COLLEGE OF AMERICAN PATHOLOGISTS (CAP) - REGULATORY COMPLIANCE

Medical Director's Delegation of Authority

August 27, 2024

In accordance with standards established by the Clinical Laboratory Improvement Amendments (CLIA) and adopted by the College of American Pathologists (CAP) TLC.11425 (Delegation of Functions), the Medical Director for the Laboratory of Pathology, NCI, CCR has delegated responsibilities and authority to Section Directors / Technical Supervisors (Section Heads) and General Supervisors, meeting the CLIA qualifications for the specialties supervised.

All section heads, Technical Directors, for LP's clinical services meet the CLIA requirements for supervising high-complexity testing (GEN.53400) and are identified on the sections' Laboratory Personnel Evaluation Roster. The performance of section Technical Directors and General Supervisors (GEN.55525) are assessed upon initial appointment, and their annual performance assessed using the NIH Performance Management and Appraisal Program (PMAP) administrative elements.

Technical Supervisors / Technical Directors have authority and responsibilities to include:

- Ensuring availability to the laboratory section as needed for on-site, telephonic or electronic consultation.
- Managing technical and regulatory compliance for the assigned discipline or service. Implements and maintains CAP standards, selection of equipment and methodologies, validation and implementation of new methods and instruments, communication of laboratory data, resolution of technical problems and ensuring remedial actions are taken when necessary, and an appropriate education, research and development for the sections' disciplines.
- Ensuring policies and standard operating procedures (SOPs) are relevant and appropriate, and SOPs are reviewed biennially. Note: new policies/SOPs or significant revisions must be approved initially by the Medical Director.
- Oversees biennial accreditation self-inspections on opposite years of CAP onsite inspections.
- Establishing and maintaining an effective Quality Management (QM) program for the clinical service that covers all areas of the laboratory and beneficiaries of services. This includes establishing quality indicators of pre-analytic, analytic, and post-analytic phases of testing, investigating and resolving quality variances, and performs root-cause-analyses when necessary.
- Ensuring enrollment in Proficiency Testing programs for all analytes, and ensuring compliance with Quality Assurance, Quality Control, and Performance Improvement programs. Ensures a safe work environment for staff.
- Managing Personnel: ensuring appropriate number of staff adequate for the complexity of work and workload; ensuring appropriate staff qualifications, training, competency, and continuing education requirements are met.
- As Technical Directors/Supervisors, identifies training needs and have authority to train and competency assess technical and administrative staff that support patient-care responsibilities in their clinical sections.

The following staff have been delegated as Technical Directors, designees by the Medical Director, tasked with authority of roles and responsibilities listed above:

Elaine S. Jaffe, MD	Head of Hematopathology
David Kleiner, MD, PhD	Head of Post-Mortem, Laboratory Information System, and Tissue Procurement and Processing Facility (TPPF)
Markku Miettinen, MD	Head of General Surgical Pathology and Immunohistochemistry
Armando Filie, MD	Head of Cytopathology and Quality Management Committee Chair
Martha Quezado, MD	Program Director AP Residency, Deputy Head Surgical Pathology
Stefania Pittaluga, MD, PhD	Hematopathology Fellowship Program,
Liqiang Xi, MD	Technical Director for NCI COMPASS Section
Hao-Wei Wang, MD, PhD	Head of Flow Cytometry Unit
Joseph Chinquee, DHSc, MT(ASCP)DLM	Clinical Manager, Head Histopathology and Clinical Operations Regulatory Compliance and LP Safety Officer

Each clinical service has one or more General Supervisor(s) under the supervision of the section technical director. General Supervisors have delegated authority to:

- Resolve technical problems in accordance with policies and procedures established by the laboratory's medical director or technical supervisor(s).
- Monitor test performance and ensures remedial actions at taken when test systems deviate from established performance specifications. Review of quality control and maintenance documents, and ensure corrective actions are appropriate if applicable.
- Perform training and competency assessment in their disciplines but must meet the general supervisor qualifications for high complexity testing if assessing staff performing high-complexity testing.
- Ensure qualified, credentialed, and trained personnel perform testing, and staff records are maintained.
- Facilitate staff participation in section and NIH-wide continuing education programs.

The following General Supervisory staff have delegated authority as designees to the Technical Directors to conduct all roles and responsibilities delegated to the Technical directors.

Jung Kim, PhD	Clinical Next Generation Sequencing Facility of NCI COMPASS
Zied Abdullaev, PhD	Clinical Methylation Unit of NCI COMPASS
Manoj Tyagi, PhD	Clinical Bioinformatics of NCI COMPASS
Vacant	Histopathology Laboratory
Patricia Fetsch, MT(ASCP)	Immunohistochemistry Section
True Ho, MLS(ASCP)CM	Flow Cytometry Unit

NOTES: The following functions may not be delegated, and are only facilitated/approved by the Medical Director:

- Provision of appropriately trained supervisory and technical staff and the identification of their responsibilities.
- Personal on-site assessment of physical/environmental conditions and adequacy of staffing on a periodic basis.
- Approval of new technical policies and procedures, as well as substantial changes to existing documents.

Frederic G. Barr, MD, PhD
Medical Director, Deputy Chief
Laboratory of Pathology

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Kenneth D. Aldape, MD
Chief
Laboratory of Pathology

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