

performed at a frequency determined by the laboratory. Cite D5209 (§493.1235). If these people perform testing on patient specimens, they are required to have the six required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities (see §493.1413(b)(8) / §493.1451(b)(8)).

Testing personnel in laboratories with a PPM certificate

Testing personnel in PPM laboratories, including mid-level practitioners, are required to undergo competency assessment that includes the six procedures found in §493.1413(b)(8). Use D5209 or appropriate Technical Consultant D-tag (D6046 through D6052) relating to competency assessment.

KEY POINT: In situations in which more than one citation may be used, choose the one that is most specific to the situation. This will best allow the laboratory to understand the problem and correct it.

Probes §493.1235

How does the laboratory evaluate the competency of its employees?

If the laboratory uses non-testing personnel to perform preanalytic functions how does it ensure their competency?

If a laboratory utilizes a consultant, how does the laboratory determine if the consultant is competent? Does the laboratory have a policy/procedure to determine consultant competency? Use D6030 or D6103.

How does the laboratory evaluate personnel for consistency in slide review (e.g., ANA, manual differential, urine sediment)?