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February 2003

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## AUTO13-A2

### Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition

This document identifies important factors that designers and laboratory managers should consider when developing new software-driven systems and selecting software user interfaces.

Also included are simple rules to help prepare validation protocols for assessing the functionality and dependability of software.

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A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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# Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition

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## Abstract

Clinical and Laboratory Standards Institute document AUTO13-A2—*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition* provides user interface design recommendations that make new software programs easier for laboratory personnel to learn and use. Additionally, the guideline addresses the preparation and execution of validation plans for software purchased from manufacturers; custom software commissioned by the laboratory; or in-house applications developed to collect, interpret, or report laboratory, patient, or quality control information.

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### 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 document 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:

- |                                                  |                                                        |                                                               |                                                                      |
|--------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------------|----------------------------------------------------------------------|
| Documents & Records<br>Organization<br>Personnel | Equipment<br>Purchasing & Inventory<br>Process Control | Information Management<br>Occurrence Management<br>Assessment | Process Improvement<br>Service & Satisfaction<br>Facilities & Safety |
|--------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------------|----------------------------------------------------------------------|

AUTO13-A2 addresses the quality system essentials (QSEs) indicated by an "X." For a description of the other NCCLS documents listed in the grid, please refer to the Related NCCLS Publications section at the end of the document.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
X GP2-A4	X	X GP21-A	X	X	X	X	X		X	X	X GP18-A

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

## Foreword

Many *in vitro* diagnostic instruments and specimen processing devices in the hospital laboratory are now computer controlled and actuated. Instrument manufacturers design and develop the embedded software that provides the functionality for these systems. The computer software presents an “interface” to the user that can make operation of the instrument a reasonable task to learn and perform.

In addition to other computerized information management systems, laboratorians in the modern clinical laboratory use a host of different computer controlled instruments, each with its own (sometimes unique) user interface. This multitude of different user interfaces affects learning, training, productivity, and potentially patient outcomes in the laboratory. Part I (Sections 3 through 10) provides guidelines for the design of software user interfaces that offer developers a common, consistent design direction for laboratory device applications.

Whether they purchase software from third-party vendors or develop the software themselves, laboratory personnel are responsible for the validation of this software. Part II (Sections 11 through 14) contains recommendations for preparation and execution of validation plans for software packages.

## Key Words

Data management systems, laboratory instrumentation, process control, software design, software validation, user interface

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# Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition

## 1 Scope

The scope of this document is limited to issues that affect ease of learning and the ease of use of software user interfaces. Although there is a need to improve the hardware interface between operators and instruments (e.g., keyboard, mouse, touch screen, printer, reports, voice, and light pens used when adding or removing patient samples, reagents, and waste), these topics are not within the scope of this guideline. AUTO13-A2 is not intended as a tool to be used in the selection, recommendation, or judgment of the suitability of specific input/output technologies, since these may change rapidly. Since it is described elsewhere,<sup>1,2</sup> the transfer of electronic information between information and/or automation systems (such as between a laboratory information system or laboratory automation system software and an instrument) is not the subject of this document.

This document identifies the most important factors that designers and laboratory managers should consider during the development of a new software-actuated system and when selecting a software user interface intended to improve the ease of learning and use within the clinical laboratory. Without attempting to provide a comprehensive or exhaustive discussion of software user interfaces or trying to define an identical appearance for user interfaces by describing a single, detailed design solution, this document addresses some common design elements. This discussion is intended to encourage manufacturers of laboratory instruments and specimen handling devices to develop more uniform software user interfaces within their product lines.

The primary focus of this document is the software user interface within the centralized laboratory environment. The guidelines presented in this document are not directly constructed for point-of-care, physician-office, or over-the-counter devices, although many of the principles discussed apply to these devices as well. The primary focus of this document is software user interfaces on instruments, although the guidelines also apply to interfaces on laboratory systems and other associated information systems used in the laboratory.

These design guidelines and examples are not, however, universally applicable to all laboratory systems. Implementation of a specific design depends on the size, complexity, and cost of a device, as justified by its intended use.

This document provides some simple rules to help laboratory personnel prepare validation protocols that fulfill the laboratory's obligation to test and verify the functionality and dependability of its software. This document does not advocate relieving software developers of their duty to validate the software products that they develop; AUTO13 offers assistance to the purchaser when no other means of validation is available. Developers should refer to sources such as IEEE sources for specific guidelines for software system validation.<sup>3,4</sup>

## 2 Introduction

This document provides guidelines for the design of software user interfaces (also referred to as “human-computer interaction”) that focus on two related areas. First, it identifies elements of a user interface that are most likely to facilitate ease of learning and use. Second, it provides some direction as to commonalities in “look and feel” that further the development of an easier-to-use software interface, as well as improve its design. The subcommittee believes that AUTO13-A2 will initiate a dialogue between users (e.g., laboratorians) and developers of software. This dialogue is intended to bring laboratorians and manufacturers closer to an agreement as to what elements should be consistent among software user interfaces if the goals of ease of learning and use are to be accomplished.

In the modern clinical laboratory, it is necessary for clinical laboratory personnel to learn and use various user interfaces for many computer-actuated devices, including clinical instruments and laboratory information systems. The user interfaces of computer-driven devices help to manage the workflow of laboratory personnel; for this reason, they have a major effect on productivity and the effectiveness of laboratory processes. Because these interfaces have such an effect on productivity, it is important to ensure that they are easy to learn and use. This is especially true at a time when laboratorians are frequently asked to perform more tasks, as well as new tasks (e.g., CLIA compliance), with fewer or less highly skilled staff members.

In concept, “easy-to-learn” and “easy-to-use” software user interfaces have the potential to improve laboratory productivity. The reality is that user software interfaces are often difficult to learn and use. First, software user interfaces are different from one manufacturer to another; frequently, they are also different from one product to another from the same manufacturer. This makes it difficult for technicians to learn one interface and apply that learning to another interface. Second, many interfaces are difficult to use, because current knowledge in software user interface design is not applied during the development of the products. Furthermore, many products are not tested by their designers for ease of learning and use.

This document will help designers of computer-actuated diagnostic instrument systems identify those areas of a software user interface where commonalities in design, rather than product differentiation, can provide the greatest benefit to the laboratorians. AUTO13-A2 also provides guidelines for purchasers of computer-actuated diagnostic instrument systems that establish common benchmarks by which to judge the suitability of a potential acquisition; these guidelines move laboratorians closer to an important goal—a decrease in the total cost of laboratory operations.

AUTO13-A2 also offers help to laboratorians in the preparation and execution of end-user validation plans for software developed to collect, interpret, or report laboratory, patient, or quality control information from various sources, including:

- software purchased from vendors;
- custom software commissioned by the laboratory; and
- applications constructed in-house.

There was some discussion about splitting this document into two independent guidelines, because the audience for each part was different: product software designers for Part 1 and end users for Part 2. While there is some logic to that approach, it was felt that the two sections should be kept in one document to promote active discussion and interaction between both target audiences and to maximize the acceptance and utility of any software interface to laboratorians.

Software validation is a requirement of laboratories before it can be implemented, and user interface designers must understand the laboratory’s need for effective, easy-to-use and easy-to-validate software

**Related NCCLS Publications\***

- GP2-A4**      **Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition (2002).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the laboratory testing community.
- GP18-A**      **Laboratory Design; Approved Guideline (1998).** This guideline provides a foundation of information about laboratory design elements that can be used to help define the issues being considered when designing a laboratory.
- GP21-A**      **Training Verification for Laboratory Personnel; Approved Guideline (1995).** This document provides background and recommends an infrastructure for developing a training verification program that meets quality/regulatory objectives.

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\* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

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