



Association for Academic Pathology

Promoting Excellence In Academic Pathology

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September 11, 2026

Dr. Mehmet Oz, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3485-NC
P.O. Box 8016, Baltimore, MD 21244-8016.

Re: Response to Request for Information (RFI) Clinical Laboratory Improvement Amendments (CLIA) of 1988 Regulations (Submitted online at [Regulations.gov](https://www.regulations.gov))

Dear Dr. Oz:

The Association of Academic Pathology (AAPath) appreciates the opportunity to provide much needed input on CLIA regulations which are important to quality of clinical laboratory testing. AAPath is a non-profit society that serves as the voice of U.S. academic departments of Pathology. AAPath provides leadership and advocacy for the discipline of Pathology, and enables departments to meet demands of clinical practice, education, and research. The majority of our members are responsible for oversight of clinical laboratories within their academic health systems.

Below we provide our comments on key elements of the RFI. These are formatted according to the outline of topics questions within the RFI.

Please note that we strongly recommend caution in updating CLIA regulations based on the national responses from this RFI:

- Professional guidelines provided by national organizations may be more appropriate for many of the topics.
- CLIA regulations should be agnostic to technology since technology changes rapidly.
- Artificial intelligence is a rapidly changing area which should be monitored closely with an iterative approach to recommendations and regular updates.

We encourage thoughtful expert analysis of this data with the participation of a multi-disciplinary group of health care professionals, including pathologists and laboratorians, to ensure that any future change to federal regulations meets the modern practices of the laboratory and fulfills the expectations of the public for safe, accurate and high quality laboratory testing.

Laboratory Processes and Procedures

Pathology Specimen Block Retention

What types of requests does the laboratory receive for additional testing on pathology specimen blocks after the required 2-year retention period, and how frequently does the laboratory receive

them? *Many cancers can recur after many years of “silence”. An example is breast cancer, one of the most common cancers of women. The ability to return to the original tumor for comparison can be important. In addition, new tests and therapies become available requiring retrospective testing on old blocks. For this reason, the College of American Pathologists’ accreditation checklist requires a minimum of ten years for retention of specimen blocks. Academic medical centers (which our organization represents) make every effort to retain specimen blocks for as many years as space is available, often indefinitely, since most large academic centers receive several thousands of requests each year for “additional testing” (including second opinion requests) on blocks between 2 and 10 years old. Additionally, most large academic centers receive several hundreds of requests each year for “additional testing” on tissues between 10 and 20 years old. These are conservative estimates.*

Specimen Preparation Activities and Personnel

1. What activities does the laboratory consider to be part of specimen preparation (for example, centrifuging, aliquoting, loading on analyzers, adding chemicals for preparation, tissue processing, slide staining, inoculating culture plates, DNA/RNA extraction)? *All the examples listed are part of specimen preparation as they can impact the quality and validity of clinical test results. Tissue processing and slide preparation and staining are somewhat unique re: impact of pre-analytic issues since tissue can be more difficult or even impossible to recollect if quality issues are noted. Other specimens are relatively easy to recollect (ex.: needle stick for blood or patient self-collection for urine or saliva), but tissue requires a more invasive procedure (ex.: surgery, large bore needle biopsy) with risk of bleeding or infection. Also, a small lesion may be completely removed in the first collection making recollection impossible.*

2. What is the education and experience of the personnel who perform specimen preparation activities for your laboratory? *Many academic laboratories require formal training and certification for histotechnologists from professional organizations. Accreditation by CAP personnel performing certain high-complexity tasks, such as histotechnology and in-situ hybridization to have an associate degree in a course of study detailed in CAP’s Lab General Requirements. to meet minimum educational and training requirements for personnel performing certain high-complexity tasks, including histotechnology and in-situ hybridization.*

3. What types of training does the laboratory provide for the personnel who perform specimen preparation activities? *On-site practical training is typically provided locally; didactic education can be provided remotely by many educational programs, including professional organizations.*

4. How does the laboratory ensure that personnel who perform specimen preparation activities remain competent? *There are competency assessment across all areas of the lab, including those involved in specimen preparation activities, as outlined in the existing CLIA regulation.s*

Establishment and Verification of Performance Specifications

1. For tests that are not FDA-cleared or approved, including modifications of FDA-cleared or approved tests, what challenges does the laboratory encounter when establishing adequate performance specifications and appropriate acceptance criteria? Specify the relevant test or procedure associated with such challenges. *FDA-approved tests for the pediatric population and for rare diseases are often not commercially available. The laboratory must therefore modify existing tests to meet their local needs, performing local evaluations on normal and affected populations to define normal and abnormal ranges for results; however, because of the uncommon nature of some diseases being tested and the limitations associated with working with children, controls can be difficult to obtain for validation. Published guidelines from professional societies and the*

medical literature can often be helpful in defining acceptable results and also outlining the approach to validation of non-FDA cleared methods.

Emergency Preparedness, Biosafety and Biosecurity, and Cybersecurity

1. What challenges does the laboratory face in biosafety and biosecurity? *The COVID-19 pandemic illustrated the disconnect between public health labs and clinical labs re: resources, funding and personnel necessary to build a strong partnership, and demonstrated a reluctance to share information and resources with hospital labs, especially the clinical laboratories at academic medical centers where the sickest, most complex patients are treated. Laboratories are often on the front line during a public health emergency, and during the pandemic, were able to provide a huge amount of the testing available, despite the challenges mentioned. Ideally, pre-selected clinical laboratories could serve as public health laboratory extenders in emergencies like pandemics, similar to the current designation of select medical centers/laboratories as Ebola treatment sites. This would eliminate the need for CDC to evaluate individual laboratories during a crisis to determine if they are reliable and appropriate partners and would facilitate timely services and care.*

4. Which laboratory job position(s) is responsible for cybersecurity in the laboratory? *Oversight of laboratory information systems (LIS), including LIS cybersecurity and development and implementation of related policies, typically belongs to the health systemwide IT unit. The individual responsible for LIS functions is therefore a member of the health system's IT unit, though assigned to and ideally "embedded" within the laboratory environment. Degree of "embeddedness", dedication and responsiveness of IT professionals to cybersecurity and other LIS functions may vary based on institution and individual assigned.*

Specialty Testing Areas

1. General

1. What specific challenges or limitations, if any, does your laboratory currently experience with the test specialty and subspecialty categories in the CLIA regulations? For example, are there areas where existing CLIA test specialty and subspecialty categories could be revised to better reflect current laboratory testing practices? *CLIA standards for cytology do not meet the needs of contemporary practice regarding digital cytology and remote review. Current CLIA '88 regulations were established prior to the advent of digital cytology systems and require "...that all cytologic screening be done on the premises of a laboratory that is certified under this section" (Public Law 100-578, 102 Stat. 2903 4.B.vi). Remote digital cytology review is similar to remote digital review in surgical pathology which is allowed under CLIA regulations. Remote digital review during the COVID-19 pandemic demonstrated safety and accuracy for both cytology and surgical pathology. Unlike surgical pathology, cytology was not allowed to continue remote digital review post-pandemic after expiration of the Emergency Use Authorization only because of the existing CLIA '88 regulation (which is non-existent for surgical pathology), and was not because of error or safety concerns related to remote digital cytology. This is a substantial discrepancy and unnecessary limitation that adversely affects efficiency and timeliness of reporting, and ultimately negatively impacts patient care.*

This issue demonstrates that CLIA accreditation should not be location-based, but should instead reflect quality of performance regardless of location. This is particularly important since there is substantial growth for clinical laboratories serving large hospital networks, a trend that will continue and that did not exist in 1988 with current standards.

2. Are there additional specialties or subspecialties that CMS and the CDC should consider incorporating into the CLIA regulations to ensure comprehensive oversight of laboratory testing as specialties evolve? Provide evidence-based rationale supporting their inclusion, including considerations related to patient safety, testing complexity, and public health impact. ***CLIA-certification is currently non-specific and is not aligned with tests being performed. For example, there are laboratories performing complex molecular testing who advertise as CLIA-certified; however, no molecular expertise or training is present within the laboratory and existing certification is based on performance in other commonplace areas such as general chemistry which does not reflect competency or quality in specialty testing. This is misleading to the public and to referring physicians regarding quality, and is a concerning potential source of quality issues.***

Microbiology

1. What best practices has the laboratory implemented to reduce and monitor blood culture contamination (BCC)? ***Many academic laboratories assess standard blood culture contamination rates per month for each specimen collection site (example: various nursing units, clinics, emergency dept, etc.) to identify trends and locations for improvement.***
2. What challenges does the laboratory face in maintaining low BCC rates? ***The source of contamination is outside the laboratory and therefore outside the direct control of the laboratory. Collaborative work is necessary to achieve change, but is not always the priority of other units. In academic medical centers, trainees may contribute to contamination due to inexperience and improvement may not be sustained due to rotation of trainees and staff turnover.***

Thank you again for the opportunity to contribute information. We look forward to next steps in evaluating the data received and encourage caution as well as thoughtful participation of the laboratory community in any potential regulatory updates.

Sincerely,



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Health