

Massachusetts Department of Public Health Clinical Laboratory Program

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# **CLIA AND STATE LICENSURE**

**Acceptable documentation for laboratory personnel**

CMS has clarified acceptable forms of documentation required by CLIA regulations for qualifications of moderate and high comp1exity laboratory personnel. For an individual employed in a clinical laboratory as director, general supervisor, technical consultant, technical supervisor, laboratory technologist, cytologist, cytology supervisor or technician the laboratory must establish the employee’s qualifications according to CMS and State regulations.

**Acceptable Documentation**

* Resumes or CVs may be submitted but are not utilized to determine whether an individual qualifies under CLIA and State regulations. They are only utilized as a guideline.
* Documentation must include copies of highest level of academic achievement (medical school, doctorate, baccalaureate, associate degrees). If the diploma does not indicate the major then a transcript must be obtained to verify that the degree received was in a chemical, physical, or biological science. Primary Source Verification may be utilized to confirm the applicant’s education, but this verification must be documented by the laboratory. If the applicant has foreign education an equivalency to a US degree must be obtained through an evaluation service. Certificates from colleges are not acceptable (e.g., medical assistant or LPN certificates).
* Ph.D.’s or Physicians qualifying as laboratory director must provide proof of board certification as appropriate. For CLIA purposes physicians qualifying as laboratory director must also provide a current license to practice in the State.
* For supervisory positions, the applicant must meet the necessary experience requirements. This may include letters from previous employers documenting, not only the time period employed, but also the responsibilities of the applicant during their employment at the facility.
* High school diplomas or G.E.D. certificates are required for moderate complexity testing personnel who have no higher education degrees.
* HEW/HHS certificates are acceptable documentation for laboratory technologists performing high or moderate complexity testing

These guidelines do not cover all situations that might arise. For additional information regarding the regulatory personnel qualifications for CLIA and State refer to the following links:

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>

<https://www.mass.gov/regulations/105-CMR-18000-the-operation-approval-and-licensing-of-clinical-laboratories>