D6076 (Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1441 Condition: Laboratories performing high complexity testing; laboratory director

The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart.

Interpretive Guidelines §493.1441

The Condition of laboratory director is not met when the laboratory director:

- Position is not filled;
- Is not qualified; or

Does not fulfill the laboratory director responsibilities.