactory.
5. a policy requiring the facility director to submit a signed Director Response Form within 30 days of receipt of unsatisfactory results.
6. policies governing external proficiency testing, which include:
   a) if more than one analyzer performs the same test, establish an internal process to correlate external proficiency testing results between analyzers.
   b) integrating external proficiency testing samples within the routine facility workload.
   c) ensuring personnel who are deemed competent to test patient samples analyze external proficiency testing samples.
   d) reviewing, correcting and reporting unacceptable results on external proficiency testing reports.
   e) documenting evidence of quarterly reviews of external and internal proficiency testing by the facility director.

[10] See also the Quality Management Program Standard.

2.2.9 A Discipline Specific Procedure Manual

2.2.9.1 The Discipline Specific Procedure Manual must set out procedures for each test performed in the facility. The Discipline Specific Procedure Manual must include:

1. each procedure beginning on a new page, with the following information at the top of the first page:
   a) facility name.
   b) title of manual.
   c) procedure or policy title.
   d) page number.
   e) authorized/approved by.
   f) date of approval.
2. each procedure written in a standard format equivalent or substantially similar to the following format:
   a) title of procedure in full.
   b) principle.
   c) specimen requirement.
   d) pre and post examination requirements.
   e) equipment and materials[11].
   f) reagents and preparation.
   g) standards.
   h) positive and negative controls.
   i) procedure (method).
   j) quality control.
   k) detection and evaluation of non-conformities.
   l) known interferences or limitations.
   m) special precautions, safety and notes.
   n) flow sheets, keys and differential tables.
   o) linearity.
   p) precision.
   q) reference ranges.
   r) clinical significance (summary).
   s) critical values.
   t) interim reporting.
   u) reporting and interpreting results, using the correct unit values.
   v) author.
   w) references, edition, current revision date and revision number.
   x) authority for issue; signature required.
   y) for new procedures**,** the work-up for methods yielding qualitative results including at least the following (where appropriate).
      (i) patient correlation
      (ii) sensitivity
      (iii) specimen stability
      (iv) interference
   z) use manufacturer's package inserts to supplement but not replace the Procedure Manual.
   aa) maintain an up-to-date file of manufacturer's inserts.

[11] It is acceptable to use verbatim or refer to some or all of an equipment manual or product brochure in a procedure write-up as long as the manual or product brochure is clear and describes what is done in the laboratory. Irrelevant material and alternatives which are never used must be omitted.

3.0 SAFETY

3.1 Legislation

3.1.1 A facility director must establish and maintain workplace health and safety policies and procedures that adhere to the *Manitoba Workplace Safety and Health Act* and Regulations requirements.

3.1.2 A facility director must ensure that a facility meets all applicable federal and provincial legislation, acts, and regulations requirements.

3.2 Personnel Training

3.2.1 A facility must:

3.2.1.1 provide competency based safety training for all new employees as part of the orientation process.

3.2.1.2 have documented orientation and annual updates in training for facility personnel in:

1. general safety.
2. fire safety[12].
3. WHMIS.
4. handling medical emergencies.

3.3 Physical Space

3.3.1 A facility must:

3.3.1.1 post clear signage to direct patients and indicate areas of restricted access.

3.3.1.2 provide a secure and private location for personnel to change clothing and store personal items.

3.3.1.3 provide separate storage space for patient consumables.

3.4 Site Specific Safety Risks[13]

3.4.1 A facility must establish and maintain policies and procedures governing the following risks:

3.4.1.1 General Workplace Safety and Health.
3.4.1.2 Routine Practices.
3.4.1.3 Waste Management and Disposal.
3.4.1.4 Electrical Safety.
3.4.1.5 Eyewash Safety.
3.4.1.6 Fire Safety.

3.4.2 A facility must establish and maintain policies and procedures governing the following risks, as applicable to the specific site:

3.4.2.1 Hazardous Materials.
3.4.2.2 Carcinogens Safety.
3.4.2.3 Chemical Hazards.
3.4.2.4 Compressed Gas and Liquid Nitrogen.
3.4.2.5 Radiation Safety.

3.5 Safety Documentation

3.5.1 The Safety Manual must be available to personnel in hard copy format.

3.5.2 All safety records, including records of monitoring and quarterly checks, must be retained for at least 5 years.

[12] See the Manuals Standard, Safety Manual, Fire Safety.
[13] Requirements in relation to specific types of risks are found in the Manuals Standard, Safety Manual.

4.0 EQUIPMENT

"Equipment" includes processing equipment, consumables, computer hardware and software and information and analytical systems.

4.1 General

4.1.1 A facility must:

- 4.1.1.1 have the equipment necessary to perform the scope of testing offered by the facility and suitable for that purpose.
- 4.1.1.2 keep equipment clean and in good working condition.
- 4.1.1.3 operate equipment only as intended by the manufacturer.
- 4.1.1.4 safeguard equipment from unauthorized adjustments or tampering.
- 4.1.1.5 permit only authorized and trained personnel to operate equipment.
- 4.1.1.6 situate equipment as required for safe operation.
- 4.1.1.7 uniquely identify equipment.
- 4.1.1.8 schedule quality control testing and maintenance as specified by the manufacturer and the quality management program.
- 4.1.1.9 protect wires and cables that are located in traffic areas.

4.2 Emergency Power

4.2.1 A facility must maintain critical equipment:

- 4.2.1.1 on an emergency power system, if available.
- 4.2.1.2 on a robust uninterrupted power supply, if an emergency power system is not available.

4.3 Site Specific Equipment

4.3.1 A facility must establish and maintain policies and procedures governing equipment:

- 4.3.1.1 maintenance.
- 4.3.1.2 monitoring.
- 4.3.1.3 record creation and retention.
- 4.3.1.4 quality control/quality assurance.

4.3.2 A facility must establish and maintain policies and procedures governing the following equipment, as applicable to the specific site:

- 4.3.2.1 autoclaves.
- 4.3.2.2 automated stainers.
- 4.3.2.3 balances.
- 4.3.2.4 biological safety cabinets.
- 4.3.2.5 fume hoods.
- 4.3.2.6 centrifuges.
- 4.3.2.7 computers.
- 4.3.2.8 electrophoresis equipment.
- 4.3.2.9 electron microscope.
- 4.3.2.10 film processing/photographic equipment.
- 4.3.2.11 flow cytometers.
- 4.3.2.12 fluorescent microscopes.
- 4.3.2.13 glassware and plastics.
- 4.3.2.14 heating devices/incubators.
- 4.3.2.15 microscopes.
- 4.3.2.16 microtomes.
- 4.3.2.17 paraffin baths.
- 4.3.2.18 potenz hydrogen meters (pH).
- 4.3.2.19 pipettes and pipetting devices.
- 4.3.2.20 radio assay equipment.
- 4.3.2.21 refrigerators and freezers.
- 4.3.2.22 spectrophotometers.
- 4.3.2.23 thermometers.
- 4.3.2.24 tissue processors.

5.0 ANATOMIC PATHOLOGY

Each facility which offers anatomical pathology services must adhere to the standards set out in the most recent edition of the College of American Pathologists ("CAP") Accreditation Program Anatomic Pathology Checklist.

6.0 CLINICAL BIOCHEMISTRY

6.1 Specimen Procurement

6.1.1 A facility must establish a procedure requiring personnel to:

6.1.1.1 centrifuge blood specimens to ensure complete separation.
6.1.1.2 protect specimens for light/heat sensitive analytes.
6.1.1.3 provide written instructions for:

1. collection of special tests.
2. stimulation/challenge test protocols.

6.2 Manual Chemistry

6.2.1 A facility must:

6.2.1.1 monitor absorbance and linearity by a filter or standard solution at least every 3 months or sooner if quality control results indicate a problem.
6.2.1.2 run calibration curves at least monthly and after reagent change and maintenance, including bulb changes.

6.3 Automated Chemistry

6.3.1 A facility must record or plot function checks to readily detect instrument malfunction.

7.0 CLINICAL MICROBIOLOGY

7.1 General

7.1.1 A facility must:

7.1.1.1 limit the scope and extent of testing according to the classification level of the facility.
7.1.1.2 comply with the most current edition of the Health Canada Laboratory Biosafety Guidelines.

7.2 Quality Assurance

7.2.1 A facility must:

7.2.1.1 use media that is sterile and supports microbiological growth and biochemical reactivity.
7.2.1.2 perform and document quality control on each new batch of gram stain reagent and weekly thereafter.
7.2.1.3 run and document positive and negative controls on all stains.
7.2.1.4 establish a procedure to check:

1. antibiotic disks for Kirby Bauer testing for activity against ATCC organisms with known patterns of susceptibility with each new lot of MH agar or disks and weekly thereafter.
2. commercial broth or agar microdilution systems for identification and susceptibility test results with ATCC organisms with each new lot and weekly thereafter.

7.3 Respiratory Cultures - Including Sputum

7.3.1 A facility must:

7.3.1.1 perform a confirmatory throat culture if the antigen detection method is negative.
7.3.1.2 identify gram negative bacilli when they occur in significant numbers in cultures of sputum or other deep respiratory samples.

7.4 Urine Cultures

7.4.1 A facility must perform quantitative urine cultures on midstream urine specimens.

7.5 General Cultures

7.5.1 A facility must:

7.5.1.1 screen vaginal specimens at the time of the testing for:

1. yeast.
2. trichomonas.
3. the agents of bacterial vaginosis.

7.5.1.2 use only cervical and urethra swabs (not vaginal swabs) for isolation of Neisseria Gonorrhea.

7.5.1.3 have a procedure that defines criteria for Group B Streptococcus isolation during pregnancy and that describes the action taken in the event of a positive result.

7.6 Stool Cultures

7.6.1 A facility must:

7.6.1.1 accept only one stool specimen per patient per day, even if multiple specimens are submitted on the same day.

7.6.1.2 use enrichment or selected media to permit recovery of small numbers of enteric pathogens in asymptomatic patients, when requested.

7.6.1.3 use differential media and special cultural circumstances when indicated to allow recovery and identification of Salmonella, Shigella, Escherichia Coli 0157 or other verotoxin producing Escherichia Coli, Campylobacter spp, Aeromonas, Yersinia, large numbers of yeast or Staphylococci.

7.6.1.4 establish procedures:

1. specifying that rectal swabs must not be used routinely for recovery of organisms.
2. specifying conditions for which rectal swabs are acceptable (e.g.: rectal swabs will be accepted only for recovery of Neisseria Gonorrhea and screening of MRSA and VRE), and include this in the criteria for rejection of specimens.

7.7 Spinal Fluid Cultures

7.7.1 A facility must establish procedures:

7.7.1.1 for microscopic and antigen detection of Cryptococcus Neoformans.

7.7.1.2 to prioritize testing in the event of small sample volume.

7.8 Blood Cultures and Sterile Fluid, Other Than CSF

7.8.1 A facility must define optimal volumes collected per sample for adult and pediatric age groups.

7.9 Bone Cultures

7.9.1 A facility must:

7.9.1.1 establish a policy that, if a smear is provided, it must be from the same site that the culture material is taken.

7.9.1.2 clearly identify bone bank specimens as distinct from diagnostic specimens.

7.10 Mycology

7.10.1 A facility must specify if it uses a commercial biochemical identification system.

7.11 Parasitology

7.11.1 A facility must:

7.11.1.1 have an ocular micrometer available for determining the size of eggs, larvae cysts or trophozoites.

7.11.1.2 calibrate the ocular micrometer for the microscope in which it is used and recalibrate it whenever eye pieces or objective lenses are changed.

7.11.1.3 if zinc sulphate is used, check the solution for specific gravity.

7.11.1.4 require examinations of unformed and formed stool to include:

1. a direct wet mount of a fresh specimen, where appropriate.
2. a concentration procedure.
3. permanent stained preparations.

7.11.1.5 wash blood films after they have been stained, with water or buffer with a pH of 7.0 to 7.2.

7.11.1.6 examine at least 100 oil immersion fields of blood films for malarial parasites.

7.11.1.7 examine both thick and thin blood films for malarial parasites.

7.12 Virology

7.12.1 A facility must:

- 7.12.1.1 specify isolation algorithms for types of viruses suspected and/or source of specimens.
- 7.12.1.2 establish criteria for IgM testing.
- 7.12.1.3 check continuous cell lines for Mycoplasma infections.
- 7.12.1.4 use two or more host systems for diagnostic isolation.
- 7.12.1.5 discard continuous and semi-continuous cell lines at specific passage numbers.

8.0 CYTOLOGY

8.1 General

8.1.1 Each facility which offers cytology services must adhere to the standards set out in the most recent edition of the College of American Pathologists (CAP) Accreditation Program Cytology Checklist.

8.2 Specimen Collection

8.2.1 There must be documented specimen collection techniques for staff and healthcare providers as required.

8.2.2 There must be a documented policy for returning slides to the originating laboratory when slides are referred out to a referral facility. The date of referral must be documented.

8.3 Specimen Labelling and Requisition

8.3.1 Patient specimen containers and slides must be labelled with two unique patient identifiers: patient's first and last name as well as a personal identification number such as the Manitoba Personal Health Identification number, RCMP number, military number, other territorial or provincial health number or Passport number.

8.3.2 Patient requisition form must include:

- 8.3.2.1 referring healthcare provider name and billing number (or Nurse Provider Number as issued by CervixCheck)
- 8.3.2.2 address of referring hospital or clinic.
- 8.3.2.3 type of specimen.
- 8.3.2.4 date specimen was collected.
- 8.3.2.5 date specimen was received.
- 8.3.2.6 test ordered.
- 8.3.2.7 anatomic site and laterality of specimen.
- 8.3.2.8 appropriate medical history.
- 8.3.2.9 date of birth.
- 8.3.2.10 gender
- 8.3.2.11 patient name and unique identifier (as described in 8.3.1.1).

8.4 Specimen Rejection

8.4.1 A facility must establish policies for:

- 8.4.1.1 the proper labelling of specimens with two unique patient identifiers.
- 8.4.1.2 the identification used when a patient does not have a Manitoba Personal Health Identification Number (PHIN).
- 8.4.1.3 when the specimen patient information does not agree with the accompanying requisition.
- 8.4.1.4 when a broken slide is received.
- 8.4.1.5 when a slide is received without an accompanying requisition.
- 8.4.1.6 defined acceptable transit times for specimens.

8.5 Specimen Staining

8.5.1 A facility must have procedures that include:

- 8.5.1.1 when performing special stain for organisms or cell products, that appropriate control slides must be used and reviewed.
- 8.5.1.2 that stain quality must be visually checked and documented daily.
- 8.5.1.3 documenting the correction of suboptimal results.

8.6 Reports

8.6.1 Patient reports must clearly state whether a specimen is Satisfactory versus Unsatisfactory.

8.6.2 There must be documented evidence for abnormal Pap tests that include:

8.6.2.1 management recommendations as per CervixCheck, CancerCare Manitoba.

8.6.2.2 if the current Pap test is abnormal, the results of the retrospective rescreening must be stated on the report.

8.6.3 Patient reports must include all the information from the requisition and the date of the report.

8.6.4 All positive gynecological (GYN) cytology reports must be reported by a pathologist.

8.6.5 The patient report must contain the names of the cytotechnologist and pathologist involved in the case.

8.6.6 The pathologist must sign all their reports.

8.6.7 The report must have a clearly stated diagnosis that represents the highest degree of abnormality present. Other abnormalities must be documented in the microscopic/comment section.

8.7 Records

8.7.1 All patient reports, slides, and blocks must be retained in accordance with the Canadian Society of Cytology guidelines.

8.7.2 There must be separate files for normal and abnormal cervical vaginal GYN and non-GYN cytology slides.

8.8 Gynecology Cytology

8.8.1 Rescreening of negative GYN cytology practices must include:

8.8.1.1 prospective – targeted, random and rapid.

8.8.1.2 retrospective – all negative GYN cytology from the previous 3 years in a woman with current cytology showing greater than or equal to (>/=) high-grade squamous intraepithelial lesions (HSIL) or adenocarcinoma in situ (AIS) must be referred to a pathologist.

8.8.1.3 all manual rescreening must be performed by a cytotechnologist with established competence.

8.8.1.4 targeted rescreening must be performed on slides that belong to patients in high risk group that include:

1. recent history of vaginal bleeding or spotting.
2. history of cervical/vaginal/vulvar carcinoma.
3. recent cytology reported as >/= atypical squamous or glandular cells.
4. abnormal cervix on speculum examination.
5. history of diethylstilbestrol (DES) exposure.

8.8.1.5 a random rescreening of a selected proportion of negative GYN cytology.

8.8.1.6 a rapid screening review of all negative GYN cytology using a specified period (e.g. less than 1 minute).

8.9 Screening Practices for Cytotechnologists

8.9.1 A cytotechnologist must:

8.9.1.1 screen all fine needle aspirates (FNA).

8.9.1.2 screen all non-GYN specimens.

8.9.1.3 screen all GYN specimens.

8.9.1.4 not screen more than 90 slides in a 24 hour period.

8.9.2 The facility director and supervisory cytotechnologist must determine when circumstances for adequate screening by a cytotechnologist require fewer numbers of slides to be screened in the same time period.

8.9.3 A cytotechnologist must evaluate each slide to determine whether or not the material is satisfactory for diagnostic purposes and consistent with the stated site of origin.

8.9.4 Cytological abnormalities must be appropriately marked on each slide.

8.9.5 Interpretative notations must be documented on the working documents along with the identification of the screener(s).

8.10 Referrals to Pathologists

8.10.1 All GYN cytology other that “negative for intraepithelial lesion or malignancy” must be referred to a pathologist for reporting.

8.10.2 Pathologists must report all cytology referred to them by the cytotechnologists.

8.10.3 A pathologist must review any case of concern presented to them by a cytotechnologist or another pathologist.

8.10.4 There must be timely and adequate feedback on case material by the pathologists to the cytotechnologists.

8.11 Performance Indicators

8.11.1 Gynecological Cytology

8.11.1.1 There must be policies for addressing performance indicators which include:

1. the total number and rates of satisfactory specimens with and without a transformation zone.
2. unsatisfactory GYN cytology specimens.
3. false negative rate of the laboratory.
4. screening misses which include atypical squamous cell (ASC) or atypical glandular cells (AGC).
5. the total number and rates of abnormal GYN diagnoses and specific diagnostic categories.
6. the accuracy of negative cytology in the preceding three years to a histology confirmed carcinoma in situ or carcinoma.
7. the cyto-histological correlation rates for each grade of squamous intraepithelial lesions (SIL) (e.g. low-grade and high-grade) and for the cases of carcinoma on Pap tests.
8. correlation with corresponding surgical materials.
9. turnaround times (from the date the specimen is received in the laboratory to the date of the finalized report is issued).

8.11.2 Non-Gynecological Cytology

8.11.2.1 There must be policies for addressing performance indicators which include:

1. the total number of non-GYN cases categorized by anatomic site and types of specimens.
2. the rates of major diagnostic categories (e.g. unsatisfactory, negative, atypical, suspicious, malignant) must be calculated for major groups of non-GYN cytology (e.g. breast, thyroid).
3. correlation of results of fine needle aspirate (FNA) with their corresponding surgical material.
4. the rates of major diagnostic categories (e.g. unsatisfactory, negative positive, atypical).
5. non-GYN material malignant diagnoses correlated with tissue results and/or outcomes.
6. turnaround times (from the date the specimen is received in the laboratory to the date of the finalized report is issued).

9.0 HEMATOLOGY

9.1 Specimen Procurement

9.1.1 A facility must establish a procedure requiring personnel to:

9.1.1.1 visually check all specimens for clots, hemolysis and lipemia.

9.1.1.2 collect coagulation specimens in sodium citrate anticoagulant.

9.1.1.3 centrifuge coagulation specimens as required to ensure platelet poor plasma.

9.2 Automated Blood Cell Counts

9.2.1 A facility must:

9.2.1.1 perform checks of each mode of analyzers with two modes of aspiration for precision and accuracy.

9.2.1.2 establish procedures governing:

1. setting limits at which abnormal high and low counts are verified.
2. calibration using whole blood samples, a stabilized material, or a certified hemoglobin material traceable to a reference method.
3. when a manual peripheral blood film assessment is warranted.
4. correcting the automated white blood cell count if nucleated red cells or megakaryocytes are detected.

5. the follow-up of instrument flags.
6. defining lower limits for body fluid cell counts when the use of an automated or a semi-automated cell counter is not reliable.
7. reporting red cell indices from the instrument.
8. background counts on the diluent and lysing agent to check for contamination.
9. checking daily with stabilized whole blood reference material.
10. checking the calculated Mean Cell Hemoglobin Concentration (MCHC) if not computed by the instrument.
11. investigating MCHC values exceeding the upper limits of the normal reference range.
12. correcting for lipemia where there is a high MCHC.
13. correcting a low hematocrit on automated instruments.

9.3 Manual Platelet and White Cell Counts

9.3.1 A facility must:

9.3.1.1 use a certified coverslip.

9.3.1.2 establish procedures governing:

1. checking samples for clots prior to performing manual counts.
2. manual counts in cases of leucopenia or thrombocytopenia to offset increased chances of error associated with counting smaller numbers of cells.
3. manual cell counts using a system to ensure that dilution fluids and reagents are free of contaminants.
4. performing cell counts in duplicate. (The counts must correlate to within 20% of each other and the average of the two counts reported.)
5. correlating manual platelet counts and stained peripheral blood films.

9.4 Peripheral Blood Films

9.4.1 A facility must:

9.4.1.1 positively identify peripheral blood films by two unique identifiers.

9.4.1.2 have peripheral blood films of good quality, well stained and free of precipitate.

9.4.1.3 regularly assess the quality and staining of peripheral blood films.

9.4.1.4 establish procedures governing:

1. reporting white cell morphology.
2. the estimation of platelets on peripheral blood films.
3. which differential will be used on the final report, if the manual differential varies considerably from the automated.
4. reporting red cell morphology in a standardized format on all blood films.
5. the review of stained peripheral blood films by a supervisor.
6. the referral of stained peripheral blood films to a hematologist/hematopathologist/ pathologist.

9.4.1.5 report differential white counts in absolute values. Percentages are optional.

9.4.1.6 record abnormal distribution, such as platelet clumps, satellitism and abnormal size.

9.4.1.7 require a blood film examination, if significant numbers of giant platelets and/or platelet clumps are detected, to prevent reporting spuriously high white cell counts.

9.4.1.8 establish a policy defining which peripheral blood films (abnormal and normal) are to be retained for future reference.

9.5 Coagulation Studies

9.5.1 A facility must:

9.5.1.1 perform coagulation tests on platelet-poor plasma or platelet-poor frozen plasma. Platelet counts must be performed on fresh plasma at weekly intervals to validate platelet poor plasma is being used in testing.

9.5.1.2 establish procedures governing:

1. the follow-up on samples with unexplained prolonged coagulation results.
2. detecting and special handling of specimens with an elevated hematocrit.
3. using of appropriate International Sensitivity Index (ISI) to the particular prothrombin time (PT) reagent and instrumentation.
4. defining interval checks of patient reports for correct INR calculations, patient results and reference ranges when there is:
   a) a change in the lot number or type of PT reagent.
   b) a change in instrument.
   c) a new PT reference range established.
   d) a change in INR calculation.
5. defining interval checks with two different levels of control for manual, automated or semi-automated coagulation testing systems.
6. an in-house range and cutoff for D-dimer testing.
7. a standardized template method for bleeding times.

9.5.1.3 perform manual coagulation determinations in duplicate; tolerance limits between duplicate assays must be defined.

9.5.1.4 handle blood samples for platelet aggregation and platelet function studies at room temperature prior to testing.

9.6 Bone Marrow Examination

9.6.1 A facility must:

9.6.1.1 establish a procedure governing:

1. the handling of bone marrow specimens.
2. the number of cells counted in a bone marrow differentials.

9.6.1.2 label slides and biopsies with two unique identifiers (patient first name, patient last name, and unique identification number).

9.6.1.3 satisfactorily prepare and stain bone marrow smears for interpretation.

9.6.1.4 do iron stains for evaluation of iron stores where indicated.

9.6.1.5 correlate the results of ancillary studies.

9.6.1.6 if performed, use bone marrow biopsies in conjunction with the aspirate to evaluate the bone marrow.

9.6.1.7 have a qualified hematologist/hematopathologist/pathologist evaluate bone marrow specimens and prepare a written report.

9.6.1.8 file slides and keep readily available for review.

9.6.1.9 establish a policy for retention of bone marrow slides.

9.7 Hemoglobinopathy Investigations

9.7.1 A facility must:

9.7.1.1 further investigate specific hemoglobin variants when abnormal hemoglobins are found in screening.

9.7.1.2 quantify hemoglobin variants.

9.7.1.3 have a hematopathologist/hematologist interpret any abnormal hemoglobin results.

9.7.1.4 establish separate procedures for the reporting of hemoglobinopathy investigations on infants.

9.8 Malarial Parasites

9.8.1 A facility must establish a procedure respecting malarial parasite investigation, governing:

9.8.1.1 performing screening within a specified time frame.
9.8.1.2 using both thin and thick blood films.
9.8.1.3 washing films with water or buffered with a pH of 7.0-7.2, after blood films have been stained.
9.8.1.4 examining at least 100 oil immersion fields of blood films for malarial parasites.
9.8.1.5 issuing preliminary reports on initial microscopy with significant parasitemia.
9.8.1.6 reporting the percentage of parasitemia at the time of the initial identification and reporting of malarial parasites and on follow-up films.
9.8.1.7 reporting the identification of the organism/species within 24 hours on all blood films positive for malarial parasites (*plasmodium spp*).

9.9 Erythrocyte Sedimentation Rate (ESR)

9.9.1 ESR's must be performed in a temperature controlled area.

9.10 Reticulocyte Count

9.10.1 A facility must:

9.10.1.1 establish a procedure for:

1. manual or automated reticulocyte counts.
2. storage of specimens if counts are not performed immediately.

9.10.1.2 report the results as a percentage and/or absolute value.

10.0 IMMUNOLOGY

10.1 General

10.1.1 The results of tests performed by personnel other than a licensed medical laboratory technologist (MLT) must be reviewed within 24 hours by a supervisor who is a licensed MLT.

10.1.2 A facility must:

10.1.2.1 establish a procedure to address sample identity and integrity (e.g. aliquots, dilutions etc.).
10.1.2.2 establish reference ranges for the population being tested.
10.1.2.3 use kit procedures only as recommended by the manufacturer[14].
10.1.2.4 test procedures for which there is no commercial calibration or control material available to verify the accuracy of the patient test results.

11.0 SEMEN ANALYSIS

11.1 Specimen Procurement

11.1.1 A facility must:

11.1.1.1 provide specific, clearly written patient instructions for:

1. specimen collection , including abstinence requirements.
2. specimen delivery to facility (if applicable) including protection from extremes of temperature for motility testing requirements.
3. method of collection (e.g. masturbation vs. coitus interruptus).
4. acceptable containers. A clean, wide-mouthed container made of glass or plastic is acceptable. A condom is not acceptable.

[14] See also Manuals Standard

11.1.1.2 document for each semen specimen:

1. patient first name, patient last name and unique identification number.
2. date and time of collection.
3. completeness of collection.
4. times/days of abstinence.
5. collection or transport problems (e.g. incomplete specimen, exposure to temperature extremes, etc).
6. time between collection and receipt of specimen.
7. time between receipt and analysis of specimen.

11.2 Specimen Analysis

11.2.1 Macroscopic Examination

11.2.1.1 A facility must:

1. evaluate viscosity and pH.
2. record abnormalities of liquefaction.
3. allow sufficient time for liquefaction.
4. note and report all characteristics of semen specimens (e.g. gelatinous clumps, viscosity, contaminants, blood).

11.2.2 Microscopic Analysis – Sperm Morphology

11.2.2.1 A facility must:

1. examine semen specimens immediately after liquefaction.
2. classify morphologic defects in the following categories:
   a) Head defects.
   b) Neck and midpiece defects.
   c) Tail defects.
   d) Cytoplasmic droplets.

11.2.3 Microscopic Analysis – Sperm Count and Motility

11.2.3.1 A facility must:

1. employ a concentrating technique on seminal fluid for azoospermic specimens and post-vasectomy checks for sterility.
2. define when viability measurements will be performed on specimens with abnormally low percent motility (e.g. <30%).
3. assess at least five microscopic fields in a systematic manner to classify at least 200 spermatozoa.
4. evaluate forward progression of sperm.
5. evaluate and grade sperm motility percent and progression within one hour of receipt.
6. document immature germ cells or agglutination of spermatozoa, if seen.

11.2.4 Quality Control

11.2.4.1 A facility must:

1. have available for consultation an individual with expertise in sperm morphology.
2. maintain a file of unusual slides.

12.0 TRANSFUSION MEDICINE

Each facility which offers transfusion medicine services must adhere to the standards set out in the most current edition of the American Association of Blood Blanks (“AABB”), Standards for Blood Banks and Transfusion Services.

13.0 URINALYSIS

13.1 Specimen Procurement

13.1.1 A facility must:

13.1.1.1 provide adequate patient specimen collection and handling instructions in each area where urine specimens are collected:

1. for routine, midstream and 24 hour urine collection and preservation.
2. specific to males, females, infant boys and infant girls.

13.1.1.2 establish timelines within which:

1. urine specimens are analyzed or the specimens must be refrigerated.
2. urine specimens are cultured.

13.2 Urinalysis

13.2.1 Macroscopic Analysis

13.2.1.1 A facility must have a procedure for macroscopic and chemical analysis.

13.2.2 Microscopic Analysis

13.2.1.1 A facility must:

1. establish procedures that:
   a) clearly define when a microscopic urinalysis is to be performed.
   b) outline reporting requirements for microscopic analysis.
2. correlate the results of the microscopic and macroscopic analysis, investigate any discrepant results and resolve the discrepancy.
3. establish a program for personnel to maintain competence in identification of all elements found in urine sediment (eg: artifacts, cells, crystals, ova, parasites etc.).