

**WAC 246-338-028 On-site inspections.** (1) The department may conduct an on-site review of a licensee or applicant at any time to determine compliance with chapter 70.42 RCW and this chapter as described in Table 020-1.

(2) The department may at any time examine records of the medical test site to determine compliance with chapter 70.42 RCW and this chapter.

(3) The department will:

(a) Provide written notice of deficiencies to the medical test site;

(b) Allow the owner a reasonable period of time, not to exceed sixty days after department approval of the written plan of correction, to correct a deficiency unless the deficiency is an immediate threat to public health, safety, or welfare; and

(c) Impose a directed plan of correction or a partial directed plan of correction as an alternative sanction for any laboratory that has serious deficiencies per 42 C.F.R. 493.1832 and RCW 43.05.100.

(4) The medical test site must:

(a) Present a written plan of correction to the department within fourteen days following the date of postmark of the notice of deficiencies;

(b) Comply with the written plan of correction within a specified time, not to exceed sixty days, after department approval of the written plan of correction which must detail how and when the medical test site will correct the deficiencies;

(c) Submit to inspections by CMS or CMS agents as a condition of licensure for the purpose of validation or in response to a complaint against the medical test site;

(d) Authorize the department to release all records and information requested by CMS to CMS or CMS agents;

(e) Cooperate with any on-site review conducted by the department; and

(f) Authorize the accreditation organization to submit, upon request of the department:

(i) On-site inspection results;

(ii) Reports of deficiencies;

(iii) Plans of corrections for deficiencies cited;

(iv) Any disciplinary or enforcement action taken by the accreditation organization against the medical test site and results of any disciplinary or enforcement action taken by the accreditation organization against the medical test site; and

(v) Any records or other information about the medical test site required for the department to determine whether or not standards are consistent with chapter 70.42 RCW and this chapter.

[Statutory Authority: RCW 70.42.220, 43.70.041, and 42 C.F.R. 493.1291(1), 1832, 1241(b), 1299, 1256 (2)(iv, v), 1273(a). WSR 16-18-073, § 246-338-028, filed 9/2/16, effective 10/3/16. Statutory Authority: RCW 70.42.005 and 42 C.F.R. Part 493. WSR 05-04-040, § 246-338-028, filed 1/27/05, effective 3/19/05. Statutory Authority: RCW 70.42.005, 70.42.060. WSR 01-02-069, § 246-338-028, filed 12/29/00, effective 1/29/01. Statutory Authority: RCW 70.42.005, 70.42.060 and chapter 70.42 RCW. WSR 00-06-079, § 246-338-028, filed 3/1/00, effective 4/1/00.]