

**D6004**

*(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)*

**§493.1407 Standard; Laboratory director responsibilities**

**The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.**

***Interpretive* Guidelines §493.1407**

If the laboratory has more than one person qualifying as director, the laboratory is required to designate one individual who has ultimate responsibility for overall operation and administration of the laboratory.

The requirement that a laboratory must be under the direction of a qualified person is not automatically met simply because the director meets the education and experience requirements. It must be demonstrated that the individual is, in fact, providing effective direction over the operation of the laboratory.

In determining whether the director responsibilities are met, consider deficiencies found in other conditions, e.g., facility administration, general laboratory systems, preanalytic systems, analytic systems, postanalytic systems, and proficiency testing.

**(a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of §§493.1409, 493.1415, and 493.1421, respectively.**

***Interpretive* Guidelines §493.1407(a)**

If the laboratory director is not qualified as a technical consultant or clinical consultant, he or she must employ individuals meeting the appropriate qualifications.

**(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.**