Accreditation of Individualized Quality Control Plans by the College of American Pathologists

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KEYWORDS

• Laboratory accreditation • Laboratory inspection • Quality control
• Risk management • Clinical laboratory • Medical laboratory

KEY POINTS

- Accreditation of a laboratory that has implemented an individualized quality control plan (IQCP) is grounded in principles of risk management.
- Inspection of an IQCP activity evaluates process rather than outcome.
- All 3 elements of an IQCP must be documented: risk assessment, the laboratory's quality plan, and follow-up assessment.
- New accreditation requirements had to be written and old requirements related to equivalent quality control rewritten.
- Robust support systems, particularly training and communication, are essential to the success of the IQCP accreditation process.

When the Centers for Medicare and Medicaid Services (CMS) announced their plan to allow each laboratory to devise its own approach to analytical quality control (QC),[1] the Laboratory Accreditation Program (LAP) of the College of American Pathologists (CAP) was faced with a decision. Should the LAP follow suit and allow its participants to develop individual schemes for QC? QC is central to the reliability of laboratory testing. Structured requirements for inspecting QC, initiated 50 years earlier, had dismissed the notion of QC strategies that varied from laboratory to laboratory. A control system based on individualized risks, with the determination of those risks to be performed by the laboratory itself, seemed impossible to inspect.

At the same time, administrators of the program realized that at least some of its subscribers would seek to develop an individualized QC plan (IQCP) for 1 or more

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of its tests. To refuse to inspect a laboratory's IQCP implementation was in the best interest of neither the laboratory nor the program. A fundamental change in how the LAP would regard quality management was inevitable.

This article discusses that dilemma, how it was solved, and the inspection tools developed by the college for accreditation of a laboratory that chooses to follow its unique QC plan. It addresses the options imagined by the LAP and the resources amassed to sort through those options. Both the requirements for accreditation regarding IQCPs and the support systems available to participating laboratories are described.

BACKGROUND

The CAP accredits nearly 8000 laboratories in 50 countries. The CAP is deemed by the CMS as an accreditation organization (AO) under Clinical Laboratory Improvement Amendments (CLIA).[2] Most certified laboratories offering a range of specialty tests choose the CAP as their AO. CMS requires each AO to inspect for compliance with the CLIA regulations. An AO is allowed to impose additional requirements, but, at a minimum, on-site inspectors must compare the laboratory's performance with the CLIA regulations.

CAP accredits a wide variety of clinical laboratories. Some have thousands of employees, and others are small. Hospital laboratories integral to a health care delivery system are accredited, as are independent laboratories. The CAP's accreditation program spans all of the clinical laboratory specialties. The complete set of LAP checklist requirements in the 2015 edition totals 2890, although only those requirements defined by the laboratory's scope of activity are printed on its checklist, which is tailored to its on-site inspection. CAP inspectors are practicing laboratory professionals who volunteer their time and expertise in the spirit of peer review. It is critical that checklist requirements be written in precise language to avoid differences in interpretation but be sufficiently succinct to be managed within the time allotted. That CAP inspectors evaluate those requirements in a uniform manner is a tenet of the program. To introduce a requirement intended to be evaluated differently from site to site was unfamiliar territory.

The consensus process of the Clinical and Laboratory Standards Institute (CLSI) preceded the regulated IQCP option. CAP, a founding member of CLSI, participated in the development of those consensus documents. CLSI had developed EP18-A, *Quality Management for Unit-Use Testing*, in 2002.[3] EP18-A described how a manufacturer of an in vitro testing device and its users, particularly those self-contained devices that use cartridges used only once, identifies and controls the modes of failure specific to the use of that device. The subsequent version, EP18-A2, published as *Risk Management Techniques to Identify and Control Laboratory Error Sources*,[4] focused on the process of risk assessment.

EP18-A2 became the theoretic construct behind CLSI's EP23-A, *Laboratory Quality Control Based on Risk Management*.[5] EP23-A is a consensus guideline, not an evaluation protocol. It was developed by individuals broadly representative of the laboratory community: regulatory authorities, manufacturers of in vitro devices, and clinical laboratory professionals. Unlike traditional QC (most often described as 2 levels of external controls per test per day), the IQCP option expects the laboratory to identify and then control failure modes along the entire path of workflow (ie, from preanalysis, the assay itself, to postanalysis). Failure-mode analysis directs the user to consider personnel training, environmental conditions, patient populations, and logistical support systems as well as the analytical process.