The section of the federal regulations titled "Standards and Certification: Laboratory Requirements" is issued by the Centers for Medicare & Medicaid Services (CMS) to enact the CLIA law passed by Congress (see below). In general terms, the CLIA regulations establish quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health. The final CLIA'88 regulations were first published in 1992, phased in through 1994, and amended in 1993, 1995, and 2003. Please visit the CLIA History page to search and view the Federal Register Notices and former editions of the Code of Federal Regulations (published annually in October).

The interpretive guidelines to the CLIA regulations are published in the CMS State Operations Manual (SOM). The SOM is used by state offices to administer various federal programs, such as clinical laboratory certification under the CLIA regulations, and enforced by CMS. It is also a source of guidance to laboratories for interpreting the CLIA regulations.

The Clinical Laboratory Improvement Amendments of 1988 statute is an amendment to the Public Health Services Act in which Congress revised the federal program for certification and oversight of clinical laboratory testing. Two subsequent amendments were made after 1988. The law continues to be cited as CLIA '88 as named in legislation.
CLIA Law United States Code History:

- Clinical Laboratory Improvement Act of 1967 (81 Stat. 536, Public Law 90-174, Sec. 5)
- Clinical Laboratory Improvement Amendments of 1988 (102 Stat. 2903, Public Law 100-578)
- Food and Drug Administration Modernization Act of 1997 [111 Stat. 2324, Public Law 105-115, Sec. 123(h)]

1 See 1997 changes to CLIA ’88
2 See 2012 changes to CLIA ’88