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An American National Standard

Standard Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures¹

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1. Scope

1.1 This guide covers the process of defining and documenting the capabilities, the logical data sources and pathways of data exchange within a given network architecture of a Health Information Network (HIN) serving a set of constituents. It is not a technical implementation standard but, rather, it describes how the implementation methods and techniques can be used to logically coordinate clinical laboratory services and Electronic Health Record (EHR) systems involving participating organizations and sites connected by a networked communication system. It covers the content of the nodes and arcs of the resulting logical network involving both laboratory and EHR-capable sites. It also considers the various purposes and organizational arrangements for coordinating laboratory services within the network boundaries and the considerations for connections among external networks.

1.2 It refers to other standards for conventions within various data domains, such as Clinical Laboratory Information Management Systems (CLIMS) and EHR systems, and for messaging conventions. It is intended to outline how integration of CLIMS and EHR Systems can be undertaken to result in a transparent clinical decision support environment, regardless of the underlying implementation architecture, by describing the logical interoperability of information domains as facilitated by Information and Communications Technology (ICT).

1.3 It is directed at clinical laboratorians, information system managers and information systems vendors for use in planning and implementing coordinated laboratory services through effective dialogue.

2. Referenced Documents

2.1 ASTM Standards:

- E 792 Guide for Selection of a Clinical Laboratory Information Management System (CLIMS)²
- E 1238 Specification for Transferring Clinical Observations

- Between Independent Computer Systems²
- E 1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Electronic Health Record (EHR) Systems²
- E 1340 Guide for Rapid Prototyping of Computerized Systems²
- E 1381 Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems²
- E 1384 Guide for Content and Structure of the Electronic Health Record (EHR)²
- E 1394 Specification for Transferring Information Between Clinical Instruments and Computer Systems²
- E 1466 Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory²
- E 1467 Specification for Transferring Digital Neurophysiologic Data Between Independent Computer Systems²
- E 1578 Guide for Laboratory Information Management Systems (LIMS)³
- E 1633 Specification for Coded Values Used in the Electronic Health Record²
- E 1639 Guide for Functional Requirements of Clinical Laboratory Information Management Systems²
- E 1712 Specification for Representing Clinical Laboratory Procedure and Analyte Names²
- E 1713 Specification for Transferring Digital Waveform Data Between Independent Computer Systems²
- E 1714 Guide for Properties of a Universal Healthcare Identifier (UHID)²
- E 1715 Practice for an Object-Oriented Model for Registration, Admitting, Discharge and Transfer (RADT) Functions in Computer-based Patient Record Systems²
- E 1744 Guide for View of Emergency Medical Care in the Computer-based Patient Record²
- E 1762 Guide for Electronic Authentication of Healthcare Information²
- E 1769 Guide for Properties of Electronic Health Records and Record Systems²
- E 1869 Guide for Confidentiality, Privacy, Access and Data

¹ This guide is under the jurisdiction of ASTM Committee E31 on Healthcare Informatics and is the direct responsibility of Subcommittee E31.13 on Clinical Laboratory Information Management.

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² *Annual Book of ASTM Standards*, Vol 14.01.

³ *Annual Book of ASTM Standards*, Vol 03.05.



Security Principles for Health Information Including Computer Based Patient Records²
E 1985 Guide for User Authentication and Authorization²
E 1986 Guide for Information Access Privileges to Health Information²
E 1987 Guide for Individual Rights Regarding Health Information²
E 1988 Guide for Training Persons Who Have Access to Health Information²
E 2017 Guide for Amendments to Health Information²
E 2084 Specification for Authentication of Healthcare Information Using Digital Signatures²
E 2085 Guide on Security Framework for Healthcare Information²
E 2086 Guide for Internet and Intranet Healthcare Security²
PS 115 Specification for Audit and Disclosure Logs for Use in Healthcare Information Systems²
2.2 *ANSI/IEEE Standards:*⁴
ANSI X3.172 American National Dictionary for Information Systems
ANSI/IEEE 610.2 Standard Glossary of Computer Applications Terminology
ANSI/IEEE 610.5 Standard Glossary of Information Management Terminology
ANSI/IEEE 610.12 Standard Glossary of Software Engineering Terminology
ANSI/IEEE 729 Fundamental Terms in Software Engineering
ANSI/IEEE 830 Software Requirements Specification
ANSI/IEEE 1074 Standard for Developing Software Life Cycle Processes
ANSI/IEEE 1074.1 Guide for Implementing Life Cycle Processes
ANSI/IEEE 1058 Software Project Management Plans
ANSI/IEEE 1062 Recommended Practice for Software Requirements
ANSI/IEEE 1063 Software User Documentation
ANSI/IEEE 1073 Framework and Overview
ANSI/IEEE 1073.2 Application Profile Framework and Overview
ANSI/IEEE 1073.3.1 Transport Profile
ANSI/IEEE 1073.4.1 Physical Layer-Cable Connected
ANSI/IEEE 1074 Standard for Developing Life Cycle Processes
ANSI/IEEE 1074.1 Guide for Developing Life Cycle Processes
ANSI/IEEE 1220 Standard for Application and Management of the System Engineering Process
ANSI/IEEE 1233 Guide to Preparing System Requirements Specifications
ANSI/IEEE 1320.1 Standard for Conceptual Modeling Language - Syntax and Semantics for IDEF0
ANSI/IEEE 1320.2 Standard for Conceptual Modeling Language - Syntax and Semantics for IDEF1X97 (IDEF Object)

⁴ Available from IEEE, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331.

ANSI/IEEE 1362 Guide for Information Technology - System Definition -Concept of Operations Document
ANSI/IEEE 1490 Guide to Project Management Body of Knowledge
ANSI/IEEE 1498 Trial Use Standard for Information Technology - Software LifeCycle Processes - Software Development: Acquirer - Supplier Agreement
ANSI/IEEE 12207.0 Standard for Information technology - Software Life Cycle Processes
ANSI/IEEE 12207.1 Guide for Information technology - Software Life Cycle Processes - Life Cycle Data
ANSI/IEEE 12207.2 Guide for Information technology - Software Life Cycle Processes - Implementation Considerations
IEEE P1157.1 Trial Use Standard for Healthcare Data Interchange - Information Model Methods
2.3 *ANSI/HL7 Standards:*⁵
ANSI/HL7 Interface Standard v2.3.1
HL7 Message Development Framework v 3.0 Jan 1997
2.4 *ISO Standards:*⁶
ISI/IEC TR 9789 Information Technology - Guidelines for the Organization and Representation of Data Elements for Data Interchange - Coding Methods and Principles
ISO 12200 Computer Applications in Terminology - Machine-Readable Terminology Interchange Format (MARTIF) - Negotiated Interchange
ISO 12620 Computer Applications in Terminology - Data Categories
ISO IS 12207 Information Technology-Software Life Cycle Processes
ISO IS 15188 Project Management Guidelines for Terminology Standardization
ISO WD 15288 System Life Cycle Processes
ISO 15440 Guide for Life Cycle Processes
ISO 15189 Quality Management in the Clinical Laboratory
ISO DIS 15194 Measurement of Quantities in Samples of Biologic Origin - Reference Materials
ISO DIS 15193 Measurement of Quantities in Samples of Biologic Origin - Reference Methods
ISO 15195 Requirements for Reference Measurement Laboratories
ISO 15711 Traceability of Calibration and Control Materials
2.5 *Other Standards:*
ANSI/ADA 1000.0 Introduction, Model Architecture, and Specification Framework⁷
ANSI/ADA 1000.1 Individual Identification⁷
ANSI/ADA 1000.2 Codes and Nomenclature⁷
ANSI/ADA 1000.3 Individual Characteristics⁷
ANSI/ADA 1000.4 Population Characteristics⁷
ANSI/ADA 1000.5 Organization⁷
ANSI/ADA 1000.6 Location⁷
ANSI/ADA 1000.7 Communication⁷

⁵ Health Level 7, 3300 Washtenaw Ave., Suite 227, Ann Arbor, MI 48108.

⁶ Available from International Standards Organization, 1 Rue de Varembe, Case Postale 56, Crt1221, Geneva 20 Switzerland.

⁷ Available from the American Dental Association (ADA), Dept. of Dental Informatics, 211 East Chicago Ave., Chicago, IL 60611.

ANSI/ADA 1000.8 Healthcare Event⁷
ANSI/ADA 1000.9 Health Material⁷
ANSI/ADA 1000.10 Health Services⁷
ANSI/ADA 1000.11 Health Service Resources⁷
ANSI/ADA 1000.12 Population Health Facts⁷
ANSI/ADA 1000.13 Patient Health Facts⁷
ANSI/ADA 1000.14 Health Condition Diagnosis⁷
ANSI/ADA 1000.15 Health Service Plan⁷
ANSI/ADA 1000.16 Patient Health Service⁷
ANSI/ADA 1000.17 Clinical Investigation⁷
ANSI/ADA 1000.18 Comments Subject Area⁷
DICOM Supplement 15 Visible Light Image, Anatomic Frame of Reference, Accession and Specimen for Endoscopy, Microscopy, and Photography⁸
CEN ENV 1613 Medical Informatics - Messages for the exchange of laboratory information⁹
CEN ENV 1614 Healthcare informatics - Structure for nomenclature, classification and coding of properties in clinical laboratory sciences⁹
CEN ENV 12017 Medical Informatics Vocabulary (MIVoc)⁹
CEN ENV 12264 Categorical Structures of Systems of Concepts -Model for Representation of Semantics (MOSE)⁹
Internet RFC 1521 N. Borenstein, N Freed MIME [Multi-purpose Internet Mail Extensions] Purpose: Mechanisms for Specifying and Designating the Format of Internet Message Bodies, Bellcore Innosoft, Sept. 1993, ANSI X12⁹
NCCLS AUTO1-A Laboratory Automation: Specimen Container/Specimen Carrier¹⁰
NCCLS AUTO2-A Laboratory Automation: Bar codes for Specimen Container Identification¹⁰
NCCLS AUTO3-A Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices and Information Systems¹⁰
NCCLS AUTO4-A Laboratory Automation: Systems Operational Requirements, Characteristics and Information Elements¹⁰
NCCLS AUTO5-A Laboratory Automation: Electromechanical Interfaces¹⁰
ANSI/NCCLS ASTP2 Point of Care In-vitro Diagnostic Testing¹⁰
ANSI/NCCLS GP19 Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and Software Systems Validation, Operations and Maintenance¹⁰
IUPAC/IFCC Silver Book: Compendium of Terminology and Nomenclature of Properties in Clinical Laboratory Sciences¹¹
IUPAC/IFCC Properties and Units in Clinical Laboratory

Sciences X Properties and Units in General Clinical Chemistry¹¹
IUPAC/IFCC Properties and Units in Clinical Laboratory Sciences XII Properties and Units in Clinical Pharmacology and Toxicology¹¹

3. Terminology

3.1 Definitions:

3.1.1 Terminology related to general information systems appears in X3.172, IEEE 610 series, and IEEE-729 Terminology relating generally to healthcare information appears in CEN EN 12264 and EN 12017, and in UMLS. The terms used frequently from these sources appear here, in addition to those terms specific to this guide.

3.1.2 *health information network*—a set of data domains (nodes) and communications pathways (arcs) serving a healthcare constituency with information management services.

3.1.3 *identifier*—a symbol used to name, indicate or locate. Identifiers may be associated with such things as data structures, data items, or program locations. **(IEEE 610.12)**

3.1.4 *practitioner, licensed*—an individual at any level of professional specialization who requires a public license/certification to practice the delivery of care to patients. A practitioner may also be a provider. **(E 1384)**

3.1.5 *provider*—a business entity which furnishes healthcare to a consumer. It includes a professionally licensed practitioner who is authorized to operate a healthcare delivery facility. **(E 1384)**

3.2 *Acronyms*—The following acronyms are used in this standard and may also appear in other referenced documents:

CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention, Dept. of Health and Human Services
CDSS	Clinical Decision Support Systems
CLIMS	Clinical Laboratory Information Management System
CPR	Computer-based Patient Record
DHHS	Department of Health and Human Services
EC	Electronic Commerce
EDI	Electronic Data Interchange
HIN	Health Information Network
IDS	Integrated Delivery Systems
ISA	Information Systems Architecture
LAS	Laboratory Automation System
LIMS	Laboratory Information Management System
MDSS	Management Decision Support System
MCO	Managed Care Organization
MPI	Master Person/Patient Index
NCVHS	National Committee on Vital and Health Statistics
NPF	National Provider File
NPI	National Provider Identifier
NPS	National Provider System
POC	Point-of-Care
POCT	Point-of-Care Testing
PPO	Preferred Provider Organization
SSAN	Social Security Account Number (also SSN)
UMLS	Unified Medical Language System

4. Significance and Use

4.1 Health Information Networks (HINs) have arisen in recent years as a way to share common information within organizational arrangements among healthcare facilities which have been formed into large, more comprehensive Integrated Delivery Systems (IDS) and Managed Care Organizations (MCO) offering a full range of healthcare services, both inpatient and ambulatory. The specific organizational structure

⁸ Available from ACR/NEMA.

⁹ Available from CEN, Central Secretariat, Rue Strassart 36, B-650, Brussels, Belgium.

¹⁰ Available from NCCLS, 940 West Valley Rd, Suite 1400, Wayne, PA 19087-1898.

¹¹ Available from IUPAC, c/o CRC Press, 2000 Corporate Blvd. NW, Boca Raton, FL 33431.

to which the term was originally applied most probably have evolved into something quite different. Furthermore, IDS organizations are contracting with other IDSs by offering specialty services, such as clinical laboratory services, that have a market larger than a single IDS itself and buying such services for themselves rather than offering them internally. Because of the proliferation of specialty laboratory procedures and the introduction of automation of laboratory operations which require a larger volume to begin offering than is internally available, specialty laboratory procedures are being marketed beyond just the host IDS. Moreover, initiatives directed at automation in the clinical laboratory will need a frame of reference for the global information to which that automation will contribute.

4.2 Another aspect is the development of instrumentation for testing at Point-of-Care (POCT) for high value immediate-benefit services. POCT, however, needs supervision and training from skilled laboratorians, whether that supervision comes from within the IDS or outside of it. This range of operation is only achievable by distributed HIN structures which must have the same quality of clinical and data services as offered by laboratories close at hand. Data Management of POCT has been documented separately but such data management must be placed into the broader context of this guide. Thus, this guide should be used to first organize the global domain and then the interconnected subdomains.

4.3 In order to provide common systematics for documenting coordination of laboratory services within the HIN structure, the problem has been broken down within this guide into identification and characterization of, first, the global domain and the business framework into which coordinated laboratory services will fit as a component. Then the constituent subdomains are addressed and are represented as nodes in the network. Next, the characterization of the arcs in the network are treated, again focusing on the logical content and not the implementation. When the logical structure of the network is well understood in terms of its scope, purpose and constituents, then enumeration of alternative implementation strategies and methods/techniques can be effectively considered, followed by selection of an alternative, or a set of compatible alternatives. Finally, selection of an evaluation methodology and its use in managing ongoing operation and evolution of lab services coordination as part of the overall evolution of the HIN itself are covered. Such an approach should then allow laboratorians, information system personnel, and any external suppliers who may be involved, to define, plan, implement, and utilize a networked architecture for coordination of the lab service component of a EHR environment implemented in a networked architecture. This development can be organized into the Life Cycle Processes defined in IS 12207 and 15288 and in ANSI IEEE 12207.0, 12207.1, 12207.2. CLIMS used to serve as components within this architecture can be procured with the help of Guide E 792.

5. Identification of the Network Domain

5.1 In order to encompass all of the aspects to be served by a networked architecture provided for coordinating the services requested of the clinical laboratory by each specific care setting and type, the global business objectives must be stated and the

increasingly specific content of the domain to be networked must be established. This is usually done using a matrix model that defines all of the dimensions starting from the most general to the more technical. Table 1 gives an example of such a matrix. The technique, detailed further in 5.2, has been described by Zachman **(1)**¹² as the Information Systems Architecture (ISA) Framework and has been implemented using several software tools **(2-4)**. From examination of this matrix format, further modeling of the business components, the processes and the data structures and representations is sequentially undertaken in order to identify the nodes and arcs of the network that support the business case for the network. The detailed modeling of the data domains, using the business considerations given in 5.2, is then applied, as appropriate, to each node. This activity will identify both the data that is required for activities internal to the node and that which may be exchanged with other domains. The business case for each node must be understood as part of the identification of the node and so a detailed internal business model should result that drives the process model for that node and which may be independent of the models for a different node of the same type. Since the interactions of the nodes are known from identification of the arcs, those data needed by each arc can be generally identified and later characterized, as noted in Section 7. Following these steps, which identify the requirements of a network, effective delineation of implementation strategies that are consistent with the business case can be documented and a selection made of implementation tools and techniques that are appropriate to the selected Life Cycle.

5.2 *Modeling of the Business Domain*—A Zachman ISA Framework matrix of the dimensions of the informatics standards applied to healthcare is given in Table 1. From this broad domain, standards dealing with those aspects relevant to coordination of laboratory services are shown in Table 2. The enterprise that is developing a networked architecture for coordinating laboratory services in a EHR environment must refine this perspective to that embracing the interests of the enterprise. This refinement will begin by looking at each of the cells in the upper left of the matrix dealing with Scope and Concept of Operations - See IEEE 1362 (ISA matrix cells 1-6) and then moving to the right followed by moving down from content issues to implementation issues reflecting use of a particular technology and techniques. Once a refined framework is available, then more specific modeling of Processes and Data take place. These will be focused first on the source and destination information domains (nodes) and then on the arcs.

5.2.1 *Representative Case*—Most healthcare enterprises, and probably most laboratory services (Table 3), will consist of both ambulatory and inpatient settings (6.3) in addition to central laboratory sites appropriately located. The “Concept of Operations” (ANSI/IEEE 1362) prepared as Cells 1-2 and 1-3 in Table 1 should enumerate, for the enterprise, the range of support that each laboratory location will provide with respect to the identified care settings served. The focus of Cell 1-6 in

¹² The boldface numbers in parentheses refer to the list of references at the end of this standard.



TABLE 1 ISA Framework for Healthcare Informatics Standards

	Why	When	Who	What	How	Where
Vision [Guidelines]						
Scope (contextual)	Goals (motivation)	Events (time)	Stakeholders (people)	Values (content)	Processes (function)	Locations (network)
	1. Personal/Public Health; care delivery business case	2. Identification of significant care/care delivery events	3. Essential health Service Organizations and Functions	4. Description of important healthcare service and care delivery information	5. Important healthcare and care delivery services	6. Identification and description of organization and individual locations
Design [Standards]						
Enterprise Model (Conceptual)	Objectives	Timeline	Organization	E-R Data Model	Process Model	Interface Architecture
	7. Personal health benefit and care delivery business objectives	8. Sequence and timelines of healthcare services	9. Healthcare information workflow	10. Semantic description of healthcare processes	11. Conceptual activity model of healthcare delivery	12. Structure and interrelationship of healthcare facilities
System Model (Logical Design)	Requirements	Phases	Hierarchies	Logical Data Model	Data Flow	Network Model
	13. System Functional Requirements	14. Healthcare event phases and process components	15. Healthcare information system human-system interface architecture	16. Logical data model for healthcare information	17. Application architecture with function and user views	18. Connectivity and distributed system architecture
Implementation [Standards]						
Technology Model (Physical Design)	Knowledge Design	Control Structure	Human-Technology Architecture	Physical Data Model	Structure Chart	System Architecture
	19. System Operational Requirements	20. Healthcare information system control structures	21. Healthcare information system human system interface description	22. Physical data model for healthcare information	23. System Design, language specification and structure charts	24. Health system information network detailed architecture
Components (Modules and Subsystems)	Knowledge Definition	Timing Definition	Security Architecture	Data Dictionary	Program Description	Network Architecture
	25. Technical Requirements	26. Healthcare Information System component timing descriptions	27. System Security Architecture and Operations	28. Healthcare Information Metadata and DBMS scripts	29. Code Statements, Control blocks, DBMS stored procedures	30. Physical data network components, addresses and communication protocols
Operation [Standards]						
Functioning System	Strategy	Schedule	Organization	Data	Function	Network
	31. Technology Operational Requirements	32. Healthcare information system operation Schedules	33. IS participant description	34. Functioning database, knowledge base	35. User procedural system and documentation	36. Operating health system communication network

Table 1 should be to document the specimen and patient referral patterns of the care sites (see Appendix X1, Fig. X1.1) and to show the enterprise organizational network diagram. The pattern of intercommunication between nodes, the logical network, would be prepared as Cell 3-6. An example of this is shown in Appendix X1, Fig. X1.2. These boundary conditions allow each laboratory node to identify its own business plan for internal management purposes as a complement to the Enterprise Business Plan. The example in Appendix X1 gives a basic documentation of this process phase for a laboratory serving a family practice ambulatory care clinic and a general practice hospital. POC Testing laboratories are present in the Family Practice Ambulatory Clinic. The initial ISA Matrix is shown in Table 2 which identifies the models for the enterprise and those for each POCT location needed to characterize the main information domains. Process models for the enterprise and each location are developed followed by data models for CLIMS and EHR domains as guided respectively by 6.2 and 6.3. These models identify data elements and associated value sets required throughout the enterprise. When full character-

ization of nodes has been completed, additional node specific data will next be identified.

5.3 Modeling of the Processes—Several techniques are available for the modeling of processes, including IDEF0 (Ref (3) and IEEE 1320.1), Use Cases (4) and Data Flow Diagrams (6). In each technique both actions and the “actors” (4), or individuals/organizations, must be identified and their activity described first globally and then in detail in order to identify scenarios involving clinical laboratory services. An example of this technique is shown below. Process models are generally hierarchical if using IDEF0 (but also using Use Cases), starting first at the global level and then increasingly refined to an appropriate level of detail needed to fully understand the activities within the defined domain. The purpose of these process models is to systematically and comprehensively examine all of the processes producing information that affects the defined business case noted in 5.2. They should be applied first to the Enterprise and then to the nodal domains. Fig. 1 shows a representative Use-case/Actors model for a POL type POCT scenario and setting (see 6.2) in an enterprise view.



TABLE 2 ISA Framework for Clinical Laboratory Informatics Standards

Zachman	Why	When	Who	What	How	Where
Vision [Guidelines]						
Scope	Goals Provide lab services; Provide integrated decision support	Events 24 Hr Service; Just-in- time inventory; Continuous Resource Mgt; Immediate Claims processing	Stakeholders Clinical Laboratory; Practitioner Clientele; Suppliers; Payors; Patients	Values Services; Requested Data; Supplier Data	Processes Services; Request Data; Specimen accession; Work Mgt; Resource Mgt; Claims processing	Locations Central Lab; Distributed Lab; Practitioner Site of Care Network Domain
Generic [Standards]						
Enterprise Model	Objectives Request services; Collect/transport Specimens	Timeline Milestone Chart; PERT/CPA/Gantt	Organization IDS; MCO; Reference Lab	E-R Data Model High Level Data Model (IDEFIX)	Process Model Process Model UseCase/Actors (IDEFO)	Interface Architecture Patterns of Service Utilization; Health Benefits/Objectives
System Model	Requirements Functional requirements; Health Knowledge Architecture	Phases IDEF3 Timeline Diagram	Hierarchies Organizational Hierarchies	Logical Data Model CLIMS Data Model; CPR Data Model; IDEFIX/Objects	Data Flow	Network Model Information Architecture
Implementation [Standards]						
Technology Model	Knowledge Design	Control Structure	Human-Technology Architecture Interface Style Guide	Physical Data Model CLIMS/CPR Database Models	Structure Chart	System Architecture
Components	Knowledge Definition Populate Knowledge Databases	Timing Definition	Security Architecture	Data Dictionary CLIMS/CPR Data Dictionaries	Program Description Structure Charts	Network Architecture
Utilization [Standards]						
Functioning System	Strategy	Schedule	Organization	Data	Function	Network

TABLE 3 Clinical Laboratory General Sizes and Types

Office Practice Laboratory (service types/configurations)
POCT Work Station (service types/configurations)
Large Ambulatory Clinic Laboratory
Hospital/Inpatient-Facility Laboratory
Commercial Reference Laboratory
An external non-clinical LIMS (eg environmental)
Master Patient Index
National Provider File

5.4 Modeling of the Data Domains—Data modeling, as noted in 5.2, involves systematically and comprehensively describing the DATA involved in processes detailed in 5.3. It includes identifying or constructing the terminologies needed to populate value sets for the defined data attributes. For example, this technology function must draw on consensus vocabularies developed by professional specialty groups, public agencies or other involved organizations with broad involvement in healthcare, if true interoperability is to be achieved (See Specification E 1712 and the LOINC.¹³ The value sets may be selected from these more global vocabularies. In order to truly understand the data structures and data representations, an understanding of the processes is required. Thus, processes modeling should, but many times due to haste does not, precede data modeling. In the case where data modeling shuns formal process modeling, an intuitive - and thus generally incomplete - process model drives the data modeling. The urge to omit the process modeling phase should

be resisted. Rather, the modeling activities may be carried out iteratively first at a high level and then at increasing detail. Guide E 1639 and Practice E 1715 delve into data modeling in constituent functional domains. These activities, however, need to be placed in the context established by the Business model (5.2) and the Process models (5.3). This task is taken up in Section 6.

6. Characterization of the Network Nodes

6.1 One of the reasons that this standard is a guide and not a specification is that it is not possible to detail, in a global document such as this, the specifics of the various factors which may need to be considered at the individual enterprise level. Likewise, for each of the node types only a general guide to the issues that need to be considered is given here. The steps given in IS 12207 on Software Life Cycles and 15288 on System Life Cycles will need amplification and specification as part of the documentation for a specific enterprise and specific project. In considering the types of nodes that may be involved in coordination of clinical laboratory services, a wide variety of activities become recognized that may not generally be included as separate data domains. Some of those included are shown in Table 4. Because the view of clinical laboratory services from the perspective of the performers of the services in each of these other domains may not be a realistic picture of the activity required to conduct its role at these other nodes, this section sets out to identify, and generally characterize, the business, the processes, and the data that may be involved in a representative real instance of each type of node in a working network so that network planners and designers have a

¹³ See the website, <http://www.regenstrief.org>.