Personnel

From RLM, COM, GEN and TLC Checklists

- The laboratory should have an organizational plan, personnel policies, and job descriptions that define qualifications and duties for all positions.
- Personnel files must contain diplomas or transcripts, references, competency assessments, health records, and continuing education records for each employee.
- Ideally, these files should be located in the laboratory. However, they may be kept in the personnel office or health clinic if the laboratory has ready access to them (i.e. easily available to the inspector).

Inspecting Personnel

- Randomly select files to include several different job descriptions
  - If ≤ 10 employees, must review ALL personnel records
  - If 11-100, must review 8-10 files
- All newly hired personnel for the last two years must be reviewed (if applicable), both laboratory and non-laboratory.
- DO NOT allow laboratory staff to select which personnel records to review. Randomly select specific individuals from the Laboratory Personnel Evaluation Roster

Inspecting Personnel

- For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed and recorded to ensure that their training and qualifications are equivalent to CLIA requirements. The equivalency evaluations should be performed by a nationally recognized organization.

CLIAspeak

- The term "section director" may be considered synonymous to the technical supervisor in the checklist requirements. The term "supervisor" may be considered synonymous to the general supervisor in the checklist requirements.
- Within the laboratory's organizational structure, the actual position titles may be different. A qualified laboratory director may serve as the section director and general supervisor, and may set position requirements more stringent than defined in the checklist.

Andrology

- The section director of the andrology laboratory must have the appropriate training and background to assume responsibility for the overall operation and administration of the laboratory, including hiring competent personnel, formulating laboratory policies and protocols, and communicating regularly regarding patient progress and patient protocols as they affect laboratory aspects of treatment.
- The andrology section director must be accessible to the laboratory for on-site, telephone or electronic consultation as needed.

Andrology

- RLM.08200 Personnel Qualifications Phase II
- The andrology section director and all other personnel in the andrology laboratory meet the requirements described in the Laboratory General Checklist and the Team Leader Assessment of Director and Quality Checklist.

- NOTE: The andrology section director must have two years experience in a laboratory performing andrology procedures. This experience should include quality management, quality control, inspection, accreditation and licensing procedures, as well as andrology procedures.
- Evidence of Compliance:
- ✓ Records of qualifications including degree or transcript, certification, current license (if required) and work history in related field

Section Director (Technical Supervisor)

- **REVISED** 08/17/2016
- GEN.53400 Section Director (Technical Supervisor) Qualifications/Responsibilities Phase II

- Section Directors/Technical Supervisors of high complexity testing meet defined qualifications for the specialties supervised and fulfill the expected responsibilities.
- For high complexity testing, one or more individuals qualified as a technical supervisor must be identified on the CAP's Laboratory Personnel Evaluation Roster form.

Section Director (Technical Supervisor)

- An individual will meet the qualifications of a technical supervisor providing the following qualifications are met:
- ● MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located with at least one year of training and/or experience in high-complexity testing*; or
- ● Doctoral degree in chemical, physical, biological or clinical laboratory science from an accredited institution with at least one year of laboratory training and/or experience in high complexity testing*; or
- ● Master's degree in a chemical, physical, biological, or clinical laboratory science or medical technology from an accredited institution with at least two years of laboratory training and/or experience in high complexity testing*; or
- ● Bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution with at least four years of laboratory training and/or experience in high complexity testing*.

Technical Supervisor (Section Director)

- The section director, as designated by the laboratory director, must be accessible to the laboratory as needed for on-site, telephone, or electronic consultation and is responsible for the technical and scientific oversight of the laboratory. The section director is responsible for performing and recording competency assessment for high complexity testing. The duties for performing the competency assessment may be delegated, in writing, to individuals meeting general supervisor qualifications for high complexity testing.
- Other responsibilities of the technical supervisor include:
  - ● Selection of test methodology
  - ● Establishment or verification of laboratory test performance specifications
  - ● Enrollment and participation in proficiency testing
  - ● Establishment of a quality control program to monitor ongoing test performance
  - ● Resolution of technical problems and ensuring that remedial actions are taken
  - ● Ensuring that patient results are not reported until corrective actions are taken and test systems are functioning properly
  - ● Identification of training needs

Technical Supervisor (Section Director)

- For functions that are delegated, such as review of quality control data, assessment of competency, or review of proficiency testing performance, delegation must be in writing and the technical supervisor is responsible to ensure that those functions are properly carried out by a qualified individual.
  - Evidence of Compliance:
    - ✓ Records of qualifications including degree, transcript, equivalency evaluation, or current license (if required) AND
    - ✓ Certification/registration (if required) and work history in related field AND
    - ✓ Description of current duties and responsibilities AND
    - ✓ Record of delegation of duties

General Supervisor

- **REVISED** 08/17/2016
- GEN.53600 General Supervisor Qualifications/Responsibilities Phase II
- Supervisors/general supervisors meet defined qualifications and fulfill expected responsibilities.
  - NOTE: For high complexity testing, one or more individuals qualified as a general supervisor must be defined on the CAP's Laboratory Personnel Evaluation Roster form.
  - Supervisors who do not qualify as a laboratory director or section director/technical supervisor must qualify as testing personnel and possess the minimum of a:
    - 1. Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology with at least one year of training and/or experience in high complexity testing; or
    - 2. Associate degree in a laboratory science or medical technology with at least two years of training and/or experience in high complexity testing; or
    - 3. Have previously qualified or could have qualified as a general supervisor prior to 2/28/1992

General Supervisor

- The supervisor of high-complexity testing must be accessible to the laboratory as needed for on-site, telephone, or electronic consultation and is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.
- Individuals meeting the qualifications of a general supervisor for high complexity testing may assess the competency of high complexity testing personnel, if this duty is delegated, in writing, by the section director. Other responsibilities of the general supervisor include:
  - ● Resolution of technical problems in accordance with policies and procedures established by the laboratory director or technical supervisor
  - ● Monitoring of test performance
  - ● Ensuring that remedial actions are taken when test systems deviate from the laboratory's established performance specifications
  - ● Providing orientation of testing personnel

- Evidence of Compliance:
  - ✓ Records of qualifications including degree, transcript, equivalency evaluation, or current laboratory personnel license (if required) AND
  - ✓ Certification/registration (if required) and work history in related field AND
  - ✓ Description of current duties and responsibilities

Clinical Consultant

- **REVISED** 08/17/2016
- GEN.53650 Clinical Consultant Qualifications/Responsibilities Phase II
- Clinical consultants meet defined qualifications and fulfill expected responsibilities.
- NOTE: This requirement applies to laboratories performing moderate complexity testing and/or high complexity testing. One or more individuals qualified as a clinical consultant must be identified on the CAP's Laboratory Personnel Evaluation Roster form.
- Clinical consultants must be an MD, DO, DPM licensed to practice medicine in the jurisdiction where the laboratory is located (if required) or doctoral scientist certified by an HHS-approved board.
- The clinical consultant must be available to provide and ensure that consultation is available on test ordering, and interpretation of results relating to specific patient conditions, and for matters relating to the quality of test results reported. The clinical consultant must also ensure that patient reports include pertinent information required for interpretation. See TLC.10440, TLC.10500, and TLC.10700.
- Evidence of Compliance:
- ✓ Records of clinical consultant qualifications (i.e. a valid medical license AND
- ✓ Written job description or contract AND
- ✓ Records of activities performed by the consultant during visits consistent with the job description (e.g. meeting minutes, activity logs, signed summaries or data with evidence of review)

All Personnel

- **REVISED** 08/17/2016
- GEN.54000 Organizational Chart Phase II
- There is an organizational chart for the laboratory, or a narrative description that describes the reporting relationships among the laboratory's owner or management, the laboratory director, section director(s)/technical supervisor(s), technical consultant(s), clinical consultant(s), and supervisor(s)/general supervisor(s), as appropriate.

All Personnel

- **NEW** 08/17/2016
- GEN.54025 Laboratory Personnel Evaluation Roster Phase II
- The Laboratory Personnel Evaluation Roster is current and accurate and is audited by the laboratory director or designee at least annually for nonwaived testing personnel and personnel fulfilling supervisor roles.
- NOTE: The laboratory's audit of the laboratory personnel evaluation roster must include a review of a mixture of the following types of personnel:
  - ● All nonwaived testing personnel hired within the last 12 months (laboratory and nonlaboratory)
  - ● Laboratory and non-laboratory (POC, PPT, Radiology, Respiratory, etc.) personnel
  - ● Full and part-time nonwaived testing personnel on all shifts and throughout all departments
  - ● Personnel fulfilling supervisory roles (e.g. laboratory director, technical supervisor)
  - Personnel performing any CLIA-defined duty must be listed on the roster.
- Personnel performing waived testing only or whose duties are limited to phlebotomy, clerical work or specimen processing are not required to be listed on the Laboratory Personnel Evaluation Roster.

All Personnel

LABORATORY PERSONNEL EVALUATION ROSTER

LABORATORY TESTING PERSONNEL ONLY (NONWAIVED)

Last Name, First Name	Complexity Moderate (M)/ High (H)	Education Verification Source				Began Testing within Last 2 years (X)	FLORIDA LABS ONLY				
		Diploma	Transcript	License*	Primary Source Verification		Shift 1,2 or 3	Hrs Per week	License #	Exp Date	Licensed Specialties
BEHNKE, Erica J PhD	H	X									
CHOHAN, Moveed BS	H	X									
CLICK, Leah BS	H	X									
EKK, Susan BS MT	H	X									
LEFFEL, Rex MS	H	X									
MAYER, Kendall MS	H	X									
PIERCE, Megan BS	H	X									
SMITH, Bonnie BS	H	X									

*License is acceptable for Laboratory Personnel ONLY- based on state requirements

I certify that all individuals listed on this roster qualify to function in the position indicated, according to the personnel requirements set forth by the College of American Pathologists. I also certify that education records (diploma, transcript, license, or credential verification organization documentation) (electronic or hard-copy) will be available for review by the CAP inspection team.

Laboratory Director: Erica J Behnke, PhD, HCLD(ABB) Signature: Erica J Behnke, PhD, HCLD(ABB) Date: 2/8/2017

Print Director name listed on CLIA/CLIP certificate

CAP#:

All Personnel

- GEN.54200 Continuing Education Phase I
- There is a functional continuing laboratory education program adequate to meet the needs of all personnel.
- Evidence of Compliance:
- ✓ Written policy for continuing laboratory education

All Personnel

- **REVISED** 08/17/2016
- GEN.54400 Personnel Records Phase II
- Personnel files are maintained on all current technical personnel and personnel records include all of the following, as applicable:
- 1. For nonwaived testing personnel, copy of academic diploma , transcript, or primary source verification (PSV) reports confirming credentials
  - The file must include records demonstrating that each individual meets the required educational qualifications for the position(s) held, such as a copy of the academic diploma, transcript, or primary source verification (PSV) report.
  - If PSV reports are used, the laboratory must have a defined system for reviewing the reports, with written criteria for acceptance. PSV is typically performed by a third-party agent or company that directly contacts institutions and former employers to verify training and experience, such as diplomas, board certification, licensure, and reported work history. PSV reports confirming the required qualifications may be retained in lieu of obtaining paper copies of these records. If there are required elements for the qualifications that the PSV report does not adequately verify (e.g. transcripts, educational equivalency for personnel trained outside of the US, or reports lacking the type of degree earned), there must be records showing that qualifications are met using other means.

All Personnel

- If the laboratory is located in a state that requires laboratory personnel licensure, the license may be used instead of the diploma or transcript to show that educational qualifications were met. Licensure records for any other discipline cannot be used to meet educational qualifications for non-waived laboratory testing. These individuals must have all required educational and training records in their files.
- ● While certification of technical personnel by a professional organization, such as ASCP or AMT, is highly desirable, records of the certification alone are not considered adequate to demonstrate that educational qualifications have been met.
- ● The training and qualifications of all personnel trained outside of the US must be evaluated to determine equivalency of their education to an education obtained in the United States, with records of the evaluation available in the personnel file. The equivalency evaluations should be performed by a nationally recognized organization.
- Evidence of Compliance:
  - ✓ Copies of diplomas, transcripts, equivalency evaluation, or current laboratory personnel licensure (if required) accessible at the laboratory OR
  - ✓ Policy for use of primary source verification reports, with criteria for acceptance, if used AND
  - ✓ Primary source verification reports with required elements

All Personnel

- 2. Laboratory personnel license, if required by state, province, or country
- 3. Summary of training and experience
- 4. Certification, if required by state or employer
- 5. Description of current duties and responsibilities as specified by the laboratory director: a) Procedures the individual is authorized to perform, b) Whether supervision is required for specimen processing, test performance or result reporting, c) Whether supervisory or section director review is required to report patient test results
- 6. Records of continuing education
- 7. Records of radiation exposure where applicable (such as with in vivo radiation testing), but not required for low exposure levels such as certain in-vitro testing
- 8. Work-related incident and/or accident records
- 9. Dates of employment

- All records, in either electronic or paper form, must be readily available for review by the inspector at the time of the CAP inspection.

Testing Personnel

- **REVISED** 08/17/2016
- GEN.54750 Testing Personnel Qualifications Phase II
- All testing personnel meet the following requirements.
- 1. Personnel performing high complexity testing must have a minimum of one of the following:
  - ● Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; or
  - ● Associate degree in a laboratory science (chemical or biological science) or medical laboratory technology from an accredited institution, or equivalent laboratory training and experience meeting the requirements defined in the CLIA regulation 42CFR493.1489.

- For high complexity testing, equivalent laboratory training and experience includes the following:
- ● 60 semester hours or equivalent from an accredited institution that, at a minimum, includes either 24 semester hours of medical laboratory technology courses, OR 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology, and 12 semester hours of chemistry, biology or medical laboratory technology in any combination; AND
- ● Laboratory training including either completion of a clinical laboratory training program approved or accredited by the ABHES, NAACLS, or other organization approved by HHS (note that this training may be included in the 60 semester hours listed above),
- OR at least three months documented laboratory training in each specialty in which the individual performs high complexity testing.

Testing Personnel

- 2. Personnel performing moderate complexity testing, including non-laboratory personnel, must have a minimum of one of the following:
- ● Associate degree in a chemical, physical, or biological science or medical laboratory technology from an accredited institution; or
- ● High school graduate or equivalent and have successfully completed an official military medical laboratory procedures course and have held the military enlisted occupational specialty of Medical Laboratory Specialist; or
- ● High school diploma or equivalent and have a record of training defined in the CLIA regulation 42CFR493.1423

- For moderate complexity testing personnel qualifying with a high school diploma or equivalent qualifications only, training records must demonstrate skills for the following:
  - ● Specimen collection, including patient preparation, labeling, handling, preservation, processing, transportation, and storage of specimens, as applicable;
  - ● Implementation of all laboratory procedures;
  - ● Performance of each test method and for proper instrument use;
  - ● Preventive maintenance, troubleshooting and calibration procedures for each test performed;
  - ● Working knowledge of reagent stability and storage;
  - ● Implementation of quality control policies and procedures;
  - ● An awareness of interferences and other factors that influence test results; and
  - ● Assessment and verification of the validity of patient test results, including the performance of quality control prior to reporting patient results.

Testing Personnel

- Students gaining experience in the field must work under the direct supervision of a qualified individual.
- If more stringent state or local regulations are in place for personnel qualifications, including requirements for state licensure, they must be followed.

- Evidence of Compliance:
  - ✓ Records of qualifications including diploma, transcript, equivalency evaluation, or current laboratory personnel license (if required) AND
  - ✓ Work history in related field

All Personnel

- GEN.55400 Visual Color Discrimination Phase I
- Personnel are tested for visual color discrimination.
  - NOTE: Personnel performing testing or other tasks that require color discrimination should be evaluated for difficulty with visual color discrimination. Evaluation is not required for personnel who do not perform such functions. Evaluation limited to discrimination of those colored items pertinent to the job is sufficient.
  - Evidence of Compliance:
    - ✓ Record of color discrimination testing OR functional assessment, if indicated

All Personnel

- **REVISED** 08/17/2016
- GEN.55450 Initial Training Phase II
- There are records that all laboratory personnel have satisfactorily completed initial training on all instruments/methods applicable to their designated job.
- NOTE: The records must cover all testing performed by each individual. Training records must be maintained for a minimum of two years (five years for transfusion medicine). After the initial two year (or five-year) period, records of successful ongoing competency assessment may be used to demonstrate compliance with this requirement.
- Retraining must occur when problems are identified with personnel performance.

All Personnel

- **REVISED** 08/17/2016
- GEN.55500 Competency Assessment of Testing Personnel Phase II
- The competency of each person performing patient testing to perform his/her assigned duties is assessed.
- Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance as required in GEN.55450. Retraining and reassessment of employee competency must occur when problems are identified with employee performance.
- During the first year of an individual's duties, competency must be assessed at least semiannually
  - ● After an individual has performed his/her duties for one year, competency must be assessed at least annually
  - ● Competency assessment must include all six elements described below for each individual on each test system during each assessment period, unless an element is not applicable to the test system

Competency Assessment

- Elements of competency assessment include but are not limited to:
  - 1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
  - 2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
  - 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
  - 4. Direct observation of performance of instrument maintenance and function checks
  - 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
  - 6. Evaluation of problem-solving skills

Competency Assessment

- Many of the elements of competency assessment are performed during routine review of an employee throughout the year. Records of these elements, including adherence to laboratory policies and procedures, observation of test performance, results reporting, instrument maintenance, review of worksheets, recording QC, performance of PT, and demonstration of taking appropriate corrective actions are examples of daily activities that can be used to demonstrate competency.
- If elements of competency are assessed by routine review, the competency procedure must outline how this routine review is used to evaluate competency.
- Competency assessment during routine review may be recorded using a checklist.

Competency Assessment

- The laboratory director must ensure that the individuals performing competency assessments are qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing.
  - ● Testing personnel performing high complexity testing must be assessed by the section director, or individual meeting general supervisor requirements if delegated in writing by the section director.
  - ● Testing personnel performing moderate complexity testing must be assessed by an individual meeting the qualifications of a technical consultant.
- Evidence of Compliance:
  - ✓ Records of competency assessment for new and existing testing personnel reflecting the specific skills assessed, the method of evaluation AND
  - ✓ Written procedure defining the method and frequency for assessing competency

Competency Assessment

- **REVISED** 07/28/2015
- GEN.55525 Performance Assessment of Supervisors/Consultants Phase II
- The performance of section directors/technical supervisors, general supervisors, and technical consultants is assessed and satisfactory.
- NOTE: All responsibilities of section directors (as technical supervisors in laboratories performing high complexity testing) and technical consultants (in laboratories performing moderate complexity testing, but not high complexity testing) must be delegated by the laboratory director in writing. Unsatisfactory performance must be addressed in a corrective action plan.
- The assessment may take the form of a checklist or other written record of performance of responsibilities, as defined by the individual's job description. If assessment of these individuals is not performed or there are inadequate or inconsistent records, a deficiency should also be cited for TLC.11425 (Director Responsibility - Delegation of Functions) in the Team Leader Assessment of Director and Quality Checklist.
- If the individuals in these roles are also performing nonwaived patient testing, competency assessment requirements for testing personnel (GEN.55500) also apply, including all six elements of competency.
- Evidence of Compliance:
  - ✓ Job descriptions that list regulatory responsibilities AND
  - ✓ Records of performance assessment

Competency Assessment

- GEN.57000 Competency Corrective Action Phase II
- If testing personnel fail to demonstrate satisfactory performance on the competency assessment, the laboratory follows a plan of corrective action to retrain and reassess competency.
- NOTE: If it is determined that there are gaps in the individual's knowledge, the employee should be re-educated and allowed to retake the portions of the assessment that fell below the laboratory's guidelines. If, after re-education and training, the employee is unable to satisfactorily pass the assessment, then further action should be taken which may include, supervisory review of work, reassignment of duties, or other actions deemed appropriate by the laboratory director.

- Evidence of Compliance:
  - ✓ Records of corrective action to include evidence of retraining and reassessment of competency
  - ✓ Written procedure for competency assessment corrective action

Team Leader Assessment of Director & Quality Checklist

- This checklist will help you evaluate the qualifications of the laboratory director and the effectiveness of the director in implementing the Standards of the Laboratory Accreditation Program, including the laboratory's quality management plan.
- This checklist must be completed by the team leader or a team member who is qualified and trained to be a team leader. It is important to cite IN THIS CHECKLIST, any systemic issues identified, and to elaborate on these findings in the Inspector's Summary Report, Part A (ISR-A).

Team Leader Checklist

- The following activities provide the information needed to complete the requirements in this checklist:
  - 1. Interview the laboratory director.
  - 2. Interview laboratory supervisory personnel and other laboratory personnel as appropriate.
  - 3. Observe the operation of the laboratory during your time on-site.
  - 4. Review the laboratory organizational chart, quality management plan and records, committee minutes, and other relevant documents for appropriate director involvement.
  - 5. Interview the hospital administrator. If the laboratory is an independent organization, interview an executive from the organization.
  - 6. Interview the chief of the medical staff (for laboratories associated with a medical staff).
  - 7. Discussion with members of the inspection team to assess the extent of deficiencies. Deficiencies that directly affect patient safety, or are pervasive in the laboratory, may warrant a deficiency in the Director Oversight Responsibilities section of this checklist.
- Interviews with the laboratory director, hospital or organization administrator, and representative of the medical staff are essential parts of the inspection. If for any reason one of these interviews was not performed, discuss the circumstances in the Inspector's Summation Report.

Team Leader Checklist

- Meeting with the Laboratory Director
- Purpose: To help determine if the laboratory director has sufficient responsibility and authority for operation of the laboratory. Allow a minimum of 15-20 minutes for the meeting.
- The interview is an opportunity to:
  - ● Evaluate the director's activities as listed in the Standards for Laboratory Accreditation
  - ● Review any problems that the inspection experience might serve to resolve (e.g. space problems, staffing shortages)
  - ● Determine whether the laboratory director also functions as a technical supervisor, clinical consultant, general supervisor, or as a testing personnel. If so, review the Personnel section of the Laboratory General Checklist for qualifications and responsibilities.

Team Leader Checklist

- Meeting with the Organization/Hospital Administrator/Chief Executive Officer (CEO)
- For hospital-based laboratories, the inspector should meet with the hospital administrator/CEO. Allow at least 15-20 minutes for the meeting. Avoid scheduling the meeting early in the inspection to have a sense of the laboratory's operations first. For independent laboratories, meet with an executive from the laboratory organization.
- Purpose: To extend the College's appreciation for participating in the accreditation program, to record an evaluation of the laboratory from the administration's viewpoint, and help assess the director's involvement in the administration of the laboratory.

Team Leader Checklist

- The interview is an opportunity to:
  - ● Ascertain the administration's perception of the laboratory service
  - ● Discuss administration's view of the laboratory director's role in ensuring high quality laboratory services to fulfill the needs of the institution's patients and clinicians
  - ● Determine if the institution gives the director the authority to fulfill the director's responsibilities under CAP
  - ● Address the effectiveness of the working relationship among the laboratory, its director and administration
  - ● Identify any areas of conflict
- Discuss all laboratories being inspected. Do not discuss any financial and/or contractual arrangements.
- When speaking with the hospital administrator, ask if the laboratory service level is appropriate to the needs of the institution. Ask about participation in hospital-wide committees, how effective the director is in working with the medical and administrative staffs, and whether they meet the expectations of the administration.
- Record key findings from this interview in Part A of the Inspector's Summation Report.

Team Leader Checklist

- Meeting with a Representative of the Medical Staff
- For laboratories associated with organized medical staffs, it is important for the team leader to interview the chief of the medical staff (or other knowledgeable medical staff representative, such as the chief medical officer, or a physician who uses the laboratory's services frequently).
- Ask questions about the scope, quality and timeliness of laboratory services. The team leader should ask the medical staff representative for input participation in committees, participation in institutional quality management (performance improvement) and patient safety activities, and participation in teaching conferences.
- The inspector may record information from this interview in Part A of the Inspector's Summation Report.

Team Leader Checklist

- **REVISED** 08/17/2016
- TLC.10100 Laboratory Director Qualifications Phase II
- The laboratory director satisfies the personnel requirements of the College of American Pathologists.
  - a. MD, DO, or DPM licensed to practice (if required) in the jurisdiction where the laboratory is located, and have one of the following:
    - i. Certification in anatomic or clinical pathology, or both, by the American Board of Pathology or American Osteopathic Board of Pathology, or possess qualifications equivalent to those required for certification; or
    - ii. Have at least one year of laboratory training during residency/fellowship;
    - or
    - iii. Have at least two years of experience supervising high complexity testing;
  - OR
  - b. Doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution, and have current certification by a board approved by HHS**

Team Leader Checklist

- TLC.10200 Section Director Qualifications Phase II
- If the laboratory director is not qualified to direct any of the individual sections of the laboratory, the laboratory retains the services of individuals qualified to direct those sections.
  - Evidence of Compliance:
    - ✓ Records of section director qualifications (e.g. current CV, degree, license, board certification, training and experience) appropriate for the specialty

Team Leader Checklist

- TLC.10430 Director Responsibility/Authority Phase II
- The laboratory director has sufficient responsibility and authority to implement and maintain the standards of the College of American Pathologists.
- NOTE: Examples of how the team leader may obtain information on the laboratory director's responsibility and authority include: interviews with the laboratory director, institution's administration, medical staff, laboratory management and laboratory supervisory staff; review of the laboratory organizational chart; and review of minutes of quality management and other laboratory meetings.

Team Leader Checklist

- **REVISED** 07/28/2015
- TLC.10440 Effective QM Phase II
- The laboratory director ensures an effective quality management program for the laboratory.
  - NOTE: The laboratory director must be involved in the design, implementation and oversight of the laboratory's quality management program. This includes all aspects of test performance, including the preanalytic, analytic, and postanalytic phases of testing.
  - Evidence of Compliance:
    - ✓ Written QM plan covering all areas of the laboratory AND
    - ✓ Records of laboratory director approval of the QM plan and the selection of quality indicators
    - AND
    - ✓ Records (e.g. reports, QM meeting minutes) of laboratory director review of quality indicators, annual assessment of QM plan, complaints, and incidents with development and implementation of plans of corrective action

Team Leader Checklist

- TLC.10460 Director Responsibility - PT/QC Phase II
- The laboratory director ensures proficiency testing, alternative assessment, and QC procedures are sufficient for the extent of testing performed in the laboratory.
- Evidence of Compliance:
  - ✓ Records of PT and alternative assessment data attesting to completeness AND
  - ✓ Records of investigation and corrective action, as applicable AND
  - ✓ Written QC procedures for all areas of the laboratory AND
  - ✓ Records of laboratory director or designee review of QC and corrective actions

Team Leader Checklist

- **NEW** 07/28/2015
- TLC.10475 Director Responsibility - New Method Validation/Verification Phase II
- The laboratory director ensures that the performance specifications for new tests, instruments, and methods introduced to the laboratory have been properly validated or verified prior to being used for patient testing.
  - NOTE: Specific requirements are in the All Common Checklist (Instruments & Equipment, Test Method Validation/Verification, and Method Performance Specifications sections) and in other checklists.
  - Evidence of Compliance:
    - ✓ Written procedures for validation/verification studies AND
    - ✓ Records of new method validation/verification approval and supporting data

Team Leader Checklist

- TLC.10500 Director Responsibility - Communication Phase II
- The laboratory director ensures communication of laboratory data and appropriate patient result reporting.
  - Evidence of Compliance:
    - ✓ Records of oversight of computer services and changes AND
    - ✓ Evidence that test reports have been reviewed within the medical record OR
    - ✓ Lab communications, newsletters, etc.

Team Leader Checklist

- **REVISED** 07/28/2015
- TLC.10700 Director Responsibility - Consultations Phase II
- The laboratory director provides for intralaboratory consultations and clinical consultations regarding the ordering of appropriate tests and the medical significance of laboratory data.
  - NOTE: Only physicians or doctoral scientists may provide clinical consultations.
  - The laboratory director must be accessible to the laboratory for on-site, telephone, or electronic consultations, as needed, or ensure that a qualified designee is available in the director's absence.
  - Evidence of Compliance:
    - ✓ Laboratory director's authorization for activities of consultant(s) AND
    - ✓ Listing of laboratory contacts/consultant(s) available to the clinical services AND
    - ✓ Records of laboratory director's involvement in resolution of problems relating to inappropriate test ordering practice AND
    - ✓ Records of discussions between consultants and clinical services

Team Leader Checklist

- TLC.11200 Director Responsibility - Education/R&D Phase II
- The laboratory director ensures provision of educational programs, strategic planning, and research and development appropriate to the needs of the laboratory and institution.
- Evidence of Compliance:
  - ✓ Schedule or description of available educational activities AND
  - ✓ Records or minutes from strategic planning sessions demonstrating participation and role of laboratory director AND
  - ✓ Policy for assessing clinical needs, implementing and evaluating solutions

Team Leader Checklist

- **REVISED** 07/28/2015
- TLC.11300 Director Responsibility - Personnel Phase II
- The laboratory director ensures sufficient numbers of personnel with appropriate educational qualifications, documented training and experience, and adequate competency to meet the needs of the laboratory.
  - NOTE: For laboratories subject to US regulations, all personnel must meet the personnel requirements of CLIA or other US equivalent regulations (e.g. Clinical Laboratory Improvement Program Procedures for Department of Defense laboratories, Veterans Health Administration Handbook). For laboratories not subject to US regulations, all personnel requirements must be defined and met.
  - Staffing should be considered insufficient if there is clear evidence from quality monitoring records, data derived from complaints or concerns, turnaround time, and error statistics, etc.
  - Evidence of Compliance:
    - ✓ Records indicating personnel meet requirements for the level of testing (complexity) performed AND
    - ✓ Records of employee training, competency assessment, and continuing education in personnel files

Team Leader Checklist

- TLC.11400 Director Responsibility - Safe Environment Phase II
- The laboratory director ensures implementation of a safe laboratory environment in compliance with good practice and applicable regulations.
  - NOTE: The laboratory director must ensure compliance with OSHA and national, state, and local regulations, as well as other applicable safety regulations. Details may be found in the Safety and Transport Services sections of the Laboratory General checklist.
  - Evidence of Compliance:
    - ✓ Records of review of safety procedures AND
    - ✓ Records of safety audits with corrective action taken to correct violations, as applicable AND
    - ✓ Safety meeting minutes AND
    - ✓ Chemical hygiene plan up-to-date with annual evaluation for effectiveness

Team Leader Checklist

- **REVISED** 07/28/2015
- TLC.11425 Director Responsibility - Delegation of Functions
  Phase II
- Delegation of the laboratory director's functions or responsibilities is in writing.
  - NOTE:
  - 1. Functions that may be delegated include review of QC data, proficiency testing performance, and test methodology performance studies. The laboratory director remains responsible [A] that all persons performing delegated functions are qualified to do so; and [B] that the delegated functions are properly carried out.
  - 2. Functions that may not be delegated include provision of appropriately trained supervisory and technical staff and the identification of their responsibilities. The laboratory director must document personal, on-site assessment of physical and environmental conditions and the adequacy of staffing.

Team Leader Checklist

- 3. The responsibilities and duties of supervisors, consultants, and testing personnel involved in preanalytic, analytic, and postanalytic phases of testing must be defined in writing, with records of authorization to perform testing, and the level of supervision required, as applicable.
- 4. If a delegated duty is not being properly performed by the designee, with no evidence of corrective action, the team leader should cite this requirement as a deficiency, in addition to the specific checklist requirement(s) that relates to the duty not being performed (e.g. monthly QC review, approval of method validation/verification studies).
- Evidence of Compliance:
  - ✓ Policy or statement signed by the laboratory director authorizing individuals by name or job title to perform tasks on behalf of the laboratory director AND
  - ✓ Records showing that delegated tasks are performed by designee, as required

Team Leader Checklist

- TLC.11450 Director Responsibility - Interaction with Government or Regulatory Interaction Phase II
- The laboratory director or designee interacts with government and other agencies as appropriate.
  - NOTE: The laboratory director or designee must interact with agencies such as national, state and local health departments, as appropriate, for laboratory-related matters.
  - Evidence of Compliance:
    - ✓ Records of any required reports of infectious diseases to the federal, state or local health department AND
    - ✓ Response to any inquiry by government and other agencies, as appropriate AND
    - ✓ Reports to OSHA, FDA or other agency, as required

Team Leader Checklist

- TLC.11475 Director Responsibility - Equipment/Services Phase I
- The laboratory director or designee is directly involved in the selection of all laboratory equipment, supplies, and services with respect to quality.
  - NOTE: The intent is to ensure that the laboratory director has appropriate control over the process. The fact that economic issues are a major factor in these selections does not relieve the laboratory director of responsibility for ensuring the quality of the technical, clinical and operational aspects of the laboratory. The director must ensure that reagents, fluids, parts, materials, and other items supplied by the laboratory meet the requirements for use with instruments and equipment.
  - Evidence of Compliance:
    - ✓ Meeting minutes indicating the laboratory director's presence when purchases are discussed OR
    - ✓ Written approval from the laboratory director to purchase equipment

Team Leader Checklist

- TLC.11485 New Director Procedure Approval Phase II
- Following a change in laboratory directorship, the new laboratory director approves the laboratory policies and procedures over a reasonable period of time.
  - NOTE:
  - 1. The approval of the policies and procedures must be recorded.
  - 2. The format of such documentation is at the discretion of the laboratory director. It must include an itemization of the documents reviewed and approved, signatures and dates, and demonstrate that all procedure manuals have been approved.
  - 3. The approval should be completed within three months of the change of directorship for most laboratories.
  - 4. Different requirements for approval of new and substantially changed policies and procedures and for routine reviews (at least every 2 years) appear in the All Common Checklist.

Team Leader Checklist - Off-Site Director

- NOTE TO THE TEAM LEADER: The following two requirements apply to laboratory directors who are not present full-time at the laboratory.
- Off-site laboratory directors must ensure that all laboratory director responsibilities defined in the other sections of the checklist are carried out as required.
- Refer to TLC.11425 for information on delegation of duties and duties that may not be delegated.
  - "Functions that may not be delegated include provision of appropriately trained supervisory and technical staff and the identification of their responsibilities. The laboratory director must document personal, on-site assessment of physical and environmental conditions and the adequacy of staffing."

Team Leader Checklist - Off-Site Director

- **REVISED** 07/28/2015
- TLC.11600 Director Off-Site Phase II
- There is a written agreement or policy defining the frequency of, and responsibilities for activities to be performed by the laboratory director during on-site visits and remotely, with records of the director's activities.
  - NOTE: If activities are conducted remotely, the policy or agreement must define the communication mechanisms that will be used and how records of the communications will be maintained.
  - Evidence of Compliance:
    - ✓ Records for frequency of on-site visits AND
    - ✓ Meeting minutes showing director participation AND
    - ✓ Laboratory director review of quality management records AND
    - ✓ Records of electronic review or consultation

Team Leader Checklist - Off-Site Director

- **REVISED** 07/28/2015
- TLC.11800 Director Visits and Remote Consultation Phase II
- The involvement of the laboratory director, including activities conducted during on-site visits and remote consultation, follows the written policy or agreement and is considered adequate by the laboratory and medical staff and the inspection team.
- NOTE: The requirement is not met if the hospital administrator, the chief of staff, laboratory supervisors, or most technical staff desire greater personal involvement on the part of the laboratory director. If activities are conducted remotely, the laboratory director must ensure that there is an effective communication mechanism in place between the laboratory director and laboratory management and staff.
- The requirement is also not met if the laboratory director is not performing duties as defined in the policy or agreement or if the inspector identifies that the visits and remote involvement are not sufficient to carry out the laboratory director responsibilities or provide sufficient oversight of the laboratory. Such situations may include, but are not limited to, serious quality or safety issues that are not addressed in a timely manner, duties delegated by the laboratory director to other staff that are not being carried out in an effective manner, and improper implementation of new laboratory practices.

Embryology

- The section director of the embryology laboratory must have at least two years of experience in a laboratory performing in vitro fertilization or assisted reproductive technologies related procedures. Section directors of embryology laboratories who are not physicians or qualified doctoral scientists, but who were functioning as embryology directors on or before July 20, 1999 are considered in compliance with the personnel requirements in the Laboratory General Checklist, as long as they meet all other requirements.
- Effective January 1, 2006, all new laboratory directors must hold HCLD (High Complexity Laboratory Director), ABB-ELD (American Board of Bioanalysis Embryology Laboratory Director), or equivalent certification. If the laboratory is also performing testing for the purpose of diagnosis (e.g. semen analysis, hormone assays), the laboratory director must meet the personnel requirements defined in the Team Leader Assessment of Director and Quality Checklist.

Embryology

- RLM.10166 Embryology Section Director Qualifications Phase II
- The section director of the embryology laboratory has proper qualifications through education and experience to provide direction and administration of the laboratory.
  - Evidence of Compliance:
    - ✓ Records of qualifications including degree or transcript, certification, current license (if required) and work history in related field, as applicable

Embryology

- RLM.10250 Assisted Reproductive Technology (ART) - Personnel Qualifications Phase II
- Embryology laboratory personnel performing assisted reproductive technology (ART) procedures must have appropriate education and records of training.
  - NOTE: Embryology laboratory personnel must have records of training for each of the ART laboratory procedures performed. An embryologist must have a minimum of a bachelor's degree in a chemical, physical, biological, medical technology, clinical or reproductive laboratory science from an accredited institution.
  - Embryologists performing ART laboratory procedures prior to January 1, 2012, are considered in compliance with this requirement, as long as there is recorded training for the ART laboratory procedures performed and the embryologist meets the laboratory's defined personnel qualifications.
  - If embryology personnel are also performing testing for the purpose of diagnosis (e.g. diagnostic semen analysis, hormone analysis), the embryologist must also qualify under the testing personnel requirements defined in the Laboratory General Checklist.
  - Evidence of Compliance:
    - ✓ Records of qualifications including degree or transcript, current license (if required) and work history in related field, as applicable

Embryology

- RLM.10253 Embryology Training/Evaluation Phase II
- There is a written program to train and evaluate personnel in their competency to perform embryology, including micromanipulation and other assisted reproductive technology techniques.
- NOTE: For laboratories performing embryology, there must be a training program for new personnel, using animal model systems or nonviable human oocytes.
  - Evidence of Compliance:
    - ✓ Records of training and competency

Embryology

- RLM.10255 Off-Site Embryology Section Director Visits Phase II
- For laboratories that do not have an on-site embryology section director, there must be records of visits from the embryology section director at a minimum of once per quarter.
- NOTE: If the laboratory performs andrology testing, state and federal requirements for director visits must be followed, which may be more stringent.

Embryology

- RLM.10260 Oversight Responsibility Phase II
- For laboratories that do not have an on-site, full time embryology section director, or the medical director is also the embryology section director, there is a designated on-site individual qualified as an embryology supervisor, to provide oversight of daily activities and assist with troubleshooting or other unusual situations.
  - NOTE: The intent is to ensure that the laboratory continues to function properly in the embryology section director's absence and to ensure that resources are available to quickly assist with unusual problems to minimize any adverse impact on patient care.

Embryology

- RLM.10265 Embryology Supervisor Phase II
- Embryology supervisors must have at least one year of supervisory experience in all aspects of embryology performed by the laboratory or a minimum of 60 cycles over a period of not less than six months.
- NOTE: Technical supervisor certification is highly recommended.
- If the laboratory performs andrology testing, personnel requirements defined in the Laboratory General Checklist must be followed.

Embryology

- RLM.10832 Back-up Personnel Phase II
- The laboratory has a policy to provide back-up laboratory personnel as needed, to ensure timely embryology services.
  - NOTE: Staffing levels must be appropriate for the size and volume of the program.
  - If routine staffing of the laboratory does not provide sufficient back up for laboratory personnel, the laboratory must have a policy describing how patient care needs will be met for its laboratory services in the event of a staffing shortage or emergency.
  - The laboratory director is responsible to ensure that the qualifications of each individual are adequate for the duties to be performed.

Personnel and TLC

- If at any time the discussion becomes heated or uncomfortable, take a break and call CAP to discuss the situation.
- There should be no discussion of monetary matters – personnel salaries, contract agreements, etc. during any portion of the inspection. The laboratory director may black-out that information if it appears in documents prior to your review.

Summation Conference?

- Citations in this checklist are optional for discussion at the summation conference to which laboratory staff, hospital administration, and others may be invited. The team leader may instead choose to discuss them with the laboratory director in a private summation meeting.