LABORATORY DIRECTOR DELEGATION POLICY

I. Purpose

Regulatory and accreditation standards allow the Laboratory Director to delegate his or her responsibilities, provided 1) the responsibilities can be delegated, and 2) the delegation is in writing. Medical and technical responsibilities may be delegated to physicians, doctoral scientists, and qualified laboratory personnel as appropriate. Administrative functions may be delegated to qualified laboratory managers and supervisors that meet the qualifications for and function as general supervisors. The Laboratory Director, however, remains responsible for the overall operation and administration of the laboratory to assure that quality patient services are provided.

II. Policy

In compliance with the Final CLIA ’88 Rule 42 CFR Part 493 Subpart M (§493.1443) published in the Federal Register on 24 January 2003 and the College of American Pathologists (CAP) Standards for Laboratory Accreditation: Standard I, the Director of the LSUHSC-S Anatomic and Clinical Laboratories meets the defined qualifications for Laboratory Director and Clinical Consultant. As such, the Laboratory Director maintains the responsibilities listed in Section A and delegates responsibilities as listed in Sections B and C to Technical and General Supervisors.

A. Director’s Responsibilities (not delegated)

1. Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed providing a safe environment in which employees are protected from physical, chemical, and biological hazards.

2. Ensure that the laboratory employs technical supervisors (section directors), who meet the qualification requirements for CLIA, for each of the specialties/subspecialties of service in which high complexity testing is performed and that they provide technical supervision in accordance with regulatory agencies. Responsibilities are outlined in Civil Service job descriptions.

3. Ensure that a general supervisor (section manager) provides on-site supervision of test performance by qualified testing personnel.

4. Specify in writing the responsibilities and duties of each person involved in all phases of the testing process (see Civil Service job descriptions).

5. Reviews and approves all new policies and procedures, as well as substantial changes to existing documents, before implementation.

B. Clinical Consultant Responsibilities (delegated by Laboratory Director)

The Clinical Consultant must be qualified to consult with and render opinions to the laboratory’s clients concerning the diagnosis, treatment and management of patient care. The Clinical Consultant provides consultation regarding the appropriateness of testing ordered and interpretation of test results. At LSUHSC, the Clinical Consultant role is performed by the Clinical Laboratory Medical Director and staff pathologists.

1. Ensure that reports of test results include pertinent information required for specific patient interpretation.

2. Ensure that consultation is available and communicated to the laboratory’s clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

C. Technical Supervisor Responsibilities (delegated by Laboratory Director)

Technical Supervisors are responsible for technical and scientific oversight of the laboratory. At LSUHSC, Technical Supervisor role is performed by the Medical Director of Clinical Pathology or by the section Directors (M.D, Ph.D.).

1. Select and/or develop test methodologies appropriate for the clinical use of the tests and have the capability of providing the quality of results required for patient care.
2. Ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

3. Ensure personnel are performing the test methods as required for accurate and reliable results.

4. Ensure adequate enrollment in approved Proficiency Testing activities as required by the regulations and the accrediting organizations.

5. Ensure that PT samples are tested as required by accrediting agencies and that results and returns within the timeframes established by the PT program.

6. Ensure that all PT reports received are reviewed by the appropriate staff to evaluate the laboratory’s performance and to identify any problems that require corrective action and to develop a corrective action plan for any result found to be unacceptable or unsatisfactory.

7. Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

8. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

9. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory’s established performance characteristics are identified and that patient results are reported only when the system is functioning properly.

10. Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

11. Ensure all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and demonstrate that they can perform all testing operations reliably to provide and report accurate results.

12. Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly, proficient, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

D. General Supervisor Responsibilities (delegated by Laboratory Director and Technical Supervisor) The General Supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing laboratory activities and testing and reporting of results. At LSUHSC, the General Supervisor role is performed by the section Medical Lab Managers and Supervisors (MT, ASCP).

   1. In the absence of the director and technical supervisor, is responsible for the proper performance of all testing.

   2. Ensure that proficiency testing activities are performed, reported and reviewed, and that an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory.

   3. Ensure that all necessary remedial actions are taken and documented whenever significant deviation from the laboratory’s established performance characteristics are identified and that patient results are only reported when the system is functioning properly.
4. Providing orientation to all testing personnel and annually evaluating and
documenting performance of all testing personnel.
5. Ensure employment of a sufficient number of laboratory personnel with the
appropriate education and either experience or training to provide appropriate
consultation, properly supervise and accurately perform tests and report test results
in accordance with CLIA and the accrediting organizations.
6. Ensure that prior to testing patients’ specimens, all personnel have the appropriate
education and experience, receive the appropriate training, for high complexity
testing, and have demonstrated that they can perform applicable testing operations
reliably to provide and report accurate results.
7. Ensure that employees who perform pre-analytical, analytical, and post-analytical
phases of testing are competent and maintain competency to process specimens,
perform test procedures, and report test results promptly and proficiently. When
necessary, identify needs for remedial training or continuing education to improve
skills.
8. Provide an approved technical procedure manual to all personnel responsible for any
aspect of the testing process
9. Ensure that testing is performed according to manufacturer instructions and
laboratory established policies and procedures.
10. Available for resolving technical problems in accordance with policies and procedures
approved by the technical supervisor.
11. Responsible for monitoring tests analyses and specimen examinations to ensure that
acceptable levels of analytic performance are maintained.
12. Provide effective and efficient administration of the respective services including
budget planning and control with responsible financial management, in accordance
with institutional assignment of such responsibilities.
13. Implement a safe laboratory environment in compliance with good practice and
applicable regulations.
14. Ensure review of intermediate test results or worksheet, QC records, PT results and
preventative maintenance records.
15. Ensure assessment of test performance through testing previously analyzed
specimens, internal blind testing samples, or external PT samples.
16. Ensure that performance of all individuals responsible for high complexity testing are
done at least semiannually during the first year the individual tests patient specimens.
If test methodology or instrumentation changes, prior to reporting patient test results,
the individual’s performance must be re-evaluated to include the use of the new
methodology or instrumentation.

E. Cytology General Supervisor Responsibilities (delegated by Laboratory Director and Technical
Supervisor) The General Supervisor is responsible for the day-to-day supervision or oversight
of the laboratory operation and personnel performing laboratory activities and testing and
reporting of results. The Cytology General Supervisor must possess a current Louisiana
license and (1) must be qualified as a technical supervisor under 493.1449 (b) or (k); or be
qualified as a cytotechnologist under 493.1483 and have at least 3 years of full-time experience
as a cytotechnologists within the preceding 10 years.
1. Be accessible to provide on-site telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures.

2. Document slide interpretation results of each gynecologic and nongynecologic cytology cases he/she examined or reviewed (as specified under 493.1274(c).

3. For each 24 hour period, document the total number of slides he/she examined or reviewed in the lab as well as the total number of slides examined or reviewed in any other lab or for any other employer.

4. Document the number of hours spent examining slides in each 24 hour period.

III. Implementation of Job Duties

The regulations designate technical and general supervisors; therefore we must assign these roles as appropriate to the position titles within our organization. The Medical Director of Clinical Pathology and/or section Directors (M.D., Ph.D.) fulfill the role of technical supervisors. The responsibilities and duties are outlined in the appropriate Civil Service job description. The faculty have additional responsibilities and duties as specified by the Department Of Pathology. Medical Laboratory Managers/Supervisors (MT,ASCP) fulfill the role of general supervisor. Job duties and responsibilities are outlined in the appropriate Civil Service job description for Medical Laboratory Manager/Medical Laboratory Supervisor. All Technical Supervisors and General Supervisors meet the qualifications required by CLIA. Appendix A lists current laboratory sections and individuals performing as technical and general supervisors. Appendix B is a summary of documents and designees who are responsible for the review of these documents.

IV. References

A. Interpretive Guidelines for Laboratories (Appendix C or CLIA regulations)
B. CAP Checklists

V. Related Documents (N/A)

VI. Appendices and Forms

A. Appendix – Responsibility Roster
B. Appendix – Summary of Document Review

Policy  ; Laboratory Director Delegation Policy
Effective: Date: Dec. 19, 2011
Written:

Department Approval:

Stephen M. Bonsib, M.D./Director, Department of Pathology Date: Dec. 19, 2011

Division Approval:

James Cotelingam, M.D./Medical Director, Clinical Division Date: Dec. 19, 2011

Division Approval:

Jaiyeola O. Thomas-Ogunniyi, M.D./Medical Director, Anatomic Division Date: Dec. 19, 2011
### DOCUMENT REVIEW SUMMARY

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<th>October 20, 2011</th>
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| PROFICIENCY TESTING           |                      |                  |                    |                        |          |
| Commercial                    | X                    |                  |                    |                        |          |
| ---Signoff on submission      | X                    |                  |                    |                        |          |
| ---Review of evaluation summary reports | X | X | * | * |          |
| ---Alternate Performance Assessment Review | X | X | * | * |          |
| ---Followup (internal documentation) | X | X | * | * |          |
| ---Review and sign PTES       | X | X | X | X | X |          |

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| AUTOVERIFICATION/AUTO RELEASE            |                      |                  |                    |                        |          |
| --Procedure                               | X                  | X                |                    |                        |          |
| --Validation                              | X                  | X                |                    |                        |          |
| --Annual Review of process                | X                  | X                |                    |                        |          |

| LABORATORY COMPUTER SERVICES             |                      |                  |                    |                        |          |
| Documentation of approval of all changes, additions, deletions in programs, major computer functions before release | X | X | X | X | X |          |

* The Medical Director or Director may sign in the absence of the section Director, the Director may sign in the absence of the Medical Director.