Technical Requirements and CLSI Guidelines for Laboratory Test Method Life Phases
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			REQUIREMENTS				CLSI GUIDELINES**
	Phases	**Activity**	**FDA QSR[1]**	**CLIA[2]**	**NYS[3]***	**ISO[4-8]**	
Establishment	**1. Feasibility and Design**		21 CFR 820.30		QMS FS; S1-S7 Director: DR FS; S1-S5 Human Resources: HR FS; S1-S10	**ISO 9001:2015** Clauses: 8.2.1, 8.2.2, 8.2.3, 8.3.1 through 8.3.6	General: EP12, QSRLDT Process Management: EP19, QMS13 Documents: QSRLDT, QMS02
	2. Development	General	820.30, 820.50, 820.181, 820.40, 820.60, 820.65		Facility: FD FS; S1-S3 Safety: LS FS; S1-S17 Resources: RM FS; GRM S1-S7 Equipment LEI S1-S9 Reagents: RGM S1-S5 QC S1	**ISO 9001:2015** Clauses 8.3.1 through 8.3.6 **ISO 13485:2016** Clauses 7.1 through 7.3	Facilities: QSRLDT Suppliers: QSRLDT, QMS21 Equipment: QSRLDT, QMS01, QMS13, AUTO08 Process Management: EP19, QMS18, QSRLDT, EP23, EP12 Documents: QMS13, QMS26, QSRLDT
		Risk Analysis, Evaluation, and Control		493.1253(b)(3) & c, 493.1256	QC S2	**ISO 14971:2019** **ISO 17025:2017** Clause 8.5 **ISO 22367:2020**	EP18, EP21
	3. Validation	General	820.30 820.75 820.86	493.1253(a), 493.1253(b)(2), 493.1253(b)(2)(vii), 493.1253(c), 493.1254(b)	Test Performance Specifications: TPS S2-S4	**ISO 13485:2016** Clauses 7.5, 7.6 **ISO 17025:2017** Clause 7.2.2 **ISO 15189:2012** Clauses 5.5.1.1, 5.5.1.3, 5.5.1.4, 5.5.2	General: EP19, QMS18 Process Management: EP19, QMS18 Documents: QMS02, QMS26, QSRLDT Process Management: EP12 NCE Management: QSRLDT Assessment: QSRLDT
		Precision			Calibration: CAL S1-S2		EP05
		Accuracy		493.1253(b)(2)(i) & c			EP09
		Measuring Interval		493.1253(b)(2)(v) & c			EP06, EP34
		Reference Interval		493.1253(b)(2)(vi) & c			EP28
		Detection Capability		493.1253(b)(2)(iii) & c			EP17
		Analytical Specificity		493.1253(b)(2)(iv) & c			C56, EP07, EP37
		Clinical Validation					EP24, EP27
		Reagent/Sample Stability		493.1253(b)(3) & c, 493.1256			EP25
	TRANSFER TO IMPLEMENTATION						

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	Phases	**Activity**	**FDA QSR**	**CLIA**	**NYS**	**ISO**	
Implementation	**4. Preliminary Evaluation**		820.30 820.70 820.140 820.150 820.160 820.170		QMS FS Director: DR FS; S1-S5 Human Resources: HR FS; S1-S6 Facility: FD FS; S1-S3 Safety: LS FS; S1-S17	**ISO 17025:2017** Clauses 6.1 - 6.4; 6.6; 7.1 **ISO 15189:2012** Clauses 4.3 - 4.7; 5.1, 5.2, 5.3, 5.10 **ISO 15190:2020**	Facilities: QMS01, QMS23 Personnel: QMS03 Suppliers: QMS01 Equipment: QMS01, QMS13 Process Management: EP12, QMS01, QMS02, EP10 Documents: QMS02, QMS26
	5. Verification	General	820.30 820.86		Resources: RM FS Equipment LEI S1-S9 Reagents: RGM S1-S5 Test Performance Specs: TPS S1: S3-S5 Calibration: CAL S1	**ISO 17025:2017** Clause 7.2.1 Clause 7.11.2 **ISO 15189:2012** Clauses 4.3, 5.3.1.7, 5.5.1.2	Personnel: QMS03, EP12 Equipment: QMS23 Process Management: QMS18, EP23, C24 Documents: QMS02, QMS26
		Risk Assessment		IQCP in Interpretive Guidelines; refers to 493.1256(d) https://www.cms.gov/regulations-and-guidance/legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html 493.1253(b)(3) and c	QC S2	**ISO 17025:2017** Clause 8.5 **ISO 15189:2012** Clause 4.14.6	EP18, EP21, EP23
		Precision		493.1253(b)(1)(i)(B) & c		**ISO 15189:2012** Clauses 5.5.1.4, 5.5.2 **ISO 17025:2017** Clauses 7.6	EP15, EP09, EP21, EP12
		Accuracy		493.1253(b)(1)(i)(A) & c			EP07
		Measuring Interval		493.1253(b)(1)(i)(C) & c			EP06, EP34
		Reference Interval		493.1253(b)(1)(ii) & c			EP28
		Detection Capability					EP17

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			REQUIREMENTS				CLSI
	Phases	**Activity**	**FDA QSR**	**CLIA**	**NYS**	**ISO**	**GUIDELINES**
	6. Preparation and Launch		820.30 820.50 820.120, 820.130	493.1236, 493.1252, 493.901-905, 493.1100-1105, 493.1200-1299	QMS: S1-S3 Resources: GRM S1-S7 LIS: LIS-FS; S1-S6 Documents: DC-FS; DC S1-S5 Referral Labs: RCL S1-S3 Preanalytic: PRS FS; TR S1-S4; SP S1-S8 Analytic: AS FS; TPC S1-S2; TPS S1, S3-S4 Calibration: CAL S1 QC S1-S8 Postanalytic: PAS-FS; RR S1-S2 Confidentiality: CON S1-S3	**ISO 13485:2016** Clauses 4.2.3, 7.4 **ISO 17025:2017** Clauses 6.5; 7.3 through 7.8; 7.11 **ISO 15189:2012** Clauses 4.3 through 4.7 Clauses 5.4 through 5.10	Customer Focus: QMS18, QMS19 Facilities: QMS01, GP17, M29, GP05 Personnel: QMS16, QMS03 Suppliers: QMS21, QMS05 Equipment: QMS04, QMS13, QMS23 Process Management: QMS01, QMS02, QMS18, QMS26, AUTO15, QMS06, EP23 Documents and Records: QMS18, QMS02, QMS26 Information Management: AUTO08, QMS22 Nonconforming Events: QMS11 Assessments: QMS17, QMS24, QMS12, QMS15

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Appendix A. (Continued)

			REQUIREMENTS				CLSI
	Phases	**Activity**	**FDA QSR**	**CLIA**	**NYS**	**ISO**	**GUIDELINES**
Implementation, continued	**7. Maintenance**	General	820.30, 820.40, 820.72, 820.90, 820.100, 820.181, 820.184, 820.186, 820.198, 820.200	493.1200, 493.1201-493.1227, 493.1230, 493.1233, 493.1234, 493.1235, 493.1236, 493.1239, 493.1240, 493.1241, 493.1242, 493.1249, 493.1251, 493.1252, 493.1289	Director: DR S5 QMS: S4–S7 Human Resources: HR S7-S10 Equipment: LE S5-S9 Calibration: CAL S2 Nonconformance: RR S3 Reporting: REP S1-S6 Public Health: S1-S2 Confidentiality: CON S1-S3 Retention: DSR FS; S1-S12 Investigation: ICA FS; S1-S5	**ISO 13485:2016** Clauses 4.2.3; 8.1 through 8.5 **ISO 17025:2017** Change control and Clauses 7.9, 7.10, 7.11; 8.3, 8.4, 8.6 through 8.9 **ISO 15189:2012** Change control and Clauses 4.3; 4.8 through 4.15	Organization: QMS14 Customers: QMS19 Facilities: GP17 Personnel: QMS03 Suppliers: QMS21, QMS05, EP26 Equipment: QMS13, QMS23 Process Management: QMS18, C24, EP23 Documents: QMS02, QMS26 Information Management: AUTO08, AUTO15 Nonconforming Events: QMS11 Improvement: QMS06
		Quality Assessment		Subpart H, 493.1236, 493.1254, 493.1255, 493.1256	Director: DR S4 QC: S9-S14 Proficiency Testing: PT FS; S1-S16	**ISO 17025:2017** Clause 7.7 **ISO 15189:2012** Clause 5.6	QMS17, QMS24, QMS12, QMS15
		Result Comparability		493.1281(a) 493.1281(b)	TPS S5		EP26, EP31
		Results Review and Follow-up		493.1290, 493.1291, 493.1299	RR S1-S2		EP31
	8. Retirement		820.180	493.1105	Document Control: DC S6 Retention: DSR FS Safety: LS S13	**ISO 13485:2016** Clauses 4.2.3, 4.2.4, 4.2.5 **ISO 17025:2017** Clauses 7.11, 8.3, 8.4 **ISO 15189:2012** Clauses 4.3, 4.13, 5.3.1.7, 5.10	Organization: QMS14 Customers: QMS18, QMS19 Equipment: QMS13, M29 Documents: QMS02, QMS26

* NYS Clinical Laboratory Standards Tables 1 and 2 contain discipline-specific requirements. Readers should refer to the standards document for this information.

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