A Laboratorian’s View on the College of American Pathologists’ Laboratory Accreditation Program for Clinical Laboratories*†

HON FONG L. MARK, Ph.D.‡ and LIONELLE WELLS, M.D.§

‡Lifespan Academic Medical Center Cytogenetics Laboratory, Rhode Island Hospital and Brown University School of Medicine, Providence, RI 02903
and
§Harvard Pilgrim Healthcare of New England, Providence, RI 02906

Introduction

The quality of laboratory testing is a critical component of quality patient care. One way to assure laboratory quality is to utilize an impartial and objective system for the evaluation of clinical laboratories. The need for external and independent review thus provides the prime rationale for the Laboratory Accreditation Program (LAP) of the College of American Pathologists (CAP), which was initiated in 1961 and has since grown in size, complexity and effectiveness.

In the following short review, a general introduction will be given to the CAP’s LAP. The laboratory accreditation process will be illustrated by describing a typical CAP inspection, specifically that of a clinical cytogenetics laboratory.

The Laboratory Accreditation Program of the College of American Pathologists

The CAP is the world’s largest independent accrediting organization for clinical laboratories. Since 1962, the CAP’s LAP has provided external peer review for clinical laboratories. The CAP-LAP currently accredits over 8,000 laboratories worldwide, including many of the largest and most complex in the United States. More than 300 laboratories accredited by the CAP provide clinical cytogenetic services.

The CAP is “deemed” by the Health Care Financing Administration (HCFA) as a certifying agency under the Clinical Laboratory Improvement Amendment of 1988 (CLIA 1988). “Deeming” authority means that CAP accreditation is recognized to meet and/or exceed all CLIA standards and can be used in lieu of a CLIA inspection for laboratory certification. The LAP is also recognized and used for the certification of laboratories by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and many state agencies. A laboratory is accredited by the CAP board based on four standards. The CAP’s booklet, Standards for Laboratory Accreditation defines and explains the principles of the program. A checklist with questions is used to evaluate a laboratory to ascertain compliance with the four standards.

* This article is dedicated to F. William Sunderman Sr., M.D., Ph.D., on the occasion of his 100th birthday, who together with others, was largely responsible for the birth of the Laboratory Accreditation Program of the College of American Pathologists.
† Send reprint requests to: Hon Fong L. Mark, Ph.D., Department of Pathology, Rhode Island Hospital, 593 Eddy Street, Providence, RI 02903.
(table I). The standards and checklist questions are products of committees composed of leading practitioners in each specialty area. The checklists are frequently updated to reflect the latest laboratory practice and to include the standards of laboratory practice required by the CLIA regulations.

The goal of the LAP is quality improvement in the clinical laboratory. Towards this end, the LAP examines all aspects of quality control and quality assurance in the laboratory including test methodologies, reagents, control media, equipment, specimen handling, procedure manuals, test reporting, and internal and external proficiency testing and monitoring as well as personnel safety and overall management practices that distinguish a quality laboratory.4 The emphasis is educational with sufficient detail to exceed CLIA regulatory standards and provide for legal certification through accreditation.

The American College of Medical Genetics and its Partnerships with the CAP

The American College of Medical Genetics (ACMG) is the newest specialty of the American Board of Medical Specialties (ABMS).5 Fellows of the ACMG are diplomates of the American Board of Medical Genetics (ABMG). Like the CAP, the ACMG has promulgated written standards of acceptable performance for cytogenetics testing. The CAP's standards4 are broadly phrased principles for laboratory excellence with performance expectations monitored by checklist questions. The ACMG standards target genetic testing with specific standards and guidelines for cytogenetics laboratories.3 The publication entitled “Standards and Guidelines: Clinical Genetics Laboratories,”6 has been recognized among cytogeneticists as a standard of care.

Recently, the ACMG formed a partnership with the CAP to assure the expertise properly needed to inspect genetic testing laboratories, benefitting both the CAP and the ACMG. A list of individuals certified by the ABMG serves as a pool from which genetics experts are recruited as laboratory inspectors. This timely collaboration between CAP and ACMG has enhanced the quality of cytogenetic specialty laboratories. Similar programs have been implemented by the CAP in other highly specialized areas.

Proficiency Testing

The CAP requires that accredited laboratories participate in the CAP Interlaboratory Comparison (Surveys) Program (i.e., CAP Proficiency Testing). This program, the first of its kind, was started in the 1940s by pathologists to assure laboratory quality. The program started with a distribution of a limited number of specimens to a few selected laboratories. Since then, it has been greatly expanded, refined and continually updated to meet the expanding needs of laboratory medicine.4

The Surveys Program of the CAP is the world's largest program for proficiency testing. More than 20,000 laboratories are currently enrolled in the CAP Surveys Program.4 There are more than 100 different surveys currently available.3 Laboratory surveys for medical genetics include fluorescent in situ hybridization (FISH), molecular genetics, and biochemical genetics. Over 320 laboratories currently subscribe to the ACMG/CAP cytogenetics proficiency testing (PT) survey.3 Participation in an appropriate proficiency testing program is required for accreditation by the CAP when the appropriate survey is available.

The CAP surveys are designed to be educational instruments for laboratory improvement. The first PT challenge offered by the CAP in genetics was Survey CY (Cytogenetics) in 1986.7 The American Society of Human Genetics (ASHG) joined as a co-sponsor in 1991. This co-sponsorship was subsequently transferred to the ACMG in 1994. Survey CY consists of three mailings per year. These challenges are now required in order to maintain a laboratory license under CLIA.

A proficiency testing (PT) challenge is an external audit system that gauges the quality and accuracy of a laboratory's results using samples simultaneously assayed in hundreds of
laboratories. A laboratory must demonstrate its competence under the CLIA regulations by submitting to an external evaluation of its performance relative to the performance of other laboratories that specialize in the same field. For example, in a clinical cytogenetics laboratory, PT may entail culturing a blood sample for banding analysis or making a diagnosis via conventional karyotyping alone. The most effective challenge is a system that endeavors to match an actual clinical scenario with minimal variables and artifacts so that the survey results ensure a reliable evaluation of the laboratory’s performance.

All proficiency testing samples are handled as if they were real clinical specimens. Grading is done by consensus. There must be at least an 80 percent consensus among the participants or referee laboratories before a challenge is considered acceptable for evaluation. Although no minimum score is required in cytogenetics (in contrast to some other laboratory specialties), active review of the survey results is required by accredited laboratories. Accredited laboratories must document corrective actions as well as internal reviews for all performance issues identified through the surveys.

**On-site Laboratory Inspection**

The CAP-LAP is a voluntary program for laboratory improvement. The LAP program is based on peer-review including an on-site inspection and continuous PT. A cytogenetics laboratory may voluntarily elect the CAP to be its certifying agency under CLIA. Many laboratories (of all types) use accreditation by the CAP to meet federal and state regulatory requirements, even though alternatives are available. While CLIA certification is required, a laboratory typically chooses to seek CAP-LAP accreditation to demonstrate its commitment to meet the CAP’s published standards for laboratory practice. Actions by payers or managed care organizations have increased many-fold the value of CAP accreditation for clinical laboratories, as many insurers and Managed Care Organizations (MCO) restrict contracts to laboratories accredited by independent organizations, such as the CAP. The CAP accreditation is recognized as a distinction in the marketplace of laboratory services. The CAP accreditation is awarded only when a laboratory can demonstrate that it meets the standards of CAP. A laboratory inspection is performed every two years by a qualified inspector. Self-inspection using the same checklist is performed during the intervening years. Complaint investigations can occur at any time when there is evidence of non-compliance with the standards in a currently accredited laboratory. As part of the “deemed” status of the program, complaint investigations must comply with applicable CLIA standards for such an investigation.

**The CAP Accreditation Process**

To obtain CAP-LAP accreditation the laboratory must first file an application with the CAP. The application requires several preparatory steps which lead to the initial on-site inspection of the laboratory. First, the laboratory applying for CAP accreditation must pay a fee, which covers the entire process, to the CAP Laboratory Accreditation Department. This fee must be paid to receive an application. The laboratory director then receives an application with copies of the standard checklist(s) for review to ensure that the laboratory becomes capable of fulfilling the requirements for accreditation. The laboratory is allowed up to one year to complete accreditation after application. During this time the laboratory should make any reforms needed to meet CAP standards. During this period of preparation, interpretative literature is provided to the laboratory along with consultation with state and regional commissioners and the central office staff. The application requires data on laboratory ownership, personnel, workload, equipment and PT. Once the application is completed, is returned, and has passed review by the central accreditation office, the laboratory is ready for an on-site evaluation by an inspector. An inspector will be assigned within 3 to 4 months.
A laboratory must renew its accreditation annually. The renewal request is sent by the CAP to the laboratory in advance so that application materials can be processed by the CAP 150 days prior to the accreditation anniversary date. It is the laboratory's responsibility to complete the application for reinspection within 35 days of receipt.

Prior to the initial CAP inspection, the laboratory must participate in, and successfully complete, the appropriate PT challenges. If a PT program is not available from the CAP, the laboratory must develop an alternative program. Accreditation is facilitated when the laboratory has already undergone one or two rounds of PT with corrective actions, before the actual CAP inspection.

Objective Standards for Laboratory Accreditation

Accreditation is the result of the process by which it is determined that a laboratory has successfully met the Standards for Laboratory Accreditation of the CAP-LAP. The Commission on Laboratory Accreditation (CLA) is a group of pathologists appointed by the president of the CAP and approved by their governing board. The LAP is composed of a chair, a vice-chair, and regional commissioners who are responsible for and conduct the business of the program. Each regional commissioner is responsible for a specific geographic area and is assisted by deputy and state commissioners. Other commissioners with specific duties are also available. In addition, the Commission keeps current with continuously evolving technologies by drawing on the expertise of numerous CAP scientific resource committees.

The laboratory inspections are performed by a team of inspectors recruited by a chief inspector. This chief inspector is the team leader and is usually a trained, board-certified pathologist, or, as in the case of a cytogenetics inspection, an ABMG-certified cytogeneticist. The chief inspector is recruited and appointed by state, deputy, and regional commissioners from lists of trained inspectors. Throughout the inspection, the chief inspector is responsible for answering checklist questions, observing the laboratory, and monitoring compliance in accordance with the Standards for Laboratory Accreditation of the CAP. In order to avoid any conflicts of interest, the laboratory inspector should not be a close acquaintance or a business competitor of the laboratory director.

Following the on-site inspection, the CAP technical staff, in conjunction with the appropriate regional commissioner, reviews the inspection reports and the laboratory's plans for corrective actions of identified deficiencies. These must be submitted and implemented within 30 days under CLIA regulations. After corrections are made and documented, the LAP receives a recommendation from the regional commissioner for accreditation. The CLA meets three times each year to develop standards, guidelines, and policies for the LAP and to accredit laboratories. It is through this commission that final decisions are made regarding an award or denial of accreditation of every laboratory. It is also by this commission that all relevant issues are reviewed, and program changes are prepared, debated, and finalized for implementation.

Prior to inspection, the criteria for evaluating a laboratory are made available to each on-site inspector, as well as past laboratory inspection findings. Checklist questions and program standards have evolved through years of study, debate, and rigorous review by the LAP and are the basis for accreditation. These have been approved by the CAP's Board of Governors. The checklists have been developed to facilitate the review of the laboratory's compliance with the standards. In table I is a summary of the currently available checklists according to specific laboratory discipline or management operations.

The Four Standards for Laboratory Accreditation

Standard I pertains to the qualification of the director. Standard II pertains to the physical facilities and safety aspect of the laboratory.
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TABLE I

Available College of American Pathologists' Checklist According to Discipline and/or Important Management Operation*

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<td>Blood gas laboratory</td>
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*Adopted from Laboratory Accreditation Manual, with permission.

Standard III pertains to quality control and performance improvement. Standard IV pertains to inspection requirements.

**STANDARD I: DIRECTOR**

The director is a sole individual responsible for the overall operation and administration of the laboratory. The director ensures the employment of personnel who are competent to perform test procedures, record, and report test results that are proficient and in compliance with applicable regulations. The director must be board-certified or qualified by experience in the appropriate specialty. The director must have sufficient authority to implement and maintain the standards established by the CAP. The CAP lists 15 items under qualifications, responsibilities, and the role of the director. The majority of the items focus on maintaining and improving the quality of patient care services provided by the director's laboratory.

**STANDARD II: PHYSICAL FACILITIES AND SAFETY**

The CAP stipulates that there should be a safe environment for patients and employees with sufficient resources and a positive environment to support the missions of the laboratory. During the on-site inspection, there is a review of the written safety plans, as well as a specific review of measures to guard against electrical, fire, chemical, and other safety hazards. Material safety data sheets (MSDS) must be on file for each hazardous chemical. The location of the MSDS file should be conspicuously posted for employees. Appropriate vaccination plans for employees and records of follow-up actions taken for injuries and accidents are also reviewed. Each laboratory must also have a formal chemical hygiene plan in place and available for review by the CAP.

**STANDARD III: QUALITY CONTROL AND PERFORMANCE IMPROVEMENT**

Assuring quality control, quality assurance, and proficiency testing are important components of accreditation and excellence. Quality control is a systematic surveillance process recording the consistency of performance. Quality assurance includes quality control and is the aggregate of processes and techniques designed to detect, reduce, and correct deficiencies throughout the pre-analytic, analytic, and post-analytic process. Quality assurance documents the actions taken when performance does not conform to standards that have been established by the laboratory.4

Quality improvement (part of quality assurance) is the process of ensuring that all services involved in the delivery of patient care are appropriate, of high quality, and improve overall excellence in medical practice. The Inter-laboratory Comparison Program (CAP Surveys) are proficiency testing programs
designed to promote improvements in patient care through external monitoring of a laboratory's performance.

**STANDARD IV: INSPECTION REQUIREMENTS**

The CAP requires laboratory participation during an on-site inspection by an external team and during interim self-inspection. When deficiencies are noted, the laboratory must take an appropriate corrective action that is documented and subject to review by the CLA. Uncorrected deficiencies at the next on-site inspection are considered recurrent. The laboratory is also expected to participate in the inspection of other laboratories when asked by a commissioner.

**Deficiencies and Responses**

A deficiency is any finding or observation that represents a deviation from the performance standards for the LAP. Deficiencies are classified as Phase 0, Phase I, and Phase II. Inspector recommendations are also reported.

Each question on the inspection checklist is assigned a "phase" category. Phase 0 questions are for information only. Phase I questions represent items that are considered important in the management of an outstanding laboratory service. Phase I deficiencies should be corrected, but the correction need not be immediate for accreditation. Phase II questions represent items that are essential for the proper operation of a laboratory. Phase II deficiencies must be corrected before accreditation can be granted. The recommendations may either represent the opinion of the inspector about issues not covered in the checklists or may include educational suggestions where practices and interpretations differ between laboratories.

Each question has only 3 possible answers "Not Applicable (NA)," "Yes," or "No."* A

* The LAP is in the process of developing graded questions (e.g., full compliance, partial compliance, minimal compliance) in response to the requests from laboratories and other accrediting bodies that make use of the CAP accreditation reports.

“No” response on a Phase I or Phase II question is considered a “Deficiency.” The laboratory must submit deficiency responses to Phase I and Phase II deficiencies and documentation of corrective action for Phase II deficiencies to the central office within 30 days of the inspection date. Any laboratory that does not respond within the 30-day period will receive a certified letter indicating that their accreditation is in immediate jeopardy. While a short additional period of time for response may be granted, continued non-response will result in a recommendation for the denial or revocation of laboratory accreditation. Only the entire Commission or the executive committee may make the decision to deny or revoke the accreditation of a laboratory.

**The On-Site Inspection Process**

The single most important tool used during an on-site inspection is the checklist. A checklist is a detailed series of questions appropriate to each area of the laboratory designed to implement the Standards for Laboratory Accreditation of the CAP. For those laboratories seeking renewal of their accreditation, the results of the previous on-site inspection will be included in the inspection packet provided to the chief inspector. Any recurring deficiencies are noted for careful review. A review of previous deficiencies for adequate resolution also forms a part of the on-site inspection.

The on-site inspection process begins with a meeting between the laboratory director, appropriate laboratory staff, and the inspection team. The CAP Laboratory Accreditation Manual recommends that the Chief Inspector initially meet with the laboratory director to determine whether the director has sufficient responsibility and authority to run the day-to-day operation of the laboratory. Meetings with the hospital administrator and a representative of the medical staff may also be required to evaluate the performance of the laboratory in the institution.
An Example of a CAP Inspection: Cytogenetics

The cytogenetics laboratory inspection is guided by the questions given in the Checklist "Section 9." The cytogenetics checklist includes sections reviewing the extent of services provided, proficiency testing, quality assurance, quality control, specimen handling, procedures and tests, personnel, physical facilities, and laboratory safety.

EXTENT OF SERVICES PROVIDED

This section delineates the scope of testing including the analysis of blood, bone marrow, amniotic fluids, neoplastic and nonneoplastic solid tissues. It also determines whether or not karyotyping is by manual methods using enlarged photographic prints or whether or not karyotyping is automated using digital image processing. Questions concerning special studies, including in situ hybridization, are also asked. This section is used to direct the inspector to appropriate questions on the remainder of the checklist and to document the testing services being accredited.

PROFICIENCY TESTING

This section determines whether or not the laboratory participates in a PT program that is appropriate to the kind of testing that the laboratory performs. It also confirms that there is evidence of active review by the cytogenetics laboratory director and staff of the Surveys results. The CAP checklist questions also probes for evidence of evaluation and prompt corrective action when a result is "unacceptable." The CAP requires that the records of Surveys be maintained for a minimum of two years.

QUALITY ASSURANCE

This set of questions deals primarily with the director's and supervisor's role, responsibility, and authority to monitor the quality of cytogenetic testing and ensures that an appropriate program is implemented throughout the laboratory.

QUALITY CONTROL

This set of questions deals primarily with the director's role in assuring appropriate reviews of quality control activities on a weekly basis. The laboratory procedure manuals are reviewed for compliance with the standard by the National Committee for Clinical Laboratory Standards (NCCLS) for preparing procedure manuals. An annual review of all procedures must be performed by the director or designee.

SPECIMEN HANDLING

This section deals with specimens submitted to the laboratory and specifies what information must be included on requisition slips. The CAP requires that adequate patient sample identification be provided throughout all phases of analysis. Sections on reports, record-keeping, reagents, instruments, equipment, and their maintenance are all included under this heading.

PROCEDURES AND TESTS

Proper procedures and controls are included in the questions on quality control. Specific questions for each procedure, such as the number of cells counted for each tissue, are included. The recommended number of cells to be analyzed is also given, as is the required number of karyotypes and the level of band resolution.

Finally, under this heading, there is a section on FISH and validation of commercial FISH probes. All FISH results must be reported in accordance with the appropriate International System for Human Cytogenetic Nomenclature (ISCN).

Although physical appearance (such as interior decorating and the age of the equipment) greatly influences an inspector's initial impres-
sion, the CAP recognizes that the single most important parameter for a quality laboratory is the composition of its technical staff.

PERSONNEL

Under this section, the CAP reviews the credentials of laboratory personnel. The laboratory must be directed by a person who qualifies as one of the following:

1. A pathologist with at least two years of specialized training and experience in cytogenetic procedures;
2. A physician certified in a specialty other than pathology, with at least two years of specialized training and experience in cytogenetic procedures; and
3. A person with a doctoral degree in a biologic science with at least two years of training and experience in cytogenetic procedures and who must be certified in cytogenetics by the ABMG or equivalent by 9/1/96.

A “No” answer to any one of the previous credentials constitutes a Phase II Deficiency. Furthermore, failure of the director to be specifically certified in cytogenetics by the ABMG or equivalent board constitutes an additional Phase I deficiency.

A checklist determines the qualification of a “technical supervisor” who is responsible for the technical performance of cytogenetic studies. This individual may be the laboratory director. The term “laboratory supervisor” fits the description of a supervisor who should have at least a bachelor’s degree in science and at least two years experience in cytogenetic methods under a qualified director. These terms “technical supervisor” and “laboratory supervisor” are defined by CLIA and are, therefore, used in the checklists.

According to the CAP, persons performing the technical work of cytogenetics must be qualified as one of the following:

1. Persons qualified as director or supervisor;
2. CLSp (CG) certified;
3. Persons with an undergraduate degree in a related scientific field; or
4. High school graduates with hire dates between 4/25/95 and 8/31/97 who have an associated degree or its equivalent by 9/1/97.

The CAP further determines whether or not there is at least one full-time technologist certified in cytogenetics in the laboratory. A defined method to ensure continuing competency of the personnel to perform assigned duties is also required.

PHYSICAL FACILITIES

This section deals with the adequacy of space for administrative, clerical, and technical functions.

LABORATORY SAFETY

The issues surrounding laboratory safety are investigated under the laboratory general checklist.

Upon completion of the inspection, all deficiencies are noted on the summation report. Deficiencies are written on “pink sheets;” other recommendations for laboratory improvement are written on “orange sheets.”

Conclusion

In limited space the complex CAP program has been briefly reviewed. The program is tailored to each specialty laboratory as well as the general clinical laboratory. As noted by Mark et al.9 clinical laboratories, including genetic testing laboratories, are currently caught in the winds of change in healthcare sweeping across the United States. To ensure survival, they will need to adapt quickly. Today’s genetic testing laboratories can no longer afford to ignore inefficiencies. However, efficiencies must not be gained at the expense of quality. With the advent of declining reimbursements and corporate down-sizing, persons may be thrust into administrative roles without specialized knowledge, such as cytogenetics, and replace experts
in pivotal decision-making roles. In some healthcare settings, the qualified experts may no longer be able to exercise control over factors that directly impact the quality of care in their clinical laboratories. Thus, helping to maintain laboratory standards in this environment may become one of the major challenges for the CAP and other major quality-monitoring organizations as we enter the next millennium.

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References