

COLLEGE OF PHYSICIANS AND SURGEONS OF SASKATCHEWAN



Guidelines for Inspectors

Laboratory Quality Assurance Program

January 2007

Competent caring medical professionals providing quality health care.

INSPECTOR MANUAL

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1.0 PREAMBLE

These guidelines are designed for inspectors of clinical laboratories for the purposes of accreditation in Saskatchewan. It is intended that a general framework for consistent and thorough inspections in diagnostic medical laboratories will be the end result.

The philosophy of the Laboratory Quality Assurance Program is based on a peer review process to educate, facilitate and standardize continuous improvement in the quality of laboratory services.

The College of Physicians & Surgeons of Saskatchewan Laboratory Quality Assurance Program acknowledges your dedication and commitment to ensuring quality laboratory services.

2.0 INTRODUCTION

The mandate of the Laboratory Quality Assurance Program is to monitor and improve the quality of clinical laboratory services in Saskatchewan. In order to meet this mandate, the Program developed a process for accreditation that included requirements for on-site inspections of medical laboratories and a proficiency testing program to monitor testing performed.

The Laboratory Quality Assurance Program examines all aspects of quality assurance and quality control in the laboratory, including test methodologies, reagents, control media, equipment, specimen handling, procedure manuals, test reporting, internal and external proficiency testing and monitoring, safety, overall management practices and personnel qualifications and competency.

The Laboratory Quality Assurance Program is a peer review process with a goal to improve laboratory performance through objective evaluation and constructive criticism.

2.1 STANDARDS FOR LABORATORY ACCREDITATION

The “Standards” utilized are a compilation of standards from the Clinical Laboratory Services Institute (CLSI), College of American Pathologists (CAP), Canadian Society for Transfusion Medicine (CSTM), American Association of Blood Banks (AABB) and QA committee input. The Committee recognizes that some of the standards may be controversial and what is a requirement today may not be regarded in this light tomorrow,

due to the constantly changing spectrum of laboratory practice. Consequently, these standards are under continuous review and revised annually.

3.0 INSPECTION PROCESS

3.1 PRE-INSPECTION

GENERAL

1. Inspection documents/checklists are circulated to laboratories 90-120 days prior to the established date of inspection. Returned completed documents are provided to inspectors, electronically whenever possible.

THE CHECKLISTS/QUESTIONNAIRES FOR ACCREDITATION:

- provide a point of reference for interpreting the standards
 - serve as a mechanism for correlating what occurs in daily laboratory practice
 - reflect what is recognized as good laboratory practice
 - provide inspectors with a guide through the critical points of the inspection
2. Official date for inspection is confirmed with the site.
The official notification must include:
- (i) a listing of team members, specifying the team leader and contact number
 - (ii) timetable for inspection
 - (iii) a list, in chronological order, of whom the inspection team would like to meet
 - (iv) specific areas to be examined, based on performance to date

3.2 TEAM COORDINATOR/TEAM LEADER

The Laboratory Quality Assurance Program has the primary role to coordinate, organize and provide consistency across all inspections, and hence, will contact the laboratory and make appropriate arrangements for the inspection. In most cases, an experienced inspector (MD or MLT) will be asked to coordinate the team. Duties include:

1. Selection of Team Leader and team members.
2. Confirming inspection date(s) and actual inspection.
3. Ensuring that all team members are prepared and have the appropriate documentation for the inspection.
4. Coordinating and preparing the inspection report.
5. Assessing follow-up action in consultation with appropriate Team members in response to deficiencies as outlined in the inspection report in a timely manner.

6. Ensuring a thorough, objective review is conducted.
7. Ensuring confidentiality.
8. Acting as liaison to the Director of the Laboratory Quality Assurance Program.

3.3 TEAM LEADER RESPONSIBILITIES

A Team Leader is selected that is either a pathologist or clinical specialist with appropriate laboratory expertise.

The responsibilities include:

1. Working with the Inspection Coordinator to confirm inspection date, protocol, (two month notice is appropriate); specific persons to interview, etc
2. Communicate with the team members to review package material, in advance, and set up a pre-inspection meeting time.
3. Meet with the team to discuss protocol and address questions.
4. Assure the team members that you will check with them during the inspection to provide assistance and support.
5. Emphasize adherence to protocols and timeframes established.
6. Collect individual team evaluations and collate to present a final report.
7. Participate with the team members to expedite the process.
8. Be specific.

3.4 TEAM MEMBER RESPONSIBILITIES

Team members are selected based on their discipline-specific expertise and knowledge of good laboratory practice.

1. Review and become familiar with information provided regarding the upcoming inspection.
2. List queries, etc. to raise with the team leader or team at pre-inspection meeting.
3. Adhere to the agenda and timeframe established.
4. Address any area that arises on the checklists and correlate with supportive information obtained during inspection.
5. Accurately record observations as made.
6. Raise any problems or concerns that you have difficulty interpreting as soon as possible, before summation conference or report release.
7. Participate with the team leader to expedite the process.
8. Be specific.

4.0 GENERAL GUIDELINES FOR INSPECTION TEAMS

1. *be supportive, open-minded*
2. *coach labs towards excellence — make tactful suggestions*
3. *be informed*
4. *tour lab and look for obvious*
5. *ask open-ended questions – tell me about; describe; show me*
6. *review procedure manuals and PT results*
7. *review QC policies and documentation*
8. *evaluate physical space and other ergonomic issues; cleanliness, safety, etc.*
9. *directly observe work practices*
10. *review the lab safety issues (fire extinguisher, flammables, electrical, chemicals, hazardous waste, etc.)*
11. *review findings with team leader*
12. *check for proper use of gloves and shields*
13. *review environment - clean, clutter-free, cables, wires, etc.*
14. *accurately record observations*
15. *identify any/all conflict of interests*

5.0 CONDUCTING THE INSPECTION

Each medical laboratory should be considered as an individual entity working and serving the particular needs within its organization and region. It is recommended that each inspection team adopt what it considers to be the most appropriate approach for the facility. Items that must be addressed, however, include directorship and supervision, personnel qualifications and continuing education, policy and procedure manuals, records, quality assurance and quality control, instrument maintenance and safety.

It is imperative that inspectors have expertise in the areas they are inspecting. Prior to the inspection, the inspector must review all pertinent information submitted so as to be familiar with the laboratory. Review of personnel qualifications, testing modalities and volumes, analytical systems, and quality assurance/control methods will ensure a well-focused, meaningful inspection.

Upon arrival, an initial tour of the entire laboratory will give a general overview of the laboratory operation and key personnel.

During the inspection, inspectors must gather details where deficiencies have occurred and identify areas for improvement. In areas where a lab has demonstrated exemplary practices, these should also be noted and commended.

6.0 INTERVIEWS (USUALLY CONDUCTED BY TEAM LEADER)

6.1 LABORATORY DIRECTOR

- emphasize purpose of inspection
- request point of view of lab performance
- availability of incidence reports
- responsibility defined
- adequate staffing, supervision/training/CE/maintenance of competence

Purpose: to determine qualifications, authority, overall plan and philosophy of Director.

6.2 ADMINISTRATION

- thank for cooperation and participation
- evaluate laboratory service from an administrative point of view
- areas of concern
- responsibility

Purpose: to determine administrative support for quality laboratory services, areas of concern and administrative expectations.

6.3 MEDICAL STAFF

- effectiveness of working relationship
- adequacy of service
- confidence in service

Purpose: to determine if laboratory services are responding to physicians needs in timeliness, pathology contributions and cooperation between medical staff.

6.4 OTHER PERSONNEL

- verification of personnel qualifications
- sufficient numbers for workload
- availability of staff
- POCT operations

7.0 MAJOR POINTS TO COVER

- I. READ – OBSERVE – ASK** – the three methods of eliciting information during the inspection process. These three methods may be used throughout the day in no particular order. Plan the inspection in a way that allows adequate time for all three components.

READ = Review of Records and Documents

Document review verifies that procedures and manuals are complete, current, available to staff, accurate and reviewed, and describe good laboratory practice. Make notes of any questions you may have, or processes you would like to observe as you read the documentation.

OBSERVE – ASK = Direct Observation and Asking Questions

Observing and asking questions accomplish the following:

1. Verifies that the actual practice matches the written policy or procedure
2. Ensures that the laboratory processes are appropriate for the testing performed
3. Ensures that outcomes for any problem areas, such as PT failures and issues/problems identified through the quality management process, have been adequately investigated and resolved
4. Ensures that previously cited deficiencies have been corrected

Use the following techniques:

- **Observe laboratory practices** – look at what the laboratory is actually doing. Compare the written policy/procedure to what you actually observe in the laboratory to ensure the written policy/procedure accurately reflects laboratory practice. Note if practice deviates from the documented policies/procedures.
- **Ask open ended, probing questions** – these are starting points that will allow you to obtain large amounts of information, and help you clarify your understanding of the documentation you've seen and observations you've made. This eliminates the need to ask every single checklist question, as the dialogue between you and the laboratory may address multiple checklist questions.
- Ask open-ended questions that start with phrases such as “show me how...” or “tell me about ...” or “what would you do if...”. By asking questions that are open-ended, or by posing a hypothetical problem, you will avoid “cookbook” answers. For example, ask “Could you show me the specimen transport policy and show me how you ensure optimum specimen quality?” This will help you to determine how well the technical staff is trained, whether or not they are

adhering to the lab's procedures and policies, and give you a feel for the general level of performance of the laboratory.

- Ask follow-up questions for clarification. Generally, it is best not to ask the checklist questions verbatim. For example, instead of asking the checklist question "Is there documentation of corrective action when control results exceed defined tolerance limits?" ask, "What would you do if the SD or CV doubles one month?" A follow-up probing question could be, "What would you do if you were unable to find a cause for the change in SD or CV?"

II. Evaluate Selected Specimens and Tests in Detail

For the Laboratory General Checklist: Follow a specimen through the laboratory. By following a specimen from collection to test result, you can cover multiple checklist questions in the Laboratory General checklist: questions on the specimen collection manual; phlebotomy; verbal orders; identification of patients and specimens; accessioning; and result reporting, including appropriate reference ranges, retention of test records, maintaining confidentiality of patient data, and proper handling of critical values and revisions to reports.

For the individual laboratory sections: Consult the laboratory's activity menu and focus on tests that potentially have the greatest impact on patient care. Examples of such tests include HIV antibodies, hepatitis B surface antigen, urine drugs of abuse, quantitative beta-hCG, cultures of blood or CSF, acid-fast cultures, prothrombin time and INR reporting, and compatibility testing and unexpected antibody detection. Other potentially high-impact tests may be identified by looking at very high or low volume tests in the particular laboratory, or problems identified by reviewing the Variant Proficiency Testing Performance Report.

To evaluate preanalytic and postanalytic issues: Choose a representative specimen and "follow" the specimen through the laboratory or section of the laboratory, reviewing appropriate records in the preanalytic and postanalytic categories.

To evaluate analytic processes: Choose 2 or 3 analytes and perform a comprehensive review of records, including procedure manuals, quality control and proficiency testing records, instrument maintenance records and method performance validations for the last 2 years, selecting timeframes at the beginning, mid-point, and end of this timeframe. Compare instrument print-outs to patient reports and proficiency testing results to ensure accurate data entry. If problems are identified, choose additional tests or months to review.

- III. Verify that proficiency testing problem have been resolved:** From the inspector's packet, review the Variant PT Performance Report that identifies, by analyte, all of the PT scores below 100%. Correlate any PT problems to QC or maintenance records from the same time period. Be thorough when reviewing these representative records, selecting data from the beginning, middle and end of the period since the last on-site inspection.
- IV. Review correction of previous deficiencies:** Review the list of deficiencies from the previous on-site inspection provided in the inspector's packet. Ensure that they have been appropriately addressed.

8.0 POST INSPECTION

THE SUMMATION CONFERENCE is one of the most important functions of the inspection. This is a mechanism for the Inspection team to summarize their findings and to report to the lab staff. Allow enough time to present findings, answer questions and address discrepancies. An educational approach should be used to handle unresolved differences and/or deficiencies. Offer suggestions for improvement.

There should be no surprises on the final report. Everything should be raised at the summation conference, identifying any deficiencies or areas for improvement. Accolades should also be extended. This will reflect what the final report will state.

9.0 THE REPORT

The report is a compilation of all findings of the team. The results of the Inspection should be clearly documented and signed by the Inspection team. It is comprised of general observations, requirement and recommendations.

Auditors characterize deficiencies as major and minor. Emphasis on major deficiencies require special attention.

MAJOR - may seriously affect the quality of patient care, or the health and safety of hospital or laboratory personnel. Requires action within 30-60 days.

MINOR - does not seriously affect the quality of patient care or significantly endanger the welfare of a laboratory worker. Requires written response.

RECOMMENDATION - good laboratory practice

Any assistance, such as a list of appropriate reference texts, equipment evaluations, or examples from other centers would greatly benefit the site being inspected.

An evaluation form should be left for completion and returned to the Laboratory Quality Assurance Program, 3475 Albert Street, Regina Saskatchewan, S4S 6X6.

Within two weeks of the on-site inspection, the inspection team must return all components to the College:

1. a hard copy of the report;
2. a copy of the report by email or disk;
3. completed questionnaire; and
4. expense claim forms
5. personal information sheet

The report should be provided to the site within 60 days of the inspection. An invoice will accompany the final report. Timelines must be adhered to, so inspectors are asked to complete their tasks within the guideline.

10.0 FOLLOW-UP

The Laboratory must reply in writing, outlining corrective action and timeframes for each deficiency listed as a requirement.

The laboratory response will be reviewed by the Program. Appropriateness of the response or follow-up will be determined by consensus.

11.0 ACCREDITATION STATUS

If there are no deficiencies, an accreditation certificate is issued, indicating satisfactory performance.

If deficiencies are identified, the laboratory is given a specified time in which to comply. An accreditation certificate is issued once all factors are satisfied. Additional inspections may be scheduled, based on report status.

12.0 HONORARIA & EXPENSES

All inspectors will be paid a per diem and expenses related to inspection.

The facility/region will be invoiced for the accreditation by the College. All audits will be based on a cost-recovery basis.

13.0 GENERAL PRINCIPLES

The QA Policy Manual is the framework for quality improvement to meet the criteria of the discipline-specific committees.

As members of CLSI, we are provided with all CLSI documents. The Program recommends all laboratories default to these standards, where no other standard or policy has been developed. The Lab QA Program serves as a loan library and provides these documents to laboratories for 30 day loan. A complete listing of the CLSI documents is provided, to each laboratory.

Wherever possible, the Lab QA Program will attempt to meet established laboratory practices. The Standard Council of Canada, through the International Organization for Standardization (ISO) has developed guidelines for quality management of medical labs, ISO 15189. CLSI has created a quality document in healthcare; HS1-A that may also assist the process and CAN/CSA-Z15189-03.

14.0 FREQUENTLY ASKED QUESTIONS

1. How does the laboratory show that they have performed a self-evaluation and corrected any deficiencies?

As a team leader/inspector, you must review written documentation. Remember if it isn't documented, it wasn't done. Documentation should include: completed self-evaluation checklists; narrative regarding deficiencies and supporting documentation that demonstrates deficiencies were addressed.

2. What is the best way for an inspector to use the checklists?

Every checklist item needs to be addressed. Checklists should not be used by rote, but as a guide for inspectors to formulate questions and determine sources of documentation to be examined that support laboratory activities which demonstrate compliance with the checklist items.

3. What are the most common deficiencies:

The single most significant deficiency is a lack of documentation. Also, include:

- safety issues
- lack of QC corrective action;
- lack of defined QI program;
- failure to annually review procedures;
- lack of review of controls and instrumentation function;
- inadequate monitoring of vapor concentrations in histology.

4. How does an inspector assess the severity of space deficiencies?

By determining if there is adequate space to perform the procedures required of the laboratory service such that equipment, methods or personnel are not compromised in these activities.

5. What does the College mean when they use non-specific terms like "periodically" or "as appropriate"?

These terms are generally considered as good laboratory practice, with timelines attached. The procedure is performed routinely enough to maintain the quality of services provided. It is the laboratory's responsibility to define these terms in their policies and procedures. Documentation that illustrates that procedures are working adequately must be maintained.

6. How does the inspector assess the adequacy of the laboratory's Quality Improvement Program?

Look for evidence of a comprehensive program that includes a set of appropriate indicators, continuous monitoring and response to monitoring outcomes. The program should include, but not restricted to the following elements: technical and procedural monitoring, review of the quality of diagnostic reports, active pathology participation and review of personnel competency.

The 12 Quality System Essentials (QSE) developed by CLSI may provide a fact-finding assessment.

7. Are there any special requirements for the anatomic pathology quality improvement program?

Surgical Pathology: Checklist questions assist the inspector in determining adequate technical and procedural quality control and an active program of surveillance of the quality of surgical pathology activities, particularly the diagnostic reports. The program must include appropriate combinations of activities such as the use of intra- and extra-departmental consultations, circulation of diagnostic material, periodic review of completed surgical reports, and participation in self-assessment and performance improvement programs.

Autopsy: Checklist questions also assist inspectors in determining the presence of an active program of surveillance and the quality of autopsy diagnostic reports and the utilization of the information obtained to enhance the quality of patient care.

Cytopathology: Additionally, checklist questions in cytopathology address technical and procedural quality control, negative and positive diagnoses, appropriate combinations of activities such as hierarchic review, a minimum rescreening of cases, correlation of cytological and histological materials, participation in inter laboratory comparison, self-assessment and performance improvement programs, and appropriate intra- and extra-departmental consultation, as well as pathology and cytotechnologist involvement in the review of QA surveillance results.

8. What are some of the most common deficiencies noted in the safety section of the checklist?

- (i) Lack of knowledge related to biohazards and aerosol affect
- (ii) PPE – absence of glove and protective clothing
- (iii) Handling of sharps and wastes
- (iv) Handwash areas separate from discard areas
- (v) Lack of instructions for emergency clean up of hazardous spills
- (vi) Inadequate monitoring of vapor concentration in histology

9. Do inspectors have to practice universal precautions and other safety regulations while inspecting hazardous areas?

Yes, all precautions apply.

10. What are the minimum requirements for a procedure manual?

Procedure manuals must be in substantial compliance with CLSI GP2-A4. The format does not have to be identical to GP2-A4, but a similar process is acceptable.

How often does the procedure manual need to be reviewed? By whom?

Each procedure in the manual must be reviewed by the director or his/her designate on an annual basis.

11. Is it acceptable to use a manufacturer's package insert as a procedure manual?

No, it is not generally accepted. However, it may be used as part of the procedure manual if there is no deviation from the procedure as stated in the manufacturer's instruction. The laboratory must review the procedures for compliance.

12. Under what circumstances would an inspection team inspect analytical patient testing outside the main laboratory?

If that testing is under the direction of the laboratory director and coordinated by the laboratory. Examples include whole blood glucose testing at the bedside.

13. What is the purpose of the summation conference?

To thank the laboratory being inspected for their cooperation in the process.

To summarize all findings of the inspection team so that there are no surprises in the final report.

14. What should be done if there are unresolved differences of opinion concerning the interpretation of checklist questions?

Unresolved differences of opinion should be handled using an educational approach. The laboratory has the opportunity to refute with documentation any deficiency that is cited during the inspection. The laboratory's response and documentation will be reviewed by a technical associate in the Laboratory Quality Assurance Program office. If the deficiency was cited in error, it will be removed from the final deficiency commentary.

15. In what detail should the deficiency summary be completed?

The deficiency must be listed and a brief explanation why the laboratory was cited. Partial compliance should be noted.

16. Is a procedure manual written substantially in compliance with accepted standards and available at the workbench or work area?

The procedure manual should be available at the workbench and should include: principle, specimen type, required reagents, calibration, quality control, procedure, calculations, reference ranges and interpretation. The procedure manual must also include documentation of initial and annual reviews by the Director or designate.

17. Are new reagent lots checked against old reagent lots or with suitable reference material before being placed in service?

New reagents must be run in parallel or validated with old reagents or checked against other reference material to ensure appropriate reactivity. For qualitative tests, minimum cross-checking includes retesting at least one known positive and one

known negative patient sample from the old reagent lot against the new reagent lot, ensuring that the same results are obtained with the new lot.

18. Is there documentation of corrective action taken when controls, etc. exceed defined tolerance limits?

Records of controls must show evidence of corrective actions when results exceed tolerance limits or criteria for acceptability.

19. Has the laboratory documented a system for determining the accuracy and reliability of analytic results on patient samples for which no external proficiency testing program is offered?

A mechanism must be developed for assessing accuracy and reliability of the laboratory's analytical procedures for those tests not evaluated through external proficiency testing. Blind testing of specimens of known results, exchange of specimens or equivalent may accomplish this.

20. How were the checklists developed?

The Lab QA Program developed the checklists using a compilation of the Alberta (ALQEP), Ontario (QMPLS) and College of American Pathologists (CAP) accreditation checklists, and based on auditor experiences.

21. What if a laboratory challenges a standard, policy or guideline?

Inspection team members should welcome questions and/or queries. If you do not have the information/answer at your fingertips, forward it to the Lab QA Program. We will research it and provide a response. This serves as a valuable educational tool for all.

22. Is there a standard for running controls?

The manufacturer's instructions must be followed. However, the QA Committees have developed a generic standard that would apply in most circumstances.

Controls should be run, as a minimum, each day of use for most testing. POCT and qualitative kit tests require meeting the manufacturer's recommendation, with a minimum of once per month and upon initiation of a new lot number or shipment.

****Refer to checklist for appropriate application.***

Are key indicators of quality monitored and evaluated to detect problems and opportunities for improvement?

NOTE: Key indicators are those that reflect activities critical to patient outcome, that affect a large proportion of the laboratory's patients, or that have been problematic in the past. The laboratory must document that the selected indicators are regularly compared against a benchmark, where available and applicable. The benchmark may be a practice guideline, surveys by commercial providers or the laboratory's own experience. New programs or services should be measured to evaluate their impact on laboratory service. The number of monitored indicators should be consistent with the laboratory's scope of care. Special function laboratories may monitor a single indicator; larger laboratories should monitor multiple aspects of the scope of care commensurate with their scope of service. (However, there is no requirement that an indicator(s) be assessed in every section of the laboratory during every calendar year.)

Examples of key indicators include, but are not limited to the following.

- 1. Patient/Specimen Identification. May be any of the following: percent of patient wristbands with errors, percent of ordered tests with patient identification errors, or percent of results with identification errors.*
- 2. Test Order Accuracy. Percent of test orders correctly entered into a laboratory computer.*
- 3. Stat Test Turnaround Time. May be collection-to-reporting turnaround time or receipt-in-laboratory-to-reporting turnaround time of tests ordered with a "stat" priority. Laboratories may monitor mean or median turnaround time or the percent of specimens with turnaround time that falls within an established limit.*
- 4. Critical Value Reporting. Percent of critical values with documentation that values have been reported to caregivers*
- 5. Customer Satisfaction. Must use a standardized satisfaction survey tool with a reference database of physician or nurse respondents.*
- 6. Specimen Acceptability. Percent of general hematology and/or chemistry specimens accepted for testing.*
- 7. Corrected Reports – General Laboratory. Percent of reports that are corrected.*
- 8. Corrected Reports – Anatomic Pathology. Percent of reports that are corrected.*
- 9. Surgical Pathology/Cytology Specimen Labeling. Percent of requisitions or specimen containers with one or more errors of pre-defined type.*
- 10. Blood Component Wastage. Percentage of red blood cell units or other blood components that are not transfused to patients and not returned to the blood component supplier for credit or reissue.*
- 11. Blood Culture Contamination. Percent of blood cultures that grow bacteria that are highly likely to represent contaminants.*

While there is no requirement that the specific key quality indicators listed above be monitored, these indicators have been field-tested and shown to be measurable in a

consistent manner, to demonstrate variability from laboratory-to-laboratory, and to be important to clinicians and to patient care. Action plans should be developed for any indicator in which laboratory performance falls below the 25th percentile (i.e., 75% or more of the other laboratories in the study perform better). Use of the indicators listed above does not require enrollment in any quality monitoring product.

APPENDIX - AIDS FOR INSPECTORS

APPENDIX A - AIDS FOR INSPECTORS

These aids are extracted from the Alberta documents and are aimed at assisting the auditor and uncover information relevant to a quality system.

Laboratory General

a. Organization

The manner in which a laboratory is organized and operates should be carefully evaluated.

The inspection team should establish that:

- a comprehensive description of the organization, staffing and operations of the laboratory exists;
- the laboratory staff is fully aware of the actual manner in which the laboratory is organized and functions;
- there is documentation to clearly indicate the range of work, the work referred elsewhere, to whom the services of the laboratory are provided and when the services are available.

Throughout the course of the assessment, requested documentation provided by the laboratory with the questionnaires should be referred to and any differences between the submitted documentation and the actual manner in which the laboratory is organized and functions should be documented.

b. Personnel

The responsibility and authority for the day-to-day operations of the laboratory along with qualifications and competency of staff are critical factors in the credibility of a laboratory.

The inspection team should, therefore, establish that:

- the management structure and authority/responsibility relationships within the laboratory are appropriate;
- the professional qualifications of senior personnel are appropriate;
- the total number of staff and the ratio of professional to sub-professional staff are adequate in relation to the range and volume of work being done;
- staff are adequately supervised in their work;
- satisfactory provisions exist for the control and supervision of laboratory operations during any absence of the person in charge or section supervisors;
- there is provision for continuing education and maintenance of competence;
- staff are adequately trained prior to assuming responsibilities.

c. Physical Facility

The accommodation provided will vary considerably from one laboratory to another, depending upon the nature and requirements of the work being done. The space and environment should not in any way inhibit the proper performance of the tests, or compromise the health and safety of personnel.

The inspection team should determine:

- whether any of the laboratory's tests require a controlled environment in respect to temperature, relative humidity, illumination level, air flow or air quality and if so, the manner in which these conditions are controlled and monitored effectively;
- that all sensitive equipment is suitably situated, and isolated from any unfavorable environmental conditions which are likely to affect performance (e.g. vibration, dust, corrosive fumes, direct sunlight, voltage fluctuations);
- that all ancillary services are available and suitably located (e.g. gas, electricity, water, waste disposal, fume extraction);
- that an appropriate standard of tidiness, housekeeping and cleaning is being maintained;
- that appropriate provision is made for all laboratory functions, including sample preparation and storage, clerical operations, storage of documentation, etc.

d. Records

Records must be clear and unambiguous, be complete in respect to the performance of the test, and permit the tracing of results from receipt of sample to the issued report and vice versa. The application of these concepts will vary from one laboratory to another and will depend upon the extent to which the records system is computerized. The following guidelines will generally be applicable.

The inspection team should ensure that:

1. requisitions are appropriate;
2. test records contain all information needed to show what has been done, by whom and when. This will usually mean inclusion of the following details:
 - Patient name
 - Second patient identifier (eg: personal health number)
 - Date of birth/gender
 - Name of requesting physician /health care provider
 - Date/time of collection, where necessary
 - Test requested
 - Reference values
 - Date of the report
 - Time of the report
 - Name of the site performing the test

- Accession number
3. when corrections are made to the recorded data, they should be made without obliterating the original data. The reasons for the corrections should be recorded, and the corrections should be signed or initialed by the person making them;
 4. there is a system in place to detect clerical errors or unusual laboratory results and that the system provides for timely correction of errors. This also includes computer systems;
 5. the whole records system is organized in an orderly manner so that an element (sample records, test data, copies of test reports, etc.) may be readily retrieved;
 6. if reports are computer generated, that the system provides an audit trail that allows identification of each individual contributing to, or editing the printed result. The data must be secure and the back-up system functional;
 7. If reports are transcribed, it is verbatim and the identity of the originating laboratory is noted.

Electronic signatures are permissible if the pathologist has personally verified the results.

e. Specimens

The collection, handling, transport, reception and labeling of specimens are an integral part of the testing process and must be examined in the same depth as the testing operations. To assess this component of the laboratory, it is suggested that the inspector have the technologist/technician responsible “walk” them through the process from sample collection to testing.

The inspection team must ensure that:

- instructions are provided for the collection and handling of specimens for all tests and that these are available to all persons responsible for collecting specimens outside of the laboratory;
- universal precautions are observed;
- there is criteria for the rejection of unsuitable samples;
- the system for sample identification/accessioning is appropriate.

f. Procedure Manual

Review of the procedure manual for each area is key to the inspection.

The following should be considered during this assessment:

- that the procedures reflect actual laboratory practice;
- that the procedures are written in a standardized format and are complete. (Refer to section on manuals in the standards);
- that there is a historical cover page that includes a history of revisions and verifications of annual review by the medical director or designate;

- that a working copy of the procedure manual is readily available for staff.

g. Quality Assurance/Quality Control

Accreditation requires that the laboratory have a planned and systematic program for monitoring and evaluation of the quality and appropriateness of its patient care services.

Quality Control - There must be a well-structured program for the validation of test results for each test performed.

The following should be considered in assessing quality control:

- that the procedures are clearly defined;
- that the laboratory director reviews all quality control results;
- that the laboratory director uses results from the quality control to evaluate performance;
- that corrective actions are taken where necessary; and
- that tolerance limits for procedures are defined in the manuals.

Results from the Laboratory Proficiency Testing Program for the past two years must be reviewed.

h. Equipment

A list of equipment must be appended to the questionnaires.

The inspection team should establish that the equipment is well maintained and appropriate for the testing being done.

The examination of the equipment should take into account:

- the environment in which the equipment is situated; and
- the condition of the equipment and the manner in which it appears to be maintained.

The laboratory must have a schedule for maintenance and calibration. The records must be readily available and be reviewed.

Safety

Review of the laboratory's safety program is one of the most important parts of the inspection.

Some parts of the questionnaires are based upon our current understanding of hazard control, others are based upon provincial or federal regulations, and others upon common sense.

The inspector must be familiar with these regulations, as it is important to the credibility of the Laboratory Accreditation Program that no instance of non-compliance with such regulations be overlooked during an inspection.

When a team inspects the laboratory, each member of the team must survey safety hazards for the portion of the laboratory for which he/she is responsible.

a. General Safety

The inspection team should ensure that:

- the policies of the safety program are written;
- the procedures that are to be followed are posted or otherwise available to all affected employees;
- there is documentation of employee review during orientation;
- the Safety Manual is complete;
- all injuries or occupational illnesses are documented and that there is appropriate review and follow-up.

The inspector should select several safety items and quiz an employee concerning these items (e.g. process for needlestick injuries, clean up of biological waste spill).

b. Fire Safety

The inspection team should ensure that:

- there are adequate fire alarms;
- there is documentation of fire drills;
- fire evacuation routes are posted;
- fire extinguishers are of the appropriate type and number, and are properly located.

c. Chemical Hazards

The inspection team should ensure that:

- workplace Hazardous Materials Information System (WHMIS) regulations are met and that staff is aware of them;
- Material Safety Data Sheets (MSDS) are available for each hazardous chemical; and
- protective equipment/clothing is available, where applicable.

d. Electrical Safety

The inspection team should ensure that:

- there is documentation to ensure that all laboratory instruments and appliances are adequately grounded and checked for current leakage at least annually.

e. Compressed Gases

The inspection team should ensure that:

- compressed gases are properly received, stored, and labeled as to content;
- cylinders are equipped with an approved functional valve system.

f. Protective Apparel

The inspection team should ensure that:

- the use of laboratory coats/gowns is appropriate;
- there is a policy for gloves.

g. Infectious Hazards

The inspection team should ensure that:

- universal precautions are observed;
- protective apparel and proper equipment (e.g. gloves, glasses, biosafety cabinets) are available and used, where appropriate;
- there are procedures and schedules for bench decontamination.

h. Contaminated Waste

The inspection team should ensure that:

- policies and procedures are in place to ensure proper packaging, labeling, transportation and disposal of biological hazardous waste;
- the “depot” at which wastes are collected for transportation or disposition is appropriate.
- The inspector may question the technologists regarding the segregation of wastes to determine whether they understand the facility's policy.

APPENDIX B – ANATOMIC PATHOLOGY

The following approach should provide a logical sequence for inspecting the various areas of anatomic pathology (surgical pathology, histology, autopsy pathology, cytopathology, and electron microscopy).

1. The inspector should evaluate the specimen identification procedure as each section of this department is inspected.
2. It is useful to observe a surgical pathology consultation including preparation of a frozen section and the reporting procedure. The quality of the preparation should be evaluated.
3. During the inspection of the physical facility, special attention should be given to the adequacy of ventilation.
4. Procedure manuals and instrument maintenance activities in anatomic pathology should adhere to the same standards as in other areas of the laboratory.
5. The inspector should evaluate the quality of the preparations from the histology, cytology, and if applicable, electron microscopy laboratories. For review of special stains, including immunohistochemistry procedures, it is important to examine the control slides prepared by the laboratory.
6. As in other sections of the laboratory, safety policies and practices are very important. Special attention should be paid to procedures for the handling of tissues and materials from patients with known or suspected infectious diseases such as AIDS, hepatitis, Jakob-Creutzfeldt syndrome, or an undiagnosed encephalopathy.
7. After a survey of the procedural and technical (quality control) aspects of anatomic pathology, the inspector should then review the quality of the diagnostic reports. In surgical pathology, the gross descriptions should be clear and concise and contain adequate information about the lesions present. The final diagnoses should correlate with the descriptions, provide sufficient information to contribute to patient management, and be available in a timely fashion.
8. In cytopathology, the inspection process must also consider the important role of the cytotechnologist in the diagnostic process. The inspector should determine whether sufficient personnel are available to process and evaluate the volume and variety of cases submitted to the laboratory.
9. Review of autopsy pathology is generally similar to other sections of anatomic pathology. Items to be emphasized include timely reporting of both preliminary and final diagnostic

findings, and policies regarding proper conduct of autopsies on patients with known or suspected infectious diseases.

10. Quality Assurance/Quality Control - In anatomic pathology, the “test result” is a consultative opinion developed by the pathologist through subjective interpretation of morphologic observations. The results, therefore, may not be subject to the same kind of statistical evaluation as in many other sections of the laboratory. As noted above, the procedural and technical aspects of quality control are similar to those in effect in other areas of the laboratory.

Quality control of abnormal cytologic findings should include such activities as evaluation of slide material for adequacy of specimen, hierarchic review, correlation of cytologic and histologic findings, and appropriate use of consultation. Evaluation of the quality of negative findings is more difficult but is very important in reducing the likelihood of a “false negative” report. Among the useful techniques are review of previous material whenever a significant abnormality is identified and rescreening a portion of negative cases. Random re-screening of a portion of negative gynecologic cytology specimens may be a useful component of a quality control program but is generally ineffective as the sole procedure. Re-screening of cases from “high risk” patients is more likely to be effective. Reports from cytopathology should provide for narrative diagnostic comments by the pathologist.

Typically, pathologists are actively involved in quality assurance in anatomic pathology. These activities often include the use of intra- and extra-departmental consultation, case review, correlation of frozen section and final diagnoses, correlation of cytologic and histologic material, hierarchic review in cytology, review of completed diagnostic reports, and participation in educational and self-assessment activities.

What may be lacking are formal organization and documentation of these efforts. The type of program developed for a specific laboratory may vary depending on staff size and the volume and type of diagnostic material. The design of the program is the responsibility of the laboratory director, but the basic quality control/quality assurance, principles of organization, systematic review, and documentation should apply.

APPENDIX C - CHEMISTRY

The chemistry laboratory is usually the largest department in a full-service laboratory, and the test repertoire may be extensive. Time does not permit a detailed review of every procedure, calibration of every pipette and thermometer, or an extensive review of every quality control record. The emphasis should be selective, focusing on the areas of both highest and lowest volume as well as on areas where test results are particularly critical, and on any apparent problem areas. It is usually more instructive to review the records for a few analytic tests comprehensively than to review the records for all tests superficially.

1. The quality control program in a clinical chemistry laboratory is generally the most extensive of any section. It is important to evaluate the quality of data, especially in view of the usual great quantity. Inspect evidence that the system actually results in useful “real time” data regarding the ongoing analytic validity of the various analytical systems. There must be evidence of appropriate review, evaluation and corrective action.
2. Questions regarding the procedure manual, specimen handling, result reporting, and controls and standards should follow. In no area of the clinical chemistry laboratory is the inspector's judgment more important than in evaluating the adequacy of control specimens (type and frequency) for the various analytical systems employed by that laboratory. The laboratory must be able to convincingly demonstrate ongoing system stability, especially if it has elected infrequent control for certain systems. If available, appropriate multi-level control specimens must be used at least daily whenever patient specimens are run.
3. Items such as pipettes, glassware, thermometers, centrifuges, analytical balances, spectrophotometers, and other basic analytic systems may or may not require scrutiny depending on the sophistication and scope of testing of the laboratory. In general, if a laboratory employs such equipment as primary analytical techniques, then adequate evaluation is mandatory. When such systems are maintained for backup purposes and are infrequently employed, then evaluation should be directed to adequacy of maintenance of the system for such backup purposes. Policies and procedures must be written and be adequate to describe the analytic performance characteristics that must be present and documented before such a system can be used for patient testing.
4. For Multiple Analysis Automated Instruments and Systems, the importance of “real time” quality control with documentation of its appropriate use is especially critical. There must be written standard procedures for the set up, operation, and control of the systems that provide adequate detail to ensure the integrity of the system.

5. Also to be considered are the physical facilities and laboratory safety. The unique physical requirements for the various analytical systems used in the laboratory must be adequate. (For safety, refer to the section on “Safety”.)

Toxicology – Drugs of Abuse

The same general requirements must be met in toxicology as in other departments. The department must have written procedures and use reference materials to monitor the performance of each element in the test system.

APPENDIX D - HEMATOLOGY

a. Automated Blood Cell Counting

The laboratory must have a written, detailed procedure for calibration, including clear indications of when recalibration is required. For calibration, the laboratory may use fresh whole blood specimens whose values are determined by reference methods, or stabilized commercial preparations whose values are certified by the manufacturer as being determined by primary reference methods.

Procedures for control may include running stabilized commercial controls and/or re-running retained patient samples. Tolerance limits must be defined with written evidence of action taken when values exceed these limits. Quality control and proficiency testing results must be reviewed. There must be evidence of appropriate review, evaluation and corrective action.

The inspector should be aware that the use of surrogate particles in commercial control material may introduce considerable bias into the system when these materials are used for calibration, quality control, and external proficiency testing. Control materials must not be used as calibrators.

The laboratory must have written procedures for detection of spurious results and interferences (e.g. nucleated red cells, pseudomacrocytosis from cold agglutinins, clots in the specimen, etc.)

b. Chamber Counting

The laboratory must have a procedure for increasing the number of squares counted in leukopenia/thrombocytopenia, to avoid increasing statistical imprecision when few cells are counted.

c. Automated Differential Counters

The laboratory must have a longitudinal process control system using either commercial material or peripheral smear review with manual differential counts. There must be written criteria defining when differential count results must be validated by other methods.

d. Peripheral Blood Smear Evaluation

The laboratory must have appropriate written criteria for review of blood smears by a pathologist, hematology supervisory, or other technologist qualified in hematology.

The inspector should assess the quality of stain by looking at some slides under the microscope.

e. Coagulation Tests

Patient results should be reported with accompanying reference (normal) ranges. Prothrombin time controls should be used as internal controls for quality assurance purposes. If the laboratory is located in an acute care hospital, it should perform sufficient routine and emergency testing for evaluation of common coagulation disorders.

f. Supplementary Procedures

If time permits, the inspector should observe a technologist performing a routine complete blood count including manual differential.

Also, items such as pipettes and pipettors, glassware, centrifuges, etc., should be assessed. Instrument maintenance must also be reviewed.

APPENDIX E - MICROBIOLOGY

Immunology

The major emphasis in this section on the laboratory is on quality control. Positive and negative controls must be run with all reactions, and new kits or reagents must be run in parallel with the old to ensure comparable reactivity. The number of parallel runs should be defined in the procedure manual or the quality control manual.

Microbiology

Depending on the size of the facility, this portion of the inspection may include several subsections: bacteriology, mycobacteriology, mycology, parasitology and virology.

a. Quality Control

This section of the questionnaires includes quality control requirements for prepared and purchased culture media, staining procedures, reagents, antimicrobial susceptibility tests, instruments, and equipment. Each procedure, medium, reagent, item of equipment, etc. to be controlled should have the control methods defined, as well as the frequency of testing, limits for acceptability, and action to be taken when not acceptable.

The inspector should be aware of several important points concerning commercially prepared culture media. The laboratory is responsible for assuring that all media used, whether purchased or prepared by the laboratory, are sterile, able to support growth appropriately, and are appropriately reactive biochemically. For laboratories preparing their own media, it will be necessary to maintain stock or reference organisms and to test the media at the time of preparation or concurrently with use. Explicit documentation that each lot of purchased medium has been tested for sterility, ability to support growth of appropriate organisms, and biochemical reactivity at the time of preparation or concurrent with use in the laboratory. The recipient laboratory should have a copy of the CLSI Document Number M-22-A, Quality Assurance for Commercially Prepared Microbiological Culture Media. The manufacturer or preparer must document to the user that their quality control activities meet the CLSI guidelines. For each lot the preparer should certify that quality control performance was acceptable and a record of the lot numbers for all media will be retained for at least two years. The user laboratory may record that fact in place of the more detailed documentation of media performance. The user must visually examine each shipment for breakage, contamination, appearance, or evidence of freezing or overheating. The user must also continue to test each lot of chocolate, Thayer-Martin, Campylobacter, and similar media having a relatively high failure rate using quality control methods that are used for media manufactured in-house. In addition, each lot of a commercial identification system must be tested for performance.

Quality control of antimicrobial susceptibility tests is accomplished by monitoring the performance of either disk diffusion tests or micro-dilution systems with appropriate reference control organisms.

b. Bacteriology

Discretion on the part of the inspector is necessary when evaluating a laboratory's protocols for specimen work-up and identification of organisms and test systems. For example, no specific requirements for extent of work-up of specimens such as sputum, urine, stools, and wounds are listed. The laboratory should develop policies that are mutually acceptable to the medical staff and the laboratory. Selection of antibiotics to be tested and reported with each antimicrobial susceptibility test is also a decision requiring input from the pharmacy department and the medical staff.

A variety of blood culture systems is available for use in the laboratory. The inspector should assess the adequacy of the system for detection of microorganisms from the patient population served by the laboratory. The laboratory should also keep blood culture statistics to include number of true positive cultures and number of contaminated cultures. This information can be used to monitor the collection techniques and maintain a low level of contamination of blood cultures.

c. Mycobacteriology and Mycology

The extent of services offered in these two subsections varies widely from one laboratory to another. Policies and procedures should reflect the level of service provided. Safety precautions, especially the requirement for biological safety cabinets, should be evaluated closely by the inspector. All staining procedures must be checked with appropriate controls.

d. Parasitology

Concentration procedures and permanent stained preparations must be performed on all soft and liquid stools submitted for parasitological examination. A direct wet mount may be used if the specimen is submitted fresh. The examination of a formed stool should include a concentration procedure. Laboratories must have an ocular micrometer available for determining the size of eggs, larvae, etc., and the micrometer should be calibrated for the microscope in which it is used.

Nuclear Medicine

The questions have been designed as if the radionuclides were in a dedicated section of the laboratory. In practice, the radionuclide procedures may be found in chemistry, hematology, endocrinology, etc., or in several sections. The questions generally cover

requirements for licensure by the Atomic Energy Control Board. Quality control requirements are similar to those in chemistry with regard to procedure manuals, instrument maintenance, and use of reference materials for standardization and control.

APPENDIX F – TRANSFUSION MEDICINE

a. Component Accession and Disposition Records

The component records must be traceable from inventory to disposition. It must be possible to account for every unit, including quarantine, ultimate disposition, wastage, incineration, and other records. For transfusion services, it must be possible to identify the patient receiving a given unit.

b. Technical Procedures

Blood typings and compatibility procedures should be observed, with comparison to the procedures authorized by the procedure manual of the institution.

c. Transfusion and Apheresis

Patient care activities provided by the laboratory should be observed with particular emphasis on patient identification and blood component administration procedures. Those off-site activities that interface directly with the laboratory, such as blood transfusion and maintenance of remote refrigerators, should be observed as a measure of the effectiveness of laboratory communication. Transfusion reaction records and similar clinical pathology consultation should be reviewed carefully. There must be a procedure to identify and investigate transfusion reactions.

Competency Assessment

Has the competency of each person to perform his/her assigned duties been assessed?

NOTE: The manual that describes training activities and evaluations must be specific for each job description. Those activities requiring judgement or interpretative skills must be included. The records must make it possible for the inspector to determine what skills were assessed and how those skills were measured. The competency of each person to perform the duties assigned must be assessed following training, and periodically thereafter. Some elements of competency assessment include, but are not limited to:

- Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
- Monitoring the recording and reporting of test results;
- Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
- Direct observation of performance of instrument maintenance and function checks;
- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
- Evaluation of problem-solving skills