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Quality Management for Unit-Use Testing; Approved Guideline

This guideline recommends a quality management system for unit-use devices that will aid in the identification, understanding, and management of sources of error (potential failure modes) and help to ensure correct results. It is targeted for those involved in supervision of laboratory-testing quality management, and it addresses issues related to specimen collection through reporting of results.

A guideline for global application developed through the NCCLS consensus process.

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Quality Management for Unit-Use Testing; Approved Guideline

Abstract

NCCLS document EP18-A—*Quality Management for Unit-Use Testing; Approved Guideline* recommends a quality management system for unit-use test devices that is based on expert opinion, is practical to implement, and is applicable to various devices and settings, so that sources of error (potential failure modes) are identified, understood, and managed. This system will assist device manufacturers, users, regulators, and accrediting agencies in assuring correct results. It addresses regulatory considerations (e.g., principles and accountability), recommends the development of a partnership between users and manufacturers, provides a source of errors matrix, and suggests approaches to quality monitoring/identification of the problems.

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Quality Management for Unit-Use Testing; Approved Guideline

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Foreword

Unit-use testing has existed for many years. Conventional methods and lyophilized or aqueous materials were generally used for quality control and quality assurance. Because these materials were readily available and generally accepted as capable of ensuring trueness and precision, they became part of the quality assurance program for early unit-use test systems such as urine dipsticks.

The concepts of quality control over the last half-century have developed in two primary directions. The first is the more familiar, in which a continuous process that generates measurements is monitored to determine whether the process is stable or is headed out of control. The concepts of statistical quality control were applied to the clinical laboratory with the introduction of Levey-Jennings charts, with many subsequent statistical and interpretation enhancements developed to provide additional capabilities of process control to the clinical laboratory measurement process. Similar quality control practices are also used by manufacturers to release lots of reagents, including unit-use reagents. This quality control regimen guards against continuous processes that drift or become unstable, generating trends or increased imprecision.

The second area of quality control is acceptance sampling, where a “lot” of individual items is sampled to determine that an acceptable level of performance has been obtained. Continuous variable measurement, as used in process control, uses quantitative measurements which have standard deviations and means. Acceptance sampling (in its simplest and most common applications) classifies items in two discrete categories: defective and valid. Use of acceptance sampling protects against failures that appear to occur randomly. These failures can occur from a continuous process that has no detectable mean shift and in some cases no detectable increased imprecision, e.g., they can occur in conventional diagnostic analyzers that exhibit acceptable, conventional quality control.

In the clinical laboratory, only the first of these two general areas has found wide application, whereas acceptance sampling is sometimes used by manufacturers in release criteria for reagent lots. With the introduction of unit-use devices for clinical sample testing, it is necessary to incorporate the concepts of the second type of quality control. The assumptions and implications of each approach are different, and it is now necessary to combine both approaches for many of the new *in vitro* devices now in the marketplace. Two varieties of systems are currently in use for quality control of the unit-use device. One system consists of self-contained unit-use disposable devices; the other is a combination of a unit-use disposable device (test strip, cassette, disk, card, etc.) and a reader (reflectance meter, fluorescence, spectrophotometry device, etc).

No conventional quality control (QC) method and material can completely control any test system. With some devices, quality control in clinical laboratories that is used to detect process changes may be less relevant for unit-use systems, assuming that the manufacturer has carried out conventional quality control during manufacturing. This is because the additional “process” that takes place in a conventional diagnostic analyzer at a clinical laboratory has already occurred for a unit-use system in the manufacturing environment, rather than the clinical laboratory. Acceptance sampling, while impractical for clinical laboratories, is also carried out by manufacturers when appropriate.

Conventional quality assurance and quality control methods in and of themselves do not assure quality. A one-size-fits-all or prescribed quality control testing protocol such as “two levels per day of use” may not be appropriate for all testing systems. The diversity among regulatory requirements, accreditation practices, and user needs coupled with the financial aspects of this QC method led to the formation of the NCCLS Subcommittee on Unit-Use Testing.

It is the subcommittee’s intent to provide a comprehensive and flexible guideline that will enable users, manufacturers, and regulators to identify potential sources of errors in unit-use test systems and implement processes to manage these errors using new quality management models.

Foreword (Continued)

The subcommittee has limited the discussions within this document to unit-use test systems. While it is the committee's expectation that the guideline will be used primarily to address the issues around point-of-care (POC) devices that utilize single-use disposables, EP18 should not be considered as exclusive to unit-use systems. However, as these concepts are further refined with actual experience, an additional, perhaps broader-based guideline could be undertaken to address multiuse systems and include all aspects of statistical process control and error reduction.

Key Words

Quality assurance, quality control, quality management, quality system, unit-use system

A Note on Terminology

NCCLS, as a global leader in standardization and harmonization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. NCCLS recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in NCCLS, ISO, and CEN documents; and that legally required use of terms, regional usage, and different consensus timelines are all obstacles to harmonization. In light of this, NCCLS recognizes that harmonization of terms facilitates the global application of standards and is an area of immediate attention. Implementation of this policy must be an evolutionary and educational process that begins with new projects and revisions of existing documents.

In the context of this guideline, it is necessary to point out that several terms are used differently in the USA and other countries, notably those in Europe.

In order to align the usage of terms to ISO, the term "trueness" is used in this document when referring to the closeness of the agreement between the average value from a large series of measurements and to an accepted reference value. The term "accuracy," in its metrological sense, refers to the closeness of the agreement between the result of a (single) measurement and a true value of a measurand, thus comprising both random and systematic effects.

The Quality System Approach

NCCLS subscribes to a quality system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS HS1—*A Quality System Model for Health Care.* The quality system approach applies a core set of "quality system essentials (QSEs)," basic to any organization, to all operations in any healthcare service's path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

QSEs

Documents & Records	Information Management
Organization	Occurrence Management
Personnel	Assessment
Equipment	Process Improvement
Purchasing & Inventory	Service & Satisfaction
Process Control	Facilities & Safety

EP18-A addresses the following quality system essentials (QSEs):

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
					X		X	X	X		

Adapted from NCCLS document HS1—*A Quality System Model for Health Care.*

Quality Management for Unit-Use Testing; Approved Guideline

1 Introduction

Unit-use testing presents unique challenges to manufacturers, users, regulators, and accrediting agencies in terms of quality control and quality assurance. Conventional schemes of quality control, with strictly defined materials and frequency, are not always applicable to unit-use test systems due to the very nature of these devices. Furthermore, quality assurance and oversight take on new dimensions with the utilization of many of these test systems outside traditional laboratory test settings, and with test performance by a variety of healthcare personnel.

Even though the committee considered the use of all unit-use (point-of-care) test systems in this guideline, the primary focus is the use of these unit-use systems within professional settings, i.e., hospitals, physician offices, etc. and not for patient self-testing or in-home testing. It is in the professional settings that the healthcare professional has assumed the responsibility of ensuring the quality of the testing system. Moreover, these testing sites are subject to regular and routine inspections or surveys by various accrediting agencies. Therefore, some guidance as to how to deal with various test system errors is important. It is no less important in self-testing situations, but it is the patient along with his/her physician that is responsible for the quality of the testing system. Further, there is no organization that requires and monitors the patient's compliance to any quality systems. However, as technology becomes more advanced by making test systems simpler to operate for the layperson, some portions of this guideline may become appropriate for review and use by the individual consumer.

The following basic concepts directed the development of this guideline:

- Unit-use devices are extremely diverse in their technology, design, and function. Every unit-use test system is subject to certain preanalytical, analytical, and postanalytical errors. The relative importance and likelihood of these errors varies with the device, the specimen, the user, and the environment. In addition, a high level of variability exists in terms of skill and knowledge level among the end users of the unit-use device as opposed to the user in the hospital or commercial laboratory. While it is evident that all *in vitro* diagnostic (IVD) devices are subject to these issues, this document focuses strictly on unit-use test devices and may be expanded in future versions.

- A single quality control/quality assurance regimen cannot be developed to cover all unit-use test systems (as well as most, if not all IVD systems) and detect all possible errors.

- The principles of traditional, statistical quality control need to be customized and adapted for the unit-use test system. It is impractical to consume large numbers of unit-use systems needed to detect the low rate of defects found in properly designed, manufactured, shipped, and stored unit-use systems. A multitier approach to quality control and quality assurance has been proposed within this document. This approach provides the user with the means to inspect goods upon arrival through the use of limited acceptance sampling to detect variables such as shipping conditions, lot changes, and new operators. It also allows for further quality assurance testing when device results deviate from established QC control ranges, and it allows for an assessment of operator competency. Periodic quality control also serves as an indicator of operator competency.

- Quality control/assurance programs may evolve with increasing experience with the unit-use test system. These programs should focus on errors which may occur relatively frequently and/or have the potential for significant clinical impact.