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Crosswalk of Regulations and Guidance Affecting Laboratories

Sorted by Quality System Essentials

About the Crosswalk

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.) are grouped by QSE. In some instances, terms and references appear in more than one QSE. For example, the QSE "Process Management" applies to pre-analytic, analytic and post-analytic 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, jump to the QSE sections using the Table of Contents, below; find the regulation categories/topics in the first column of the table and follow the line across the row to find the regulation reference or to view related regulations.

Key Terms

40 CFR 141 . National Primary Drinking Water Regulations

AAVLD ..... American Association of Veterinary Laboratory Diagnosticians

ABFT ..... American Board of Forensic Toxicology

AIHA ..... American Industrial Hygiene Association

ANAB AR ..... ANSI National Accreditation Board Accreditation Requirements

ANSI ..... American National Standards Institute

CAP ..... College of American Pathologists

CFR ..... Code of Federal Regulations

CLIA ..... Clinical Laboratory Improvement Amendments, 42 CFR, 493

DW Manual .. US Environmental Protection Agency (EPA) Laboratory Certification Manual for Drinking Water

IEC..... International Electrotechnical Commission

ISO ..... International Organization for Standardization

ISO/IEC 17025: 2017: General requirements for the competence of testing and calibration laboratories

ISO 15189: 2022: Medical laboratory requirements for quality and competence

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

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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 health threats.

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Introduction

Regulation Category	ISO/IEC 17025: 2017	ISO 15189: 2022	DW Manual (EPA 815), 2005	CLIA, 2024	AIHA LAP Main Checklist, 2023	TNI, 2016	40 CFR 141	ABFT Checklist 2023	AAVLD	ANAB AR 3125	CAP 2024 Lab General	CAP 2024 All Common
Scope	1 Scope	1 Scope	Chap 1: Introduction	§493.1 Basis & Scope	2A.1 Scope	Module 2, 1.2 Scope	§141.1 Applicability	• A-1 (written mission statement) • C-3	Page 3 (Mission Statement and list of Objectives)	1.1 Scope	Introduction	Introduction
References	2 Normative References	2 Normative References	Footnotes: Chap IV, Chap V and Chap VI	N/A	2A.2 Normative References	Module 2, 2.0 Normative References	§141.131(a)(2) Analytical requirements	None Provided	N/A	2 References	N/A (in each Tag)	N/A (in each Tag)
Terms and Definitions	3 Terms and Definitions	3 Terms and Definitions	Appendix C: Definitions and Abbreviations	§493.2 Definitions	2A.3 Terms and Definitions	Module 2, 3.0 Terms and Definitions	§141.2 Definitions	Provided throughout as deemed necessary	Appendix 2: Glossary of Terms	3 Terms and Definitions	Definition of Terms	Definition of Terms

Organization and Leadership

Regulation Category	ISO/IEC 17025: 2017	ISO 15189: 2022	DW Manual (EPA 815), 2005	CLIA, 2024	AIHA LAP Main Checklist, 2023	TNI, 2016	40 CFR 141	ABFT Checklist 2023	AAVLD	ANAB AR 3125	CAP 2024 Lab General	CAP 2024 All Common
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Management System (QA System)	8 Management System Requirements	8 Management System Requirements	• 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.8.10 Management System Requirements (Option B)	Module 2, 4.2 Management	N/A	Section E. Quality Assurance and Quality Control and Reporting	4.2 Quality System	8.1.3 Additional Option B requirements	Quality Management System	Quality Management

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Management Reviews (Effectiveness of system)	8.9 Management Reviews	8.9 Management Reviews	N/A	• §493.1239 (b), Standard: General Laboratory Systems Quality Assessment • §493.1249(b), Standard: Preanalytic Systems Quality Assessment • §493.1289(b), Standard: Analytic Systems Quality Assessment • §493.1299(b), Standard: Postanalytic Systems Quality Assessment	2A.8.9 Management Reviews	Module 2, 4.15 Management Reviews	N/A	C-4, C-6, C-7, C-9, C-13	4.12 Management Reviews	8.9.1.1 Annual Review Requirement	Quality Management System	Quality Management
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Customer Focus

Regulation Category	ISO/IEC 17025: 2017	ISO 15189: 2022	DW Manual (EPA 815), 2005	CLIA, 2024	AIHA LAP Main Checklist, 2023	TNI, 2016	40 CFR 141	ABFT Checklist 2023	AAVLD	ANAB AR 3125	CAP 2024 Lab General	CAP 2024 All Common
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Safety (Labs follow the various subparts of OSHA 29 CFR 1910 for safety)	N/A	6.3.2 Facility Controls	• Chap IV, Sec 4.4 Lab Safety • Chap V, Sec 4 General Lab Practices—Intro • Chap VI, Sec 4.4 Safety	• §493.1101 Standard: Facilities • §493.1804 General Considerations	2A.9 Safety and Health	N/A	N/A	Section L. Safety	N/A	N/A	Laboratory Safety	N/A

Personnel Management

Regulation Category	ISO/IEC 17025: 2017	ISO 15189: 2022	DW Manual (EPA 815), 2005	CLIA, 2024	AIHA LAP Main Checklist, 2023	TNI, 2016	40 CFR 141	ABFT Checklist 2023	AAVLD	ANAB AR 3125	CAP 2024 Lab General	CAP 2024 All Common
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Supplier and Inventory Management

Regulation Category	ISO/IEC 17025: 2017	ISO 15189: 2022	DW Manual (EPA 815), 2005	CLIA, 2024	AIHA LAP Main Checklist, 2023	TNI, 2016	40 CFR 141	ABFT Checklist 2023	AAVLD	ANAB AR 3125	CAP 2024 Lab General	CAP 2024 All Common
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Sub-contracting	6.6 Externally provided products and services	• 6.6 Reagents and Consumables • 6.7 Service Agreements • 6.8 Externally provided products and services	Appendix A Chain of Custody Procedures	§493.1242 Standard: Specimen Submission Handling and Referral	2A.6.6 Externally Provided Products and Services	Module 2, 4.5 Subcontracting of Environmental Tests	N/A	E-41 Reference Laboratories	4.5 Subcontracting of Test Services	N/A	Results Reporting and Referral of Testing	N/A
Purchasing	• 6.6 Externally provided products and services • 7.1 Review of requests, tenders, and contracts	• 6.6 Reagents and Consumables • 6.7 Service Agreements • 6.8 Externally provided products and services • 7.1 General • 7.2 Pre-examination processes	• Chap IV Sec 4.1.1 Chap VI Sec 4.1	• §493.1252 Standard: Test systems, equipment, instruments, reagents, materials and supplies	2A.6.6 Externally Provided Products and Services	Module 2, 4.6 Purchasing Services and Supplies	N/A	E-13, E-14, E-23 Reagent and Standard Verification	4.6 Purchasing Services and Supplies	N/A	N/A	Reagents Instruments and Equipment
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Equipment Management

Regulation Category	ISO/IEC 17025: 2017	ISO 15189: 2022	DW Manual (EPA 815), 2005	CLIA, 2024	AIHA LAP Main Checklist, 2023	TNI, 2016	40 CFR 141	ABFT Checklist 2023	AAVLD	ANAB AR 3125	CAP 2024 Lab General	CAP 2024 All Common
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Process Management

Regulation Category	ISO/IEC 17025: 2017	ISO 15189: 2022	DW Manual (EPA 815), 2005	CLIA, 2024	AIHA LAP Main Checklist, 2023	TNI, 2016	40 CFR 141	ABFT Checklist 2023	AAVLD	ANAB AR 3125	CAP 2024 Lab General	CAP 2024 All Common
Technical Requirements General	• 8.1.1 Management system requirements, general • 8.1.2, Option A	8.1 General Requirements	N/A	N/A	2A.8.1 Options	Module 2, 5.1 General	N/A	• Section G • Section H • Section I • Section J • Section K	N/A	7.0 Process Requirements	Quality Management System	Quality Management—General Issues
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Assurances	7.7 Ensuring the Validity of Results	7.3.7 Ensuring the Validity of Examination Results	• Chap III ◦ Sec 11.7 Analytical Procedures ◦ Sec 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.7.7 Ensuring the validity of results	Module 2, 5.9 Quality Assurance for Environmental Testing	• §141.23 Inorganic chemical sampling and analytical requirements • §141.24 Organic chemicals, sampling and analytical requirements • §141.89 Analytical Methods	• Section D (Chain of Custody) • Section E (Quality Assurance) • G-11 (New Assay Validation)	5.9 Ensuring the Quality of Test Results	7.7 Ensuring the validity of results	Quality Management System	Proficiency Testing
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Documents and Records Management

Regulation Category	ISO/IEC 17025: 2017	ISO 15189: 2022	DW Manual (EPA 815), 2005	CLIA, 2024	AIHA LAP Main Checklist, 2023	TNI, 2016	40 CFR 141	ABFT Checklist 2023	AAVLD	ANAB AR 3125	CAP 2024 Lab General	CAP 2024 All Common
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Information Management

Regulation Category	ISO/IEC 17025: 2017	ISO 15189: 2022	DW Manual (EPA 815), 2005	CLIA, 2024	AIHA LAP Main Checklist, 2023	TNI, 2016	40 CFR 141	ABFT Checklist 2023	AAVLD	ANAB AR 3125	CAP 2024 Lab General	CAP 2024 All Common
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Reporting Results	7.8 Reporting of Results	7.4.1 Reporting 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	N/A	Module 2, 5.10 Reporting the Results	• §141.31 Reporting Requirements • §141.721 Reporting Requirements	• E-31, E-32, E-37—E-41 (General Report) • G-2, G-4, G-10 (Chromo/MS results in valid range)	5.10 Reporting Test Results	7.8 Reporting of Results	Results Reporting and Referral of Testing	Results Reporting

Nonconforming Event Management

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Assessments

Regulation Category	ISO/IEC 17025: 2017	ISO 15189: 2022	DW Manual (EPA 815), 2005	CLIA, 2024	AIHA LAP Main Checklist, 2023	TNI, 2016	40 CFR 141	ABFT Checklist 2023	AAVLD	ANAB AR 3125	CAP 2024 Lab General	CAP 2024 All Common
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Management Reviews (Effectiveness of system)	8.9 Management Reviews (Option A)	8.9 Management Reviews	N/A	• §493.1239 (b), Standard: General Laboratory Systems Quality Assessment • §493.1249(b), Standard: Preanalytic Systems Quality Assessment • §493.1289(b), Standard: Analytic Systems Quality Assessment • §493.1299(b), Standard: Postanalytic Systems Quality Assessment	2A.8.9 Management Reviews	Module 2, 4.15 Management Reviews	N/A	• C-6—C-7 (Management Review of SOPs) • E-8 (Management Review of Controls) • E-17 (Proficiency Testing Review)	4.12 Management Reviews	8.9 Management Reviews (Option A)	Quality Management System	Quality Management
Assurances	7.2 Ensuring the validity of results	7.3.7 Ensuring the Validity of Examination Results	• Chap III ◦ Sec 11.7 Analytical Procedures ◦ Sec 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 ◦ Sec 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	Module 6 Proficiency Testing and Round Robin Programs	• Module 1, Proficiency Testing • Module 2, 5.9 Quality Assurance for Environmental Testing	Subpart C—Monitoring and Analytical Requirements	• Section D (Chain of Custody) • Section E (Quality Assurance) • G-11 (New Assay Validation)	5.9 Ensuring the Quality of Test Results	7.7 Ensuring the validity of results	N/A	Proficiency Testing

Continual Improvement

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