

# CLIA Regulations Assessment Workgroup Interim Report

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**DR. KIMBERLE CHAPIN**  
**DR. GREGORY SOSSAMAN**

# CLIA Regulatory Assessment Workgroup

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## Co-Chairs

Dr. Kimberle Chapin

Dr. Gregory Sossaman

## Workgroup Charge

- **Established to provide** input to CLIAC for deliberation on how CLIA might specifically be updated, considering the April 2019 reports by the Personnel Regulations, Non-Traditional Workflow Models, and Next Generation Sequencing workgroups.
- **Charged with providing advice** to CLIAC for consideration in making recommendations to the Department of Health and Human Services on revising the CLIA regulations.

# Discussion Topics

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**Total Testing Process Review**

**Data as a Specimen**

**Digital Pathology**

**Analytical Testing Specifications**

**Histopathology**



# Workgroup Members

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- Kimberle C. Chapin, MD, ABMM, FCAP – Workgroup Co-Chair
- Gregory N. Sossaman, MD – Workgroup Co-Chair
- Tariq S. Adwan, PhD
- Erica F. Andersen, PhD, FACMG
- Jonathan B. Bakst, MBA, MHS, PA(ASCP)<sup>CM</sup>
- Michael Black, MBA, MLS/DLM (ASCP)
- Qing Jackie Cao, MD, PhD
- Alexis B. Carter, MD
- David Chhieng, MD, MBA, MSHI, MSEM, MLS
- Sugganth Daniel, MD, FCAP
- Denise K. Driscoll, MS, MT(ASCP)SBB
- Birgit Funke, PhD, FACMG
- John E. Gibson MA, MT(ASCP), DLM
- William A. Glover II, PhD, D(ABMM), MT(ASCP)
- Lee Hilborne, MD, MPH, DLM(ASCP), FASCP, FCAP
- Karen Kaul, MD, PhD, FASCP
- Eric Klee, PhD
- Robert Klees, PhD
- Jordan Laser, MD, FCAP
- Christina Lockwood, PhD, DABCC, DABMGG
- Valerie Ng, MD, PhD
- Liron Pantanowitz, MD, MHA
- Elizabeth L. Palavecino, MD, FACP
- Beverly Rauch, MS
- Faiqa M. Sadique, MS, SBB, MT(ASCP), CQA(ASQ)
- Owatha “Tootie” Tatum, PhD, HCLD/CC (ABB), MBA
- Erika Tyburski
- Kevin Wickware MLS(ASCP), MBA
- Sarah Bennett, MT(ASCP) – CMS Ex Officio
- Víctor R. De Jesús, PhD – CDC Ex Officio
- Tamara Pinkney, MT(ASCP) – FDA Ex Officio
- Heather L. Stang, MS, MT(AMT) – Workgroup DFO

# Workgroup Questions - Histopathology

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- Are additional personnel categories needed in CLIA to address anatomic pathology testing processes?
- Should CLIA recognize the role that histotechnicians, histotechnologists, and pathology assistants play in the total testing process?
- What personnel qualifications and responsibilities should be required for histotechnicians, histotechnologists and pathology assistants?
- What is an appropriate timeframe for review and confirmation of the tissue findings by the technical supervisor after the gross tissue examination is performed by qualified high complexity testing personnel?

# Workgroup Discussion

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- Currently, histotechnicians and histotechnologists are not considered “testing personnel.” A CLIA category would be helpful to define appropriate qualifications but should not be too strict to have a negative impact on the current existing workforce.
- CLIA should recognize the role that histotechnicians, histotechnologists, and pathology assistants play in the total testing process.
- Processes that currently fall under anatomic pathology processing should be covered under CLIA, and the CLIA personnel requirements for education and training should be updated to address the personnel performing those tasks.
- CAP requires that anatomic pathology processing meet its accreditation requirements. CLIA should be updated to include personnel requirements for anatomic pathology processing. Other members agreed that embedding is part of the pathology processing procedure, and if performed incorrectly, there could be inaccurate test results and patient harm.

# Workgroup Discussion

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- Personnel qualifications would ideally match the certification requirements imposed by ASCP. More stringent standards could negatively impact the availability of this workforce.
- Members noted the National Society for Histotechnology (NSH) [public comment](#) from the November 2018 CLIAC meeting should be reviewed when developing personnel qualifications and responsibilities.
- The *Histopathology, Cytology, and Clinical Cytogenetics Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988* Request for Information (RFI) published on July 13, 2023, as part of the CY2024 Physician Fee Schedule proposed rule ([CMS-1784-P](#)) asked for public comments related to the CLIA regulations for histopathology, cytology, and clinical cytogenetics. These comments should be used in conjunction with the CLIA Regulations Assessment Workgroup report to update the CLIA regulations for personnel qualifications and an acceptable time interval to review a gross tissue specimen.

# Workgroup Agreements

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- CLIA should be updated to include personnel requirements for anatomic pathology processing.
- A CLIA personnel category for histotechnicians, histotechnologists, and pathology assistants should be created with defined educational requirements similar to those for high complexity testing personnel.
- Personnel qualifications for histotechnicians, histotechnologists, and pathology assistants should be similar to high complexity testing personnel qualifications.

# Thank you

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[HTTPS://WWW.CDC.GOV/CLIAAC/WORKGROUPS/REGULATIONS-ASSESSMENTS.HTML](https://www.cdc.gov/cliac/workgroups/regulations-assessments.html)