COLLEGE of AMERICAN PATHOLOGISTS

Instructions for Inspecting the New Individualized Quality Control Plan (IQCP) Checklist Requirements

If you are conducting an inspection after 1/1/2016, please follow the instructions below and use the reference documents indicated for evaluating the laboratory's quality control practices for determining compliance with the CAP's quality control requirements. If a laboratory has decreased the frequency of external quality controls for eligible tests below the minimum default requirement, an IQCP must be implemented.

1. The laboratory should have completed **both** the "List of Individualized Quality Control Plans" form and the "Individualized Quality Control Plan Summary" form, and have these completed forms available for the inspection team. It is acceptable for the team leader to contact the laboratory director to request these forms ahead of time, if desired.

2. Review the list of tests utilizing an IQCP to ensure that the tests are eligible for IQCP. To determine eligibility, please refer to the "Eligibility Determination for IQCP" flowchart included in this packet (Attachment A).

3. Once you've established the tests are eligible for IQCP, review the summary of the IQCPs and ensure that the frequency of QC is not less than that required by the manufacturer (you may need to refer to the package insert for manufacturer instructions).

4. Review the IQCP for each test to ensure it is complete. To be considered complete, the IQCP must include the 5-part risk assessment, the quality control plan signed and dated by the laboratory director prior to implementation, and the quality assessment plan. The frequency and type of QC must be specified in the quality control plan.

5. Review the quality control records and ensure that QC is recorded as defined in the quality control plan. Review ongoing quality assessment records, including corrective actions, periodic reviews of the QC results, and other records defined in the Quality Assessment process. Refer to the checklists for specific requirements.

6. If you find any instances where the above items are not met, the appropriate deficiency(ies) must be cited. Since there may be many IQCPs in place in a given laboratory, it is imperative that you clearly state on the Inspector Summation Report (ISR) which test/analyte the deficiency is for, and which elements of the IQCP are missing. For example:

   "The risk assessment for (list test(s) and instrument/device name) does not contain all the required elements. (List specific missing elements) is(are) missing".

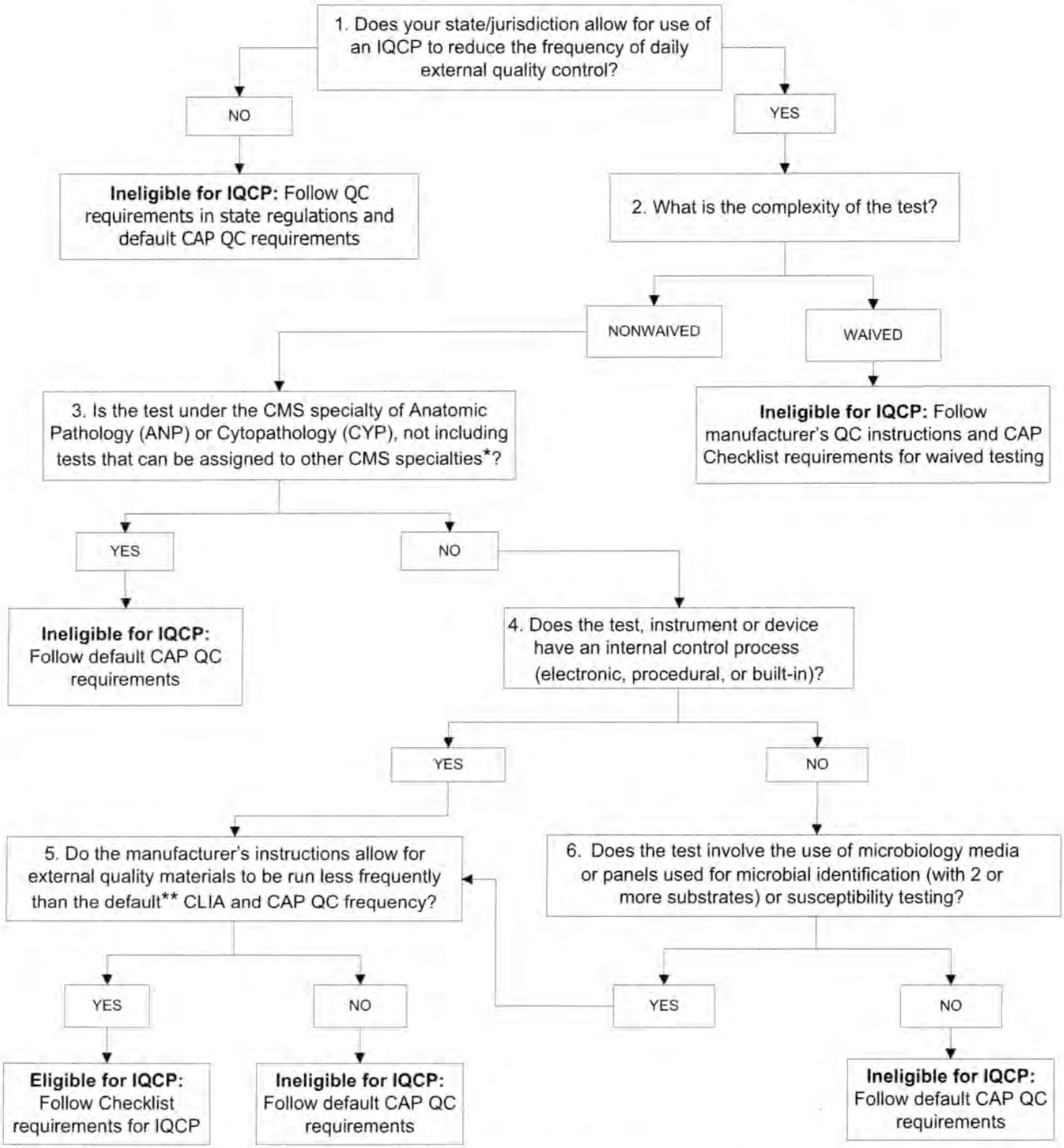
7. If you are unsure if you should cite a deficiency or a recommendation, you may also wish to refer to the enclosed "Inspector IQCP Dos and Don'ts" table for guidance (Attachment E). You may also wish to contact the CAP for additional guidance using the phone number below.

If you have any questions during the inspection, please contact the CAP's Accreditation Programs for assistance by calling 800-323-4040, option 1.

COLLEGE of AMERICAN PATHOLOGISTS

Attachment A

Eligibility Determination for Individualized Quality Control Plan (IQCP) Option



* ANP or CYP tests are ineligible for IQCP unless the testing can be billed under another CMS specialty.

** The default CAP QC frequency for external quality control materials is as follows:

1. Quantitative tests - two controls at different concentrations each day of patient testing, except for Coagulation tests (two levels every eight hours) and Blood Gas testing (one level every eight hours).
2. Qualitative tests – positive and negative controls each day of patient testing.

COLLEGE of AMERICAN PATHOLOGISTS

IQCP INSPECTOR TIPSHEET

Attachment D

Processes/Areas for Observation	• Risk Assessment • Quality Control Plan • Quality Assessment Monitoring
Key Documents to Review	1. Policies and procedures for the implementation of an IQCP 2. Completed CAP IQCP forms from the laboratory to sample records a. List of Individualized Quality Control Plans Form b. CAP Individualized Quality Control Plan Summary Form 3. Review a sampling of IQCP records with emphasis on tests with IQCPs implemented in the past two years. Must include: a. Risk Assessment 1) All three phases of the testing process: preanalytic, analytic, and post analytic 2) All five required components: Specimen, Test System, Reagent, Environment, Testing Personnel 3) Data from the laboratory's own environment, instrument/equipment performance, and testing personnel, including variations in use 4) Review of the manufacturer's instructions and recommendations to identify potential risks and processes to mitigate risk b. Quality Control Plan 1) Approval of the plan with signature of laboratory director and date before implementation 2) Number, type (external and internal quality control systems), and frequency of quality control defined 3) Quality control performed at least as frequent as required in manufacturer's instructions 4) External control materials run with new lots and shipments and at least every 31 days at minimum (does not apply to microbiology media, ID systems or susceptibility testing) 5) Additional processes for monitoring the quality of the specimen, test system, reagents, environment and testing personnel defined based on risk assessment 6) Customization of quality control plan for variations in use, including multiple identical devices, different personnel or different testing locations 7) Quality control plan followed as written c. Quality Assessment Monitoring 1) Monthly review of quality control and instrument/equipment maintenance and function check data 2) Evaluation of errors relating to all phases of the testing process 3) Separate monitoring for variations in testing 4) Evaluation of complaints on the quality of testing 5) Evaluation of corrective actions taken if problems are identified 6) Reevaluation of the risk assessment when failures are identified 7) Annual reapproval of the quality control plan

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	
COM.04000	9.) Equivalent Quality Control (EQC) is still in use without an approved IQCP – MAY ALSO NEED TO CITE DISCIPLINE-SPECIFIC CHECKLIST QC REQUIREMENTS	
	10.) Laboratory is using an IQCP for a test that is not eligible	
COM.50200	11.) Laboratory is not using the required CAP forms for IQCP List and/or IQCP Summary	