CLIA Corner

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- *Navigating the CLIA Regulations and Interpretive Guidelines*

Though CLIA Regulations and Interpretive Guidelines are extremely useful, they can be difficult to navigate without experience. In this CLIA Corner, we will break down the CLIA Regulations and Interpretive Guidelines and explain each of the Subparts.

Organization of the Regulations

The Code of Federal Regulation is divided into 50 titles that represent each of the areas subject to the Federal Regulations. 42 CFR is the title specific to Public Health. Each title is further divided into parts; 493 is the segment of the Public Health code that contains laboratory requirements. Each part is then further divided into subparts. Finally, the subparts are divided into sections, paragraphs, and subparagraphs, which make up the deficiencies. Deficiency tags are also known as D tags.

The CLIA Regulations and Interpretive Guidelines are divided into 14 subparts: A, B, C, D, E, F, H, I, J, K, M, Q, R and T. Some letters denoting subparts have been reserved for future use. Each of the subparts have specific regulations and/or D tags. Condition level deficiencies are mostly even numbered tags, while standard level deficiencies are odd numbered. The regulation is always in bold type, while the interpretive guidelines and surveyor probes are in regular font.

Subpart A

Subpart A of the CLIA Regulations and Interpretive Guidelines contains the introduction, definitions, applicability, and test categorization. The introduction contains important information including survey protocol. It explains the outcome-oriented survey process, what records will be reviewed during the survey, and how the surveyor determines if a deficiency should be cited.

The definition section of Subpart A includes common CLIA definitions such as “calibration vs. calibration verification.” Under the definition of “Accredited institution,” this section also states the requirement of obtaining an educational equivalency evaluation for individuals with foreign education.

Subparts B, C and D

These three subparts are very similar in that they:

- Explain the exceptions for having multiple CLIA sites under one certificate;
- Determine what access Centers for Medicare and Medicare Services (CMS) agents have to the laboratory;
- List the requirements for each certificate type; and

- Identify the timeframe for notification to CMS with regard to changes in ownership, name, location, director, technical supervisor, and specialties/subspecialties.

Subpart B is specific to certificates of waiver. Subpart C is specific to certificates of registration, provider-performed microscopy procedures, and compliance, while Subpart D is specific to certificates of accreditation.

Subparts E and F

Subpart E provides the regulations that allows CMS to deem, reapprove, and remove accrediting organizations and/or exempt states. Subpart F includes the structure for determining CLIA fees paid by each laboratory, including both certification and compliance fees.

Subparts E and F are not found in the Regulations and Interpretive Guidelines; they are only found in the Federal Register. The entire CLIA CFR Federal Register can be found at https://ecfr.io/Title-42/cfr493_main.

Subpart H

Subpart H contains regulations starting with D2000. This subpart explains general guidelines for participating in Proficiency Testing, including:

- Enrolling in proficiency testing (PT) when testing is performed at multiple sites, and guidelines for when an analyte is performed using different methodologies;
- Testing of proficiency testing samples: treating PT samples the same as patient specimens, rotating PT samples between testing personnel, referral of PT samples, and documentation requirements; and
- PT failures (unsatisfactory performance for specialties, subspecialties, and analytes).

Subpart I

Subpart I is not located in the Regulations and Interpretive Guidelines, but can be found in the Federal Register. There are specific analytes for which the laboratory must enroll in PT; these are called regulated analytes. The list of regulated analytes can be found in Subpart I.

This subpart is also useful because it gives the criteria for acceptable performance that PT companies must use when grading regulated analytes. When performing comparisons, laboratories can use these values as guidance for establishing acceptable limits for analyte comparison.

Subpart J

Subpart J (D3000) contains the regulations and interpretive guidelines for facility administration. Facility administration includes facility requirements ensuring: proper laboratory space and ventilation, uni-directional workflow for non-contained molecular amplification, and safety procedures. This subpart also contains regulations for transfusion services, including blood and blood product storage and distribution, and the investigation of transfusion reactions. Finally, this subpart contains retention requirements including, but not limited to test requisitions, procedures, analytic records, proficiency testing records, test reports, slides, blocks, and tissues.

Subpart K

The majority of the CLIA regulations and interpretive guidelines are located in Subpart K. This subpart is divided into four sections: general systems, preanalytic, analytic, and postanalytic.

- **General Systems, D5200:**
    - The general systems regulations include requirements for confidentiality of patient information, specimen identification and integrity, laboratory communication, personnel competency assessment policies (including competencies for testing personnel in provider-performed microscopy laboratories), the evaluation of proficiency testing performance, and quality assessment.

- **Preanalytic Systems, D5300:**
  - The preanalytic regulations include requirements for test requests; specimen submission, handling, and referral; and quality assessment.
- **Analytic Systems, D5400:**
  - The analytic regulations include requirements for procedure manuals; documentation of temperatures, maintenance and function checks; performance verification; calibration and calibration verification; quality controls (including Individualized Quality Control Plans); corrective action; and quality assessment.
  - The analytic section also includes the specific regulations for each specialty and/or subspecialty (e.g. bacteriology, blood banking, cytology, etc.).
- **Postanalytic Systems, D5800:**
  - The postanalytic regulations include requirements for test reports, reporting of panic (critical) values, manual entry of test results, and quality assessment.

Subpart M

Subpart M contains the regulations for laboratory personnel qualifications and responsibilities. The requirements for provider performed microscopy personnel start at D5980, and include laboratory director and testing personnel. The requirements for moderate complexity personnel start at D6000, and include laboratory director, clinical consultant, technical consultant, and testing personnel. The requirements for high complexity personnel start at D6076, and include laboratory director, clinical consultant, technical supervisor, general supervisor, and testing personnel.

Subpart Q

Subpart Q (D8000) includes the inspection regulations. These outline the jurisdiction for surveyors, as CMS agents, to conduct surveys and review patient records.

Subpart R

Subpart R is not located in the Regulations and Interpretive Guidelines, but can be found in the Federal Register. It details the enforcement regulations for the suspension, limitation, or revocation of CLIA certificates and allows for training and technical assistance for initial unsuccessful PT participation.

Subpart T

Subpart T is not located in the Regulations and Interpretive Guidelines, but can be found in the Federal Register. This subpart provides guidelines for consultations, such as the Clinical Laboratory Improvement Advisory Committee (CLIAC), which provides recommendations on technical and scientific aspects of the provisions of this part.

Example Deficiency

Now, let us take what you learned and apply it to a common deficiency.

D5417

42 CFR §493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

Interpretive Guidelines §493.1252(d)

In citing deficiencies, for outdated or deteriorated materials, indicate whether these materials have been used for patient testing. Also, look for contamination, drying or other signs of deterioration. This is as important as checking expiration dates.

Deficiency Breakdown

- 42CFR means this deficiency comes from the healthcare code.
- Part 493 informs us that the deficiency is a laboratory regulation.
- D5417: since the D tag is odd numbered, a standard level deficiency is indicated. We also know by the numerical designation (5417) that the deficiency is found in the analytic portion of Subpart K.
- **Bold text** indicates the actual regulation; the laboratory must not use expired or deteriorated reagents, solutions, media, controls materials, and/or other supplies.
- Regular text indicates the interpretive guidelines that give further direction and clarification of the regulation.

The CLIA Regulations and Interpretive Guidelines are an extremely important tool for surveyors and laboratory personnel. Hopefully, you now have a better understanding of their layout and can navigate them when answering questions or clarifying requirements. Finally, included is a quick reference guide list that helps clarify where specific D tags can be found. Good luck and happy navigating!

D-Tags and Regulatory Cites for CMS Survey Categories

Category	D-Tag	Regulations
Subpart H: Participation in PT		
Enrollment/Testing of Samples	D2000 - D2015	493.801
Successful Participation	D2016 - D2191	493.803 - 493.865
Subpart J: Facility Administration		
Facility Administration	D3000 – D3045	493.1100 – 493.1105
Subpart K: Quality Systems		
Specialty/Subspecialty	D5002 – D5042	493.1201 – 493.1227
General Lab Systems	D5200 – D5293	493.1230 – 493.1239
Pre-Analytic Systems	D5300 – D5393	493.1240 – 493.1249
Analytic Systems	D5400 – D5793	493.1250 – 493.1289
Post Analytic Systems	D5800 – D5893	493.1290 – 493.1299
Subpart M, Personnel		
Laboratory Director (PPM)	D5980 - D5987	493.1355 – 493.1359
Testing Personnel (PPM)	D5990 – D5995	493.1361 – 493.1365
Laboratory Director (MOD)	D6000 – D6032	493.1403 – 493.1407
Technical Consultant (MOD)	D6033 – D6055	493.1409 – 493.1413
Clinical Consultant (MOD)	D6056 – D6062	493.1415 – 493.1419
Testing Personnel (MOD)	D6063 – D6075	493.1421 – 493.1425
Laboratory Director (HIGH)	D6076 – D6107	493.1441 – 493.1445
Technical Supervisor (HIGH)	D6108 – D6133	493.1447 – 493.1451
Clinical Consultant (HIGH)	D6134 – D6140	493.1453 – 493.1457
General Supervisor (HIGH)	D6141 – D6152	493.1459 – 493.1463
Cytology General Supervisor (HIGH)	D6153 – D6161	493.1467 – 493.1471
Cytotechnologist (HIGH)	D6162 – D6167	493.1481 – 493.1485
Testing Personnel (HIGH)	D6168 – D6183	493.1487 – 493.1495
Subpart Q: Inspection		
Inspection	D8100 – D8401	493.1771 – 493.1780