

1 VAC 30 CHAPTER 46

Summary of regulatory citations for Most Frequent Inspection Findings for Inspections Conducted Between 09/01/2016 and 03/05/2018

This list may be a helpful tool for internal auditing, in conjunction with full checklists used to assess compliance with 1VAC30-46. This list does not provide a full quality system internal audit.

	Checklist Group(s)	Reference	Text
1	Methods And Method Validation	V1M2 5.4.1	See 2009 TNI Standard for text
2	Standard Operating Procedures (SOPs) / Quality Manual / Document Control	V1M2 4.2.8.5.f	See 2009 TNI Standard for text
	Standard Operating Procedures (SOPs) / Quality Manual	V1M2 4.2.8.3	See 2009 TNI Standard for text
	Standard Operating Procedures (SOPs) / Quality Manual	V1M2 4.2.8.4.i	See 2009 TNI Standard for text
	Standard Operating Procedures (SOPs) / Quality Manual	V1M2 4.2.8.4.r	See 2009 TNI Standard for text
	Standard Operating Procedures (SOPs) / Quality Manual	V1M2 4.3.1	See 2009 TNI Standard for text
	Standard Operating Procedures (SOPs) / Quality Manual	V1M2 4.3.2.1	See 2009 TNI Standard for text
	Standard Operating Procedures (SOPs) / Quality Manual	V1M2 4.2.1	See 2009 TNI Standard for text
	3	Control Of Records / Traceability	V1M2 4.13.3.a and f
Control Of Records / Traceability		V1M2 4.13.3.e	See 2009 TNI Standard for text
Control Of Records / Traceability		V1M2 4.13.1.4	See 2009 TNI Standard for text
Control Of Records / Traceability		V1M2 5.6.4.2.a	See 2009 TNI Standard for text
Control Of Records / Traceability		V1M2 4.13.2.2	See 2009 TNI Standard for text
Control Of Records / Traceability		V1M2 4.13.2.3	See 2009 TNI Standard for text
Control Of Records / Traceability		V1M2 5.6.4.2.c	See 2009 TNI Standard for text
4	Management	V1M2 4.2.2.e	See 2009 TNI Standard for text
	Organization	V1M2 4.1.7.2.e	See 2009 TNI Standard for text
5	Service To Client	V1M2 4.7.2	See 2009 TNI Standard for text
6	Corrective Action	V1M2 4.11.4	See 2009 TNI Standard for text

	Corrective Action	V1M1 6.1	See 2009 TNI Standard for text
7	Subcontracting	V1M2 4.5.4	See 2009 TNI Standard for text
8	Calibration Requirements - Support Equipment	V1M2 5.5.13.1.b	See 2009 TNI Standard for text
	Calibration Requirements - Support Equipment	V1M2 5.5.13.1.e	See 2009 TNI Standard for text
9	Internal Audits	V1M2 4.14.5.c	See 2009 TNI Standard for text
	Internal Audits	V1M2 4.14.2	See 2009 TNI Standard for text
10	Microbiological Testing - Sterility Checks	V1M5 1.7.3.1.b.iv	See 2009 TNI Standard for text
	Microbiological Testing - Matrix Spike (Ms); Matrix Spike Duplicate (Msd)	V1M5 1.7.3.3.b	See 2009 TNI Standard for text