LabLynx

LIMS Selection Workbook

for Clinical Diagnostics & Research Labs

2022 VERSION 1

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Clinical Research

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Overview

When planning a project of any type, it makes perfect sense to initially research and detail the specifics of the project to lay a solid foundation to work from. This is particularly true with software development, where careful initial planning is vital to ensuring the project is legitimate in the eyes of critical stakeholders and will meet specified goals. This demands the creation of a software requirements specification.

In the scope of developing and distributing a laboratory information management system (LIMS), the developer and distributor (i.e., the vendor) has a head-start on the targeted end user: the vendor has a standard to turn to in its requirements development. On the other hand, the laboratory seeking a LIMS doesn't really have such a standard for developing a set of requirements for their acquisition, and many labs won't even know they should develop a set of LIMS requirements before engaging in the acquisition process.

At its core, the LIMS Selection Workbook—which has seen several iterations over the years—is rooted in ASTM E1578-18 *Standard Guide for Laboratory Informatics* and is an example of typical requirements that can be used to guide the purchase, upgrade, or development of a laboratory informatics system, though it is certainly not meant to be exhaustive.

An attempt has been made to find the most relevant regulations, standards, and guidance that shape how a compliant laboratory informatics system is developed and maintained. This revision (2022) taps into more than 100 resources. Each requirement statement has at least one linked regulation, standard, or guidance item.

Primary Laboratory Workflow

1. Sample and experiment registration

Regulation, Specification, or Guidance	Requirement	Response
42 CFR Part 493.1241 APHL 2019 LIS Project Management Guidebook ASTM E1578-18 C-1-1	**1.1** The system should allow for sample registration prior to (e.g., preregistration) or after (e.g., registration) physical sample collection.	
21 CFR Part 58.105 (c) 21 CFR Part 211.84 21 CFR Part 211.101 21 CFR Part 226.80 21 CFR Part 606.120 (b) 21 CFR Part 606.121 (c–i) 21 CFR Part 606.140 (c) 29 CFR Part 1910.1030 (g) 29 CFR Part 1910.1096 (e1-6) 42 CFR Part 493.1232 ABFT Accreditation Manual Sec. D	**1.2** The system should allow for creation and use of pre-configured (e.g., for basic clinical samples) and customizable (e.g., for regulated activities such as blood collection and storage) sample labels, with barcode support.	

APHL 2019 LIS Project Management Guidebook ASTM E1492-11 4.1.1.6 ASTM E1578-18 C-1-2 CLSI QMS22 2.2.1.2 EPA ERLN Laboratory Requirements 3.2.2 EPA QA/G-5 2.2.3 E.U. Commission Directive 2003/94/EC Article 15 OECD GLP Principles 6.1 TNI EL-V1-2016-Rev.2.1 (V1,M2 5.8.6) USDA Sampling Procedures for PDP 6.4.1.2.6 WHO Technical Report Series, #986, Annex 2, 17.11		
45 CFR Part 162.410 CJIS Security Policy 5.6.1	**1.3** The system shall provide a means to assign unique identifiers such as a National Provider Identifier (NPI) or Originating Agency Identifier (ORI) to the enacting entity and any subcontracted entity. The unique identifier should be able to appear on necessary records, documents, and reports referencing those entities.	
42 CFR Part 493.1241 ASTM E1578-18 C-1-3	**1.4** The system should provide a means for automatically registering samples in the system using any number of triggers such as dates, times, web requests, and intra-system methods like APIs and web services.	
7 CFR Part 91.19 40 CFR Part 262.18 ACMG Technical Standards for Clinical Genetics Laboratories C2.1 APHL 2019 LIS Project Management Guidebook ASTM E1578-18 C-1-4 USDA Sampling Procedures for PDP 6.4.1.1.3	**1.5** The system should permit unique metadata like lot number, patient number, family identifier, client or patient demographics, sampling point, random selection process used, and industry-specific items (like EPA identification number) to be included during registration.	
ASTM E1578-18 C-1-5	**1.6** The system shall allow for the addition, modification, and removal of new, pre-defined, and custom analytical tests.	
ASTM E1578-18 C-1-6	**1.7** The system should offer safety information related to a submitted sample upon registration that is relevant to the lab's location and industry.	

ASTM E1578-18 C-1-7	**1.8** The system should support the creation and use of predefined metadata templates, as well as ad-hoc, single, and multiple samples.	
7 CFR Part 91.19 7 CFR Part 331.17 9 CFR Part 121.17 21 CFR Part 58.105 (c) 21 CFR Part 58.195 21 CFR Part 211.84 21 CFR Part 211.170 21 CFR Part 211.194 21 CFR Part 312.57 (d) 40 CFR Part 141.33 42 CFR Part 73.17 42 CFR Part 493.1105 42 CFR Part 493.1241 42 CFR Part 493.1242 42 CFR Part 493.1274 (f) 42 CFR Part 493.1283 AAFCO QA/QC Guidelines for Feed Laboratories Sec. 2.2–3 AAVLD Requirements for an AVMDL Sec. 5.7.1.2 ABFT Accreditation Manual Sec. D ACMG Technical Standards for Clinical Genetics Laboratories C2 ASTM E1578-18 C-1-8 CLSI QMS22 2.2.1.3 EPA 815-R-05-004 Chap. IV, Sec. 6 and 8 EPA 815-R-05-004 Chap. VI, Sec. 8 EPA 815-R-05-004 Supplement 1 EPA ERLN Laboratory Requirements 3.2 EPA ERLN Laboratory Requirements 4.4.10–11 EPA ERLN Laboratory Requirements 4.7.1–6 EPA QA/G-5 2.2.2 and 2.2.3 E.U. Commission Directive 2003/94/EC Article 11.4 ISO 15189:2012 5.7.2 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards OECD GLP Principles 6.1 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 5.8.6) USDA Sample Processing and Analysis Procedures for PDP 5.1 and 5.1.13 USDA Sampling Procedures for PDP 5.1	**1.9** The system shall be able to define the collection details for registered samples or specimens, including container size and type, number of containers, collection date and time, temperature, name of the collector, lot number, storage location, preservation method, collection methods used (standard and nonstandard), safety concerns, and retention period.	

WHO Technical Report Series, #986, Annex 2, 17.11 and 17.21		
ASTM E1578-18 C-1-9 ACMG Technical Standards for Clinical Genetics Laboratories G1.4 CLSI QMS22 2.2.1.3 EPA ERLN Laboratory Requirements 3.2.1 EPA ERLN Laboratory Requirements 4.4.5	**1.10** The system should allow for the addition of observations and descriptions to registered samples in the form of free text.	
ASTM E1578-18 C-1-10	**1.11** The system should support the creation of user-definable default sample registration preferences and/or input screens.	
ASTM E1578-18 C-1-11 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 5.8.7) WADA International Standard for Laboratories (ISL) 5.3.2	**1.12** The system should allow for the recording of sample delivery details such as deliverer, location, and date and time for a preregistered sample.	
21 CFR Part 58.107 (c) 21 CFR Part 211.194 42 CFR Part 493.1241 42 CFR Part 493.1274 42 CFR Part 493.1283 AAVLD Requirements for an AVMDL Sec. 5.8.2 ABFT Accreditation Manual D-3 ASTM E1578-18 C-1-12 CAP Laboratory Accreditation Manual EPA ERLN Laboratory Requirements 3.2.2 EPA ERLN Laboratory Requirements 4.1.11 EPA ERLN Laboratory Requirements 4.4.10 EPA QA/G-5 2.2.3 E.U. Commission Directive 2003/94/EC Article 15 ISO/IEC 17025:2017 7.4.2 OECD GLP Principles 6.2 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 5.8.5) USDA Sample Processing and Analysis Procedures for PDP 5.1.11 USDA Sampling Procedures for PDP 6.4.1.2.5 WADA International Standard for Laboratories (ISL) 5.3.2	**1.13** The system shall assign each sample registered in the system a unique identifier using methodologies such as an ID with an incrementing integer or a user-defined naming format.	

WHO Technical Report Series, #986, Annex 2, 17.11		
7 CFR Part 331.17 9 CFR Part 121.17 21 CFR Part 58.107 (d) 21 CFR Part 211.194 42 CFR Part 73.17 ASTM E1578-18 C-1-13 CAP Laboratory Accreditation Manual CLSI QMS22 2.2.1.3 EPA ERLN Laboratory Requirements 4.4.7 EPA QA/G-5 2.2.3 OECD GLP Principles 6.1 TNI EL-V1-2016-Rev.2.1 (V1,M2 5.8.3)	**1.14** The system shall provide a user-friendly means for tracking and acknowledging the physical reception of submitted sample or specimen material in the laboratory, including date and time of reception.	
ASTM E1578-18 C-1-14 EPA ERLN Laboratory Requirements 4.4.6	**1.15** The system shall allow for the comparison of received samples to the sampling requirements of the customer or laboratory in order to identify variances from those requirements.	
ACMG Technical Standards for Clinical Genetics Laboratories C3.3 AAVLD Requirements for an AVMDL Sec. 5.8.3 ASTM E1492-11 4.1.1.5 ASTM E1492-11 4.1.6 ASTM E1492-11 4.3.3.2 ASTM E1578-18 C-1-15 CAP Laboratory Accreditation Manual CLSI QMS22 2.2.1.3 EPA ERLN Laboratory Requirements 4.4.13 EPA ERLN Laboratory Requirements 4.11.8 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 5.8.7.2) USDA Sample Processing and Analysis Procedures for PDP 5.1.3–7 USDA Sampling Procedures for PDP 6.4.1.1.9 WADA International Standard for Laboratories (ISL) 5.3.2 and 5.3.3.1	**1.16** The system should provide a means to document any undesirable or unexpected characteristics of a submitted sample.	

A2LA C211 5.7 ASTM E1578-18 C-1-16 EPA QA/G-5 2.2.2 and 2.2.3	**1.17** The system should provide a means to document sample preparation activities for a given sample.	
7 CFR Part 331.11 7 CFR Part 331.17 9 CFR Part 121.11 9 CFR Part 121.17 42 CFR Part 73.11 42 CFR Part 73.17 42 CFR Part 493.1274 A2LA C223 4.13 A2LA C223 5.8 ABFT Accreditation Manual Sec. D-9–10 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.8.1.1 ASTM E1492-11 (throughout) ASTM E1578-18 C-1-17 CLSI QMS22 2.2.3.5 EPA 815-R-05-004 Chap. III, Sec. 12 EPA 815-R-05-004 Appendix A EPA ERLN Laboratory Requirements 3.2.3–5 EPA ERLN Laboratory Requirements 4.1.13 EPA ERLN Laboratory Requirements 4.4.8–9 EPA QA/G-5 2.2.3 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 5.8.7.5 and 5.8.8) WADA International Standard for Laboratories (ISL) (throughout)	**1.18** The system shall have the ability to maintain the chain of custody of every sample, meaning the recording of every single sample distribution step to personnel—including details such as unique identifier, name, location, date, and time—while the sample is in the laboratory's possession.	
7 CFR Part 331.16 9 CFR Part 121.16 42 CFR Part 73.16	**1.19** In the case of regulated samples (e.g., select agent or toxin, cannabis, etc.), the system shall also allow for the recording of transfers to other entities outside the laboratory, including details such as personnel involved, their certification numbers (if applicable), dates, times, and any other required information.	
ACMG Technical Standards for Clinical Genetics Laboratories G1.1 APHL 2019 LIS Project Management Guidebook	**1.20** The system shall be able to link various records together based on a record's metadata, including sample or specimen identifier, patient number, or family identifier.	

2. Sample management

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 C-2-1 EPA ERLN Laboratory Requirements 4.11.14	**2.1** The system shall record and maintain the chain of custody for the laboratory's standards and reagents.	
ASTM E1578-18 C-2-2 EPA ERLN Laboratory Requirements 4.11.14	**2.2** The system shall record the current and historical storage location for the laboratory's standards and reagents.	
ASTM E1578-18 C-2-3 EPA ERLN Laboratory Requirements 4.11.14	**2.3** The system shall allow the laboratory's previously standardized standards and reagents to be assigned a new standard value.	
ASTM E1578-18 C-2-4 EPA ERLN Laboratory Requirements 4.11.14	**2.4** The system shall require the recording of a standard and reagent's first opening date.	
ASTM E1578-18 C-2-5 EPA ERLN Laboratory Requirements 4.11.14	**2.5** The system shall allow only active standards and reagents to be shown as available for use.	
ASTM E1578-18 C-2-6 EPA ERLN Laboratory Requirements 4.11.14	**2.6** The system shall allow standards and reagents to be flagged as no longer available for use by authorized personnel.	
ASTM E1578-18 C-2-7	**2.7** The system shall allow logically associated samples or specimens to be grouped	

	together based on associated metadata such as type, test method, assigned user, and status.	
ASTM E1578-18 C-2-8 EPA ERLN Laboratory Requirements 3.2 ISO/IEC 17025:2017 7.4.2	**2.8** The system should allow for the accurate identification of a physical sample or specimen in the system via barcode or RFID technology.	
7 CFR Part 331.17 9 CFR Part 121.17 21 CFR Part 211.84 42 CFR Part 73.17 ASTM E1492-11 4.2.1 ASTM E1578-18 C-2-9 CAP Laboratory Accreditation Manual	**2.9** The system should provide a means to manually or automatically track sample or specimen inventory amounts and status.	
A2LA C211 5.4 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.9.1.1 ASTM E1578-18 C-2-10	**2.10** The system shall be able to link test methods and specifications to standards and reagents.	
21 CFR Part 211.84 21 CFR Part 211.166–7 21 CFR Part 211.194 (e) 21 CFR Part 212.40 (c) 21 CFR Part 212.61 21 CFR Part 212.70 (e) 21 CFR Part 225.58 21 CFR Part 226.58 21 CFR Part 606.65 (c) 21 CFR Part 606.151 A2LA C223 5.9 ACMG Technical Standards for Clinical Genetics Laboratories C6.2 ACMG Technical Standards for Clinical Genetics Laboratories C10–12 CAP Laboratory Accreditation Manual ASTM E1578-18 C-2-11 EPA ERLN Laboratory Requirements 3.1.2.1 EPA ERLN Laboratory Requirements 4.3.2 EPA ERLN Laboratory Requirements 4.11.3.2 EPA QA/G-5 2.2.5 NYSDOH CLEP Clinical Laboratory Standards of Practice, General	**2.11** The system shall allow samples, specimens, and tests to be created and used specifically for capturing data related to unique forms of sampling and testing such as representative sampling, calibration testing, quality control testing, preventative maintenance testing, stability testing, sterility testing, remediated testing, compatibility testing, identity testing, proficiency testing, and service-event-related testing.	

Systems Standards NYSDOH ELAP Medical Marijuana Microbiology Guidance PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M1 1.1) USDA Administrative Procedures for the PDP 8.5 USDA Hemp Production Program Laboratory Testing Guidelines, Testing Remediated Hemp Samples 2 USDA LAS Laboratory Approval Program (LAP) Policies and Procedures 12.4h WADA International Standard for Laboratories (ISL) 5.3.7 WHO Technical Report Series, #961, Annex 13, 12.1 WHO Technical Report Series, #986, Annex 2, 17.7 WHO Technical Report Series, #986, Annex 2, 17.22–25		

3. Core laboratory testing and experiments

Regulation, Specification, or Guidance	Requirement	Response
21 CFR Part 211.84 (d) ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.1.3.1 ASTM E1578-18 C-3-1 CLSI QMS22 2.2.2.1 ISO 15189:2012 5.3.2.7 WADA International Standard for Laboratories (ISL) 5.2.7	**3.1** The system shall be able to record the identity of any standards and reagents used in laboratory testing, as well as for each sample or test during result entry. Linked to their identity should also be manufacturer and supplier information (such as certificates of testing); lot numbers; reception, preparation, and expiry dates; name of preparer; reliability testing results; and approval for use.	
21 CFR Part 211.84 (e) 42 CFR Part 493.1252 (d) ASTM E1578-18 C-3-2 WADA International Standard for Laboratories (ISL) 5.2.7	**3.2** The system shall allow users to only select approved, non-expired standards and reagents for tests and experiments.	

42 CFR Part 493.1252 (d) ASTM E1578-18 C-3-3	**3.3** The system shall prevent standards, reagents, and other media from being used in testing if they would expire during the testing.	
ASTM E1578-18 C-3-4	**3.4** The system shall be able to check physical, control, and specification limits for an instrument sample.	
ASTM E1578-18 C-3-6	**3.5** The system should allow result entry for all tests linked to a single sample, as well as for multiple samples linked to a single test.	
ASTM E1578-18 C-3-7	**3.6** The system should allow user-definable result entry methods, e.g., uploading from a spreadsheet.	
ASTM E1578-18 C-3-8	**3.7** The system should allow outsourced samples to be tracked for aliquoting, chain-of-custody, results entry, and approval purposes.	
ASTM E1578-18 C-3-9	**3.8** The system shall allow the creation and assignment of retest workflow, while allowing the system or assigned user to determine the existence of a retesting due date and whether or not a new sample is required for the retest.	
ASTM E1578-18 C-3-10	**3.9** The system shall support, at a minimum, the floating point/real number, integer number, text, date, list, file, calculated, Boolean, and interval test result data types, allowing users to define the data type for specific test results.	

AIHA-LAP Policies 2022 2A.7.8.2 ASTM E1578-18 C-3-11	**3.10** The system shall allow users to enter operators such as <, >, +, and - with numeric test results.	
ASTM E1578-18 C-3-12	**3.11** The system should allow inter- and intra-assay calculations to be performed, including the use of advanced math functions.	
42 CFR Part 493.1241 ASTM E1578-18 C-3-13 EPA ERLN Laboratory Requirements 4.9.11	**3.12** The system should effectively alert users upon entry of out-of-specification test results.	
21 CFR Part 211.194 21 CFR Part 212.60 (g) 21 CFR Part 606.160 ACMG Technical Standards for Clinical Genetics Laboratories G16.1 A2LA C223 5.10 ASTM E1578-18 C-3-14 CLSI QMS22 2.1.2 CLSI QMS22 2.2.2.1 EPA ERLN Laboratory Requirements 3.1.2.3–4 EPA ERLN Laboratory Requirements 3.2 EPA ERLN Laboratory Requirements 4.3.4 EPA ERLN Laboratory Requirements 4.8.1–4 EPA ERLN Laboratory Requirements 4.11.16 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards PFP Human and Animal Food Testing Laboratories Best Practices Manual USDA Data and Instrumentation for PDP 5.4.2 USDA Data and Instrumentation for PDP 8.1.3 WHO Technical Report Series, #986, Annex 2, 15.8	**3.13** The system shall be able to record a complete record of all data created in the course of a test or experiment, including instruments used, calculations performed, and associated graphs, charts, and spectra. The record should also be able to capture the signatures of those who performed the test or experiment, as well as those who reviewed the record for compliance purposes.	
WADA International Standard for Laboratories (ISL) 1.2	**3.14** The system shall allow users to link samples, specimens, and tests to a specific accreditation approval status (e.g., World Anti-Doping Agency accreditation) so as to ensure that only the	

	appropriate accreditation labels are included on resulting test reports and related documentation.	

4. Results review and verification

Regulation, Specification, or Guidance	Requirement	Response
21 CFR Part 211.68 (b) 42 CFR Part 493.1241 ASTM E1578-18 C-4-1 CAP Laboratory Accreditation Manual CLSI QMS22 2.2.1.2 EPA ERLN Laboratory Requirements 4.9.11 EPA QA/G-5 2.4.1 ISO 15189:2012 5.5.1.4 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards WHO Technical Report Series, #996, Annex 5, Appendix 1	**4.1** The system shall allow for the verification of specification limits for accuracy or tolerances while indicating to the user when values are exceeded.	
ASTM E1578-18 C-4-2 CLSI AUTO15 1.2 EPA ERLN Laboratory Requirements 4.9.2 EPA ERLN Laboratory Requirements 4.9.11 EPA QA/G-5 2.4.1 ISO 15189:2012 5.9.2 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards	**4.2** The system shall have the capability of automatically authorizing verification check tests and samples if they are within specification limits set by the instruments used to perform the tests.	
21 CFR Part 211.68 21 CFR Part 211.100 21 CFR Part 211.160 (a) 21 CFR Part 211.188 21 CFR Part 211.194 45 CFR Part 170.315 (d) ASTM E1578-18 C-4-3 CAP Laboratory Accreditation Manual CJIS Security Policy 5.4.1.1 CLSI QMS22 2.2.2.2 EPA ERLN Laboratory Requirements 4.9.1 and 4.9.7 E.U. Commission Directive 2003/94/EC Article 9.2 ICH GCP 4.9.0 and 4.9.3	**4.3** The system shall accurately maintain a full audit trail for modified results.	

TNI EL-V1-2016-Rev.2.1 (V1,M2 4.13.2.3) WADA International Standard for Laboratories (ISL) 5.2.3.5 WHO Technical Report Series, #986, Annex 2, 15.7 and 15.9 WHO Technical Report Series, #996, Annex 5, 4.12		
21 CFR Part 211.68 (b) A2LA C211 5.9.1 A2LA C223 4.13 ABFT Accreditation Manual Sec. E-28–29 ACMG Technical Standards for Clinical Genetics Laboratories G15.1 AIHA-LAP Policies 2022 2A.7.7.2 and 7.7.3 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 4.13.2.12 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.9.4–5 ASTM E1578-18 C-4-4 CAP Laboratory Accreditation Manual CLSI QMS22 2.2.2.2 EPA ERLN Laboratory Requirements 3.2.6 EPA ERLN Laboratory Requirements 4.9.2–3 and 4.9.11 EPA ERLN Laboratory Requirements 4.11.4 EPA QA/G-5 2.2.10 EPA QA/G-5 2.4.1 E.U. Annex 11-6 ISO 15189:2012 5.7.1 ISO/IEC 17025:2017 7.8.1.1 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards PFP Human and Animal Food Testing Laboratories Best Practices Manual USDA Data and Instrumentation for PDP 10 WADA International Standard for Laboratories (ISL) 5.3.8.1 WHO Technical Report Series, #996, Annex 5, 11.9 and Appendix 1	**4.4** The system shall provide one or more levels of review, as well as interpretation and documentation of results—whether entered manually or via an automated process—before release.	
ASTM E1578-18 C-4-5 EPA ERLN Laboratory Requirements 4.9.11 EPA QA/G-5 2.2.10 EPA QA/G-5 2.4.1 E.U. Annex 11-6 ISO 15189:2012 5.9.2 NYSDOH CLEP Clinical Laboratory	**4.5** The system shall identify out-of-range results and clearly alert the appropriate individuals for further evaluation of the results.	

Standards of Practice, General Systems Standards WHO Technical Report Series, #996, Annex 5, Appendix 1		
ASTM E1578-18 C-4-6 EPA QA/G-5 2.2.10 EPA QA/G-5 2.4.1 E.U. Annex 11-6	**4.6** The system shall allow for the comparison of entered results with pre-defined specification limits from master data, clearly alerting the user when the results exceed those specification limits.	
CAP Laboratory Accreditation Manual CLSI AUTO15 4.0 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards	**4.7** The system's autoverification system should be able to be validated and have a rapid means to automatically or manually shut it down in the event of a problem or manual changes being made to the autoverification system. The autoverification should be able to be revalidated afterwards.	

5. Sample, experiment, and study approval and verification

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 C-5-1 CAP Laboratory Accreditation Manual CLSI QMS22 2.2.3.5 USDA Sample Processing and Analysis Procedures for PDP 5.9–10 WADA International Standard for Laboratories (ISL) 5.3.12.1	**5.1** The system shall accurately record details of a sample or specimen's final disposition.	
AIHA-LAP Policies 2022 2A.7.7.2 ASTM E1578-18 C-5-2 CLSI QMS22 2.2.2.2 EMA Guidance on Good Manufacturing Practice and Good Distribution Practice WHO Technical Report Series, #996, Annex 5, 4.12	**5.2** The system should allow authorized personnel to view relevant metadata for results during the review and approval process, including the instruments and reagents used, raw data from instruments, and associated reports.	

21 CFR Part 211.160 (b) ASTM E1578-18 C-5-3 EPA 815-R-05-004 Chap. IV, Sec. 6.1	**5.3** The system should provide appropriate functions for specific sample statuses like "approved" and "rejected," including the ability to handle re-test, re-sampling, re-calculation, out-of-specification response and notification, and disposition functions.	

6. Reporting

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 C-6-1	**6.1** The system shall be able to store files in an electronic format and link them to standards, reagents, and samples tested.	
EPA ERLN Laboratory Requirements 3.4 EPA ERLN Laboratory Requirements 4.1.4 EPA ERLN Laboratory Requirements 4.12–15	**6.2** The system shall be able to export data in a computer-readable (importable into a relational database) format—such as an unformatted spreadsheet, comma-separated value (CSV) file, or extensible markup language (XML) file—as well as PDF format, for reporting purposes.	
42 CFR Part 493.1291 (g) and (h) ACMG Technical Standards for Clinical Genetics Laboratories F7.2 ASTM E1578-18 C-6-2 CLSI QMS22 2.1.2.1 EPA ERLN Laboratory Requirements 4.11.4 EPA QA/G-5 2.4.2 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards	**6.3** The system shall alert stakeholders in advance to cases when the analyzed sample may be out-of-specification or may not meet expected turnaround time requirements.	

ABFT Accreditation Manual Sec. G-2	**6.4** The system shall allow an authorized individual to report final results in a semi-quantitative manner (e.g., "less than X mg/L") when doing so would provide relevant information to the report recipient.	
7 CFR Part 91.25 40 CFR Part 141.33 42 CFR Part 493.1291 (c–e) AAFCO QA/QC Guidelines for Feed Laboratories Sec. 2 AAVLD Requirements for an AVMDL Sec. 5.4.2.1 AAVLD Requirements for an AVMDL Sec. 5.10.2–5 AIHA-LAP Policies 2022 2A.7.8.1 ABFT Accreditation Manual Sec. E-12 and -32 ASTM E1578-18 C-6-3 EPA 815-R-05-004 Chap. IV, Sec. 6.6 and 8 EPA 815-R-05-004 Chap. VI, Sec. 8 ISO 15189:2012 4.5.2 ISO 15189:2012 5.8.3 ISO/IEC 17025:2017 7.5.1 ISO/IEC 17025:2017 7.8.1.1 ISO/IEC 17025:2017 7.8.2.1 ISO/IEC 17025:2017 7.8.3.1 PFP Human and Animal Food Testing Laboratories Best Practices Manual USDA LAS Laboratory Approval Program (LAP) Policies and Procedures 12.4d WHO Technical Report Series, #986, Annex 2, 15.43	**6.5** The system shall substantiate the status of verified results by using tools like a certificate of analysis, which shall include details like unique identifiers; analysis procedures used; reference intervals; environmental conditions; who provided the results; additional comments, opinions, and interpretations and who provided them; and applicable times and dates.	
7 CFR Part 91.26–27 ASTM E1578-18 C-6-4	**6.6** The system shall allow a certificate of analysis to be generated upon the verification and approval of results and associated metadata by authorized personnel.	
A2LA C211 5.10 ASTM E1578-18 C-6-5 CLSI QMS22 2.2.3 ISO 15189:2012 5.8.1 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards PFP Human and Animal Food Testing Laboratories Best Practices Manual	**6.7** The system shall provide the ability to clearly and accurately generate reports for a variety of standard situations, including certificates of analysis from testing, patient results, pending samples for approval, out-of-specification samples and tests, instruments pending calibration, expired	

TNI EL-V1-2016-Rev.2.1 (V1,M2 5.10) USDA Hemp Production Program Laboratory Testing Guidelines, Information Sharing 3 WADA International Standard for Laboratories (ISL) 5.3.8.4	reagents to be disposed, and trend charts of laboratory performance.	
7 CFR Part 331.5 9 CFR Part 121.5–6 21 CFR Part 58.185 21 CFR Part 312.64 21 CFR Part 812.150 40 CFR Part 141.31 40 CFR Part 141.721 40 CFR Part 370 Subpart C 40 CFR Part 372 Subpart B 40 CFR Part 704 40 CFR Part 717 Subpart A 40 CFR Part 720.40 42 CFR Part 73.5–6 42 CFR Part 493.43 (d) ABFT Accreditation Manual Sec. E-7 ACMG Technical Standards for Clinical Genetics Laboratories C13.3 ACMG Technical Standards for Clinical Genetics Laboratories E8 ACMG Technical Standards for Clinical Genetics Laboratories G17.1 ASTM E1578-18 C-6-7 CAP Laboratory Accreditation Manual CJIS Security Policy 5.3.1 EPA ERLN Laboratory Requirements 4.12–15 EPA QA/G-5 2.3.2 NIST 800-53, Rev. 5, IR-6 and IR-6(1) OECD GLP Principles 9.1 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (throughout) USDA Administrative Procedures for the PDP (throughout) WADA International Standard for Laboratories (ISL) 5.3.8.4	**6.8** The system should, in addition to standard reports, provide the means for custom automatic and manual reporting, including but not limited to sample registration reports, work and backlog lists, laboratory performance reports, instrument reports, statistical analysis reports, analytical worksheets, regulatory reports, incident reports, chain of custody reports, quality assurance reports, service reports, inventory analysis reports, and investigator/sponsor reports.	
7 CFR Part 91.28 21 CFR Part 58 Sec. 58.185 (c) A2LA C211 5.10.9 AAVLD Requirements for an AVMDL Sec. 5.10.9–10 CLSI QMS22 2.2.3.4 ICH GCP 4.9.3 ISO/IEC 17025:2017 7.8.8 NYSDOH CLEP Clinical Laboratory Standards of Practice, General	**6.9** The system shall clearly identify a changed, amended, or re-issued report as being such, and clearly identify any change of information and reason for change in such a report.	

Systems Standards OECD GLP Principles 9.1 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 5.10.9)		

Maintaining Laboratory Workflow and Operations

7. Document and records management

Regulation, Specification, or Guidance	Requirement	Response
7 CFR Part 331 (throughout) 9 CFR Part 121 (throughout) 10 CFR Part 20 (throughout) 21 CFR Part 7 (throughout) 21 CFR Part 58 (throughout) 21 CFR Part 211 (throughout) 21 CFR Part 212 (throughout) 21 CFR Part 225 (throughout) 21 CFR Part 226 (throughout) 21 CFR Part 312 (throughout) 21 CFR Part 606 (throughout) 21 CFR Part 810 (throughout) 21 CFR Part 812 (throughout) 21 CFR Part 820 (throughout) 29 CFR Part 1910.134 (throughout) 29 CFR Part 1910.1030 (throughout) 29 CFR Part 1910.1200 (throughout) 29 CFR Part 1910.1450 (throughout) 40 CFR Part 262.213–14 42 CFR Part 73 (throughout) 42 CFR Part 493.1200 42 CFR Part 493.1232 42 CFR Part 493.1239 42 CFR Part 493.1251 42 CFR Part 493.1291 (j) 45 CFR Part 164 (throughout) A2LA C211 4.3 A2LA C223 4.13 AAFCO QA/QC Guidelines for Feed Laboratories (throughout) AAVLD Requirements for an AVMDL (throughout) ABFT Accreditation Manual (throughout) ASTM E1188-11 3.5.2 ASTM E1492-11 4.3.3.3 and 4.4.4 ASTM E1578-18 D-1-1 CAP Laboratory Accreditation Manual (throughout)	**7.1** The system shall be capable of creating, managing, and securely holding a variety of document types, while also allowing for the review and approval of those documents using version and release controls.	

CJIS Security Policy (throughout) EMA Guidance on Good Manufacturing Practice and Good Distribution Practice (throughout) EPA 815-R-05-004 (throughout) EPA ERLN Laboratory Requirements (throughout) EPA QA/G-5 (throughout) E.U. Commission Directive 2003/94/EC (throughout) FDA Hazard Analysis Critical Control Point (throughout) ISO 15189:2012 4.3 ISO 15189:2012 5.5.3 ISO 15189:2012 5.9.3 ISO/IEC 17025:2017 5.3 ISO/IEC 17025:2017 5.5 ISO/IEC 17025:2017 8.3.2 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards NYSDOH ELAP Medical Marijuana Microbiology Guidance NIST 800-53, Rev. 5 (throughout) OECD GLP Principles 8 OSHA 1910.1200(b)(3) OSHA 1910.1450(e) and (h) PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (throughout) USDA Administrative Procedures for the PDP (throughout) USDA Data and Instrumentation for PDP (throughout) USDA Sample Processing and Analysis Procedures for PDP (throughout) WHO Technical Report Series, #961, Annex 13 (throughout) WHO Technical Report Series, #986, Annex 2 (throughout) WHO Technical Report Series, #996, Annex 5 (throughout)		
7 CFR Part 331 (throughout) 9 CFR Part 121 (throughout) 21 CFR Part 7 (throughout) 21 CFR Part 58 (throughout) 21 CFR Part 211 (throughout) 21 CFR Part 212 (throughout) 21 CFR Part 225 (throughout) 21 CFR Part 226 (throughout) 21 CFR Part 312 (throughout) 21 CFR Part 606 (throughout) 21 CFR Part 810 (throughout) 21 CFR Part 812 (throughout) 21 CFR Part 820 (throughout) 29 CFR Part 1910.134 (c) 29 CFR Part 1910.1030 (throughout) 29 CFR Part 1910.1200 (e)	**7.2** The system shall have the ability to readily provide authorized access to electronic documents such as standard operating procedures, quality manuals, laboratory management plans, instrument manuals, employee medical records, material safety data sheets, information exchange agreements, confidentiality agreements, and other applicable	

29 CFR Part 1910.1450 (throughout) 40 CFR Part 262.214 42 CFR Part 73 (throughout) 42 CFR Part 93.300–5 42 CFR Part 493.1200 42 CFR Part 493.1232 42 CFR Part 493.1239 42 CFR Part 493.1251 42 CFR Part 493.1291 (j) 42 CFR Part 493.1773 (c–d) 45 CFR Part 160.310 45 CFR Part 164 (throughout) A2LA C211 (throughout) A2LA C223 (throughout) AAFCO QA/QC Guidelines for Feed Laboratories (throughout) AAVLD Requirements for an AVMDL (throughout) ACMG Technical Standards for Clinical Genetics Laboratories (throughout) AIHA-LAP Policies 2022 Appendix H5.8 ASTM E1188-11 3.5.2 ASTM E1492-11 4.3.3.3 and 4.4.4 ASTM E1578-18 D-1-2 CAP Laboratory Accreditation Manual (throughout) CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition (throughout) CJIS Security Policy (throughout) CLSI QMS22 (throughout) EPA 815-R-05-004 (throughout) EPA ERLN Laboratory Requirements (throughout) EPA QA/G-5 (throughout) E.U. Commission Directive 2003/94/EC (throughout) FDA Hazard Analysis Critical Control Point (throughout) ISO 15189:2012 (throughout) ISO/IEC 17025:2017 (throughout) NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards NYSDOH ELAP Medical Marijuana Microbiology Guidance NIST 800-53, Rev. 5 (throughout) OECD GLP Principles 8 OSHA 1910.1020 (throughout) OSHA 1910.1200(b)(3) OSHA 1910.1450(h) PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (throughout) USDA Administrative Procedures for the PDP (throughout) USDA Data and Instrumentation for PDP (throughout) USDA Hemp Production Program	documents to designated personnel and officials.	

Laboratory Testing Guidelines (throughout) USDA LAS Laboratory Approval Program (LAP) Policies and Procedures 12.3 USDA Sample Processing and Analysis Procedures for PDP (throughout) WADA International Standard for Laboratories (ISL) (throughout) WADA International Standard for the Protection of Privacy and Personal Information (ISPPPI) (throughout) WHO Technical Report Series, #961, Annex 13 (throughout) WHO Technical Report Series, #986, Annex 2 (throughout) WHO Technical Report Series, #996, Annex 5 (throughout)		
21 CFR Part 820.40 (a) 42 CFR Part 493.1251 (e) A2LA C211 4.3 AAVLD Requirements for an AVMDL Sec. 4.3 ASTM E1578-18 D-1-3 EPA 815-R-05-004 Chap. III, Sec. 11 EPA ERLN Laboratory Requirements 4.2.4.2 EPA QA/G-5 2.1.9 ISO 15189:2012 4.3 ISO 15189:2012 5.5.3 ISO 15189:2012 5.9.3 ISO/IEC 17025:2017 7.5.2 ISO/IEC 17025:2017 8.3.2 USDA Administrative Procedures for the PDP 5.5 WHO Technical Report Series, #986, Annex 2, 15.5	**7.3** The system shall be able to clearly provide the most current version of a document and archive prior versions.	
ASTM E1578-18 D-1-4	**7.4** The system shall allow an applicable standard operating procedure revision to be linked with a test performed using that revision.	
21 CFR Part 211.160 21 CFR Part 212.20 (c) 21 CFR Part 212.60 (c) 21 CFR Part 226.58 (e) 21 CFR Part 820.250 (b) 42 CFR Part 493.43 (c) ASTM E1578-18 D-1-5 EPA 815-R-05-004 Chap. IV, Sec. 5 ISO/IEC 17025:2017 6.5 ISO/IEC 17025:2017 7.2.1.3	**7.5** The system shall allow the creation, approval, rejection, and management of sampling and test methods performed at the laboratory, capturing details about the test method, method reference, specifications, assigned limits, holding times,	

NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards NYSDOH ELAP Medical Marijuana Microbiology Guidance PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 5.4) USDA Administrative Procedures for the PDP 8.4 USDA Hemp Production Program Laboratory Testing Guidelines, Summary of Practice 1.2 USDA Hemp Production Program Laboratory Testing Guidelines, Testing Methods 3 WADA International Standard for Laboratories (ISL) 4.2.1 WHO Technical Report Series, #986, Annex 2, 15.14	etc. as required by a reference method or regulation.	
21 CFR Part 212.20 (c) 21 CFR Part 212.70 (b) A2LA C211 5.4.5 A2LA C223 5.4 AAVLD Requirements for an AVMDL Sec. 5.4.2.4 ABFT Accreditation Manual Sec. G-12, -14, and -15 ACMG Technical Standards for Clinical Genetics Laboratories C10 ACMG Technical Standards for Clinical Genetics Laboratories F7.3 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.4.5.4 EPA QA/G-5 2.2.4 ISO/IEC 17025:2017 7.2.2.1 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards NYSDOH ELAP Medical Marijuana Microbiology Guidance PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 4.13.2.3) USDA Administrative Procedures for the PDP 8.4 USDA LAS Laboratory Approval Program (LAP) Policies and Procedures 12.4b WADA International Standard for Laboratories (ISL) 4.2.1 and 5.3.6 WHO Technical Report Series, #961, Annex 13, 10.1 WHO Technical Report Series, #986, Annex 2, 4.11	**7.6** The system shall provide a means for recording validation information for modified existing or new in-house test methods, either as a method itself or through some other means. Validation information such as procedures used, specifications, performance characteristics, and results obtained shall be allowed as input.	

WHO Technical Report Series, #986, Annex 2, 15.13		
7 CFR Part 331.10 7 CFR Part 331.15 9 CFR Part 2.32 9 CFR Part 121.10 9 CFR Part 121.15 10 CFR Part 30.34 (j-3) 21 CFR Part 11.10 (i) 21 CFR Part 58.29 21 CFR Part 211.25 21 CFR Part 225.10 21 CFR Part 226.10 21 CFR Part 226.40 21 CFR Part 820.25 29 CFR Part 1910.134 (c) 29 CFR Part 1910.1030 (g-2) 29 CFR Part 1910.1030 (h-2) 29 CFR Part 1910.1200 (h) 29 CFR Part 1910.1450 (f) 40 CFR Part 262.207 40 CFR Part 262.210–12 42 CFR Part 73.10 42 CFR Part 73.15 42 CFR Part 493.43 (c) 42 CFR Part 493.1235 42 CFR Part 493.1251 45 CFR Part 164.308 45 CFR Part 164.530 A2LA C211 5.2 A2LA C223 5.2 A2LA C223 5.7 AAFCO QA/QC Guidelines for Feed Laboratories Sec. 1.4 and 1.6 AAVLD Requirements for an AVMDL Sec. 5.2 AAVLD Requirements for an AVMDL Sec. 5.4.2.2 AAVLD Requirements for an AVMDL Appendix 1 ABFT Accreditation Manual Sec. B ACMG Technical Standards for Clinical Genetics Laboratories B3–B5 ACMG Technical Standards for Clinical Genetics Laboratories C6.4 AIHA-LAP Policies 2022 (throughout) ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 4.13.2.12 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.2.1.1–3 ASTM E1578-18 C-3-5 ASTM E1578-18 D-1-6 ASTM E1578-18 E-1-6 CAP Laboratory Accreditation Manual CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition	**7.7** The system shall maintain training and certification records for personnel and allow the assignment of available training paths and certifications to specific personnel, such that only trained, certified, and experienced personnel are able to perform assigned tasks.	

CLSI QMS22 (throughout) E.U. Annex 11-2 E.U. Commission Directive 2003/94/EC Article 7.4 EPA 815-R-05-004 Chap. III, Sec. 10 and 17 EPA 815-R-05-004 Chap. IV, Sec. 1 EPA QA/G-5 2.1.8 ISO 15189:2012 4.1.2.1 ISO 15189:2012 5.1.6 ISO 15189:2012 5.1.9 ISO/IEC 17025:2017 6.2.2 ISO/IEC 17025:2017 6.2.3 ISO/IEC 17025:2017 6.2.5 ISO/IEC 17025:2017 6.2.6 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards NYSDOH ELAP Medical Marijuana Microbiology Guidance OECD GLP Principles 1.1.2 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 4.13.3) USDA Administrative Procedures for the PDP 6.1 WADA International Standard for Laboratories (ISL) 5.2.2		
ASTM E1578-18 D-1-7	**7.8** The system shall allow individual modules and sections of the system (e.g., tables, forms) to be linked to one or more documents stored in the system.	
AAVLD Requirements for an AVMDL Sec. 4.3.4 and 4.3.5 EPA ERLN Laboratory Requirements 4.10.6	**7.9** The system shall support the addition of accurate cross-references and page numbers to new documents.	
AAVLD Requirements for an AVMDL Sec. 4.3.4	**7.10** The system shall be capable of uniquely identifying documents created in and added to the system.	
APHL 2019 LIS Project Management Guidebook	**7.11** The system shall provide both standard and 'ad hoc' means to query or search for documents, records, and other types of data and information in the system.	

8. Resource management

Regulation, Specification, or Guidance	Requirement	Response
9 CFR Part 2.32 10 CFR Part 20.2103 29 CFR Part 1910.120 29 CFR Part 1910.134 (m) 29 CFR Part 1910.1030 (h-1) 29 CFR Part 1910.1450 (j) 40 CFR Part 262.207 A2LA C211 4.13.2.3 A2LA C223 5.2 A2LA C223 5.7 ACMG Technical Standards for Clinical Genetics Laboratories B3–B5 APHL 2019 LIS Project Management Guidebook CAP Laboratory Accreditation Manual CJIS Security Policy 5.2.3 EPA ERLN Laboratory Requirements 4.2.4.1 EPA QA/G-5 2.1.8 NIST 800-53, Rev. 5, AT-3 and -4 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards OSHA 1910.1020 (throughout) OSHA 1910.1200(b)(3) and (h) OSHA 1910.1450 (throughout) PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 5.2) USDA Administrative Procedures for the PDP 6.1 USDA Sampling Procedures for PDP 6.1.2.8 and 6.1.3 WADA International Standard for Laboratories (ISL) 5.2.2 WHO Technical Report Series, #996, Annex 5, 8.1	**8.1** The system shall have the ability to create and maintain individual personnel records for tracking such things as demographics, certifications, training, evaluations, medical history, and occupational exposure.	
21 CFR Part 820.198 42 CFR Part 493.1233 E.U. Commission Directive 2003/94/EC Article 13 TNI EL-V1-2016-Rev.2.1 (V1,M2 4.8) WADA International Standard for Laboratories (ISL) 5.3.10 WHO Technical Report Series, #986, Annex 2, 2.1 (j) WHO Technical Report Series, #986, Annex 2, 5.0	**8.2** The system shall allow authorized personnel to document complaints and problems reported to the laboratory or production facility.	

5 CFR Part 930.301 7 CFR Part 331.15 9 CFR Part 121.15 21 CFR Part 211.25 29 CFR Part 1910.1450 (f) 42 CFR Part 73.15 A2LA C223 5.2 APHL 2019 LIS Project Management Guidebook ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.9.3.3 ASTM E1578-18 E-1-1 CJIS Security Policy 5.2.1 EPA ERLN Laboratory Requirements 4.2.4.1 FDA Hazard Analysis Critical Control Point Guidelines NIST 800-53, Rev. 5, AT-2 and AT-3 NIST 800-53, Rev. 5, CP-3 NIST 800-53, Rev. 5, IR-2 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 5.2) USDA Sampling Procedures for PDP 6.1.2–3 WHO Technical Report Series, #986, Annex 2, 10	**8.3** The system shall allow training sessions and reviews to be scheduled for personnel.	
5 CFR Part 930.301 29 CFR Part 1910.1450 (f) ABFT Accreditation Manual Sec. B ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.2.7 ASTM E1578-18 E-1-2 FDA Hazard Analysis Critical Control Point Guidelines NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards	**8.4** The system should provide access to relevant training materials to personnel attending training sessions.	
5 CFR Part 930.301 29 CFR Part 1910.1450 (f) 40 CFR Part 262.207 A2LA C223 5.2 ACMG Technical Standards for Clinical Genetics Laboratories C6.3 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 4.13.2.12 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.2.1.1–3 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.2.6.2	**8.5** The system shall be able to record for every trainee their training attendance, progress, assessments, licenses, and certificates of completion for in-house training, continuing education courses, and other required courses of certification.	

ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.9.3.3 and 5.9.3.5 ASTM E1578-18 E-1-3 CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition CJIS Security Policy 5.2.3 EPA ERLN Laboratory Requirements 4.2.4.1 EPA QA/G-5 2.1.8 E.U. Commission Directive 2003/94/EC Article 7.4 FDA Hazard Analysis Critical Control Point Guidelines ISO 15189:2012 5.1.9 NIST 800-53, Rev. 5, AT-2–AT-4 NIST 800-53, Rev. 5, CP-3 NIST 800-53, Rev. 5, IR-2 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards TNI EL-V1-2016-Rev.2.1 (V1,M2 5.2) USDA Administrative Procedures for the PDP 6.1 USDA LAS Laboratory Approval Program (LAP) Policies and Procedures 12.4e USDA Sampling Procedures for PDP 6.1.2.8 and 6.1.3 WADA International Standard for Laboratories (ISL) 5.2.2 WHO Technical Report Series, #986, Annex 2, 2.1 (e) WHO Technical Report Series, #986, Annex 2, 9.4 WHO Technical Report Series, #986, Annex 2, 10		
ABFT Accreditation Manual Sec. B ASTM E1578-18 E-1-4	**8.6** The system should allow the results of tests taken by personnel to be uploaded and made available to authorized individuals for reference.	
ASTM E1578-18 E-1-5 NIST 800-53, Rev. 5, AT-2 and AT-3 NIST 800-53, Rev. 5, CP-3 NIST 800-53, Rev. 5, IR-2	**8.7** The system should be able to produce a training matrix of personnel.	
7 CFR Part 331.15 9 CFR Part 121.10 9 CFR Part 121.15 21 CFR Part 11.10 (i)	**8.8** The system shall map available system tasks (such as approved test methods) or sample types (such as select agents and toxins) to available	

21 CFR Part 58.29 21 CFR Part 211.25 21 CFR Part 225.10 21 CFR Part 226.10 21 CFR Part 226.40 21 CFR Part 820.25 29 CFR Part 1910.1030 (g-2) 29 CFR Part 1910.1030 (h-2) 29 CFR Part 1910.1200 (h) 29 CFR Part 1910.1450 (e) 42 CFR Part 73.10 42 CFR Part 73.15 42 CFR Part 493.43 (c) 42 CFR Part 493.1235 45 CFR Part 164.308 45 CFR Part 164.530 A2LA C223 5.2 AAFCO QA/QC Guidelines for Feed Laboratories Sec. 1.4 and 1.6 AAVLD Requirements for an AVMDL Sec. 5.2 AAVLD Requirements for an AVMDL Sec. 5.4.2.2 AAVLD Requirements for an AVMDL Appendix 1 ABFT Accreditation Manual Sec. B AIHA-LAP Policies 2022 (various parts) ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 4.13.2.12 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.2.1.1–3 ASTM E1578-18 C-3-5 ASTM E1578-18 D-1-6 ASTM E1578-18 E-1-6 E.U. Annex 11-2 EPA 815-R-05-004 Chap. III, Sec. 10 and 17 EPA 815-R-05-004 Chap. IV, Sec. 1 EPA QA/G-5 2.1.8 ISO 15189:2012 4.1.2.1 ISO 15189:2012 5.1.6 ISO 15189:2012 5.1.9 ISO/IEC 17025:2017 6.2.2 ISO/IEC 17025:2017 6.2.3 ISO/IEC 17025:2017 6.2.5 ISO/IEC 17025:2017 6.2.6 OECD GLP Principles 1.1.2 USDA Administrative Procedures for the PDP 6.1	training paths and certifications, such that only trained, certified, and experienced personnel are able to perform assigned tasks.	

9. Compliance management

Regulation, Specification, or Guidance	Requirement	Response
7 CFR Part 331.17 9 CFR Part 121.17 21 CFR Part 11.10 (e) 21 CFR Part 11.70 21 CFR Part 58.130 (e) 42 CFR Part 73.17 42 CFR Part 493.1251 (d) ASTM E1578-18 C-4-7 ASTM E1578-18 E-2-1 EPA ERLN Laboratory Requirements 4.9.1 and 4.9.7 E.U. Annex 11-9 E.U. Annex 11-14 OECD GLP Principles 8.3.5 USDA Data and Instrumentation for PDP 8.1.3	**9.1** The system shall accurately and consistently capture and add a time and date to created electronic records, as well as any modifications made to them. The system shall also prompt the user to enter a mandatory reason for any change made to a record.	
21 CFR Part 11.10 (e) 21 CFR Part 11.70 21 CFR Part 58.130 (e) 21 CFR Part 211.68 21 CFR Part 211.100 21 CFR Part 211.160 (a) 21 CFR Part 211.188 21 CFR Part 211.194 45 CFR Part 170.315 (d) ASTM E1578-18 E-2-2 CJIS Security Policy 5.4.1.1 CJIS Security Policy Appendix G.5 EMA Guidance on Good Manufacturing Practice and Good Distribution Practice EPA ERLN Laboratory Requirements 4.9.1 and 4.9.7 E.U. Annex 11-9 E.U. Annex 11-12.4 E.U. Annex 11-14 E.U. Commission Directive 2003/94/EC Article 9.2 NIST 800-53, Rev. 5, AC-2(4) and AC-6(9) NIST 800-53, Rev. 5, AU-2 and AU-3 NIST 800-53, Rev. 5, CM-5(1) OECD GLP Principles 8.3.5 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 4.13.3) WHO Technical Report Series, #986, Annex 2, 15.7 and 15.9	**9.2** The system shall document in the audit trail any event—including administrative and privileged functions—that creates, modifies, and deletes data, including user accounts, passwords, files, directories, logs, and other system resources.	

WHO Technical Report Series, #996, Annex 5 (throughout)		
21 CFR Part 11.10 (e) 21 CFR Part 11.70 21 CFR Part 58.130 (e) 21 CFR Part 211.68 21 CFR Part 211.100 21 CFR Part 211.160 (a) 21 CFR Part 211.188 21 CFR Part 211.194 42 CFR Part 493.1274 45 CFR Part 170.315 (d) ASTM E1578-18 E-2-3 CJIS Security Policy 5.4.1.1 CLSI QMS22 2.2.3.2 CLSI QMS22 2.4.3 E.U. Annex 11-12.4 E.U. Annex 11-14 E.U. Commission Directive 2003/94/EC Article 9.2 NIST 800-53, Rev. 5, AU-3 and AU-8 OECD GLP Principles 8.3.5 USDA Data and Instrumentation for PDP 8.1.4 WHO Technical Report Series, #986, Annex 2, 15.7 and 15.9	**9.3** The system's audit trail shall document the date, time, and user associated with a given event, as well as whether the event succeeded or failed.	
21 CFR Part 11.10 (e) 21 CFR Part 11.70 21 CFR Part 58.130 (e) 21 CFR Part 211.68 21 CFR Part 211.100 21 CFR Part 211.160 (a) 21 CFR Part 211.188 21 CFR Part 211.194 45 CFR Part 170.315 (d) ASTM E1578-18 E-2-4 EPA ERLN Laboratory Requirements 4.8.6 E.U. Annex 11-14 E.U. Commission Directive 2003/94/EC Article 9.2 ICH GCP 4.9.0 and 4.9.3 NIST 800-53, Rev. 5, AU-3 OECD GLP Principles 8.3.5 WHO Technical Report Series, #986, Annex 2, 15.7 and 15.9	**9.4** The system's audit trail shall document the previous and current value of a modified field.	
21 CFR Part 11.10 (e) 21 CFR Part 11.70 21 CFR Part 58.130 (e) 21 CFR Part 211.194 42 CFR Part 493.1251 (d) 45 CFR Part 164.310 ASTM E1578-18 E-2-5 EPA ERLN Laboratory Requirements	**9.5** The system shall provide electronic signature support to users who require the review, approval, rejection, modification, or disposition of a record.	

4.8.6 E.U. Annex 11-14 OECD GLP Principles 8.3.5		
21 CFR Part 11.70 E.U. Annex 11-14	**9.6** The system shall prevent a user from copying and pasting the electronic signature of another user.	
21 CFR Part 11.10 (e) 21 CFR Part 58.130 (e) 42 CFR Part 493.1274 (d) E.U. Annex 11-9 NIST 800-53, Rev. 5, AU-6 and AU-12 OECD GLP Principles 8.3.5	**9.7** The system shall be able to generate a complete and accurate copy of the audit trail in a human-readable and printable format.	

10. Instrument and equipment management

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 E-3-1	**10.1** The system should provide a means for tracking usage of laboratory equipment and instruments.	
ASTM E1578-18 E-3-2	**10.2** The system shall provide a means for planning the use of and reserving equipment and instruments.	
ASTM E1578-18 E-3-3	**10.3** The system shall be able to bring an instrument online and take an instrument offline both manually and via a configurable scheduler.	
ASTM E1578-18 E-3-4	**10.4** The system should record instrument usage time to assist	

	laboratory personnel with capacity planning and scheduling.	
ASTM E1578-18 E-3-5	**10.5** The system shall allow users to configure and record multiple instrument events for the same instrument, including different event types and different frequencies for the same event type.	
ASTM E1578-18 E-3-6	**10.6** The system shall be able to group instruments together in specific ways, including by type and laboratory location.	
21 CFR Part 211.67–68 21 CFR Part 211.160 (b-4) 21 CFR Part 212.30 (b) 21 CFR Part 212.60 (e) 21 CFR Part 225.30 (b-4) 21 CFR Part 606.60 21 CFR Part 820.70 (g) 21 CFR Part 820.72 42 CFR Part 493.1252 (b-3) 42 CFR Part 493.1255 A2LA C211 5.5.2 A2LA C223 5.5 AAFCO QA/QC Guidelines for Feed Laboratories Sec. 2 AAVLD Requirements for an AVMDL Sec. 5.5 ABFT Accreditation Manual Sec. E-20 ACMG Technical Standards for Clinical Genetics Laboratories C1.5 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.6.1.1 AIHA-LAP Policies 2022 2C.3.7–2C.3.10 ASTM E1578-18 E-3-7 CAP Laboratory Accreditation Manual CLSI QMS22 2.6.1 EPA 815-R-05-004 Chap. IV, Sec. 7 EPA ERLN Laboratory Requirements 4.11.11–13 EPA QA/G-5 2.2.6–7 ISO 15189:2012 5.3.1.4 ISO/IEC 17025:2017 6.4.7 ISO/IEC 17025:2017 6.4.8	**10.7** The system shall allow for the configuration of calibration and maintenance frequency and time frames for—as well as the manual and automatic scheduling of calibration or maintenance of—equipment, instruments, and systems. Available intervals should be include days, weeks, months, and years.	

NIST 800-53, Rev. 5, MA-2 and MA-2(2) USDA Administrative Procedures for the PDP 5.2.4 USDA Data and Instrumentation for PDP 5.2 USDA Data and Instrumentation for PDP 6 WADA International Standard for Laboratories (ISL) 5.2.4 WHO Technical Report Series, #986, Annex 2, 13.5 WHO Technical Report Series, #986, Annex 2, 16.23		
21 CFR Part 225.30 (b-4) AAVLD Requirements for an AVMDL Sec. 5.5.9 ASTM E1578-18 E-3-8 WHO Technical Report Series, #986, Annex 2, 16.23	**10.8** The system shall provide clear alerts or notifications when an instrument nears its calibration due date.	
21 CFR Part 211.160 (b-4) A2LA C211 5.5.7 A2LA C223 5.6 ABFT Accreditation Manual Sec. E-21 ASTM E1578-18 E-3-9 CLSI QMS22 2.1.2.1 ISO 15189:2012 5.3.1.5 ISO/IEC 17025:2017 6.4.9 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards TNI EL-V1-2016-Rev.2.1 (V1,M2 5.5.7) WHO Technical Report Series, #986, Annex 2, 13.10	**10.9** The system shall clearly identify any instrument that is out-of-calibration, beyond its preventative maintenance due date, or under investigation and prevent it from being selected for use.	
21 CFR Part 820.72 (b-2) ASTM E1578-18 E-3-10 EPA ERLN Laboratory Requirements 4.11.11–13 EPA QA/G-5 2.2.6–7 ISO/IEC 17025:2017 6.4.8 NIST 800-53, Rev. 5, MA-2, MA-2(2), and MA-6(1) WHO Technical Report Series, #986, Annex 2, 16.23	**10.10** The system shall be able to show all instances of scheduled calibration, preventative maintenance, and service dates for an instrument.	
21 CFR Part 820.72 (b-1) 42 CFR Part 493.1255 A2LA C211 5.6.2.1 A2LA C223 5.6 AAVLD Requirements for an AVMDL Sec. 5.6.1–2	**10.11** The system shall be able to link a calibration activity to certified reference material or	

AIHA-LAP Policies 2022 2C.3.7 and Appendix H5.1-5.3 EPA 815-R-05-004 Chap. IV, Sec. 7 ISO/IEC 17025:2017 6.5 OECD GLP Principles 4.2 TNI EL-V1-2016-Rev.2.1 (V1,M2 5.6.2.1 and 5.6.4.1) USDA Data and Instrumentation for PDP 6.1	designated measurement processes.	
ASTM E1578-18 E-3-11	**10.12** The system shall support the use of predefined intervals when calculating instrument event dates.	
21 CFR Part 211.105 (b) 42 CFR Part 493.1255 A2LA C211 5.5.4 and 5.5.5 AAVLD Requirements for an AVMDL Sec. 5.5.4–5 ASTM E1578-18 E-3-12 EPA 815-R-05-004 Chap. IV, Sec. 7 EPA QA/G-5 2.2.6–7 ISO 15189:2012 5.3.1.7 ISO/IEC 17025:2017 6.4.8 ISO/IEC 17025:2017 6.4.13 NIST 800-53, Rev. 5, CM-8 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards TNI EL-V1-2016-Rev.2.1 (V1,M2 5.5) USDA Administrative Procedures for the PDP 7.2 USDA LAS Laboratory Approval Program (LAP) Policies and Procedures 12.4j WADA International Standard for Laboratories (ISL) 4.2.1 and 5.2.4 WHO Technical Report Series, #961, Annex 13, 6.1	**10.13** The system shall be able to uniquely identify each instrument and any associated components and maintain that and other information—such as manufacturer, model number, serial number, and calibration and maintenance history—within the system.	
ASTM E1578-18 E-3-13	**10.14** The system shall be able to automatically take a parent instrument offline when a child instrument or component goes offline.	
10 CFR Part 20.2103 21 CFR Part 58.63 21 CFR Part 211.67–68 21 CFR Part 211.160 (b-4) 21 CFR Part 211.182 21 CFR Part 211.194 (d) 21 CFR Part 212.30 (b) 21 CFR Part 212.60 (e)	**10.15** The system shall be capable of chronologically logging details for scheduled and unscheduled calibration and maintenance activities for each instrument, including calibration status, calibration standard, date	

21 CFR Part 820.70 (g) 21 CFR Part 820.72 42 CFR Part 493.1254 42 CFR Part 493.1255 A2LA C211 4.13.2.1 A2LA C211 5.5.2 A2LA C211 5.10.4 AAFCO QA/QC Guidelines for Feed Laboratories Sec. 2 AAVLD Requirements for an AVMDL Sec. 5.5 ABFT Accreditation Manual Sec. E-20 and -23 ABFT Accreditation Manual Sec. F-1 and I-1 AIHA-LAP Policies 2022 2C.3.7–2C.3.10 ASTM E1578-18 E-3-14 CAP Laboratory Accreditation Manual CLSI QMS22 2.2.2.1 EPA 815-R-05-004 Chap. IV, Sec. 7 EPA ERLN Laboratory Requirements 4.11.11–13 EPA QA/G-5 2.2.6–7 ISO 15189:2012 5.3.1.4 ISO/IEC 17025:2017 6.4.4 NIST 800-53, Rev. 5, MA-2, MA-2(2), and MA-4 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards OECD GLP Principles 4.2 TNI EL-V1-2016-Rev.2.1 (V1,M2 5.5) USDA Administrative Procedures for the PDP 5.2.4 USDA Data and Instrumentation for PDP 5.4 USDA LAS Laboratory Approval Program (LAP) Policies and Procedures 12.4c WADA International Standard for Laboratories (ISL) 5.2.4 WHO Technical Report Series, #986, Annex 2, 15.46 WHO Technical Report Series, #986, Annex 2, 16.23	and time of calibration or maintenance, work performed, who conducted it, and signatures of those verifying the completed activities.	

11. Batch and lot management

Regulation, Specification, or Guidance	Requirement	Response
21 CFR Part 58.105 (a) 21 CFR Part 211.80	**11.1** The system shall provide a means for organizing samples or	

21 CFR Part 225.102 21 CFR Part 226.102 ASTM E1578-18 E-4-1 EPA ERLN Laboratory Requirements 3.3 EPA ERLN Laboratory Requirements 4.10.1 OECD GLP Principles 6.2	processes into identifiable batches based upon pre-defined criteria.	
21 CFR Part 211.80 21 CFR Part 225.102 21 CFR Part 226.102 ASTM E1578-18 E-4-2 EPA ERLN Laboratory Requirements 4.10.1	**11.2** The system shall maintain the links between component parts of a batch and track the batch throughout the system.	
21 CFR Part 211.80 21 CFR Part 225.102 21 CFR Part 226.102 21 CFR Part 820.65 ASTM E1578-18 E-4-3	**11.3** The system shall allow for identifying a batch as a unique entity that can be quality controlled in the same way as, e.g., a single sample.	
ASTM E1578-18 E-4-4	**11.4** The system should provide a means for determining the effectiveness of a process and designate the disposition of a batch based on study or experiment results.	
E.U. Annex 11-15	**11.5** The system shall allow only authorized personnel to certify the release of batches, requiring an electronic signature to do so.	

12. Scheduled event management

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 E-5-1 USDA Sampling Procedures for PDP 5.6–7	**12.1** The system shall allow users to create, maintain, and revise schedules for various laboratory tasks and processes.	

21 CFR Part 212.61 (a) 21 CFR Part 211.166 (b) ASTM E1578-18 E-5-2	**12.2** The system scheduler shall be capable of working with a variety of laboratory tasks like calibrations, maintenance, and stability studies.	
ASTM E1578-18 E-5-3	**12.3** The system scheduler shall automatically create a sample number specifically for recording the results of calibration, validation, and maintenance.	
ASTM E1578-18 E-5-4	**12.4** The system shall be capable of handling industry-specific testing characteristics (e.g., sampling points, human body sampling location).	
ASTM E1578-18 E-5-5	**12.5** The system shall provide a means for setting a standard or reagent's retest date based on a retest interval.	

13. Instrument data capture and control

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 E-6-1	**13.1** The system shall be able to trigger an instrument event after a definable number of uses of that instrument.	
ASTM E1578-18 E-6-2	**13.2** The system shall be able to automatically take an instrument offline when an instrument's calibration or maintenance date passes without calibration or maintenance taking place.	

ASTM E1578-18 E-6-3	**13.3** The system should allow auto samplers and other robotic systems to be controlled via an application programming interface or web services.	
ASTM E1578-18 E-6-4	**13.4** The system should accurately record instrument information, personnel names, dates, and times relating to entered results or determinations.	
ASTM E1578-18 E-6-5	**13.5** The system should be able to accept the results uploaded from an interfaced instrument.	
ASTM E1578-18 E-6-6	**13.6** The system should be capable of sending sample sequences (e.g., control samples, standards) to an instrument that is bidirectionally interfaced.	
ASTM E1578-18 E-6-7	**13.7** The system should provide a means to interface with simple laboratory instruments using technologies such as RS-232, TCP/IP, and USB.	
ASTM E1578-18 E-6-8	**13.8** The system should support industry communication standards like Specification E1394 and Health Level 7 for bidirectional communication with laboratory instrumentation software.	

14. Standard and reagent management

Regulation, Specification, or Guidance	Requirement	Response
21 CFR Part 58.83 29 CFR Part 1910.1200 (g) 29 CFR Part 1910.1450 (h) 42 CFR Part 493.1252 (c) ABFT Accreditation Manual Sec. E-17 ASTM E1578-18 E-7-1 ISO 15189:2012 5.3.2.4–5 OECD GLP Principles 4.4	**14.1** The system shall allow for accurate inventory management of all standards, reagents, and consumables used for laboratory testing. The system shall also be able to link manufacturer documents such as material safety data sheets and in-house instructions to their respective materials.	
7 CFR Part 331.3 9 CFR Part 121.3 21 CFR Part 312.58 (b) 42 CFR Part 73.3–4 (c) ASTM E1578-18 E-7-2 EPA ERLN Laboratory Requirements 4.1.12 ISO 15189:2012 5.3.2.4 WHO Technical Report Series, #986, Annex 2, 12.20	**14.2** The inventory system shall allow a material to be clearly identified as a controlled, regulated, or hazardous substance and flagged based on its physical and/or chemical stability.	
ASTM E1578-18 E-7-3 ISO 15189:2012 5.3.2.4	**14.3** The system shall be capable of tracking standard and reagent consumption and expiration such that a list of items nearing reorder level or expiration date can be produced on demand.	
ASTM E1578-18 E-7-4 ISO 15189:2012 5.3.2.4	**14.4** The system should be capable of tracking standards and volumetric solutions created in-house such that concentration, purity, and molarity factor are recorded and made available during calculation of results.	
ASTM E1578-18 E-7-5 ISO 15189:2012 5.3.2.4	**14.5** The system shall be capable of applying review statuses to a standard or reagent's properties, also requiring additional review if properties such as vendor lot	

	number or expiration date are changed.	

15. Inventory management

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 E-8-1 CAP Laboratory Accreditation Manual NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards	**15.1** The system should be capable of accurately tracking the specific quantities of received and consumed test samples and specimens.	
21 CFR Part 212.60 (d) ASTM E1578-18 E-8-2 CLSI QMS22 2.1.2 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards	**15.2** The system should support the recording of inventory items' attributes, including chemical name, internal name, catalog number, reorder level, consumable or reusable status, and expiration date.	
21 CFR Part 211.84 21 CFR Part 211.101 21 CFR Part 212.60 (d) 21 CFR Part 226.80 21 CFR Part 606.120 (b) 29 CFR Part 1910.1030 (g) 29 CFR Part 1910.1096 (e-6) 29 CFR Part 1910.1200 (f-6) and (f-10) 40 CFR Part 262.206 ASTM E1578-18 E-8-3 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards OSHA 1910.1200(b)(3) and (f) OSHA 1910.1450(h) WHO Technical Report Series, #986, Annex 2, 14.13, 14.35, and 14.41 WHO Technical Report Series, #986, Annex 2, 15.10–12	**15.3** The system should be capable of designing and printing labels in a variety of sizes, formats, and inventory categories.	
21 CFR Part 212.40 (c) 21 CFR Part 820.50 A2LA C211 4.6	**15.4** The system should provide a means for ordering inventory through a qualified vendor using a	

ASTM E1578-18 E-8-4 TNI EL-V1-2016-Rev.2.1 (V1,M2 4.6.4) USDA Administrative Procedures for the PDP 7.1 WHO Technical Report Series, #961, Annex 13, 7.1 and 7.3 WHO Technical Report Series, #986, Annex 2, 14.8	vendor master list containing approval status for order validation.	
21 CFR Part 211.196 21 CFR Part 212.90 21 CFR Part 225.110 21 CFR Part 606.165 29 CFR Part 1910.1450 Appendix A (I) A2LA C211 4.6 ASTM E1578-18 E-8-5 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards TNI EL-V1-2016-Rev.2.1 (V1,M2 4.6.2) USDA Hemp Production Program Laboratory Testing Guidelines, Summary of Practice 1.5	**15.5** The system should provide a means for accurately recording the receipt, approval, distribution, and disposal of materials.	
21 CFR Part 211.82 (b) 21 CFR Part 211.84 (a) 21 CFR Part 211.89 21 CFR Part 211.110 (d) 21 CFR Part 211.142 (a) 21 CFR Part 212.40 (c) ASTM E1578-18 E-8-6 WHO Technical Report Series, #986, Annex 2, 12.18	**15.6** The system should provide a means for quarantining specific material types until they can be validated by a quality control test or disposed of.	
21 CFR Part 211.89 21 CFR Part 211.110 (d) 42 CFR Part 493.1252 (d) ASTM E1578-18 E-8-7	**15.7** The system should allow authorized personnel to retire faulty or poor quality materials from use.	
21 CFR Part 211.89 ASTM E1578-18 E-8-8	**15.8** The system shall clearly designate a standard or reagent as being disposed or consumed.	

16. Investigation and quality management

Regulation, Specification, or Guidance	Requirement	Response
21 CFR Part 312.62 (b) 21 CFR Part 812.140 (a-3)	**16.1** The system shall be able to create and accurately maintain complete case histories, allowing them to be electronically signed.	
21 CFR Part 312.57 (a) 21 CFR Part 312.62 (a) 21 CFR Part 606.165 21 CFR Part 812.140 (a-2) and (b-2)	**16.2** The system shall be able to accurately track the reception, use, storage, shipment and disposition of investigational drugs, blood products, and medical devices, including details such as, but not limited to, type, quantity, unique identifiers, dates, names, reasoning for return or disposition, shipping demographics, and signatures.	
21 CFR Part 58.81 (a) 21 CFR Part 211.100 21 CFR Part 211.111 21 CFR Part 211.192 21 CFR Part 211.194 21 CFR Part 606.171 42 CFR Part 493.1253 (b-2) A2LA C211 5.4 ABFT Accreditation Manual C-16 ABFT Accreditation Manual F-2 ABFT Accreditation Manual J-3 ASTM E1578-18 E-9-1 CLSI QMS22 2.2.2.2 EPA ERLN Laboratory Requirements 3.3 EPA QA/G-5 2.2.4 ISO/IEC 17025:2017 7.2.1.7 ISO/IEC 17025:2017 7.2.2.1 ISO/IEC 17025:2017 7.10.2 ISO/IEC 17025:2017 8.7.1 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards OECD GLP Principles 7.3 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 4.9 and 5.7.2) USDA Administrative Procedures for	**16.3** The system shall be able to record instances of identified nonconformance and method deviation, as well as the actions required to restore the process to conformity. In the case of a planned deviation, the system shall require documentation, justification, proof of validation, adjusted reference intervals, and authorization for the deviated process.	

the PDP 8.2.2 WADA International Standard for Laboratories (ISL) 5.3.6 WHO Technical Report Series, #986, Annex 2, 16.3		
42 CFR Part 493.1282 ASTM E1578-18 E-9-2	**16.4** The system should clearly identify samples and tests that are out-of-specification (OOS) and out-of-trend (OOT) as unique incidents.	
21 CFR Part 606.100 (c) 42 CFR Part 493.1282 ASTM E1578-18 E-9-3 CLSI QMS22 2.1.2.1 CLSI QMS22 2.2.2.3 EPA QA/G-5 2.2.10 WHO Technical Report Series, #986, Annex 2, 17.12 WHO Technical Report Series, #996, Annex 5, 11.12	**16.5** The system should trigger an alert or notification when an OOS/OOT status is found, indicating a delay in processing and prompting a documented investigation to identify the root cause.	
10 CFR Part 30.34 (g) 21 CFR Part 225.58 (d) 21 CFR Part 225.158 21 CFR Part 606.100 (c) 21 CFR Part 820.100 42 CFR Part 493.1282 A2LA C211 4.9 and 4.11 ASTM E1578-18 E-9-4 CLSI QMS22 2.6.4 E.U. Commission Directive 2003/94/EC Article 13 FDA Hazard Analysis Critical Control Point Principle 5 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards NYSDOH ELAP Medical Marijuana Microbiology Guidance NIST 800-53, Rev. 5, IR-5 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (throughout) USDA LAS Laboratory Approval Program (LAP) Policies and Procedures 12.4h WADA International Standard for Laboratories (ISL) 5.3.9 WHO Technical Report Series, #961, Annex 13, 11.1 WHO Technical Report Series, #986, Annex 2, 2.1 (f, j) WHO Technical Report Series, #986, Annex 2, 5.0	**16.6** The system shall allow for the documentation of and corrective and preventive action towards all types of nonconformance.	

WHO Technical Report Series, #996, Annex 5, 11.12		
21 CFR Part 225.58 (d) 21 CFR Part 225.158 42 CFR Part 493.1282 42 CFR Part 493.1289 A2LA C211 4.8 and 4.11 ASTM E1578-18 E-9-5 CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition CJIS Security Policy 5.3.4 CJIS Security Policy Appendix G.7 E.U. Commission Directive 2003/94/EC Article 13 FDA Hazard Analysis Critical Control Point Principle 5 NYSDOH ELAP Medical Marijuana Microbiology Guidance NIST 800-53, Rev. 5, AU-6(1) NIST 800-53, Rev. 5, IR-4(1) and IR-5 NIST 800-53, Rev. 5, SI-2 and SI-4 WHO Technical Report Series, #986, Annex 2, 2.1 (f, j) WHO Technical Report Series, #986, Annex 2, 5.0	**16.7** The system should track and record incidents and associated corrective actions, allowing authorized personnel to document the effectiveness of the actions, identify insufficient resolutions, and curb repeat occurrences.	
ASTM E1578-18 E-9-6	**16.8** The system should provide a means for configurable workflows to manage OOS and OOT incidents according to an organization’s standard operating procedures.	
9 CFR Part 2.35	**16.9** The system should provide a means for documenting and maintaining records related to the acquisition, disposition, euthanization, and welfare of animals involved in investigations (research), with the ability to include important metadata such as name and demographics of the acquirer, their USDA license or registration number, the USDA tag/tattoo number of the animal, the animal's description, etc.	

Specialty Laboratory Functions

17. Production management

Not relevant to medical diagnostic and research labs.

18. Statistical trending and control charts

Regulation, Specification, or Guidance	Requirement	Response
21 CFR Part 820.250 AIHA-LAP Policies 2018 2A.7.7.1.3 ASTM E1578-18 E-10-1 EPA 815-R-05-004 Chap. IV, Sec. 7.2.8 EPA 815-R-05-004 Chap. VI, Sec. 7.8 FDA Hazard Analysis Critical Control Point Principle 4	**18.1** The system should allow authorized users to configure the generation of trending and control charts.	
21 CFR Part 820.250 AIHA-LAP Policies 2018 2A.7.7.1.3 ASTM E1578-18 E-10-2 EPA 815-R-05-004 Chap. IV, Sec. 7.2.8 EPA 815-R-05-004 Chap. VI, Sec. 7.8 FDA Hazard Analysis Critical Control Point Principle 4	**18.2** The system should allow authorized users to choose specific sample types, tests, and parameters associated with the statistical trending and control charts that can be generated.	

19. Agriculture and food data management

Not relevant to medical diagnostic and research labs.

20. Environmental data management

Not relevant to medical diagnostic and research labs

21. Forensic case and data management

Regulation, Specification, or Guidance	Requirement	Response
ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.8.4.3 ASTM	**21.1** The system shall be able to assign each piece of collected evidence and each scene a	

E1188-11 3.2.3 ASTM E1188-11 3.4.1 ASTM E1459-13 2.1 ASTM E1459-13 4.1.1–2 ASTM E1459-13 4.1.4.2 ASTM E1459-13 4.2.2–3 ASTM E1492-11 4.1.1 ASTM E1492-11 4.1.5	unique identifier using methodologies such as an ID with an incrementing integer (for sequential evidence numbers) or a user-defined naming format for meeting regulatory requirements.	
A2LA C223 4.13 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 4.13.2.6–10 ASTM E1492-11 4.1.1	**21.2** The system shall be able to assign each case a unique case identifier that, in addition to an electronic signature, is able to be automatically placed on, at a maximum, each page of the case's associated examination and administration records.	
A2LA C223 4.13 ASTM E1492-11 4.1.1.1–2 ASTM E1492-11 4.1.4–5 ASTM E1492-11 4.2.2–3 ASTM E1492-11 4.5.1.1	**21.3** In addition to a unique case number, the system shall provide a means to add additional information to a case file, including, but not limited to, submitting agency, agency case number, date of case receipt, name of recipient, shipping and receipt details, items associated with the case and their unique designators, notes, test data, related reports, and other documentation.	
ASTM E1188-11 (throughout) ASTM E1459-13 (throughout) ASTM E1492-11 4.4.3 and 4.5.1	**21.4** The system should be able to document evidence using an ASTM-compliant evidence log, including, but not limited to, unique identifiers, investigator and custodian names, key dates and times, evidence conditions, and storage location.	
ASTM E1492-11 4.3.1.1	**21.5** The system should be able to prevent a piece of evidence from being scheduled for destructive testing until an appropriate authorization for such analysis is acquired and documented.	

ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.8.1.1.1 ASTM E1492-11 4.1.2	**21.6** The system shall be able to record and maintain chain of custody of evidence that is subdivided in the laboratory in the same way that original evidence items are tracked.	
CJIS Security Policy 5.1.3	**21.7** The system shall be capable of recording the secondary dissemination to an authorized agency or organization of criminal history record information (CHRI) sourced from U.S. Criminal Justice Information Services (CJIS).	
CJIS Security Policy 5.4.7	**21.8** The system shall be able to record all National Crime Information Center (NCIC) and Interstate Identification Index (III) data transactions, clearly identifying the operator and authorized receiving agency or organization. III records shall also identify requester and recipient using a unique identifier.	
CJIS Security Policy 5.5.6 NIST 800-53, Rev. 5, AC-17(1)	**21.9** If the system provides remote access to authorized users over authorized devices, the remote access shall be monitored, controlled and documented, particularly for privileged functions. If remote access to privileged functions is allowed, virtual escorting that meets CJIS Security Policy 5.5.6 conditions will be required.	
CJIS Security Policy 5.6.2.1.1.1–2 CJIS Security Policy 5.6.2.1.2–3 NIST 800-53, Rev. 5, IA-5(1)	**21.10** The system shall be capable of putting into place, in their entirety, either the "basic password standards" or "advanced password standards" described in CJIS Security Policy 5.6.2.1.1.1 and 5.6.2.1.1.2. If PIN and/or one-time password is also used, the attributes in 5.6.2.1.2 and 5.6.2.1.3 shall also be required.	

CJIS Security Policy 5.6.2.2	**21.11** If the system supports user-based certificates for authentication, the system shall be configurable enough to require them to be 1. user-specific, not device-specific, 2. used only by one user at any given time, and 3. activated for each use by, e.g., a passphrase or PIN.	
CJIS Security Policy 5.10.1.2.1–2 CJIS Security Policy Appendix G.6 NIST 800-53, Rev. 5, AC-17(2) NIST 800-53, Rev. 5, SC-13, SC-28, and SC-28(1)	**21.12** The system shall allow "encryption in transit" and "encryption at rest" of criminal justice information (CJI) that meets or exceeds the requirements of CJIS Security Policy 5.10.1.2.1 and 5.10.1.2.2.	
CJIS Security Policy 5.10.1.5	**21.13** If the system is cloud-based, the vendor shall ensure that CJI is stored in databases located within the physical boundaries of APB-member countries and within the legal authority of APB-member agencies. Additionally, the vendor shall agree to not use any metadata derived from unencrypted CJI for commercial, advertising, or other purposes, unless specifically permitted for limited within the service agreement.	
CJIS Security Policy 5.11.1–2	**21.14** If the system is cloud-based, the vendor should agree to FBI and CSA compliance and security audits of CJI.	
CJIS Security Policy 5.10.3.2 CJIS Security Policy Appendix G.1	**21.15** If the system is capable of being run in a virtual environment, it shall meet the virtualization requirements set forth in CJIS Security Policy 5.10.3.2 and best practices set forth in CJIS Security Policy Appendix G.1.	

CJIS Security Policy Appendix G.5 NIST 800-53, Rev. 5, AC-6(4) NIST 800-53, Rev. 5, SC-39	**21.16** The system should provide separate processing domains in order to not only allow for more granular allocation of user privileges, but also to prevent one process from modifying the executing code of another process.	
NIST 800-53, Rev. 5, IA-2(1–2), IA-2(12), and IA-8(1)	**21.17** The system should support the use of personal identity verification—a U.S. Federal government-wide credential system—and other forms of hardware-based (i.e., public key infrastructure or PKI) token authentication, while electronically verifying those credentials and any configured token quality requirements.	
A2LA C223 5.4	**21.18** The system should support the identification and tagging of infrequently performed forensic tests or analyses in order to alert the analyst and other stakeholders that additional competency verification or method validation is required before performing the test or analysis.	
A2LA C223 5.9	**21.19** The system should allow case records to be scheduled for periodic administrative and technical review by individuals not connected with the case. The conducted review should indicate details such as who conducted the review, what the results were, and when the review was completed. If non-conforming results were discovered, records of determination and resolution should be appended to the case record.	
A2LA C223 5.9	**21.20** The system should be able to document examiner testimony and allow such testimony to be	

	scheduled for periodic evaluation. The conducted evaluation should indicate details such as who conducted the evaluation, what the results were, and when the review was completed. If non-conforming results were discovered, related records of determination and resolution should be maintained in the system.	

22. Clinical and public health data management

Regulation, Specification, or Guidance	Requirement	Response
CDC PHIN Messaging System	**22.1** The system should be capable of interfacing with the Center for Disease Control and Prevention's PHIN Messaging System.	
ACMG Technical Standards for Clinical Genetics Laboratories G1.5	**22.2** The system should support Human Genome Variation Society (HGVS) nomenclature and terminology for sequence variants.	
CLSI QMS22 2.1.2.3	**22.3** The system should be able to collect sufficient test utilization information to make necessity checks on ordered tests against established benchmarks.	
ONC USCDI v2	**22.4** The system should support the United States Core Data for Interoperability (USCDI) v2 standard, which in turn supports data interoperability across multiple clinical settings.	

23. Veterinary data management

Regulation, Specification, or Guidance	Requirement	Response
NAHLN Information Technology System VeNom Coding Group Veterinary Terminology Services Laboratory	**23.1** The system should support standardized veterinary clinical terminology such as that found in the Veterinary Extension of SNOMED CT and the Veterinary Nomenclature (VeNom) Codes.	
ICAR 15 Data Exchange VICH GL53	**23.2** The system should be able to exchange data, when necessary, in a fashion that meets International Committee for Animal Recording (ICAR) and Veterinary International Conference on Harmonization (VICH) electronic data exchange guidelines.	
NAHLN HL7 Messaging Quick User Guide	**23.3** The system should support National Animal Health Laboratory Network (NAHLN), and, by extension, Health Level 7 (HL7) result messaging.	

24. Scientific data management

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 E-11-1 EPA ERLN Laboratory Requirements 4.3.4.1 EPA ERLN Laboratory Requirements 4.8.9 EPA ERLN Laboratory Requirements 4.9.9	**24.1** The system shall capture raw instrument data and metadata either as an electronic file or directly via RS-232 or TCP/IP communication.	

ASTM E1578-18 E-11-2	**24.2** The scientific data management system (SDMS) should provide a checksum verification of source and destination data and store that verification data in a secure server with controlled access.	
ASTM E1578-18 E-11-1 EPA ERLN Laboratory Requirements 4.3.4.1 EPA ERLN Laboratory Requirements 4.8.9 EPA ERLN Laboratory Requirements 4.9.9	**24.3** The system shall store metadata related to raw instrument data in a database in such a way that the original data generated by instruments for specific samples and tests is easy to retrieve.	
ASTM E1578-18 E-11-4	**24.4** The system should be capable of capturing a complete and readable copy of original data and any previous versions of modified data in order to maintain the integrity of that data.	
AAVLD AAVLD Requirements for an AVMDL Sec. 4.10.2.3 ASTM E1578-18 E-11-5 EPA ERLN Laboratory Requirements 4.3.4.1 EPA ERLN Laboratory Requirements 4.8.9 EPA ERLN Laboratory Requirements 4.9.9	**24.5** The system should secure raw data such that it can't be deleted and provide version control when data is modified by any user or specific software.	
ASTM E1578-18 E-11-6	**24.6** The SDMS should provide tools for helping a laboratory achieve the U.S. Food and Drug Administration's defined ALCOA principles.	
ASTM E1578-18 E-11-7	**24.7** The SDMS shall provide security and access controls for protecting stored data.	
ASTM E1578-18 E-11-8	**24.8** The SDMS shall record an audit trail for each and every record created and modified, using version control.	

45 CFR Part 164.308 ASTM E1578-18 E-11-9	**24.9** The SDMS shall provide proper systems for backing up, restoring, and archiving data for long-term use.	

25. Health information technology

Regulation, Specification, or Guidance	Requirement	Response
45 CFR Part 170.315 (a-1–a-4)	**25.1** The electronic health record (EHR) module should provide computerized provider order entry (CPOE) functionality for medication orders, laboratory orders, and diagnostic imaging, including making checks for potential drug-drug and drug-allergy interactions.	
45 CFR Part 170.315 (a-5) 45 CFR Part 170.315 (a-11–a-12) 45 CFR Part 170.315 (a-15)	**25.2** The EHR module should allow authorized personnel to record, change, and access patient demographic data, including, but not limited to, race and ethnicity, patient's preferred language, birth sex, current sex, sexual orientation, gender identity, birth date, smoking status, alcohol use, family health history, psychological aspects, social aspects, and behavioral aspects.	
45 CFR Part 170.315 (a-6–a-8) 45 CFR Part 170.315 (a-10) 45 CFR Part 170.315 (a-14)	**25.3** The EHR module should allow authorized personnel to record, change, and access a patient's active problem list, medication list, medication allergy list, preferred drug list, and implantable device list, incorporating, where appropriate,	

	at a minimum the SNOMED CT nomenclature standard.	
45 CFR Part 170.315 (a-19)	**25.4** The EHR module should incorporate configurable, role-based clinical decision support tools capable of allowing authorized personnel to trigger electronic interventions based on liked reference information standardized to Health Level 7 (HL7) Version 3 implementation guides. The reference information should be sourced.	
45 CFR Part 170.315 (a-13)	**25.5** The EHR module should be able to identify education resources specific to a patient's active problem and medication lists. The educational resources should be standardized to Health Level 7 (HL7) Version 3 implementation guides.	
45 CFR Part 170.315 (b-1–b-2; b-4–b-5)	**25.6** The EHR module should allow authorized personnel to create, view, send, and receive transition of care or referral summaries in such a way that the summary is properly formatted, matched to the correct patient, and reconciled according to the standards and protocols outlined in 45 CFR Part 170.315 (b-1), (b-2), (b-4), and (b-5).	
45 CFR Part 170.315 (b-3)	**25.7** The EHR module should allow authorized personnel to conduct electronic prescribing actions such as creating, changing, cancelling, and refilling prescriptions, incorporating at least the RxNorm and NCPDP SCRIPT standards.	

45 CFR Part 170.315 (b-6)	**25.8** The EHR module should allow authorized personnel to configure, create, and store data exports, incorporating at least HL7 Version 3 implementation standards, as well as SNOMED CT and ICD-9 standards.	
45 CFR Part 170.315 (b-7–b-8)	**25.9** The EHR module should allow for the secure creation, sending, and receipt of restricted summary records, incorporating HL7 Version 3 implementation standards.	
45 CFR Part 170.315 (b-9)	**25.10** The EHR module should allow authorized personnel to create, record, change, access, and receive care plan information, incorporating HL7 Version 3 implementation standards.	
45 CFR Part 170.315 (c)	**25.11** The EHR module should provide a means to record, calculate, import, export, filter, and report on clinical quality measures according to the standards outlined in 45 CFR Part 170.315 (c).	
45 CFR Part 170.315 (d)	**25.12** The EHR module shall provide security and access controls for protecting stored data.	
45 CFR Part 170.315 (d)	**25.13** The EHR module shall record an audit trail for each and every record created and modified, using version control.	

45 CFR Part 170.315 (d-7)	**25.14** The EHR module shall either encrypt electronic health information on end-user devices after use of the technology on the device stops or prevent electronic health information from being stored on end-user devices after use of the technology on the device stops.	
45 CFR Part 170.315 (d-8)	**25.15** The EHR module shall ensure that electronically exchanged health information has not been altered during the transfer process, using at least a hashing algorithm secured to SHA-2 or better.	
45 CFR Part 170.315 (d-11)	**25.16** The EHR module should be capable of recording patient disclosures made for treatment, payment, and health care operations.	
45 CFR Part 170.315 (e-1)	**25.17** The EHR module should provide a means for patients and their authorized representatives to view, download, and transmit their personal health information and activity history log from the EHR via an internet-based technology, using the standards outlined in 45 CFR Part 170.315 (e-1).	
45 CFR Part 170.315 (e-2–e-3)	**25.18** The EHR module should provide a means for authorized users to securely send messages to and receive messages from patients, at the same time allowing for the recording, accessing, and linking of information shared by the patient electronically (as well as directly).	

45 CFR Part 170.315 (f)	**25.19** The EHR module should allow vital patient information as it relates to public health to be transmitted to immunization registries, cancer registries, and public health agencies, as well as be accessed after the fact. This includes, but is not limited to, immunization history, surveillance information, laboratory test results, cancer case information, case reports, antimicrobial reporting, and health care survey information.	
45 CFR Part 170.315 (g-3–g-5)	**25.20** The EHR developer should use user-centered and accessibility-centered design processes for creating and testing the EHR's functionality. A quality management system should be used during these processes.	
45 CFR Part 170.315 (g-6)	**25.21** The EHR module's use of clinical document architecture (CDA) should be demonstrated and verified for conformance to the standards identified in 45 CFR Part 170.315 (g-6).	
45 CFR Part 170.315 (g-7–g-9)	**25.22** The EHR module should include an application programming interface (API) that demonstrates the EHR's ability to uniquely identify a patient and corresponding ID/token in a received records or data category request in order to accurately and securely meet the request for that patient's data. The API should be well documented.	

Technology and Performance Improvements

26. Instrument data systems functions

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 E-12-1 APHL 2019 LIS Project Management Guidebook CLSI AUTO15 2.0	**26.1** The system should be able to use an application programming interface or web services to communicate with instrument data systems.	
ASTM E1578-18 E-12-2 APHL 2019 LIS Project Management Guidebook CLSI AUTO15 2.0	**26.2** The system should be capable of sending samples and test orders to instrument data systems.	
ASTM E1578-18 E-12-3 APHL 2019 LIS Project Management Guidebook CLSI AUTO15 2.0 CLSI QMS22 2.2.2.5 EPA ERLN Laboratory Requirements 4.9.16 WHO Technical Report Series, #996, Annex 5, 4.12	**26.3** The system should be capable of receiving test results from instrument data systems and verifying those results for completeness and readability.	
ASTM E1578-18 E-12-4 APHL 2019 LIS Project Management Guidebook CLSI AUTO15 2.0	**26.4** The system should be capable of generically parsing instrument data to extract important sample details and results.	

27. Systems integration

Regulation, Specification, or Guidance	Requirement	Response
21 CFR Part 211.105 (a) ASTM E1578-18 E-13-1	**27.1** The system should be capable of communicating any status changes for samples, lots, instruments, and other dynamic entities to and from external systems.	
ASTM E1578-18 E-13-2	**27.2** The system should accurately communicate overall system status changes to external systems.	
21 CFR Part 11.10 (c) 21 CFR Part 58.190 ABFT Accreditation Manual C-15 ASTM E1578-18 E-13-3 EPA ERLN Laboratory Requirements 4.9.5 and 4.9.14 ISO/IEC 17025:2017 8.4.2 OECD GLP Principles 3.4 OECD GLP Principles 10 USDA Administrative Procedures for the PDP 5.5	**27.3** The system shall provide a means to choose—based on date and type of data—electronic data and metadata to archive.	
21 CFR Part 11.10 (c) 21 CFR Part 58.51 21 CFR Part 58.190 ABFT Accreditation Manual C-15 ASTM E1578-18 E-13-4 EPA ERLN Laboratory Requirements 4.9.5 E.U. Annex 11-17 ISO/IEC 17025:2017 8.4.2 OECD GLP Principles 3.4 OECD GLP Principles 10 USDA Administrative Procedures for the PDP 5.2.1 USDA Administrative Procedures for the PDP 5.5	**27.4** The system shall provide a guaranteed means to retrieve and restore archived data and metadata that is readable and accurate.	
ASTM E1578-18 E-13-5	**27.5** The system should feature a reliable, effective, and supported data storage system.	

ASTM E1578-18 C-6-6 ASTM E1578-18 E-13-6	**27.6** The system should be able to interface directly with a third-party reporting tool.	
ASTM E1578-18 E-13-7	**27.7** The system should be capable of being configured to and conform to the laboratory's existing data storage platforms and standards.	
ASTM E1578-18 E-13-8	**27.8** The system should provide the ability to modify the data structures of the data storage mechanism as needed.	
ASTM E1578-18 E-13-9	**27.9** The system should allow for both development and production environments for its data storage tools and allow the movement of records from one environment to another.	
ASTM E1578-18 E-13-10	**27.10** The system shall provide data storage tools capable of fine-tuning the performance and security of data.	
21 CFR Part 11.10 (c) 21 CFR Part 211.68 (b) 21 CFR Part 820.180 45 CFR Part 164.308 AAVLD Requirements for an AVMDL Sec. 4.10.1.4 ASTM E1578-18 E-13-11 EPA 815-R-05-004 Chap. IV, Sec. 8 EPA 815-R-05-004 Chap. VI, Sec. 7.6 EPA ERLN Laboratory Requirements 4.9.5 and 4.9.14 EPA QA/G-5 2.1.9 E.U. Annex 11-7.2 E.U. Commission Directive 2003/94/EC Article 9.2 ISO 15189:2012 5.10.3 ISO/IEC 17025:2017 8.4.2 NIST 800-53, Rev. 4, CP-9 and CP-10 WHO Technical Report Series, #986, Annex 2, 15.9	**27.11** The system's data storage tools shall provide data backup and retrieval functions that meet or exceed industry best practices, including producing exact and complete backups that are secure from manipulation and loss.	
ASTM E1578-18 E-13-12	**27.12** The architecture of the system should be organized such that modules are clearly and logically separated, with standard interfaces provided between the modules.	

ASTM E1578-18 E-13-13	**27.13** The system should be able to optimally use system and hardware resources to allow for concurrent usage and high-peak usage.	
ASTM E1578-18 E-13-14	**27.14** The system should come with a well-documented application programming interface in order to facilitate granular interfaces with the system's underlying modular functionality.	
ASTM E1578-18 E-13-15 E.U. Annex 11-5 ISO 15189:2012 5.10.3	**27.15** The system shall provide a means to integrate and exchange data electronically based on relevant methods, and in such a way so as to ensure accurate and secure data transfer and processing.	
ASTM E1578-18 E-13-16	**27.16** The system shall be able to accurately replicate its data storage tools to ensure a recoverable system in the event of hardware failure.	
ASTM E1578-18 E-13-17	**27.17** The system should be able to interface with an external enterprise resource planning system.	
ASTM E1578-18 E-13-18	**27.18** The system should be capable of interfacing with enterprise middleware.	

28. Laboratory scheduling and capacity planning

Regulation, Specification, or Guidance	Requirement	Response
21 CFR Part 211.25 (c) ACMG Technical Standards for Clinical Genetics Laboratories B2 ASTM E1578-18 E-14-1	**28.1** The system should be able to accurately gauge and report test-based work capacity or throughput.	
ASTM E1578-18 E-14-2	**28.2** The system should provide scheduling tools for allocating	

	personnel and instruments to laboratory tasks.	
ASTM E1578-18 E-14-3	**28.3** The system should provide a means for tasks to be scheduled and allocated against available resources.	
42 CFR Part 493.1274 (d)	**28.4** The system should be able to track and limit the quantity of samples or hours worked on a type of sample by personnel, e.g., number of cytology slides or hours worked on them.	

29. Lean laboratory and continuous improvement

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 E-15-1	**29.1** The system should support a workload leveling strategy that automatically releases laboratory tasks to personnel.	
ASTM E1578-18 E-15-2 FDA Hazard Analysis Critical Control Point Principle 1	**29.2** The system should provide a means to quickly visualize and assess workflow processes at strategic points.	
21 CFR Part 211.42 (b) ASTM E1578-18 E-15-3 FDA Hazard Analysis Critical Control Point Principle 1	**29.3** The system should provide a means for mapping everyday workflow while identifying potential failure points.	

30. Artificial intelligence and smart systems

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 E-16-1	**30.1** The system should provide a means for integrating artificial intelligence (AI) into laboratory workflow as a smart agent or assistant.	
ASTM E1578-18 E-16-2	**30.2** The system should support ontology-based machine learning for assisting with the analysis of laboratory informatics datasets.	
ASTM E1578-18 E-16-3	**30.3** The system should support voice data capture and retrieval as smart laboratory assistance functions.	
ASTM E1578-18 E-16-4	**30.4** The system should be able to reschedule samples, change test assignments, and perform other laboratory activities based on voice command input.	
ASTM E1578-18 E-16-5 NIST 800-53, Rev. 5, MA-6(2)	**30.5** The system should support predictive maintenance routines for laboratory instruments and equipment.	
ASTM E1578-18 E-16-6	**30.6** The system should judiciously allow various system parameters to be optimized and ideal models set within the system by AI.	

ASTM E1578-18 E-16-7	**30.7** The system should allow AI to algorithmically infer from past learning how to customize without explicit instruction system parameters such as aggregation, transformation, and reporting of data.	
ASTM E1578-18 E-16-8 CLSI QMS22 2.1.2.1 ISO 15189:2012 5.10.3 NIST 800-53, Rev. 5, SI-4(5) and SI-4(7)	**30.8** The system should monitor laboratory operation parameters (such as capacity utilization and data integrity risks) and send notifications when necessary with recommendations for immediate and corrective action. The system should also maintain a log of all such monitored operational parameters and their status changes.	
7 CFR Part 331.11 7 CFR Part 331.17 9 CFR Part 121.11 9 CFR Part 121.17 21 CFR Part 211.28 21 CFR Part 211.46 21 CFR Part 312.58 (b) 21 CFR Part 312.69 42 CFR Part 73.11 42 CFR Part 73.17 45 CFR Part 164.310 A2LA C211 5.3.4 A2LA C211 5.4.7.2 A2LA C223 5.3 AAVLD Requirements for an AVMDL Sec. 5.3.1–2 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.3.4.1 ASTM E1492-11 4.1.8 ASTM E1492-11 4.4.2 ASTM E1578-18 E-16-9 CJIS Security Policy 5.9.1.6 CLSI QMS22 2.4.2 EPA ERLN Laboratory Requirements 4.1.13 EPA ERLN Laboratory Requirements 4.9.6 ISO 15189:2012 5.10.3 ISO/IEC 17025:2017 6.3.3 ISO/IEC 17025:2017 6.3.4 NIST 800-53, Rev. 5, MP-2 NIST 800-53, Rev. 5, PE-6(1)	**30.9** The system should allow for other types of facility monitoring (such as alarm, light, lock, and door statuses) and send notifications when necessary with recommendations for immediate and corrective action. The system should also maintain a log of all such monitored systems and their status changes.	

USDA Administrative Procedures for the PDP 5.2.1 USDA Sample Processing and Analysis Procedures for PDP 5.2 WHO Technical Report Series, #986, Annex 2, 9.5 WHO Technical Report Series, #986, Annex 2, 12.8 and 12.18		
42 CFR Part 493.1252 ASTM E1578-18 E-16-10 ISO 15189:2012 5.10.3	**30.10** The system should monitor instrument health (such as critical parameters and maintenance timing) and send notifications when necessary with recommendations for immediate and corrective action. The system should also maintain a log of all such monitored instrument activities and status changes.	
7 CFR Part 331.11 7 CFR Part 331.17 9 CFR Part 121.11 9 CFR Part 121.17 21 CFR Part 820.70 (c) 42 CFR Part 73.11 42 CFR Part 73.17 42 CFR Part 493.1252 42 CFR Part 493.1278 A2LA C211 5.3 A2LA C223 5.3 ACMG Technical Standards for Clinical Genetics Laboratories C1.2 AAVLD Requirements for an AVMDL Sec. 5.3.1–2 ABFT Accreditation Manual Sec. E-22 ASTM E1578-18 E-16-11 CAP Laboratory Accreditation Manual CLSI QMS22 2.2.3.5 EMA Guidance on Good Manufacturing Practice and Good Distribution Practice ISO 15189:2012 5.2.6 ISO 15189:2012 5.10.3 ISO/IEC 17025:2017 6.3.3 ISO/IEC 17025:2017 6.3.4 ISO/IEC 17025:2017 7.4.4 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards OECD GLP Principles 10 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2	**30.11** The system should allow for environmental control and monitoring of equipment (such as incubators and freezers) and send notifications when necessary with recommendations for immediate and corrective action. The system should also maintain a log of all such monitored equipment and their associated status changes.	

5.8.4) USDA Sample Processing and Analysis Procedures for PDP 5.2 WADA International Standard for Laboratories (ISL) 5.3.4 and 5.3.11 WHO Technical Report Series, #986, Annex 2, 12.8 and 12.16		

Security and Integrity of Systems and Operations

31. Data integrity

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 E-17-1 EMA Guidance on Good Manufacturing Practice and Good Distribution Practice WHO Technical Report Series, #996, Annex 5, 9.1	**31.1** System functionality should support ALCOA principles.	
ASTM E1578-18 E-17-2 EPA 815-R-05-004 Chap. IV, Sec. 8 A2LA C211 4.13.2.3 EMA Guidance on Good Manufacturing Practice and Good Distribution Practice EPA ERLN Laboratory Requirements 4.8.6 EPA ERLN Laboratory Requirements 4.9.1 and 4.9.7 NIST 800-53, Rev. 5, SI-12	**31.2** The system shall protect entered data so as to prevent it from being obscured by new data, keeping both the old and current data available for review.	
ASTM E1578-18 E-17-3 21 CFR Part 58.190 42 CFR Part 93.305 42 CFR Part 93.310 CLSI QMS22 2.2.2.2 EMA Guidance on Good Manufacturing Practice and Good Distribution Practice EPA 815-R-05-004 Chap. IV, Sec. 8 EPA ERLN Laboratory Requirements 4.3.4.1 EPA ERLN Laboratory Requirements 4.8.6 EPA ERLN Laboratory Requirements 4.8.9	**31.3** The system shall securely maintain a true, readable copy of an instrument's original (raw) data for on-demand review.	

EPA ERLN Laboratory Requirements 4.9.9 NIST 800-53, Rev. 5, SI-12 OECD GLP Principles 10 PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 4.13.3) USDA Administrative Procedures for the PDP 5.2.1 USDA Data and Instrumentation for PDP 8.1.3 WHO Technical Report Series, #996, Annex 5, 4.12 and Appendix 1		
7 CFR Part 91.30 7 CFR Part 331.17 (c) 9 CFR Part 2.35 9 CFR Part 121.17 (c) 10 CFR Part 20.2103–10 10 CFR Part 30.34 (g) 10 CFR Part 30.51–2 21 CFR Part 11.10 (c) 21 CFR Part 58.195 21 CFR Part 211.180 21 CFR Part 212.110 (c) 21 CFR Part 225.42 (b-8) 21 CFR Part 225.58 (c–d) 21 CFR Part 225.102 21 CFR Part 225.110 21 CFR Part 225.158 21 CFR Part 225.202 21 CFR Part 226.42 (a) 21 CFR Part 226.58 (f) 21 CFR Part 226.102 21 CFR Part 226.115 21 CFR Part 312.57 21 CFR Part 312.62 21 CFR Part 606.160 (d) 21 CFR Part 812.140 (d) 21 CFR Part 820.180 (b) 29 CFR Part 1910.120 (f)(8) 29 CFR Part 1910.1030 (h-2) 40 CFR Part 141.33 40 CFR Part 141.722 40 CFR Part 262.11 (f) 40 CFR Part 262.40 40 CFR Part 262.213 40 CFR Part 704 Subpart A 40 CFR Part 717.15 (d) 42 CFR Part 73.17 (c) 42 CFR Part 93.313 (h) 42 CFR Part 93.317 42 CFR Part 493.1105 42 CFR Part 493.1283 45 CFR Part 164.105 45 CFR Part 164.316 45 CFR Part 164.530 A2LA C223 5.4 A2LA C223 5.9	**31.4** The system shall have a mechanism to securely retain data in the system for a specific time period and enable protections that ensure the accurate and ready retrieval of that data throughout the records retention period.	

AAFCO QA/QC Guidelines for Feed Laboratories Sec. 2.4.4 or 3.1 AAVLD Requirements for an AVMDL Sec. 4.10.1.2 AAVLD Requirements for an AVMDL Sec. 4.10.2.1 AAVLD Requirements for an AVMDL Sec. 5.4.3.2 ABFT Accreditation Manual Sec. E-33 ACMG Technical Standards for Clinical Genetics Laboratories C1.5 ACMG Technical Standards for Clinical Genetics Laboratories C5.6 ACMG Technical Standards for Clinical Genetics Laboratories E2.1 AIHA-LAP Policies 2022 2A.7.5.1 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 4.14.1.2 and 4.15.1.2 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.9.3.6 and 5.9.7 ASTM E1578-18 E-17-4 CAP Laboratory Accreditation Manual CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition CJIS Security Policy 5.3.4 CJIS Security Policy 5.4.6–7 CJIS Security Policy 5.5.2.1 CLSI QMS22 2.8.3 EMA Guidance on Good Manufacturing Practice and Good Distribution Practice E.U. Annex 11-7.1 E.U. Commission Directive 2003/94/EC Article 9.1 E.U. Commission Directive 2003/94/EC Article 11.4 EPA 815-R-05-004 Chap. III, Sec. 15 EPA 815-R-05-004 Chap. IV, Sec. 8 EPA ERLN Laboratory Requirements 4.9.18 EPA ERLN Laboratory Requirements 4.11.17 EPA QA/G-5 2.1.9 ICH GCP 4.9.5 ISO 15189:2012 4.3 ISO/IEC 17025:2017 8.4.2 NIST 800-53, Rev. 5, AT-4 NIST 800-53, Rev. 5, AU-11 and AU-11(1) NIST 800-53, Rev. 5, SI-12 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards OECD GLP Principles 10 OSHA 1910.1020(d)(1)(i–ii) OSHA 1910.1450(j)(2) PFP Human and Animal Food Testing		

Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (throughout) USDA Administrative Procedures for the PDP 5.4 USDA Hemp Production Program Laboratory Testing Guidelines, Information Sharing 2 USDA LAS Laboratory Approval Program (LAP) Policies and Procedures 10c USDA Sampling Procedures for PDP 6.5 WADA International Standard for Laboratories (ISL) 5.2.3.5 and 5.4.4 WADA International Standard for the Protection of Privacy and Personal Information (ISPPPI) 10.0 WHO Technical Report Series, #986, Annex 2, 15.8–9 WHO Technical Report Series, #996, Annex 5, 11.15 and Appendix 1		
ASTM E1578-18 E-17-6 CJIS Security Policy 5.4.4 NIST 800-53, Rev. 5, AU-8 WHO Technical Report Series, #996, Annex 5, 4.12 and Appendix 1	**31.5** The system shall accurately reflect the system date and time in its use of electronic record time stamps.	
APHL 2019 LIS Project Management Guidebook ASTM E1578-18 E-17-7 CJIS Security Policy 5.6.1	**31.6** The system shall require each and every user to be assigned a unique user ID.	
ASTM E1578-18 E-17-8 21 CFR Part 11.10 (e) CJIS Security Policy 5.4.5 E.U. Annex 11-9 NIST 800-53, Rev. 5, AU-9	**31.7** The system shall prevent the modification, deletion, or disabling of its audit trail, as well as record such attempts.	
CJIS Security Policy 5.4.2 NIST 800-53, Rev. 5, AU-5 NIST 800-53, Rev. 5, SI-4	**31.8** The system shall be capable of identifying instances of audit processing failure (e.g., write errors, general failure of the audit tool, etc.), sending alerts or notifications to appropriate personnel in such cases.	

32. Configuration management

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 S-1-1 APHL 2019 LIS Project Management Guidebook	**32.1** The system shall provide tools to enter and manage user-configurable lookup or master data.	
ASTM E1578-18 S-1-2	**32.2** The system shall allow authorized users to configure the specification limits for sample and instrument tests.	
45 CFR Part 162.1002 USDA Sampling Procedures for PDP 6.3.2	**32.3** The system shall allow system nomenclature to be configured to use specific data code sets—such as the International Classification of Diseases or the Healthcare Common Procedure Coding System—or mandated terminology to support regulatory requirements.	
ASTM E1578-18 S-1-3	**32.4** The system should allow authorized personnel to configure the review and approval of multiple tests at the sample, batch, project, and experiment levels.	
ASTM E1578-18 S-1-4	**32.5** The system should allow warning and material specification limits to be entered and configured so as to allow their comparison against entered results and determinations for determining whether the results meet those specifications or limits.	

21 CFR Part 211.100 (b) 21 CFR Part 211.160 (a)	**32.6** The system should provide a configurable means of allowing the system to automatically save after each entry to help meet ALCOA, CGMP, and other requirements to contemporaneously record data into records.	
40 CFR Part 3.10 40 CFR Part 3.2000 ACMG Technical Standards for Clinical Genetics Laboratories C13.3 ASTM E1578-18 S-1-5 WHO Technical Report Series, #996, Annex 5, Appendix 1	**32.7** The system should provide a configurable (based on sample, test, or both) means of permitting electronic signatures for both entered results and approved reports.	
ASTM E1578-18 S-1-6	**32.8** The system should be capable of providing a complete list of all pending tests loaded in the system, the amount of material required for each test, and to which location the associated samples are to be sent for testing.	
ASTM E1578-18 S-1-7	**32.9** The system shall support configurable laboratory workflows based on appropriate laboratory process and procedure.	
ASTM E1578-18 S-1-8	**32.10** The system shall allow authorized personnel to assign status values for purposes of tracking sample progress or other portions of laboratory workflow.	
21 CFR Part 211.68 APHL 2019 LIS Project Management Guidebook ASTM E1578-18 S-1-9	**32.11** The system should allow authorized personnel to perform revision control of lookup or master data.	
ASTM E1578-18 S-1-10 APHL 2019 LIS Project Management Guidebook	**32.12** The system should provide a means for importing lookup or master data.	

AIHA-LAP Policies 2022 2A.7.8.4 ASTM E1578-18 S-1-11 EPA ERLN Laboratory Requirements 4.11.6 USDA Data and Instrumentation for PDP 9.1	**32.13** The system shall be able to define the number of significant figures (i.e., set rounding rules) for reported numeric data.	
ASTM E1578-18 S-1-12	**32.14** The system should allow calculated limits to be created and managed based on test results and relevant metadata.	
ASTM E1578-18 S-1-13 EPA ERLN Laboratory Requirements 3.2.6 EPA ERLN Laboratory Requirements 4.9.11	**32.15** The system should provide a clear alert or notification upon entry of out-of-specification results.	
ASTM E1578-18 S-1-14	**32.16** The system shall allow authorized personnel to update static and dynamic data.	
ASTM E1578-18 S-1-15	**32.17** The system should allow workflow events and status changes to trigger one or more user-defined actions.	
ASTM E1578-18 S-1-17 CJIS Security Policy 5.7.1 NIST 800-53, Rev. 5, AC-6(1) NIST 800-53, Rev. 5, CM-7	**32.18** The system should provide an interface for administrative access that permits approved users to configure the system without extra programming or manipulation of data storage systems.	
ASTM E1578-18 S-1-18 CAP Laboratory Accreditation Manual	**32.19** The system should allow administrators to programmatically customize system modules or build calculations within the application, while also accurately documenting those system modifications.	
ASTM E1578-18 S-1-19	**32.20** The system should provide a multiuser interface that can be configured to local user needs, including display language, character sets, and time zones.	

21 CFR Part 11.100 (a) ASTM E1578-18 S-1-20 E.U. Annex 11-14 NIST 800-53, Rev. 5, CM-5(1) WHO Technical Report Series, #996, Annex 5, Appendix 1	**32.21** The system should support rules governing electronic records and electronic signatures in regulated environments.	
7 CFR Part 331.11 9 CFR Part 121.11 10 CFR Part 20.2110 10 CFR Part 30.51 (c-1 21 CFR Part 11.10 (d) 21 CFR Part 211.68 42 CFR Part 73.11 45 CFR Part 164.308 A2LA C211 4.13.1.4 A2LA C211 5.4.7.2 AAVLD Requirements for an AVMDL Sec. 4.10.1.3–4 AAVLD Requirements for an AVMDL Sec. 5.4.4.1 ACMG Technical Standards for Clinical Genetics Laboratories C5.3 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.4.7.2.1 ASTM E1492-11 4.2.4 ASTM E1578-18 S-1-16 ASTM E1578-18 S-1-21 CJIS Security Policy 5.5.2 CLSI QMS22 2.4.3 E.U. Annex 11-12 EPA 815-R-05-004 Chap. IV, Sec. 8.6 EPA 815-R-05-004 Chap. VI, Sec. 8.6 EPA ERLN Laboratory Requirements 4.1.14–15 EPA ERLN Laboratory Requirements 4.9.4 and 4.9.14 ICH GCP 2.10 ISO/IEC 17025:2017 7.11.3 NIST 800-53, Rev. 5, CM-5 and CM-5(1) NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards PFP Human and Animal Food Testing Laboratories Best Practices Manual TNI EL-V1-2016-Rev.2.1 (V1,M2 4.13.1.4 USDA Administrative Procedures for the PDP 5.2.4 WADA International Standard for Laboratories (ISL) 5.2.3.5 WHO Technical Report Series, #986, Annex 2, 15.9	**32.22** The system shall provide a security interface usable across all modules of the system that secures data and operations and prevents unauthorized access to data and functions.	

CJIS Security Policy 5.5.2.2–3 EPA ERLN Laboratory Requirements 4.1.14–15 NIST 800-53, Rev. 5, AC-2(11)	**32.23** The system shall be able to granularly define access control down to the object level, role level, physical location, logical location, network address, and chronometric restriction level for the protection of regulated, patented, confidential, and classified data, methods, or other types of information.	
ASTM E1578-18 S-1-22 NIST 800-53, Rev. 5, IA-2(10)	**32.24** The system should support single sign-on such that a user can log in once and access all permitted functions and data.	
21 CFR Part 11.200 (a) 45 CFR Part 164.312 45 CFR Part 170.315 (d) APHL 2019 LIS Project Management Guidebook ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.4.7.2.1 ASTM E1578-18 E17-5 and S-3-1 CJIS Security Policy 5.6.1 CLSI QMS22 2.4.2.2 E.U. Annex 11-14 EPA 815-R-05-004 Chap. IV, Sec. 8.6 EPA 815-R-05-004 Chap. VI, Sec. 7.6 EPA 815-R-05-004 Chap. VI, Sec. 8.6 EPA ERLN Laboratory Requirements 4.9.4 ISO 15189:2012 5.10.3 NIST 800-53, Rev. 5, AC-2(7) and AC-3 NIST 800-53, Rev. 5, IA-2, IA-5, and IA-8 NIST 800-53, Rev. 5, MA-4 WADA International Standard for Laboratories (ISL) 5.2.3.5 WHO Technical Report Series, #986, Annex 2, 15.9 WHO Technical Report Series, #996, Annex 5, Appendix 1	**32.25** The system shall provide initial login access using at least two unique identification components, e.g., a user identifier and password, or biometric information linked to and used by the genuine user.	
21 CFR Part 11.300 (a) ASTM E1578-18 E17-5 and S-3-1 EPA 815-R-05-004 Chap. IV, Sec. 8.6 EPA 815-R-05-004 Chap. VI, Sec. 8.6	**32.26** The system shall prevent the same combination of identification components from being used across more than one account.	

ISO 15189:2012 5.10.3 NIST 800-53, Rev. 5, IA-4 and IA-5		
21 CFR Part 11.300 (b) ASTM E1578-18 E17-5 and S-3-1 CLSI QMS22 2.4.2 ISO 15189:2012 5.10.3 NIST 800-53, Rev. 5, IA-5 and IA-5(1)	**32.27** The system shall allow the administrator to define a time period in days after which a user will be prompted to change their password.	
CJIS Security Policy 5.6.3.1 NIST 800-53, Rev. 5, AC-2(3) NIST 800-53, Rev. 5, IA-4 and IA-5(1) NIST 800-53, Rev. 5, PS-4	**32.28** The system shall allow the administrator to define a time period of inactivity for a user identifier, after which it will be disabled and archived.	
CJIS Security Policy 5.5.2.2 NIST 800-53, Rev. 5, AC-10	**32.29** The system shall allow the administrator or authorized personnel to configure the allowance or prevention of multiple concurrent active sessions for one unique user.	
CJIS Security Policy 5.5.4 NIST 800-53, Rev. 5, AC-8	**32.30** The system shall allow the administrator or authorized personnel to configure approved system use (e.g., "you are accessing a restricted information system," "system use indicates consent to being monitored, recorded, and audited") and other types of notifications to appear before or after a user logs in to the system. These notifications should remain on the screen until acknowledged by the user.	
21 CFR Part 11.300 (d) 21 CFR Part 211.68 21 CFR Part 211.100 21 CFR Part 211.160 (a) 21 CFR Part 211.188 21 CFR Part 211.194 A2LA C211 4.13.2.1 ASTM E1578-18 E17-5 and S-3-1 CAP Laboratory Accreditation Manual CJIS Security Policy 5.4.1.1 CLSI QMS22 2.4.4 E.U. Commission Directive 2003/94/EC Article 9.2	**32.31** The system shall keep an accurate audit trail of login activities, including failed login attempts, unauthorized logins, and electronic signings.	

ISO 15189:2012 5.10.3 NIST 800-53, Rev. 5, CM-5(1) WADA International Standard for Laboratories (ISL) 5.2.3.5 WHO Technical Report Series, #986, Annex 2, 15.9		
21 CFR Part 11.300 (d) ASTM E1578-18 E17-5 and S-3-1 CJIS Security Policy 5.5.3 ISO 15189:2012 5.10.3 NIST 800-53, Rev. 5, AC-7	**32.32** The system shall allow the administrator or authorized personnel to define the number of failed login attempts before the system locks the user out.	
21 CFR Part 11.200 (a) ASTM E1578-18 S-3-1	**32.33** The system shall require at least one unique identification component for additional electronic signings (beyond initial login) during a single, continuous session.	
7 CFR Part 331.11 9 CFR Part 121.11 21 CFR Part 11.200 (a) 21 CFR Part 211.68 (b) 21 CFR Part 211.188 (b-11) 21 CFR Part 211.194 (a-7 and a-8) 21 CFR Part 212.50 (c-10) 42 CFR Part 73.11 ASTM E1578-18 S-3-1 CJIS Security Policy 5.6.3.2 NIST 800-53, Rev. 5, IA-5	**32.34** The vendor shall provide training materials emphasizing the importance of not sharing unique identification components with other individuals and promoting compliance review for ensuring such practices are followed.	
7 CFR Part 331.11 9 CFR Part 121.11 21 CFR Part 11.10 (d) 42 CFR Part 73.11 42 CFR Part 493.1231 45 CFR Part 164.308 45 CFR Part 164.514 45 CFR Part 170.315 (d) ASTM E1578-18 S-1-25 CJIS Security Policy 5.5.1 EPA ERLN Laboratory Requirements 4.1.14–15 NIST 800-53, Rev. 5, AC-3 NIST 800-53, Rev. 5, IA-2, IA-5, and IA-8	**32.35** The system shall support the ability to initially assign new individual users to system groups, roles, or both.	
21 CFR Part 11.100 (a) 45 CFR Part 164.312 ASTM E1578-18 S-1-24 E.U. Annex 11-14	**32.36** The system shall force a user's electronic signature to be unique and traceable to a specific user's account.	

WHO Technical Report Series, #996, Annex 5, Appendix 1		
21 CFR Part 11.100 (a) ASTM E1578-18 S-1-24	**32.37** The system shall prevent the reuse or reassignment of a user's electronic signature.	
21 CFR Part 11.50 E.U. Annex 11-14	**32.38** When the system generates a complete and accurate copy of an electronically signed record, it shall also display the printed name of the signer, the date and time of signature execution, and any applicable meaning associated with the signature. This shall be applicable for both electronically displayed and printed copies of the electronic record.	
ASTM E1578-18 S-1-26 APHL 2019 LIS Project Management Guidebook CLSI QMS22 2.8.5.3 WHO Technical Report Series, #996, Annex 5, Appendix 1	**32.39** The system should provide a means to migrate static data into the system.	
NIST 800-53, Rev. 5, IA-5(1) CLSI QMS22 2.4.2	**32.40** The system should provide a means for automatically authenticating if a user's proposed password meets the length, complexity, minimum number of changed characters, and other requirements as configured by the administrator or another authorized system user.	
NIST 800-53, Rev. 5, IA-6	**32.41** The system should provide a means for obscuring authentication feedback as it is entered into the system, e.g., displaying asterisks rather than the typed password or displaying actual typed feedback for a distinctly short period of time before obscuring it.	

33. System validation and commission

Regulation, Specification, or Guidance	Requirement	Response
ASTM E1578-18 S-2-1 CJIS Security Policy Appendix G.8 NIST 800-53, Rev. 5, SA-4(3)	**33.1** The vendor should be able to demonstrate the use of software development standards, secure coding practices, formal change control, and software revision control within its development practices. The vendor should also document its staff's skills and certifications.	
ASTM E1578-18 S-2-2 NIST 800-53, Rev. 5, SA-4(2)	**33.2** The vendor should be willing to provide access to source code through a suitable escrow.	
ASTM E1578-18 S-2-3	**33.3** The system should be able to document a summary and evaluation of enterprise performance markers and processes.	
A2LA C211 5.4.7.2 ASTM E1578-18 S-2-4 ISO 15189:2012 5.10.3 ISO/IEC 17025:2017 7.11.5 NIST 800-53, Rev. 5, SA-4(1), SA-4(2), and SA-5	**33.4** The system should be well documented by the vendor in comprehensive training material for all aspects of system use, including administration, operation, and troubleshooting.	
21 CFR Part 11.10 (a) 21 CFR Part 820.70 (i) A2LA C211 5.4.7.2 ACMG Technical Standards for Clinical Genetics Laboratories C5.7 CAP Laboratory Accreditation Manual CLSI QMS22 2.5 EMA Guidance on Good Manufacturing Practice and Good Distribution Practice E.U. Annex 11-11 EPA 815-R-05-004 Chap. IV, Sec.	**33.5** The system shall be validated initially and periodically, with those validation activities being documented, to ensure the accuracy, consistency, and reliability of system performance and its electronic records.	

8.6 EPA 815-R-05-004 Chap. VI, Sec. 8.6 E.U. Commission Directive 2003/94/EC Article 9.2 ISO 15189:2012 5.10.3 ISO/IEC 17025:2017 7.11.2 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards OECD GLP Principles 4.1 TNI EL-V1-2016-Rev.2.1 (V1,M2 5.4.7.2) WHO Technical Report Series, #996, Annex 5, 10.2		
ASTM E1578-18 S-2-2 CLSI QMS22 2.5 E.U. Annex 11-4 WHO Technical Report Series, #996, Annex 5, 10.3–7	**33.6** The documentation associated with system validation shall discuss all applicable steps of the life cycle, justify applied methods and standards, and include change control records and observed deviations during validation, if applicable.	

34. System administration

Regulation, Specification, or Guidance	Requirement	Response
21 CFR Part 11.200 (a) 45 CFR Part 164.312 45 CFR Part 170.315 (d-5) ASTM E1578-18 S-3-1 CJIS Security Policy 5.5.5 CLSI QMS22 2.4.2 NIST 800-53, Rev. 5, AC-11 and AC-12	**34.1** The system shall provide administrators with a configurable period of time to apply to user access or inactivity before again prompting a user for authentication credentials. The system shall also be able to display an explicit message indicating how much time remains before the user session terminates.	
ASTM E1578-18 S-3-2	**34.2** The system should provide a means for modifying personnel data in a batch.	

ASTM E1578-18 S-3-3	**34.3** The system should support the storage of standard and industry-specific data formats.	
7 CFR Part 331.11 9 CFR Part 121.11 21 CFR Part 11.10 (d) 21 CFR Part 211.68 (b) 42 CFR Part 73.11 45 CFR Part 164.308 45 CFR Part 164.514 APHL 2019 LIS Project Management Guidebook ASTM E1578-18 S-3-7 CJIS Security Policy 5.5.1 CJIS Security Policy 5.5.2.4 CJIS Security Policy Appendix G.5 CLSI QMS22 2.4.2 EPA 815-R-05-004 Chap. IV, Sec. 8.6 EPA 815-R-05-004 Chap. VI, Sec. 8.6 EPA ERLN Laboratory Requirements 4.1.14–15 ISO 15189:2012 5.10.2 NIST 800-53, Rev. 5, AC-2(7) and AC-3 NIST 800-53, Rev. 5, IA-2 and IA-8 NIST 800-53, Rev. 5, MA-4 NIST 800-53, Rev. 5, PS-4 and PS-5 USDA Administrative Procedures for the PDP 5.2.4 USDA Administrative Procedures for the PDP 5.5.1.2 WHO Technical Report Series, #996, Annex 5, 5.4 and Appendix 1	**34.4** The system shall support the ability to define, record, and change the level of access for individual users to system groups, roles, machines, processes, and objects based on their responsibilities, including when those responsibilities change. The system should be able to provide a list of individuals assigned to a given system group, role, machine, process, or object.	
ASTM E1578-18 S-3-8	**34.5** The vendor should provide maintenance agreements and support services for its applications and services.	
ASTM E1578-18 S-3-9 E.U. Annex 11-3.3 NIST 800-53, Rev. 5, SA-16 USDA Administrative Procedures for the PDP 5.2.4	**34.6** The vendor shall provide help desk, training, and installation support, as well as high-quality system documentation. The documentation should be reviewed to ensure that user requirements are fulfilled.	
7 CFR Part 331.11 9 CFR Part 121.11	**34.7** The vendor shall restrict logical access to database storage	

21 CFR Part 11.10 (c) 42 CFR Part 73.11 45 CFR Part 164.310 AAVLD Requirements for an AVMDL Sec. 5.4.4.3 ABFT Accreditation Manual Sec. D-5–D-8 ASCLD/LAB Supp. Reqs. for the Accreditation of Forensic Science Testing Laboratories 5.4.7.2.1 ASTM E1492-11 4.2.4 CJIS Security Policy 5.5.2 CJIS Security Policy 5.8.1 EPA ERLN Laboratory Requirements 4.9.6 E.U. Annex 11-7.1 E.U. Annex 11-12 ISO 15189:2012 5.10.2 ISO/IEC 17025:2017 7.11.3 NIST 800-53, Rev. 5, MA-5 NIST 800-53, Rev. 5, MP-2 NIST 800-53, Rev. 5, PE-3, PE-3(1), PE-6, PE-6(1), and PE-6(4) USDA Administrative Procedures for the PDP 5.2.1	components to authorized individuals. If providing a hosted service, the vendor should also restrict physical access to database storage components to authorized individuals. (In the case of an on-site solution, the buyer is responsible for limiting physical access to database storage components to meet 21 CFR Part 11, HIPAA, and CJIS guidelines.)	
CJIS Security Policy 5.5.1	**34.8** The system shall be able to tag and document an individual, group, and system account as having been validated for regulatory purposes, and remind the administrator or authorized personnel on a configurable schedule when the account should be validated again.	
7 CFR Part 331.17 9 CFR Part 121.17 42 CFR Part 73.17 ASTM E1578-18 S-3-10	**34.9** The system should provide a means of integrating with an enterprise personnel security directory, as well as physical security systems.	
7 CFR Part 331.11 9 CFR Part 121.11 42 CFR Part 73.11 ACMG Technical Standards for Clinical Genetics Laboratories C5.7 APHL 2019 LIS Project Management Guidebook ASTM E1578-18 S-3-11 CJIS Security Policy 5.10.4.1 CLSI QMS22 2.1.4 CLSI QMS22 2.6.1 EPA ERLN Laboratory Requirements 4.9.13	**34.10** The vendor should provide timely upgrades and patches, with complete documentation, that have been tested before installation and can be rolled back.	

NIST 800-53, Rev. 5, SI-2(5) NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards		
ASTM E1578-18 S-3-12	**34.11** The system shall provide a means for migrating data to a new release upon system upgrade.	
ASTM E1578-18 S-3-13	**34.12** The system should be expedient with the retrieval of stored items.	
21 CFR Part 11.10 (b) APHL 2019 LIS Project Management Guidebook E.U. Annex 11-5 E.U. Annex 11-8.1	**34.13** The system shall allow the printing of stored electronic records in a complete, accurate, and human-readable format.	
ASTM E1578-18 S-3-14	**34.14** The system should provide some sort of support for use on mobile technologies, particularly for the purpose of receiving notifications and monitoring processes.	
ASTM E1578-18 S-3-15 EPA ERLN Laboratory Requirements 4.9.13 NIST 800-53, Rev. 5, CM-3(2) NIST 800-53, Rev. 5, SI-2	**34.15** The system shall be able to install an upgrade into a test environment for testing purposes before upgrading the actual production environment.	

35. Cybersecurity

Regulation, Specification, or Guidance	Requirement	Response
42 CFR Part 493.1231 45 CFR Part 164.312 45 CFR Part 170.315 (d-9) ASTM E1578-18 S-4-1 CJIS Security Policy 5.6.4 CJIS Security Policy 5.8.2.1 CJIS Security Policy 5.10.1.2 CJIS Security Policy Appendix G.6	**35.1** The system should use secure communication protocols like SSL/TLS over Secure Hypertext Transfer Protocol with 256 bit encryption.	

CLSI QMS22 2.2.3.2 EMA Guidance on Good Manufacturing Practice and Good Distribution Practice NIST 800-53, Rev. 5, AC-17(2)		
42 CFR Part 493.1231 45 CFR Part 164.312 45 CFR Part 170.315 (d) ACMG Technical Standards for Clinical Genetics Laboratories C1.6 ASTM E1578-18 S-4-2 CJIS Security Policy 5.5.2.4 CJIS Security Policy 5.10.1.2 CJIS Security Policy Appendix G.6 NIST 800-53, Rev. 5, SC-13 and SC-28(1)	**35.2** The system should support database encryption and be capable of recording the encryption status of the data contained within.	
42 CFR Part 493.1231 CJIS Security Policy 5.6.2.2.1 CLSI QMS22 2.4.2.2 NIST 800-53, Rev. 5, AC-3 NIST 800-53, Rev. 5, IA-2, IA-2(1–4), and IA-8 NIST 800-53, Rev. 5, MA-4	**35.3** The system should be able to support multifactor authentication.	
45 CFR Part 170.202 45 CFR Part 170.315 (h)	**35.4** The system should support Office of the National Coordinator for Health Information Technology (ONC) transport standards and protocols for the reception and distribution of personal health information.	
NIST 800-53, Rev. 5, IA-7	**35.5** The system should provide a means for authenticating an individual seeking to access any embedded cryptographic module within the system, as well as the individual's role in performing services within the module.	
NIST 800-53, Rev. 5, SC-15	**35.6** The system should prevent connected collaborative computing devices (e.g., cameras, microphones, interactive whiteboards) from being activated without explicit permission from the end user, and it should provide	

	a clear indication of any activation to the end user.	

36. Information privacy

Regulation, Specification, or Guidance	Requirement	Response
45 CFR Part 164 Subpart E ACMG Technical Standards for Clinical Genetics Laboratories G17.2 ASTM E1578-18 S-5-1 CAP Laboratory Accreditation Manual	**36.1** The system shall comply with privacy protection compliance like that found in HIPAA provisions.	
10 CFR Part 20.2106 (d) 45 CFR Part 164.105 45 CFR Part 164 Subpart C 45 CFR Part 170.315 (d) ASTM E1578-18 S-5-2 ICH GCP 2.11 NYSDOH CLEP Clinical Laboratory Standards of Practice, General Systems Standards WADA International Standard for Laboratories (ISL) 5.3.8.3 WADA International Standard for the Protection of Privacy and Personal Information (ISPPPI) (throughout)	**36.2** The system should be provisioned with enough security to prevent personally identifiable information in the system from being compromised.	
45 CFR Part 164.514 ACMG Technical Standards for Clinical Genetics Laboratories C5.5 CAP Laboratory Accreditation Manual WADA International Standard for the Protection of Privacy and Personal Information (ISPPPI) 10.3	**36.3** The system shall allow authorized individuals to de-identify select data in the system, including but not limited to names, geographic locations, dates, government-issued identification numbers, telephone numbers, email addresses, full-face photos, and other personal identifiers.	
45 CFR Part 164 Subpart E NIST 800-53, Rev. 5, AC-6	**36.4** The system shall be able to verify and ensure that users authorized to view de-identified data are also not a member of a role that permits access to	

	information that re-identifies the data, i.e., segregate duties.	
NIST 800-53, Rev. 5, SI-19(7)	**36.5** The system should use validated algorithms to de-identify data in the system and be validated to use those algorithms.	