D5479 (Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1256 Standard: Control procedures

(e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.

Interpretive Guidelines §493.1256(e)(5)

The laboratory must meet any and all regulatory requirements and comply with the manufacturer's requirements to the extent that the manufacturer's requirements do not conflict with any regulatory requirements. We encourage laboratories to also comply with the manufacturer's recommendations for testing to the extent that the manufacturer's recommendations do not conflict with any regulatory requirements.