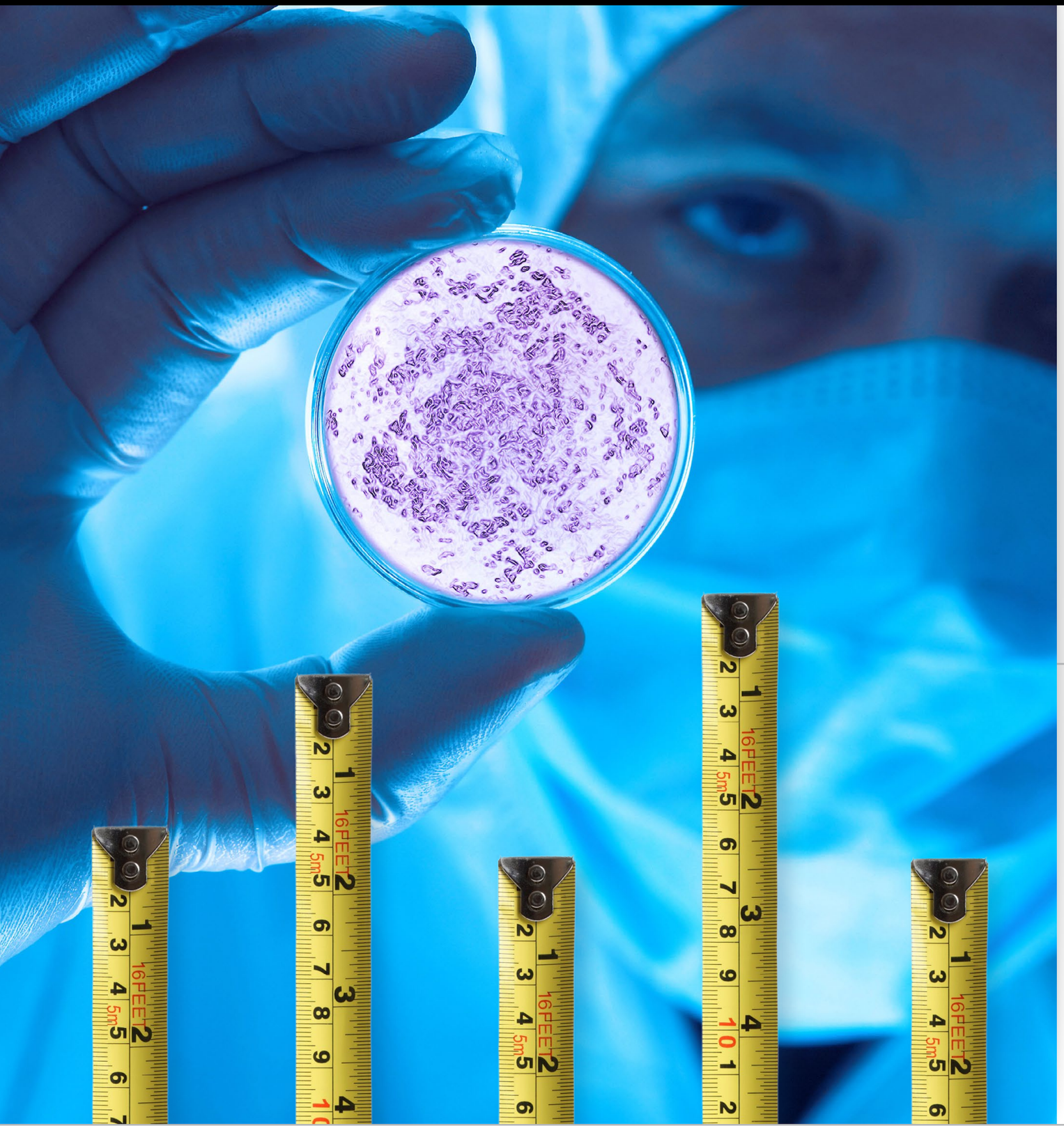


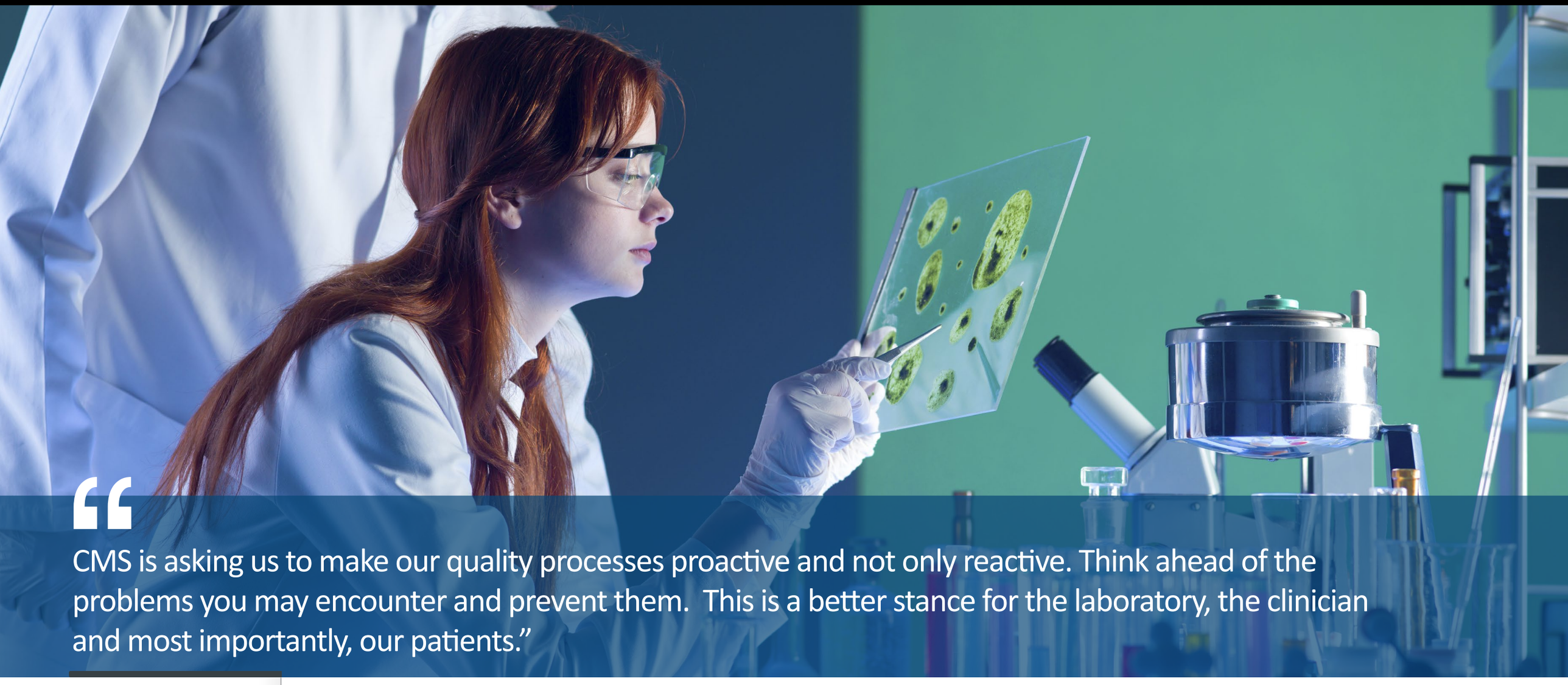
NEXT STEPS

IQCP: What Comes After the Risk Assessment?

By Kathleen Braniff, MSA, BS, MT(ASCP)

As we approach the waning months of 2015, the clinical laboratory community is entering the home stretch to devise, refine, seek approval and implement their Individualized Quality Control Plan (IQCP) or adopt the CLIA mandated minimum standard of running two levels of quality control (QC) each day of testing.

As most laboratorians know, in late 2013, the Center for Medicare and Medicaid Services (CMS) notified clinical laboratories that beginning Jan. 1, 2016, the common practice of validating and adopting a manufacturer's Equiv-



“CMS is asking us to make our quality processes proactive and not only reactive. Think ahead of the problems you may encounter and prevent them. This is a better stance for the laboratory, the clinician and most importantly, our patients.”

RELATED CONTENT

EQC Transitions to IQCP

alent Quality Control (EQC) procedure to ensure the quality of a testing platform was not enough. EQC was no longer going to be acceptable to support the laboratory’s quality practices after the close of 2015. Labs were notified that 2015 was their IQCP education and transition period and during this year, laboratories and their medical directors had to make a decision. Would they decide to adopt the CLIA standard of running two levels of external QC per day for their non-waived testing or create an IQCP for their laboratory to ensure the accuracy of their testing in pre-analytical, analytical and post-analytical phases of testing?

RISK ASSESSMENT

Many webinars, in-services, articles and presentations have been put together to run through the basics of the first step in the making of an IQCP. The risk assessment (identifying risk, analyzing risk and mitigating risk) has gotten a lot of press. Most vendors have stepped up and provided documents that define platform specific quality performance features. Each lab can use these documents to merge into their specific site details and begin the process of developing their IQCP risk assessment. Once the laboratory’s IQCP is investigated, de-

veloped, prepared, approved by the medical director and implemented, the work is not done. These tasks are only the first step of an IQCP.

QUALITY CONTROL

Quality items such as procedures, training, competency, reagent checks, environmental monitoring, quality controls, equivalent quality controls and/or process control, etc. that are adopted to help mitigate the risk identified in your IQCP risk assessment must be put into practice. The steps to mitigate risk are put into writing as part of the laboratory's quality control plan. The quality control plans should specify the type of quality control, the frequency of quality control performance and the acceptability criteria of the quality control events. This plan must be followed and it must be enforced.

QUALITY ASSURANCE

The last step of the IQCP process is an ongoing evaluation of the IQCP plan, the IQCP mitigation steps and the effectiveness of those steps. The IQCP document is not a "once and done" event. The laboratory must ensure that the IQCP evaluation and implementation has been comprehensive and not overlooked any details that would affect the quality of test results. Laboratories are famous for collecting data, which is what they do well. What that data tells the laboratory, what the quality events say, what the problem logs describe must be taken into consideration and used for continual improvement. The IQCP must grow with the laboratory to adapt to new information and new processes. In addition, CMS is asking us to make our quality processes proactive and

RELATED CONTENT

Pre-analytic Processing: Can we automate pre-analytic processing quality control?

> The IQCP must grow with the laboratory to adapt to new information and new processes."

not only reactive. Think ahead of the problems you may encounter and prevent them. This is a better stance for the laboratory, the clinician and most importantly, our patients.

Ongoing evaluation of the laboratory's IQCP should be scheduled for monthly, quarterly or semi-annual review. The evaluation must take place at a minimum of once a year. The ongoing evaluation can take many factors into consideration. Below are a few examples:

- Things change over time. Changes in collection procedures, operator staff, testing environments, and analytes tested can all affect the quality of testing in all phases.
- Have there been any near misses or failure events associated with the testing platform? Were these evaluated to see if the occurrence was a result of user error, training issues, environmental problems or other process failure?
- Are there any manufacturer enhancements like software upgrades, lock out capabilities or quality control changes put into place?
- Have there been any device recalls or vendor communications that should be taken into consideration?
- Has there been any operator input of risk that was not previously considered that needs to be taken into consideration?
- Have there been any stories about negative events from colleagues that should be considered?

The review of the laboratory's IQCP, any additions or changes should be documented and kept with the original plan documents. This evaluation and any subsequent changes to the IQCP should be reviewed and signed by the laboratory staff, laboratory leadership and laboratory medical director.

Kathleen Braniff *has been a laboratory professional since 1979. She works as a clinical compliance consultant for Clinical Lab Consulting, LLC in Indianapolis, IN.*