Crosswalk of Regulations And Guidance Affecting Laboratories—Sorted by QSE

May 2017

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

Introduction

This crosswalk of regulatory references is arranged by Quality System Essentials (QSEs), the fundamental quality elements or building blocks of organizations. Regulation terminology, (Organization, Management System, Management Reviews, etc.) is grouped by QSE. In some instances, terms and references appear in more than one QSE. For example, the QSE "Process Management" applies to preanalytic, analytic and postanalytic activities.

The "Introduction" to the crosswalk, while not a QSE, pulls from all regulation categories, including Scope (audience and purpose for the regulations and requirements), Normative References (regulatory documents referenced) and Terms and Definitions (used in the regulation document) and others.

To use the crosswalk, find the QSE category on the left and choose the desired topic. Then follow the line across the table to find the regulation reference or to view related regulations.

QSEs	Regulation Category	ISO 17025:2005(E)	ISO 15189:2012	DW Manual (EPA 815), 2005	CLIA, Jan. 24, 2003	AIHA, 2017	TNI, 2009	9 CFR Food Safety and Inspection Service, 1/2014	40 CFR 141 2012-07-01	ABFT	ASCLAD ISO 17025:2005 and ASCLD/Lab Supplemental Req.	AAVLD	AAFEO
INTRODUCTION	**Scope**	1 Scope	1 Scope	Chap 1 Introduction	§493.1 Basis & Scope	2A.1 Scope	1.2 Scope	Subpart A-General §424.1 Purpose and Scope	§141.1 Applicability	A-1 (written mission statement), C-3	1 Scope		
	References	2 Normative References	2 Normative References	Footnotes-Chap IV, Chap V and Chap VI		2A.2 Normative References	2.0 Normative References		§141.131(a)(2)		2 Normative References		
	Terms and Definitions	3 Terms and Definitions	3 Terms and Definitions	Appendix C - Definitions and Abbreviations	§493.2 Definitions	2A.3 Terms and Definitions	3.0 Terms and Definitions	§318.21(a) Definitions §381.1 Definitions	§141.2 Definitions		3 Terms and Definitions		
ORGANIZATION	**Organization**	4.1 Organization	4.1 Organization and Management	Chap I Introduction Chap III, Sec 2,3, 6, 9, and 11.1	§493.3 Applicability - 493.63 Notification for Labs Issued a Certificate of Accred. §493.1445 Laboratory Director Responsibilities	2A.4.1 Organization	4.1 Organization	§381.145 (c)(2) and §381.3 (d)(1)		A-4, Organizational chart Adequate financial resources (A-2)	4.1 Organization Supplements 4.1.4, 4.1.5 and 4.1.7	4.1 Organization and Management	1.4
	Management System (QA System)	4.2 Management System	4.2 Quality Management System	Chap III, Sec 11 Lab QA Plan Chap IV, Sec 4.5 QA; Chap V, 7.1 QA Chap VI, Sec 7 QA Supplement 1 Quality Management System	Subpart K - Quality System for Nonwaived Testing	2A.4.2 Management System	4.2 Management	§318.4 (c)(4) and §381.145 (c)(4)		Section E. Quality Assurance and Quality Control and Reporting	4.2 Management System	4.2 Quality System	1.0, 2.0 and 3.0
	Management Reviews (review of document manual)	4.15 Management Reviews	4.15 Management Reviews		§493.1251(d) Standard: Procedure Manual	2A.4.15 Management Reviews	4.15 Management Reviews			C-6 through C-9	4.15 Management Reviews	4.12 Management Reviews	No requirements beyond ISO-17025
CUSTOMER SERVICE	**Customer Service**	4.7 Service to the Customer	4.7 Advisory Services		§493.1231 Standard: Confidentiality of Patient Information §493.1234 Standard: Communications	2A.4.7 Service to the Customer	4.7 Service to the Customer		Subpart O - Consumer Confidence Reports §141.151(a) Purpose and applicability of this part	A-5 (confidentiality of info/results) A-7 (client notification of deficiencies that affect reliability)	4.7 Service to the Customer		2.0-2.2
	Complaints	4.8 Complaints	4.8 Resolution of Complaints		§493.1233 Standard: Complaint Investigations	2A.4.8 Complaints	4.8 Complaints			A-6 (complaint resolution)	4.8 Complaints 4.8.1 Suppl. (Policy/Proc for QS complaints from lab employees)	4.7 Complaints	2.13 and 2.15
FACILITIES AND SAFETY	**Facilities**	5.3 Accommodation and Environmental conditions	5.2 Accommodation and Environmental conditions	Chap IV, V, and VI Sec 2 Lab Facilities	§493.1101 Standard: Facilities	2A 5.3 Accommodation and Environmental conditions	5.3 Accommodation and Environmental conditions			L-4 D-5 through D-8	5.3 Accommodation and Environmental conditions	5.3 Accommodation and Environmental conditions	1.1 and 2.3-2.7
	Safety (Labs follow the various subparts of OSHA 29 CFR 1910 for safety)			Chap IV, Sec 4.4 Lab Safety Chap V, Sec 4 General Lab Practices - Intro Chap VI, Sec 4.4 Safety		2A.6 Safety and Health		Each method has its own safety "chapter"		Section L. Safety			

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PERSONNEL	**Personnel**	5.2 Personnel	5.1 Personnel	Chap III Sec 10 Other Considerations for Lab Certification (Personnel) Chap IV, V, and VI Sec 1 Personnel	Subpart M - Personnel for Nonwaived Testing §493.1235 Standard: Personnel competency assessment policies	2A.5.2 Personnel	5.2 Personnel	§318.21(b)(2)(i) and (c)(2)(i)		Section B. Personnel A-2 (access to literature)	5.2 Personnel	5.2 Personnel	1.1 ,1.4 ,1.6
PURCHASING AND INVENTORY	**Contracts**	4.4 Review of Requests, Tenders, and Contracts	4.4 Service Agreements	Chap III 11.2 Process used to identify Client's Data Quality Objectives	§493.1200 c) Introduction §493.1241 Standard: Test Request	2A.4.4 Review of Requests, Tenders and Contracts	4.4 Review of Request, Tenders and Contracts	§318.175 Documents to be Kept			4.4 Review of Request, Tenders and Contracts	4.4 Review of Request, Tenders and Contracts	2.0-2.2
	Sub-Contracting	4.5 Sub-Contracting of Tests and Calibrations	4.5 Examination by Referral Laboratories	Appendix A Chain of Custody Procedures	§493.1242 Standard: Specimen Submission Handling and Referral	2A.4.5 Sub-Contracting of Tests and Calibrations	4.5 Subcontracting of Environmental Tests				4.5 Sub-Contracting of Tests and Calibrations	4.5 Subcontracting of Test Services	
	Purchasing	4.6 Purchasing Services and Supplies	4.6 External Services and Supplies	Chap IV Sec 4.1.1 Chap VI Sec 4.1	§493.1252 Standard: Test systems, equipment, instruments, reagents, materials and supplies	2A.4.6 Purchasing Services and Supplies	4.6 Purchasing Services and Supplies				4.6 Purchasing Services and Supplies	4.6 Purchasing Services and Supplies	3.2
EQUIPMENT	**Equipment**	5.5 Equipment	5.3 Laboratory equipment, reagents, and consumables	Chap IV and VI Sec 3 Lab Equipment and Instrumentation Chap V Sec 3 Lab Equipment and Supplies	§493.1252 Standard: Test Systems, Equipment, Instruments, Reagents, Materials and Supplies §493.1254 Standard: Maintenance and Function Checks	2A.5.5 Equipment	5.5 Calibration Requirements			C-14 (procedure req), E-19 through E-27 (equipment and instruments) F-1 (immunoassay instr.) F-4 (pipettors/dilutors) H-1 (GC/MS/MS/LC, instr. procedures), I-1+2 (cals) J-1+2 (biochem instruments)	5.5 Equipment	5.5 Equipment Including Computers and Supplies	1.1, 2.6-2.7. and 2.12-2.31
DOCUMENTS AND RECORDS	**Document Control**	4.3 Document Control	4.3 Document Control	Chap III, Sec 11 Intro and 11.3 SOPs, 15 Chap IV, V Sec. 15 and VI Sec 7.1.1 QA	§493.1251 Standard: Procedure Manual §493.1283 Standard: Test Records	2A.4.3 Document Control	4.3 Document Control			A-3 (communicate changes to staff) C-1,2 (documented change control) C-15 (outdated SOPs)	4.3 Document Control	4.3 Document Control	2.4.4 and 3.1
	Control of Records	4.13 Control of Records	4.13 Control of Records	Chap III Sec 11.13 Record Keeping Procedures Chap IV, V, VI Sec 8 Records and Data Reporting	§493.1105 Standard: Retention Requirements	2A.4.13 Control of Records	4.13 Control of Records	§381.175 Records Required to be Kept §381.176 Place of Maintenance of Records §318.21 (b)(3)(ii)(iii)(iv) and (c)(3)(ii)(iii)(iv)	§141.33 Record Maintenance §141.722 Recordkeeping Requirements	E-33	4.13 Control of Records	4.10 Records	No requirements beyond ISO-17025

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INFORMATION MANAGEMENT	**Laboratory Information Management System**		5.10 Lab Information Management	Chap IV and VI Sec 8.2 Computer Programs									
	Reporting Results	5.10 Reporting the Results	5.7 Post-examination processes 5.8 Reporting of results 5.9 Release of results	Chap III Sec 11.8 Data Reduction, Validation, Reporting, and Verification Chap IV, V, and VI Sec 8 Records and Data Reporting	§493.1291 Standard: Test Report	2A.5.10 Reporting the Results	5.10 Reporting the Results	§381.180 Info and Reports Required from official establishment operators §381.181 reports ... Violations §381.182 Reports of inspection work	§141.31 Reporting Requirements §141.721 Reporting Requirements	E-21 through E-33 G-2 ((Chromo/MS results in valid range) H-2 through H7 (LC/MS/MS, interpretation of results)	5.10 Reporting the Results	5.10 Reporting Test Results	2.7 and 2.10-2.43
NON-CONFORMANCE MANAGEMENT	**Nonconformities**	4.9 Control of Nonconforming Testing and/or Calibration	4.9 Identification and Control of Nonconformities	Chap IV Sec 6.1 Rejection of Samples Chap IV Sec 7.2.2 QC Samples Chap VI Sec 7.8 Instrument and Method Performance	§493.1239 Standard: General Lab Systems Quality Assessment §493.1256 Standard: Control Procedures	2A.4.9 Control of Nonconforming Testing and/or Calibration Work	4.9 Control of Nonconforming Environmental Testing	§318.308 Deviations in Processing		E-9 (root cause analysis) E-10 (follow-up) C-16 (deviations from written procedures)	4.9 Control of Nonconforming Testing and/or Calibration Work	4.8 Control of Nonconforming Testing and Test Results	2.12, 2.14, 2.15 and3.2
	Corrective Actions	4.11 Corrective Action	4.10 Corrective Action	Chap III Sec 11.12 Corrective Action Contingencies	§493.1282 Standard: Corrective Actions	2A.4.11 Corrective Action	4.11 Corrective Action	§381.311 Recall Procedure §318.21 (b)(2)(ii) and (c)(2)(ii)	§141.202,3,4 Tier Level (1, 2 or 3) Public Notice Appendix A to Subpart Q of Part 141-NPDWR Violations and other situations	E-13 (corrective action for controls), C-16 (procedural deviations) E-9 (root cause analysis), E-10 (follow-up), E-13 (controls) E-16 (PT actions), E-26 (instruments)	4.11 Corrective Action	4.9 Corrective and Preventive Action	2.10-2.12
	Preventive Actions	4.12 Preventive Action	4.11 Preventive Action	Chap III Sec 11.11 Preventative Maintenance Procedures and Schedules Chap V Sec 8.5 Preventive Maintenance	§493.1254 Standard: Maintenance and Function Checks	2A.4.12 Preventive Action	4.12 Preventive Action				4.12 Preventive Action	4.9 Corrective and Preventive Action	4.12

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ASSESSMENTS	**Internal Audits**	4.14 Internal Audits	4.14 Evaluation and Audits	Chap III Sec 11.10 List Schedule of Internal and External System and Interlaboratory Comparisons	§493.1239 (b), §493.1249(b), §493.1289(b), §493.1299(b)	2A.4.14 Internal Audits	4.14 Internal Audits			(checklist does not contain require-ment, may be elsewhere)	4.14 Internal Audits	4.11 Internal Audits	2.11
	Management Reviews (**review of document manual**)	4.15 Management Reviews	4.15 Management Review		§493.1251(d) Standard: Procedure Manual	2A.4.15 Management Reviews	4.15 Management Reviews			C-6 through C-9	4.15 Management Reviews	4.12 Management Reviews	No requirements beyond ISO-17025
	Assurances	5.9 Assuring the Quality of Test and Calibration Results	5.3 Ensuring the quality of examination results	Chap III Sec 11.7 Analytical Procedures and 13.1 Proficiency Testing Samples Chap IV Sec 7.2 Specific Requirements Chap V Sec 7.2 QA Chap VI Sec 7.4 Proficiency Test Studies and 7.7 Sample Measurement QC Requirements Plus QC Requirements of Individual Methods	Subpart H - Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing §493.1236 Standard: Evaluation of Proficiency Testing Performance §493.1256 Standard Control Procedures	2A.5.9 Assuring the Quality of Test Results	5.9 Quality Assurance for Environmental Testing	§318.21 (b)(3)(v) (Physical Testing Labs) §318.21 (c)(3)(v) (Chemical Testing Labs)	§141.23(k)(3)(i) §141.24(f)(17)(i)(A) §141.89(a)(1)(i)		5.9 Assuring the Quality of Test and Calibration Results 5.9.3 Suppl (Documented program for proficiency testing) 5.9.4 Suppl(Proc for tech review of calibrn documen-tation) 5.9.4.1 Suppl(Tech reviews done by person with expertise) 5.9.5 Suppl(Admin review of calibrn record, cert, docs) no number Suppl (Scope of tech review and how documented)	5.9 Ensuring the Quality of Test Results	1.1, 2.4-2.6, 2.8-2.10 and 2.12
PROCESS IMPROVEMENTS	**Laboratory Improvement**	4.10 Improvement	4.12 Continual Improvement	Chap III Sec 11 Lab QA Plan Chap IV Sec 7.2.8 Control Charts Chap VI, Sec 7.2.8 Instrument and Method Charts/ Records	Subpart K - Quality System for Nonwaived Testing §493.1200 Introduction §493.1239(a), 1249(a), 1289(a), 1299(a) Quality Assessment	2A.4.10 Improvement	4.10 Improvement				4.10 Improvement		1.1, 2.11, 2.12, and 2.14

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PROCESS MANAGEMENT	**Technical Requirements General**	5.0 Technical Requirements	5.0 Technical Requirements			2A.5.1 General	5.1 General				5.1 General	5.1 Technical Requirements General	1.1
	Methods and Method Validation	5.4 Test and Calibration Methods and Method Validation	5.5 Examination Processes	Chap III Sec 18 Alternative Test Procedures Chap IV, V, and VI Sec 5 Analytical Methods Tables IV-2, 3, 4, and 5 Supplement 1 Microbiology Methodology	§493.1253 Establishment and Verification of Performance Specifications §493.1255 Calibration & Calib Verify Procedures Subpart K - Quality System for Non-Waived Testing	2A.5.4 Test Methods and Method Validation	5.4 Environmental Methods and Method Validation	§381.94 (a)(3) Analysis of Samples	§141.89 Analytical Methods §141.23 (k)(3)(i) Inorganic Chemical Sampling & Analytical Requirements §141.24 (f)(17)(i)(A) Organic Chemicals, Sampling & Analytical Requirements	Section F (Immunoassays) Section G (Chromatography/ Mass Spec.) G-13 (validation of LC mass spec) G-14 (val. records) Section H (GC/MS/MS), Section I-3+4, Section J (Biochem.), Section K (Testing of Other Exhibits) SOP Requirements (C3 - C5, C10 - C13)	5.4 Test and Calibration Methods and Method Validation 5.4.1.2 Suppl (Controls/ Stds specified) 5.4.2.1 Suppl (Document in-house validation against perf charact)	5.4 Test Methods	1.1 and 2.12 also, 2.4, 3.1, 2.11 2.6, 2.7, 2.9
	Traceability	5.6 Measurement Traceability	5.3.1.4 Equipment Calibration and Metrological Traceability	Chap IV Sec 7.1 General Requirements Chap IV Sec.4.1 Chemicals and Reagent Chap V Sec 3 Lab Equipment and Supplies Chap VI Sec 7.2 Balance and Weights	§493.1253 Establishment & Verification of Performance Specifications §493.1255(a)(2)(i) Calibration and Calibration Verification Procedures	2A.5.6 Measurement Traceability	5.6 Measurement Traceability			D-2 through D-4 (checking labels and specimen condition) D-9 and D10 (chain of custody) D-11 through D-12 (handling and retention)	5.6 Measurement Traceability 5.6.3.2.1 Suppl (BA cal ref materials labeled w/ID, prep date, lot) 5.6.3.2.2 Suppl (Ref materl traceable to national metrology institute)	5.6 Measurement Traceability	1.1, 2.5, 2.9, and 2.12
	Sampling	5.7 Sampling	5.4 Pre-examination Processes	Chap III Sec 11.4 Field Sampling Procedures Chap IV, V, and VI Sec 6 Sample Collection, Handling and Preservation Supplement 1 Chemistry Sample Collection Supplement 1 Microbiology Sample Collection	Handling and Referral	2A.5.7 Sampling		§381.146 Sampling at Official Establishments				5.7 Specimens	1.1 and 2.2-2.3
	Handling of Test and Calibration Items	5.8 Handling of Test and Calibration Items		Chap III Sec 11.5 Lab Sample Receipt & Handling Procedures Chap IV, V, and VI Sec 6 Sample Collection, Handling and Preservation	§493.1242 Standard: Specimen Submission, Handling, and Referral	2A.5.8 Handling of Test Items	5.8 Handling Samples and Test Items			Section D (Chain of Custody) E-11, E-12, E-17, E-18 (chromatography) G-3 - G-17 (controls and validation records Chroma/ MS)	5.8 Handling of Test and Calibration Items	5.8 Handling of Specimens	1.1 and 2.2-2.3

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PROCESS MANAGEMENT	**Assurances**	5.9 Assuring the Quality of Test and Calibration Results	5.3 Ensuring the quality of examination results	Chap III Sec 11.7 Analytical Procedures and 13.1 Proficiency Testing Samples Chap IV Sec 7.2 Specific Requirements Chap V Sec 7.2 QA Chap VI Sec 7.4 Proficiency Test Studies 7.7 Sample Measurement QC Requirements Plus QC Requirements of Individual Methods	Subpart H - Participation in Proficiency Testing for Laboratories Performing Non-waived Testing §493.1236 Standard: Evaluation of Proficiency Testing Performance §493.1256 Standard Control Procedures	2A.5.9 Assuring the Quality of Test Results	5.9 Quality Assurance for Environmental Testing	§318.21 (b)(3)(v) (Physical Testing Labs) §318.21 (c)(3)(v) (Chemical Testing Labs)	§141.23(k)(3)(i) §141.24(f)(17)(i)(A) §141.89(a)(1)(i)		5.9 Assuring the Quality of Test and Calibration Results 5.9.3 Suppl (Documented Program for Proficiency Testing) 5.9.4 Suppl (Proc for tech review of calibrn doc) 5.9.4.1 Suppl (Tech reviews by person w/ expertise) 5.9.5 Suppl (Admin review of calibrn record, cert, docs) no number Suppl (Scope of tech review and how documented)	5.9 Ensuring the Quality of Test Results	1.1, 2.4-2.6, 2.8-2.10 and 2.12
	Reporting Results	5.10 Reporting the Results	5.7 Post-examination processes 5.8 Reporting of results 5.9 Release of results	Chap III Sec 11.8 Data Reduction, Validation, Reporting, and Verification Chap IV, V, and VI Sec 8 Records and Data Reporting	§493.1291 Standard: Test Report	2A.5.10 Reporting the Results	5.10 Reporting the Results	§381.180 Info and reports required from Official Establishment Operators §381.181 Reports ... violations §381.182 Reports of Inspection Work	§141.31 Reporting Requirements §141.721 Reporting Requirements	E-21 through E-33 G-2 (Chromo/MS results in valid range) H-2 through H7 (LC/MS/MS, interpretation of results)	5.10 Reporting the Results	5.10 Reporting Test Results	2.7 and 2.10-2.43
	Integrity and Ethics		4.1.1.3 Ethical conduct	Appendix A Chain of Custody Evaluations Chap III Laboratory Ethics and Fraud Detection Deterrence (Supplement)	§493.1232 Standard: Specimen ID and Integrity		4.16 Data Integrity Investigations 5.2.7 Data Integrity Training			B-12			

Key

AAFCO: Association of American Feed Control Officials

AAVLD: American Association of Veterinary Laboratory Diagnosticians

ABFT: American Board of Forensic Toxicology

AIHA: American Industrial Hygiene Association

ASCLAD: American Society of Crime Lab Directors

CFR: Code of Federal Regulations

CLIA: Clinical Laboratory Improvement Amendment of 1988

DW Manual: Manual for the Certification of Laboratories Analyzing Drinking Water, 5th Edition plus Supplement

IEC: International Electrotechnical Commission

ISO: International Organization for Standardization

OSHA: Occupational Safety and Health Administration

TNI: The NELAC (National Environmental Laboratory Accreditation Conference) Institute

Note: 40 CFR Part 136 EPA Clean Water Regulations was reviewed but did not fit the format above, many of the components are included in method references.

Credit

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Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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