

Inspector IQCP Do's and Don'ts

IQCP REQUIREMENT	DO CITE IF:	DON'T CITE BECAUSE:
COM.50300	1.) Risk Assessment (RA) is missing one or more of the five required components (specimen, reagent, environment, testing personnel, test system)	1.) The format of RA is not "user-friendly" - RECOMMEND
	2.) RA doesn't cover all three phases of testing: pre-analytic, analytic, and post-analytic	2.) The RA doesn't look like the ones in YOUR lab - DISCUSS
	3.) RA did not include in-house data (previous QC records, environmental monitoring, etc.) or did not involve laboratory personnel	3.) You disagree with the acceptability of a specific risk - DISCUSS
COM.50400, COM.50500	4.) Quality Control Plan (QCP) was not signed by the laboratory director prior to implementation	4.) You disagree with the frequency of the QC being run - RECOMMEND
	5.) QC is performed less frequently than specified in manufacturer's instructions	5.) You think the QCP does not address potential risks - RECOMMEND
	6.) QCP is not followed as written	6.) You disagree with the acceptability of QC to mitigate a specific risk - DISCUSS
COM.50600	7.) Quality Assurance process does not monitor devices used in all locations	7.) You don't think that the lab has adequately addressed potential patient outcomes - RECOMMEND
	8.) Serious quality concerns or adverse patient outcomes have not been addressed – MAY ALSO NEED TO CITE TLC.10460	
Daily QC Requirement – Discipline-specific Checklists	9.) Equivalent Quality Control (EQC) is still in use without an approved IQCP – CITE DISCIPLINE-SPECIFIC CHECKLIST DAILY QC REQUIREMENT(S)	
	10.) Laboratory is using an IQCP for a test that is not eligible	
COM.50200	11.) Laboratory is not using the required CAP List of IQCPs form	