IQCP?…IDK…

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.FTW!

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Poll Question 1

- You probably know what IQCP stands for. But what *should* it stand for?
  1. Icelanders quietly control Pennsylvania?
  2. Initiate quantum chocolate pie!
  3. I quit completely POC.
  4. Integrated quirky conceptual pizza.
  5. In quarterfinals, crush the Padres!

Learning Objectives

- Participants will be able to:
  - Describe the regulatory and quality of care rationales for Individualized Quality Control Plan (IQCP).
  - Analyze the need for an IQCP, given a particular test system.
  - Describe the elements of an IQCP.
  - Perform and analyze risks related to laboratory testing for IQCP.
  - Find and utilize templates for IQCP from ASM and CAP.
  - Apply their newfound knowledge to IQCP development.

Outline

IQCP

- Historical and regulatory background
- What exactly is an IQCP?

IDK

- What tests are eligible?
- When do you need one?

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- What are the elements of an IQCP?
- What is a risk assessment and how do I perform them?

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- Where can you find resources and templates to make IQCP as painless as possible?

IQCP?

What is it? Why do I need it?

Quality Control Under CLIA

- Section §493.1202(c) for **unmodified moderate complexity tests**:
  - assay **at least two levels of control materials each day of testing** (a run cannot exceed 24 hours) and keep records;
  - perform and document any applicable specialty and subspecialty control procedures;
  - perform and document remedial actions as specified in §493.1219;
  - maintain records of all QC activities for 2 years or 5 years for immunohematology and 10 years for pathology as specified in §493.1221.
- For certain tests CLIA requires additional QC:
  - Blood gases, automated hematology and coagulation test systems, manual cell counts using a hemocytometer, manual coagulation testing, electrophoresis, and thin layer chromatography all require additional controls.

Microbiology QC Under CLIA

- For **microbiological media**, CLIA regulations for media [42 CFR 493.1256 (e)(4)(i-iii)] state the laboratory must:
  - **Check each batch of media for sterility** if sterility is required for testing;
  - **Check each batch of media for its ability to support growth** and, as appropriate, **select or inhibit specific organisms or produce a biochemical response**; and
  - Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.
- For **microbiology AST** the CLIA requirements at §493.1261(b)(1-2) state laboratory must check;
  - Each batch of media and each lot/shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms;
  - **Each day tests are performed**, use appropriate control organism(s) to check the procedure; zone sizes or MICs must be within established limits before reporting patient results.

Problems with CLIA QC: Microbiological media

- A large study (documented in CLSI M22-A3 and independent publications) shows that most media QC failures are due to QC strain failure.
- The actual failure rate for commonly-used media is well under .5%.
  - Jones RN, Krisher K, Bird DS; College of American Pathologists Microbiology Resource Committee. Results of the survey of the quality assurance for commercially prepared microbiology media. Update from the College of American Pathologists Microbiology Surveys Program (2001). Arch Pathol Lab Med. 2003 Jun;127(6):661-5.
- An 'exempt media' class was described in CLSI M322-A3

Table 3. Raw and Extrapolated Lot Failure Rates for 38 Media With Significant Quality Control (QC) Experience Data as Defined by ≥1000 Lots or ≥100 000 Items Screened

Medium	No. of Items	No. of Lots	No. of Lots Failed With Reason		Failure Rates, %	
			Total	QC Strains	Raw	Extrapolated*
Chocolate	15 710 003	62 119	137	64	0.36	0.17†
Thayer-Martin	1 771 833	26 761	98	76	0.64	0.49†
BACTEC bottle	1 458 169	4658	6	2	0.79	0.26†
CVA	1 243 778	18 002	57	47	0.73	0.60
LIM broth (Todd-Hewitt with CNA)	1 083 196	4793	18	14	0.31	0.24†
MacConkey with sorbitol	1 038 153	19 346	34	20	1.04	0.61
Campy blood (Blaser)	1 028 332	20 406	76	57	0.72	0.54
Selective strep agar	878 304	6781	13	5	0.10	0.04†
Martin-Lewis	851 763	8053	15	15	0.52	0.52
BacT/Alert bottle	742 626	995	6	3	0.10	0.05†
CDC laked blood with kanamycin and vancomycin	453 158	7145	16	9	0.36	0.20†
GC-II (CA/IsoVitaleX)	439 831	1679	14	7	1.37	0.68
CDC sheep blood with kanamycin and vancomycin	436 336	7132	26	11	0.42	0.18†
Bacteroides bile esculin	419 733	7472	18	8	0.39	0.14†
Brucella with hemin and vitamin K	399 979	3639	11	3	0.41	0.11†
CDC sheep blood with PEA	383 557	6504	13	5	2.03	0.78
Inhibitory mold agar	381 494	3934	8	5	0.64	0.40†
Kanamycin laked blood	365 545	3110	10	4	0.39	0.15†
Brucella agar	352 424	2760	8	4	0.25	0.13†
Todd-Hewitt	300 131	2130	6	4	0.94	0.63
GC-Lect agar	281 869	2815	17	11	0.46	0.30†
SXT agar	279 062	2551	15	5	0.31	0.10†
BHI with sheep blood with chloramphenicol and gentamicin	258 575	3494	19	6	0.34	0.17†
TSA with sheep blood with ampicilin	247 849	1102	13	2	2.00	0.31†
TCBS (*Vibrio cholerae*)	205 251	3073	19	9	0.65	0.27†
SAB with chloramphenicol and gentamicin	166 592	2018	6	2	0.25	0.08†
Brucella laked blood with kanamycin and vancomycin	163 797	2444	18	7	0.83	0.33†
Charcoal selective	133 839	2372	12	7	0.67	0.39†
Nutrient broth	125 398	985	2	2	1.32	1.32
Reagan-Lowe agar	52 044	3853	13	8	2.10	1.29
Legionella selective	76 485	2371	13	9	0.55	0.38†
Potato dextrose agar	92 335	1877	6	2	1.49	0.50†
PC (*Burkholderia cepacia*)	44 245	1867	4	4	0.48	0.48†
Cornmeal with Tween	57 659	1737	9	5	2.42	1.34
Cornmeal	34 842	1722	7	2	1.16	0.33†
Egg yolk (modified)	50 580	1346	7	3	0.59	0.25†
Inhibitory mold agar with gentamicin	95 156	1232	2	1	0.24	0.12†
BHI with sheep blood with CC	82 059	1087	8	4	1.47	0.74

* Extrapolated failure rate represents that rate resulting from QC organism testing and excludes other reasons, such as sterility, hemolysis, surface efects, etc.

† Failure rates meeting the criteria for exemption as published previously by the NCCLS M22-A[1] derived from earlier CAP statistics[2] and expanded ≤0.50% by the NCCLS in 2003.

Problems with CLIA QC: Cartridge-based test systems

A system with a dozen testing modules (what exactly is a test system anyway?*)

Each cartridge costs ~$150

Each cartridge tests 20+ targets. Does each target need QC?

Even if just 2 controls/d (not necessarily realistic; you can't really put 22 targets in one molecular control) that's $110,000/year in control testing.

All the reagents are in the cartridge, with internal controls, so if you QC one cartridge, you've QCed -- one cartridge.

* I am ***so*** not getting into that here.

Enter the IQCP…

- There's an older solution to this problem called EQC, Equivalent Quality Control. No longer allowed, mentioned for historical purposes.
- CMS/CLIA offers IQCP
- **IQCP stands for Individualized Quality Control Plan.**
- Performing an IQCP 'customizes a QC Plan for a nonwaived test in its unique environment, and offers laboratories flexibility in achieving QC compliance.'

IDK…

So exactly what does an IQCP apply to?

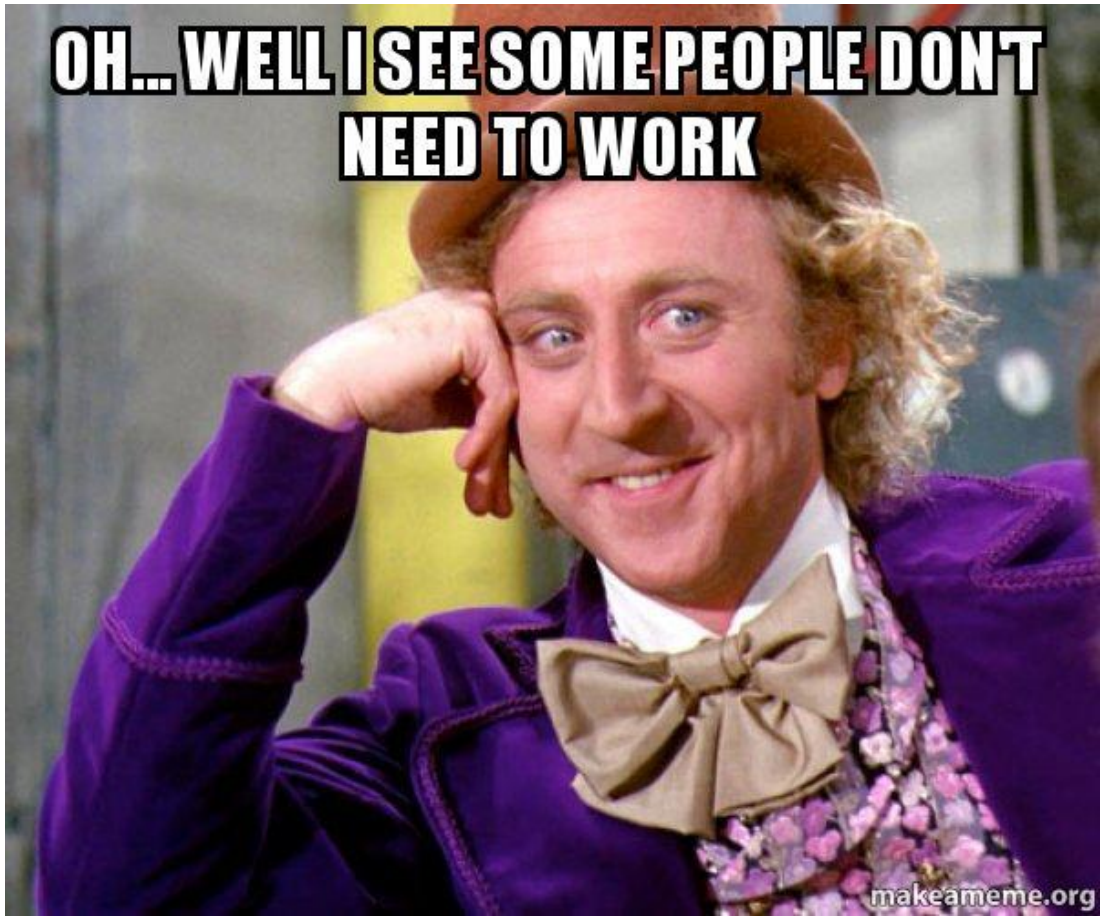
What Test Systems are Eligible for an IQCP

- Test must:
  - Be nonwaived. Waived tests are not eligible for (and do not need) an IQCP. Use manufacturer's recommendations and you're good.
  - Be in a subspecialty other than pathology or cytology.
  - Follow manufacturer's instructions at least.
  - Testing must employ an internal quality control system; electronic, procedural, or built-in, except for microbiology media and reagents.
  - If your QC policy is equal to or more stringent than the CLIA control requirements, an IQCP not required.
    - You can still do one if you want. 😕
- If it doesn't meet these criteria, it's not eligible and you must do regular QC; at least daily or each run.

When Do You Need an IQCP?

- Whenever the manufacturer recommends QC less frequently than the CLIA requirements AND
- You want to reduce your QC requirements below the CLIA required ones.

- If the answer to either is ‘no’, **you don’t need an IQCP**.



Question 2

- You get an email in your microbiology list serve. It reads:

From: <an excellent microbiologist>
Sent: Monday, August 22, 2022 1:06 PM
To: <a whole bunch of microbiologists>
Subject: <company name> IQCP Request

Hello,
Anyone having a <very good MALDI-TOF bacterial identification system>, would you be willing to share your IQCP? With an extreme staffing shortage and the ongoing COVID testing we are all facing, I have fallen so far behind and our inspection is fast approaching. I would be eternally grateful! Thank you in advance 😊.

- How would you answer this? Answer in the poll (as few words as possible) and it'll generate a Wordcloud!

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The Elements of an IQCP

- The IQCP consists of three parts:
  - Risk Assessment (RA)
  - Quality Control Plan (QCP), and
    - The IQCP QCP cannot be less stringent than the manufacturer's instructions.
  - Quality Assessment (QA)

What's a Risk Assessment?

A tool for describing risks associated with laboratory testing processes and identifying mitigation strategies.

How To Do A Risk Assessment

- A risk assessment for IQCP is not confined to the QC process.
- Must include risk evaluation:
  - Preanalytical, analytical, postanalytical risks
- And risk mitigation assessment
  - Mitigation strategies for unacceptable risks
- Data Sources
  - Manufacturers / Regulatory data
  - Laboratory experience / QC / PT data for existing systems
  - Laboratory quality monitors; temperature, etc.
  - Publications
  - Clinical information, applications, potential for impact
- Examples to come (by no means exhaustive!)
- The techniques of risk analysis can be applied well beyond IQCP, even beyond the lab.

Risk Matrix

Frequency of error occurrence:

Unlikely (once every 2-3 years)

Occasional (once per year)

Probable (once per month)

Frequent (once a week)

Severity of harm to patient:

Negligible (temporary discomfort)

Minor (temporary injury; not requiring medical intervention)

Serious (impairment requiring medical intervention)

Critical (life threatening consequences)

Freq./Severity of Harm	Negligible	Minor	Serious	Critical
Frequent	Not Acceptable	Not Acceptable	Not Acceptable	Not Acceptable
Probable	Acceptable	Not Acceptable	Not Acceptable	Not Acceptable
Occasional	Acceptable	Acceptable	Acceptable	Not Acceptable
Unlikely	Acceptable	Acceptable	Acceptable	Acceptable

Examples of Preanalytical risks

Risk Factor (Possible Sources of Error)	Frequency of error occurrence	Severity of harm to patient	Risk Level
Preanalytical			
Specimen (Primary):			
Patient identification	probable	serious	Not Acceptable
Collection/container/volume	frequent	negligible	Not Acceptable
Integrity	frequent	negligible	Not Acceptable
Transport	frequent	negligible	Not Acceptable
Storage	probable	negligible	Acceptable
Specimen (Organism):			
Sample Stability	frequent	minor	Acceptable
Inappropriate Transport Conditions/Media	unlikely	minor	Acceptable
Improper or insufficient sample collection.	frequent	minor	Not Acceptable
Sample Stability	frequent	minor	Not Acceptable

Possible Sources of Error		How can identified sources of error be reduced?
Risk Factor	Possible Error	
Preanalytical		
1A: Specimen - Biological	• Improper specimen procurement/ handling/processing	• Adhere to procedures in SOP #2.1.1 that addresses patient identification and specimen collection, labeling, transport, storage and remedial actions to control improperly handled specimens or delayed specimens. • Annually review representative specimen processing errors (N=10 to 15) with all staff involved with patient specimens. • During initial training and competency assessment, emphasize: • Proper specimen handling/processing is the most critical part of any test • Failure to set up and inoculate test properly may result in delayed or inaccurate results

From ASM/CAP/CLSI Template: IQCP for QC for molecular test system XYZ

Examples of Analytical Risks

Risk Factor (Possible Sources of Error)	Frequency of error occurrence	Severity of harm to patient	Risk Level
Analytical			
Testing Personnel:			
Training	unlikely	serious	Acceptable
Competency	unlikely	serious	Acceptable
Reagents:			
Shipping/receiving	occasional	minor	Acceptable
Storage	unlikely	serious	Acceptable
QC strain storage/prep	occasional	negligible	Acceptable
PCR Template/Amplicon Contamination	Occasional	Minor	Acceptable
Environment:			
Temperature/airflow/humidity/ ventilation	occasional	negligible	Acceptable
Utilities	occasional	minor	Acceptable
Test System:			
Extraction failure	Occasional	Minor	Acceptable
Contamination during sample prep	Probable	Minor	Unacceptable
Change in pathogen target sequences	unlikely	serious	Acceptable

From ASM/CAP/CLSI Template: IQCP for QC for molecular test system XYZ

Examples of Analytical Risk Mitigation

Possible Sources of Error		How can identified sources of error be reduced?
Risk Factor	Possible Error	
Analytical		
3: Reagents		During initial training and competency assessment, emphasize standard rules to always: • Take responsibility for reagents/supplies (all staff) • Maintain reagents at proper storage conditions • Check expiration dates • Perform required QC
Receiving/storage	• Incorrect ordering • Depleted reagent supply • Reagent integrity compromised	Designated staff member(s) assigned to inventory (order/receipt) materials to ensure supply is properly maintained and testing materials are handled appropriately on receipt
Expiration dates		See above (Reagents)
Preparation/use	Use of incorrect cartridge for analyte	Use color codes / labels on boxes of cartridges

From ASM/CAP/CLSI Template: IQCP for QC for molecular test system XYZ

Examples of Postanalytical Risks

Risk Factor (Possible Sources of Error)	Frequency of error occurrence	Severity of harm to patient	Risk Level
Postanalytical			
Test Results:			
Test reporting delays	occasional	minor	Acceptable
Transmission of results to Electronic Health Record	occasional	serious	Acceptable
Review reported results	frequent	serious	Not Acceptable
No results (Due to amplification/method failure)	Probable	Serious	Unacceptable
Environmental Contamination (Quality Failure)	Occasional	Serious	Acceptable
Clinician feedback	unlikely	serious	Acceptable

From ASM/CAP/CLSI Template: IQCP for QC for molecular test system XYZ

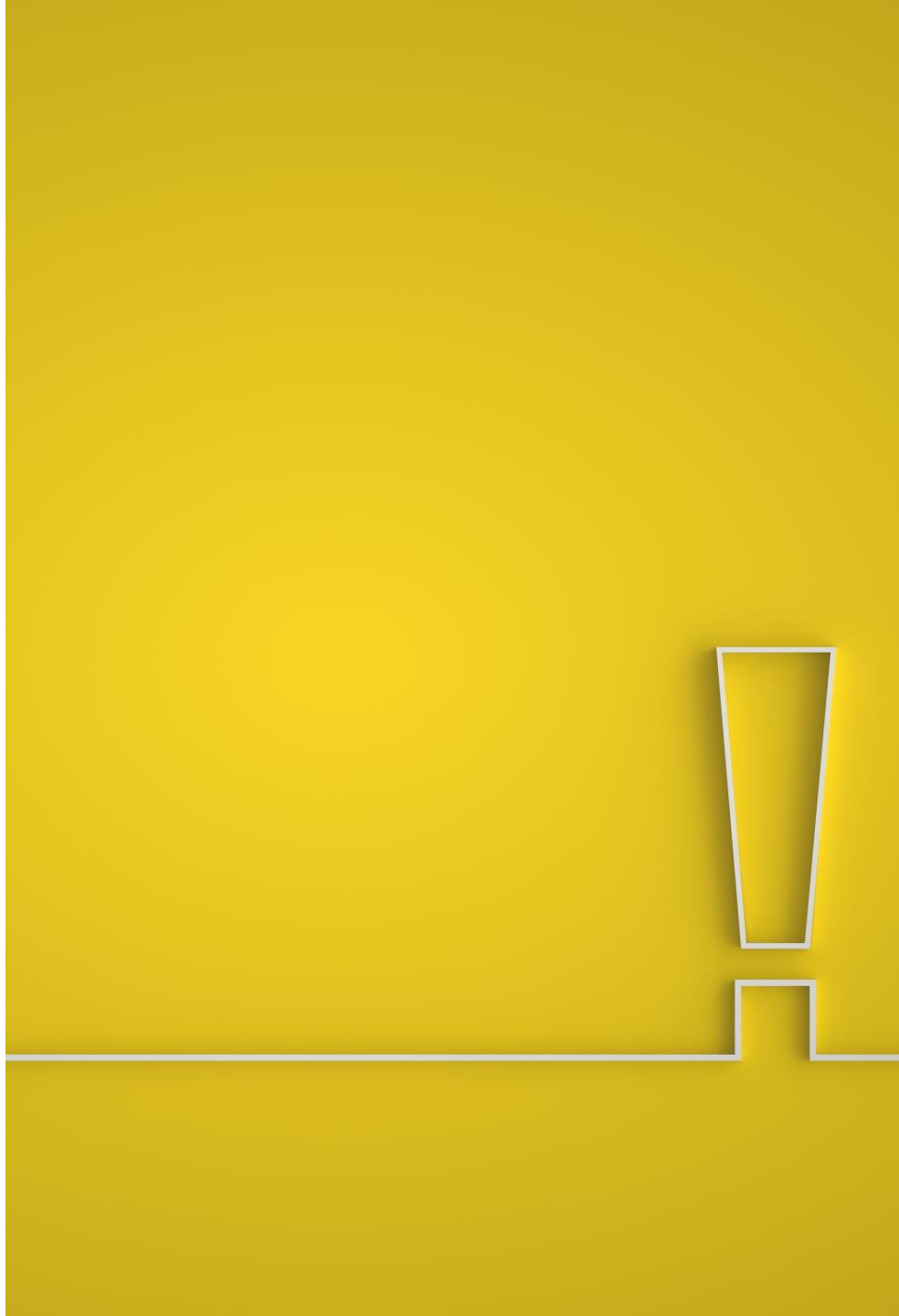
Examples of Postanalytical Risk Mitigation

Possible Sources of Error		How can identified sources of error be reduced?
Risk Factor	Possible Error	
Postanalytical		
6: Test Results		• Supervisor maintains summary of incorrect results released and meets with laboratory director monthly to review this summary • During initial training and competency assessment, emphasize timely reporting of both preliminary results and final reports
Test reporting delays	Results delayed beyond that expected for organism type	See above (Test Results)
Transmission of results to Electronic Health Record	• Incorrect transmission of results • Delay in transmission of results	See above (Test Results)
Review reported results	• Erroneous results reported	See above (Test Results)
Clinician feedback	Complaints/suggestions regarding delayed or potential erroneous results	See above (Test Results) • Incorporate suggestions into QA plan, as appropriate.

From ASM/CAP/CLSI Template: IQCP for QC for molecular test system XYZ

Question 3

- The Coagulation clinic requests to be able to monitor prothrombin time. You find them the CLIA-waived Magic Clotter system, and start discussing implementation with your medical director. What post-analytic risks would you incorporate into your IQCP risk assessment?



Question 3

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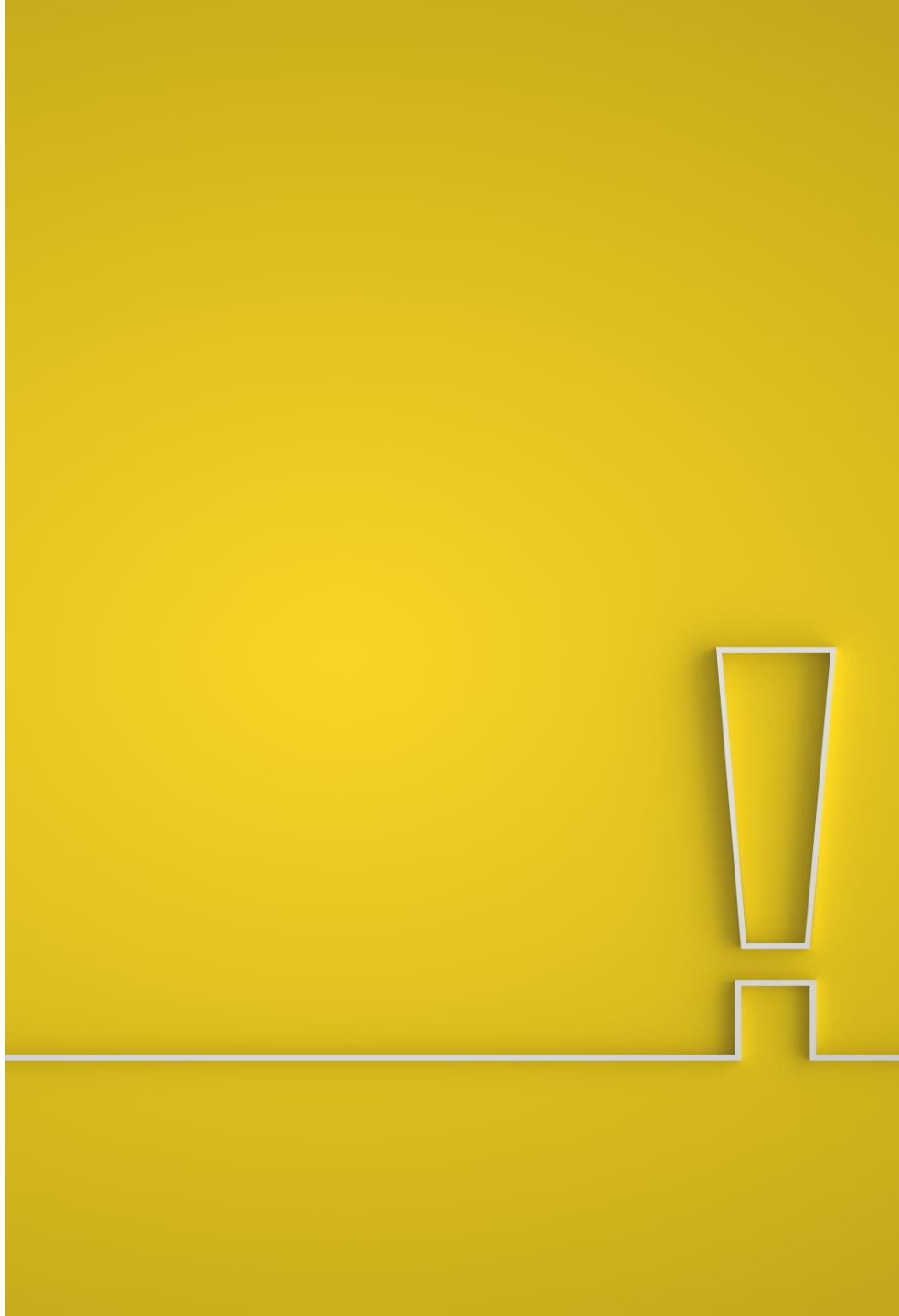
  post-analytic risks would you incorporate into your IQCP risk assessment?

Trick Question!

It's waived, so no IQCP!

Question 3.1

- The Coagulation clinic requests to be able to monitor prothrombin time. You find them the **moderate complexity** Magic Clotter system, and start discussing implementation with your medical director. What post-analytic risks would you incorporate into your IQCP risk assessment?
- Answer in the poll (as few words as possible) and it'll generate a Wordcloud!



What's a Quality Control Plan?

- A written document describing practices and procedures:
  - To reduce failures and errors in testing processes
  - To detect errors and defects in testing processes when they occur
  - To ensure accurate, reliable results
- Includes:
  - QC appropriate to the test system
  - PT
  - Maintenance
  - Training
  - Corrective actions

Example Quality Control Plan

Final QCP for Cartridge based molecular test system XYZ
Based on our risk assessment and Quality Assessment, the QCP consists of following the instructions that are provided in explicit detail in SOP #5.1.7 “XYZ System for Molecular Detection of Microbe Q”. Positive and negative QC testing will be performed at least monthly on each instrument.
Testing of appropriate QC materials on each new lot/shipment of cartridges before or concurrently with placing these materials into use for testing patient specimens.
Testing of appropriate QC materials on each cartridge type after major system maintenance or software upgrade before or concurrently with placing the equipment back into service.
Recording and evaluating QC results according to QC acceptability criteria as defined in #5.1.7 “XYZ System for Molecular Detection of Microbe Q”. Any abnormal result is immediately investigated.
System XYZ is subscribed to PT challenge WNO. Any unacceptable result is immediately investigated according to lab policy #13-1313
System XYZ has a service contract with the vendor. PM and service is monitored in the service maintenance log.
Training and competence for system XYZ are incorporated into the service training and competency forms. Training and competency will be monitored and any deficiencies rectified immediately.

Question 4

- You're gathering data for an IQCP on a novel iPTH system for the OR. The manufacturer's instructions say you can recalibrate and run QC on a monthly basis. As you do daily QC to verify stability, the system starts to drift by more than 20% on the high control after 3 weeks. You repeat the stability study and the same thing happens. How would you handle this?
- Answer in the poll (as few words as possible) and it'll generate a Wordcloud!

What's Quality Assessment?

- The process of continuously monitoring effectiveness of the IQCP.
- Includes:
  - Review of QC
  - Review of PT
  - Review of any other relevant data; complaints, errors, etc.
- Reviewed and signed-off annually by laboratory director.

Example QA Plan

Quality Assessment: Ongoing Monitoring for QCP Effectiveness (Performed by supervisor and/or section head)		
Reasons for QC failures, PT failures, and patient result reporting errors will be examined and addressed as needed in a new/updated risk assessment: 1) Has a new risk factor been identified? 2) Does this change the frequency of risk? 3) Does the risk factor change the potential severity of harm to patient?		
Daily review of patient results for reporting errors and clinician complaints. Take corrective action and revise QCP as needed.		
Monthly review of QC results by supervisor or section head. Take corrective action and revise QCP when unexpected QC failures indicate adjustment to the QC plan defined herein is needed.		
Regular review of Proficiency Testing results. Take corrective action and revise QCP if necessary, when PT results are not acceptable.		
Monthly review of all equipment maintenance/monitoring logs according to standard laboratory protocols. Take corrective action and revise QCP as needed.		
Daily monitoring and recording of instrument (room) and cartridge storage temperatures. Any out-of-range result is investigated and reported to the supervisor.		
Regular training and competency assessment according to standard laboratory protocols. Modify training and revise QCP as needed.		
Continual participation in this institution's quality program that addresses specimen handling and erroneous specimen labeling. Take corrective action and revise QCP as needed.		
This QCP has been reviewed and is approved by the laboratory director (as named on the CLIA license).	Signature	Date

FTW!

IQCP Resources

- ASM/CAP/CLSI Q&A and templates at:
  - https://asm.org/Protocols/Individualized-Quality-Control-Plan-IQCP
- CAP IQCP FAQs
  - https://documents.cap.org/documents/iqcp-faqs.pdf
- CMS IQCP Resources
  - https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP

- **CAP staff tell me that IQCP is still one of the most-questioned areas. Don't be afraid to ask, you're in good company.**

Sources

- https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/FAQs-IQCP.pdf
- https://documents.cap.org/documents/iqcp-faqs.pdf
- https://asm.org/Protocols/Individualized-Quality-Control-Plan-IQCP