

D8301

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

§493.1777 Standard: Inspection of Laboratories That Have Requested

or Have Been Issued a Certificate of Compliance

(a) Initial inspection. (a)(1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory's compliance with the requirements of this part before CMS issues a certificate of compliance.

Interpretive Guidelines §493.1777(a)

If for any reason a facility denies entry to or does not permit you to conduct a survey, take the following steps:

- Explain your authority to conduct the survey and the consequences of failure to permit a survey;
- If necessary, consult with your supervisor or the RO; and
- For failure to permit entry into or an inspection of the laboratory, use D8101.

If the laboratory continues to refuse a survey, refer to Subpart R – Enforcement Procedures beginning at §493.1800 and the Adverse Action section of the SOM at 6250.

(a)(2) The inspection may occur at any time during the laboratory's hours of operation.