

CLIA Inspection Checklist for LRN-C, RADIOBIOASSAY AND BIOMONITORING LABORATORIES

INTRODUCTION

In 2009 the Centers for Medicare & Medicaid Services (CMS) released a memorandum stating chemical terrorism (CT) laboratories will be added to the CLIA certificate under the umbrella of the main laboratory. In order to help members prepare for CLIA inspection of their LRN-C program, APHL, with guidance from CMS, created this Checklist for LRN-C, Radiobioassay and Biomonitoring laboratories.

While the Checklist intends to provide guidance to CT laboratories preparing for a CLIA inspection, the document is NOT all-inclusive. Laboratories should be aware some regions or states may have slightly different or additional requirements. Also, some items listed in the document may not be applicable in all situations. If laboratories have any questions or are unclear about specific requirements, the EHC advises laboratories to contact their [regional CMS office](#).

For further explanation on the contents and acronyms listed in the Checklist, please refer to the *CLIA Inspection Guidance for LRN-C, Radiobioassay & Biomonitoring Laboratories* document. The EHC strongly advises users of the Checklist to first read the Guidance Document before employing the Checklist. Also CMS's Interpretive Guidelines on CLIA lends more detail for compliance: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html.

THE CHECKLIST FOR LABORATORIES

CLIA Reg	Item: Laboratories must be in compliance with regulations with regard to their services	Yes	No	Not Required	Comments
	SubPart A				
§493.25	Laboratories performing tests of high complexity				
	(a) A laboratory must obtain a certificate for compliance (or be added to PHL list of specialties)				
	(b) And must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part				
	SubPart H - Proficiency Testing				
§493.801	Enrollment for each analyte				

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	Process as regular workload, just like patients, repeat only if you would for patient				
	Same personnel using routine methods				
	Analyst and Laboratory Director (LD) or Technical Supervisor (TS) attest to integration of samples				
	No collaboration with another lab, don't send sample out for analysis				
	Primary method only, if two or more methods for same analyte, compare twice a year				
	Document receipt, testing, reporting				
§493.803	Successful participation				
§493.1236	Twice-a-year accuracy verification for all analytes not included in subpart 142CFR493 or not covered by CMS CLIA approved PT providers review and evaluate results, investigate all unacceptable results				
	Review and evaluate results, investigate and document corrective actions for any unacceptable results				
	SubPart J – Facility Administration				
§493.1101	Facilities – safety, space, ventilation, all regulatory agencies, federal & state				
§493.1105	Retention requirements – two years for CLIA				
§493.1200	SubPart K – Quality Systems				
	(a) Written policies and procedures that implement and monitor quality systems for all phases of testing, pre-analytic, analytic, post-analytic, and general lab systems				
	(b) Each has an assessment component that ensures continuous improvement through ongoing monitoring				
§493.1230	General Laboratory Systems – policy and procedures (P&P) to monitor and evaluate				
1231	Confidentiality of patient information				
1232	Specimen identification and integrity (through testing & reporting)				
1233	Complaint investigations (& resolution)				
1234	Communications (system to identify & document provider, patient, staff failures to communicate)				
1235	Personnel competency assessment policies (establish P&P, see 1451 for specifications)				
1236	Evaluation of proficiency testing performance (unacceptable, unsuccessful)				

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1239	General laboratory systems assessment (P&P, dashboard of elements, score or monitor)				
§493.1240	Pre-analytic Systems				
1241	Test request (form, written, policy on oral communication documentation, components) – two forms of identification				
1242	Specimen submission, handling, and referral – P&P for patient prep, collection, labeling, storage & preservation, transport, processing, rejection criteria, specimen referral)				
	Date & time of lab receipt				
	Referred specimens only go to CLIA labs				
	Accepting referrals means directions to clients for appropriate specimen & receipt				
1249	Pre-analytic systems assessment – P&P to monitor, assess, and correct, then review effectiveness of Corrective Actions (CA)				
§493.1250	Analytic Systems				
1251	Procedure manual – all 14 elements to be included (see details below)				
1252	Test systems, equipment, instruments, reagents, materials, and supplies – identify acceptability criteria, monitor & document (read package inserts & operator's manuals)				
1253	Establishment and verification of performance specifications (PARRSS)				
1254	Maintenance and function checks – per manufacturer, perform & document at established frequency				
1255	Calibration and calibration verification procedures – use appropriate type, concentrations, frequency, and acceptability criteria				
1256	Control procedures – establish ranges, use number, type, concentration & acceptability criteria, monitor & document and review for trends				
1281	Comparison of test results – multiple instruments, methods or sites, compare twice per year				
1282	Corrective actions – documentation, investigation, root cause, corrective action, monitor, preventive action & evaluate and document effectiveness				
1283	Test records – able to retrieve patient identification, date & time, condition & disposition, test records, QC, QA, investigations				

CLIA Reg	Item: Laboratories must be in compliance with regulations with regard to their services	Yes	No	Not Required	Comments
1289	Analytic systems assessment – P&P to monitor, assess, and correct then review effectiveness of CA				
§493.1290	Post Analytic Systems				
1291	Test report – accurate, timely, calculations, secure transfer of data (electronic or manual) & reports retrievable				
	Demographic info – 2 forms of identification, location performed, date reported & performed, specimen type, results, or disposition				
	Reference range, interpretation, panic or critical value protocol, corrected or amended report protocol & documentation (preliminary, final, amended all maintained)				
1299	Post analytic systems assessment – P&P to monitor, assess, and correct then review effectiveness of CA				
	SubPart M – Personnel Qualifications and Responsibilities				
§493.1441	Condition: Laboratories performing high complexity testing; Laboratory Director. (responsibilities 493.1445)				
§493.1447	Condition: Laboratories performing high complexity testing; technical supervisor (responsibilities 493.1451)				
§493.1453	Condition: Laboratories performing high complexity testing; clinical consultant (responsibilities 493.1457)				
§493.1459	Condition: Laboratories performing high complexity testing; general supervisor (responsibilities 493.1463)				
§493.1487	Condition: Laboratories performing high complexity testing; test personnel (responsibilities 493.1495)				
§493.1771	SubPart Q – Inspection				
§493.1777	Inspection of laboratories that have requested or have been issued a certificate of compliance				
§493.1800	SubPart R – Enforcement				
	(1) To protect all individuals served by laboratories against substandard testing of specimens.				
	(2) To safeguard the general public against health and safety hazards that might result from laboratory activities.				
	(3) To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.				

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) is a national nonprofit dedicated to working with members to strengthen laboratories with a public health mandate. By promoting effective programs and public policy, APHL strives to provide public health laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.

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