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AUTO10-A

Autoverification of Clinical Laboratory Test Results; Approved Guideline

This document provides a general framework that will allow each laboratory to easily design, implement, validate, and customize rules for autoverification (automated verification) based on the needs of its own patient population.

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

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Autoverification of Clinical Laboratory Test Results; Approved Guideline

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Abstract

Clinical and Laboratory Standards Institute document AUTO10-A—*Autoverification of Clinical Laboratory Test Results; Approved Guideline* provides a general framework that will allow each laboratory to easily design, implement, validate, and customize rules for autoverification (automated verification) based on the needs of its own patient population. The goal is to provide a new set of guidelines that will take us beyond traditional autoverification to the next generation that allows the use of more sophisticated algorithms to meet laboratory needs, as well as accurately reflect the medical philosophy of the laboratory.

In addition, important supporting sections are provided that deal with the different aspects of regulatory compliance and validation of algorithms that are essential to establishing and maintaining a modern autoverification program. Through utilization of this structured approach, the end users will be able to ensure compliance with regulatory agencies (where acceptable by law), yet effectively develop and establish monitors to ensure that all aspects related to quality are maintained. Guidelines are provided for the automated delivery of high priority results that can be customized to meet a provider's specific needs, along with a confirmation process that results have been received.

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Foreword

The basis of this guideline is to provide laboratorians with a "tool set" consisting of basic and complex Boolean logic, to develop algorithms that can be used to make result verification decisions based upon available medical data. Basic Boolean logic can be defined as a statement using the words "AND" or "OR" in the creation of a logical statement (or rule). Complex Boolean logic consists of several statements combined with "AND" or "OR" that allow for precise analysis of a particular situation.[1]

Minimum requirements for the software tools to build autoverification algorithms include the following:

- ability to use multiple data elements in an unrestricted fashion;

- ability of the laboratory to define and implement changes to algorithms quickly and easily;

- retrieval of selected information from multiple data sources (e.g., EMR, pharmacy, instrument results, other laboratory data, diagnosis code);

- application of algorithms in real time; and

- flexible user interface that provides laboratory-defined information on the autoverification process in real time.

Traditionally, result verification has depended on mental algorithms that are performed by pathologists/medical technologists/technicians on a single or group of analytical results. The purpose is to identify potential analytical error before results are made available outside the laboratory. Preanalytical, analytical, and postanalytical data can be used in this process.

Autoverification is a process whereby computer-based algorithms automatically perform actions on a defined subset of laboratory results without the need for manual intervention by a laboratorian. The computer-based action could be the immediate verification of a result, repeat analysis, reflexive testing, addition of comments, or suggested manual steps including (but not limited to) manual review of the result. By automatically performing actions on results that meet well-defined criteria, more time is made available for manual processing of those results that require special attention. Autoverification ensures that every result consistently receives the very same review process. Additionally, computer-based autoverification algorithms provide the opportunity to develop more sophisticated algorithms that incorporate more extensive data than would be possible for a laboratorian to perform in a consistent, timely, and accurate manner.

Manufacturers and software developers should institute effective risk management and good software life cycle processes in the development of autoverification applications. Please consult appropriate standards such as:

- ISO 14971:2000, *Medical devices – Application of risk management to medical devices*
- AAMI/ANSI SW68:2001, *Medical device software – Software life cycle processes*

Implementation of autoverification will involve use of systems that are subject to electromagnetic interference and may be at additional risk to radio frequencies when linked to wireless systems. Manufacturers and healthcare professionals should be aware of these issues and take necessary mitigation measures. For help, consult appropriate standards such as:

- IEC 60601-1-2 (Second Edition, 2001), *Medical Electrical Equipment – Parts 1-2: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests*

- AAMI TIR No.18—1997, *Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers—Part 1: Radiated Radio-Frequency Electromagnetic Energy*

- ISO/TR 21730:2005(E), *Health informatics – Mobile wireless communication and computing technology in healthcare facilities – Recommendations for the management of unintentional electromagnetic interference with medical devices.*

The following flow diagram is an example of a simple algorithm for evaluating the BUN/creatinine ratio in human serum. The diagram is based on the use of an enzymatic BUN method, as well as an enzymatic method for creatinine. The algorithm complexity could be increased depending on the information available, such as checks of QC acceptability, etc.
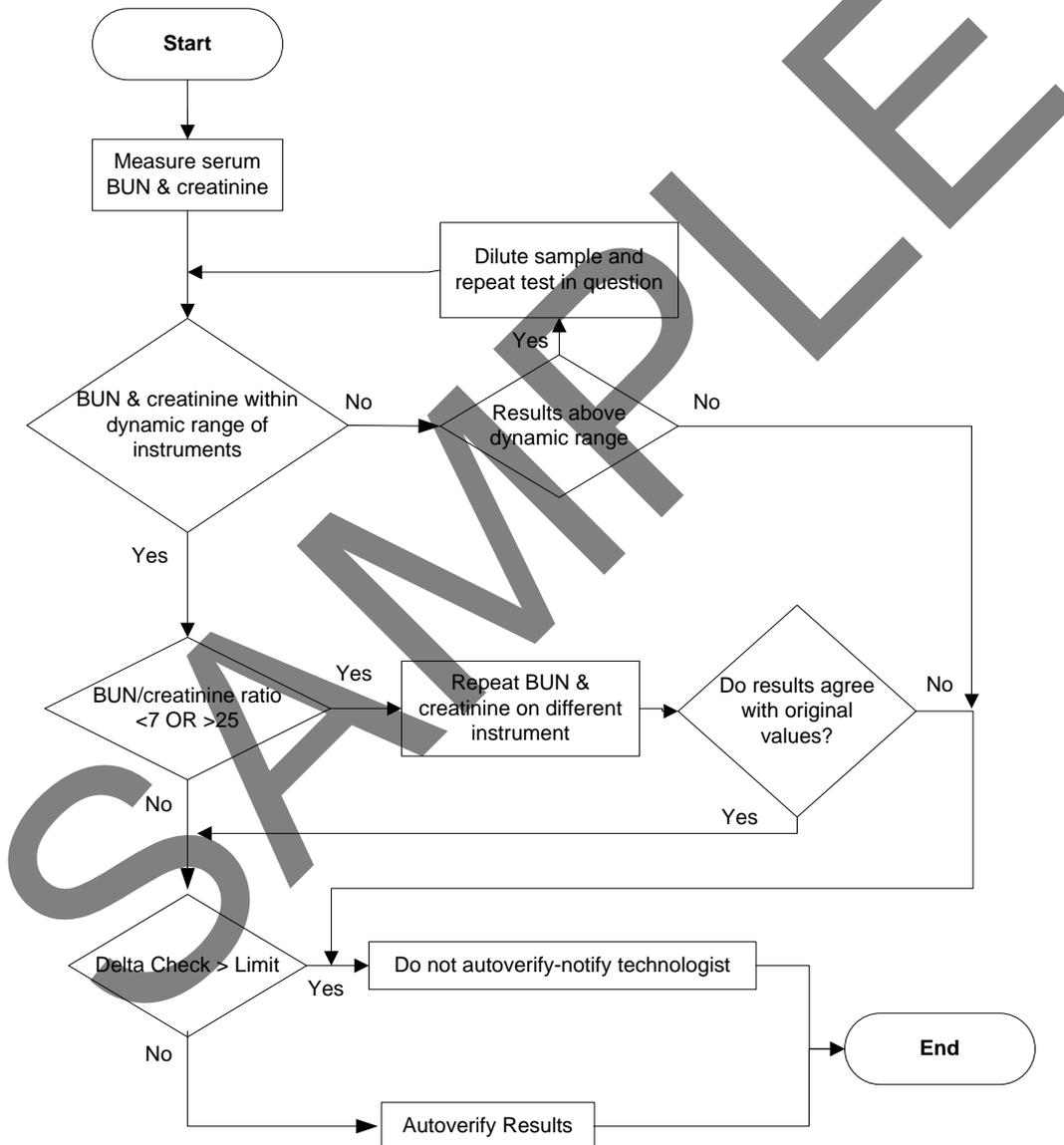
Figure 1. Example of a Simple Algorithm

The following flow diagram is provided as an example of a complex algorithm that deals with artifactual hyponatremia. If a sodium measurement is done on a patient's serum or plasma containing either very high levels of lipidemia and/or paraproteinemia, there can be an artifactual lowering of sodium levels if the chemistry analyzer does the assay on a diluted sample.

Sodium ions will be excluded or displaced from the space occupied by large amounts of lipids or paraproteins. Sodium ions are located in the aqueous portions of the sample. Accurate sodium measurements can be made if the ion-selective electrodes for sodium are placed directly in the sample where no sample dilution (nondilution or direct method) is done. If a dilution is done prior to the sodium measurement, the sodium value will be falsely low, regardless of the analytical method used. In the case of highly lipemic samples, a high-speed centrifuge can be used to physically separate the aqueous portion from the lipids and the sodium can be accurately measured. In the case of hyperparaproteinemia, high-speed centrifugation will not separate the high molecular weight molecules and a nondilution method should be used. Based on the algorithm and the methods used in the laboratory, the flowchart can instruct the technologist how to correctly handle the sample.
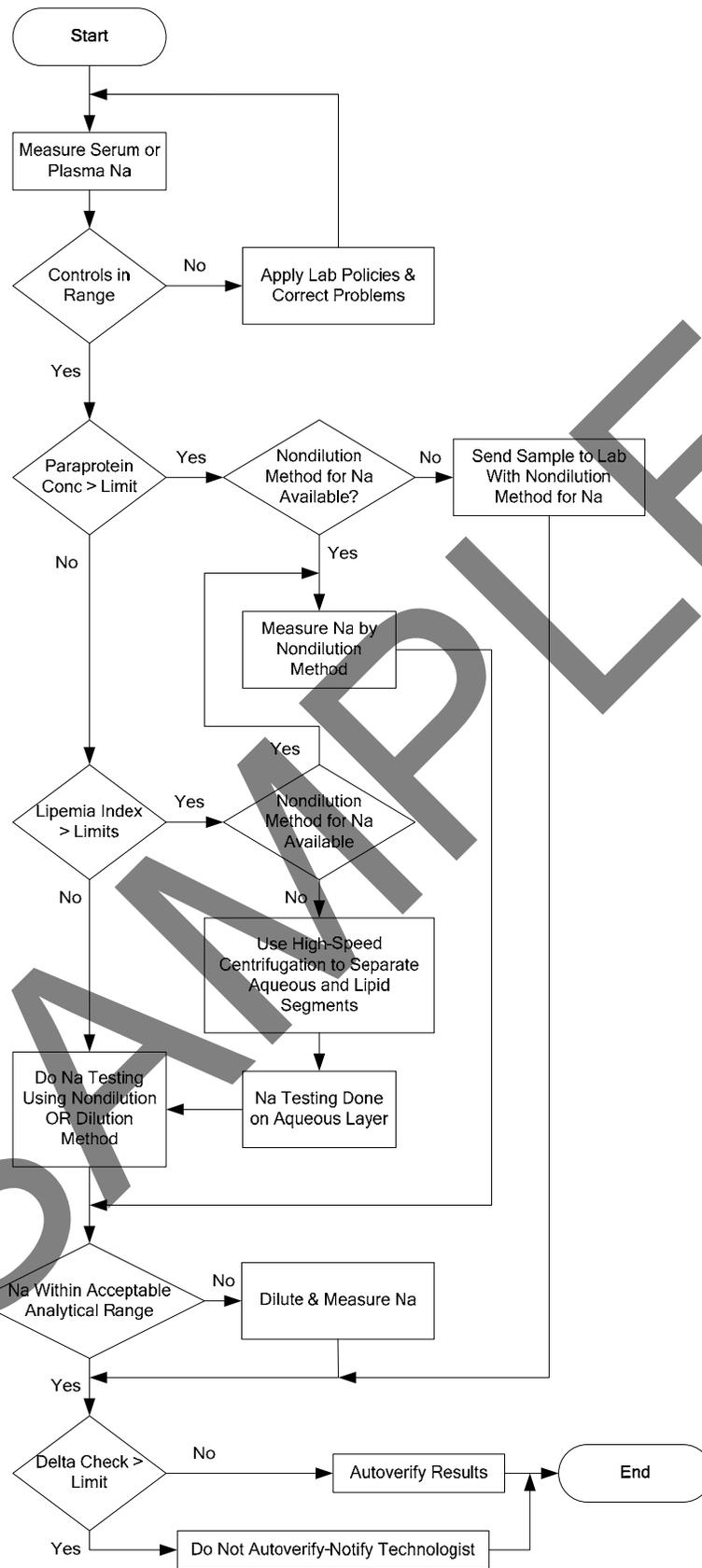
Figure 2. Example of a Complex Algorithm

Autoverification can be achieved through the use of information technology (IT) tools, but the laboratory is ultimately responsible for defining the criteria that are implemented with the IT tools to make autoverification decisions. This document provides guidelines for developing criteria that may be used in autoverification algorithms.

PREANALYTICAL INFORMATION

PATIENT INFORMATION

DIAGNOSTIC CODES

ELECTRONIC MEDICAL RECORD

PHARMACY

ANALYTICAL INFORMATION

SAMPLE INFORMATION

INSTRUMENT STATUS

RESULTS

AUTOVERIFICATION ENGINE

POSTANALYTICAL

RESULT/S VERIFIED

MANUAL INTERVENTION REQUIRED
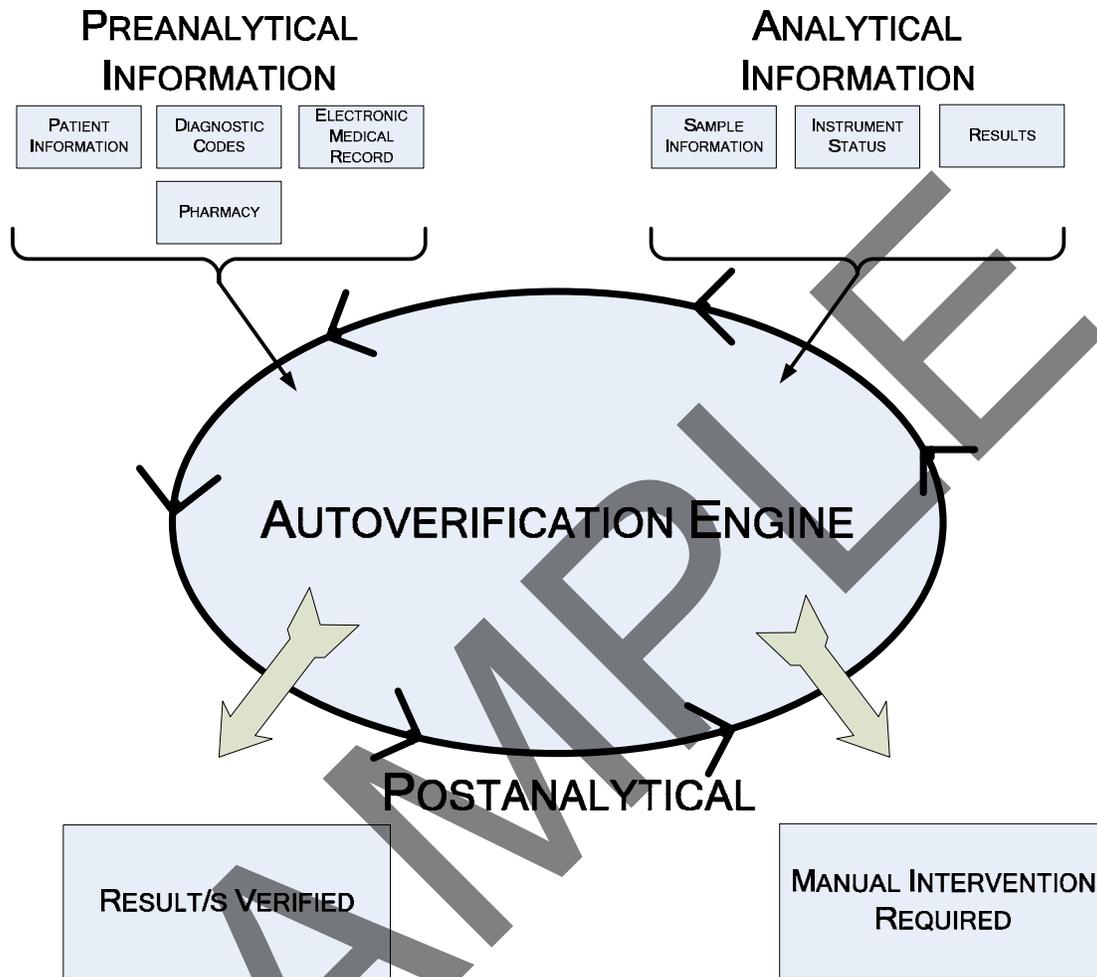
Figure 3. Autoverification Process

Key Words

algorithms, automated verification, autoverification, Boolean logic

Autoverification of Clinical Laboratory Test Results; Approved Guideline

1   Scope

This guideline specifies recommendations for the design, building, implementation, validation, and compliance of the algorithms used for autoverification of laboratory results.

The intended users of this guideline are information system vendors; hospital, reference, independent, and physician office laboratories; data management vendors; instrument manufacturers; and those involved in point-of-care testing.

This guideline is not intended to provide test parameter rules or limits for practicing medicine or methods for confirmation of result delivery. This guideline does not address hardware specifications, interface specifications, connectivity, or software configuration. Security measures are beyond the scope of this document and are assumed to be covered by country-specific policies. For additional information, refer to the current edition of CLSI document AUTO11—*IT Security of* In Vitro *Diagnostic Instruments and Software Systems.*

2   Introduction

The clinical laboratory continues to be pressured to increase productivity in response to external pressures related to reimbursement and allocated human resources. The pressures related to difficult recruitment within the technical ranks have led to a continued movement towards laboratory automation and enhanced computer systems that can help ensure adequate turnaround times (TAT) and enhancements to the quality of the result streams to the clinicians.

A natural response to these external pressures resides in the reexamination of the laboratory procedures (preanalytical, analytical, and postanalytical) related to the production of a reportable result. By the examination of these processes, the laboratory can seek mechanisms whereby enhanced services can be provided at lower costs and with enhanced quality.

The preanalytical and analytical processes continue to experience development and implementation within active laboratory environments. However, the development and implementation of postanalytical algorithms can significantly assist in the process of releasing results to the medical record. This process is known as autoverification. This postanalytical tool enables the user to electronically check analytical results against certain criteria. These criteria—including but not limited to reference ranges, quality control results, moving averages, instrument flagging, delta checks, maintenance checks, lot checks, clinician information/requests, and critical limits—can be used to make up the algorithms. The establishment of such processes can be tailored to each individual facility and is under the supervision of that facility's laboratory director and laboratory staff. Autoverification also ensures the quality of results, since every result is passed through the same rigorous algorithmic process.

As a result, a carefully planned and systematic mechanism is necessary to develop such postanalytical processes. By adhering to such a structure, the laboratory ensures that the process has been documented and examined, so the clinical and regulatory requirements are fulfilled when incorporating autoverification within the clinical laboratory environment.

Hence, this guideline was developed for the laboratory user. It is to be used strictly as a guideline to help establish, install, implement, and monitor this postanalytical process. By defining such computer-based rules and identifying such processes, the laboratory will make certain that the quality processes are met and documented.

This document provides examples of parameters and rules that can be used to develop an autoverification process. Individual laboratories may lack some of the capabilities described herein or may choose not to implement some rules in use by other laboratories for a variety of reasons. The laboratory director has the responsibility to select and implement autoverification rules and processes that are appropriate for his or her laboratory.

3   Definitions

accuracy (of measurement) – closeness of the agreement between the result of a measurement and a true value of the measurand (VIM93).[2]

algorithm – a set of rules for solving a problem in a finite number of steps, as for finding the greatest common divisor.

autoverification (automated result verification) – the automated actions performed by a computer system related to the release of test results to the medical record using criteria and logic established, documented, and tested by the medical staff of the laboratory; **NOTE:** The criteria can be simple or complex and involve many different parameters. The system offers the highest levels of consistency and the ability to handle complex algorithms in a very efficient way.

Boolean logic – developed by George Boole in the mid-1800s, operates on a set of rules that provides a consistent output based on a predefined set of input parameters; **NOTE:** The rules can be easily defined in a set of logic tables or diagrams. The most common rules are AND, OR, NAND, and NOR logic statements.

HIS (hospital information system) – the computer system used for management of data collected and generated by various services, laboratories, and facilities served by a hospital.

LAS (laboratory automation system) – a system of information and hardware technology that allows the operation of the clinical laboratory process without significant operator intervention.

LIS (**laboratory information system)** – the information system that is responsible for management of data regarding patient specimen identification, tests requested, results reported, quality control testing, and other aspects of sample analysis.

medical alert value – assay values that may require immediate medical attention, due to dangerously abnormal levels of a particular analyte; **NOTE:** Also called "critical values."

result verification – a process that is known by a variety of names, such as verifying, accepting, or releasing of results by the laboratory staff, so the results are made available or accessible to care providers outside the laboratory, such as physicians, nurses, etc.; **NOTE:** The process implies that results have been examined and meet the quality criteria established by the laboratory and can be used in the treatment and management of patients.

validation – confirmation, through the provision of objective evidence, that requirements for a specific intended use or application have been fulfilled (ISO 9000).[3]

validation plan – a written document that describes the required validation activities and acceptance criteria; **NOTE:** Validation plans are customized for each type of hardware/software that needs to be validated and should be approved by the laboratory director prior to initiation.

validation summary – the summarized, documented results of the validation plan.

The Quality System Approach

Clinical and Laboratory Standards Institute (CLSI) 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. The approach is based on the model presented in the most current edition of CLSI/NCCLS document HS1—*A Quality Management 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 (i.e., operational aspects that define how a particular product or service is provided). 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	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Service & Satisfaction
Personnel	Process Control	Assessment	Facilities & Safety

AUTO10-A addresses the quality system essentials (QSEs) indicated by an "X."

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
					X AUTO11						

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

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI/NCCLS document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow, which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

AUTO10-A addresses the clinical laboratory path of workflow steps indicated by an "X."

Preexamination					Examination		Postexamination	
Patient Assessment	Test Request	Specimen Collection	Specimen Transport	Specimen Receipt	Testing Review	Laboratory Interpretation	Results Report	Post-test Specimen Management
					X	X	X	

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

Related CLSI/NCCLS Publication[*]

AUTO11-A **IT Security of *In Vitro* Diagnostic Instruments and Software Systems; Approved Standard (2006).** This document provides a framework for communication of IT security issues between the IVD system vendor and the healthcare organization.

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[*] Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most recent editions.

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