LIS8-A
Vol. 23 No. 14
Formerly ASTM E1639-01

Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems

This document covers the capabilities needed for a logical structure of a Clinical Laboratory Information Management System (CLIMS).

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Preface

In 2001, ASTM Committee E31 decided to restructure its operations, with the intent of focusing on standards-development issues such as security, privacy, and the electronic health record. Part of the reorganization plan was to explore the option of transferring responsibility for nine E31.13 standards to NCCLS.

The NCCLS Area Committee on Automation and Informatics, at its meeting in April 2002, reached a positive assessment of the value of the ASTM standards and encouraged the NCCLS Executive Offices staff to pursue negotiations with ASTM on transferring these standards to NCCLS.

Following this transfer, these nine standards (formerly ASTM E792; E1029; E1238; E1246; E1381; E1394; E1466; E1639; and E2118) have been redesignated as NCCLS standards LIS1 through LIS9.

The Area Committee on Automation and Informatics has assumed responsibility for maintaining the documents and will revise or update each document in accord with NCCLS Administrative Procedures.

This document is the equivalent of ASTM E1639-01 but has been redesignated and is now maintained by NCCLS. This document has been approved as an American National Standard (ANSI/ASTM E1639-01).

Suggested Citation

(NCCLS. *Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems*. NCCLS document LIS8-A [ISBN 1-56238-496-1]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.)

Published
April 2003

ISBN 1-56238-496-1
ISSN 0273-3099

Standard Guide for
Functional Requirements of Clinical Laboratory Information Management Systems

1. Scope

1.1 This guide covers the capabilities needed for a logical structure of a Clinical Laboratory Information Management System (CLIMS). It was written so that both the vendors or developers of CLIMS and laboratory managers would have a common understanding of the requirements and logical structure of a laboratory data system. This guide will also help answer many of the questions faced by designers of CLIMS and provide more uniformity in the way that requirements are expressed from one laboratory to another. It is therefore applicable to users who are involved with acquiring or operating a CLIMS.

2. Referenced Documents

2.1 *ASTM Standards:*

E 1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (RADT) Systems for Automated Patient Care Information Systems[1]

E 1340 Guide for Rapid Prototyping of Computerized Systems[1]

E 1384 Guide for Content and Structure of the Electronic Health Record (EHR)[1]

E 1460 Specification for Defining and Sharing Modular Health Knowledge Bases (Arden Syntax for Medical Logic Modules)[2]

E 1578 Guide for Laboratory Information Management Systems (LIMS)[1]

E 1633 Specification for Coded Values Used in the Electronic Health Record (EHR)[1]

E 1712 Specification for Representing Clinical Laboratory Procedure and Analyte Names[1]

E 1714 Guide for Properties of a Universal Healthcare Identifier[1]

E 1715 Practice for an Object-Oriented Model for Registration, Admitting, Discharge, and Transfer (RADT) Functions in Computer-Based Patient Record Systems[1]

2.2 *ANSI Standards:*

ANSI X3.172-1990 American National Dictionary for Information Systems[3]

ANSI X11.1 M Programming Language[3]

2.3 *NCCLS Standards:*

NCCLS Auto Communications System, Instrument Systems[4]

NCCLS AUTO3–A Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices and Information Systems[4]

2.4 *IEEE Standards:*[5]

IEEE 1074 Standard for Developing Software Life Cycle Processes

IEEE 610.2 Standard Glossary of Computer Applications Terminology

IEEE 610.5 IEEE Standard Glossary for Information Management Terminology

IEEE 610.12 Standard Glossary of Software Engineering Terminology

IEEE 830 Software Requirements Specification

IEEE 1058 Software Project Management Plans

IEEE 1362 Guide for Information Technology—System Definition-Concept of Operations

2.5 *ISO Standard:*

ISO 11756 M Programming Language[3]

ISO 12207 Information Technology—Software Life Cycle Processes[3]

2.6 *Other Document:*

HL7 Health Industry Level 7 Interface Standards Version 2.3[6]

[1] *Annual Book of ASTM Standards*, Vol 14.01.

[2] Discontinued 1999. See the *1999 Annual Book of ASTM Standards*, Vol 14.01.

[3] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

[4] NCCLS, 940 West Valley Rd., Suite 1400, Wayne, PA 19087-1898.

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

[6] Health Level 7, 3300 Washtenaw Ave., Suite 227, Ann Arbor, MI 48108.

3. Terminology

3.1 *General*—Terms for computer systems can be found in ANSI X3.172-1990, IEEE 610.2, 610.5, and 610.12.
3.2
3.2.1 CAP—College of American Pathologists.
3.2.2 CLIMS—Clinical Laboratory Information Management Systems.
3.2.3 SSAN—Social Security Account Number.
3.2.4 LIMS—Laboratory Information Management Systems.
3.2.5 EHR—Electronic Health Record.

4. Background

4.1 The acquisition of CLIMS is described in LIS3, but the process for the elaboration of the requirements for such systems has not been previously documented. The general properties of Laboratory Information Management Systems (LIMS) have been described in Guide E 1578 but, because of large numbers of specimens and short turnaround requirements for patient care, CLIMS systems must have much greater data management capabilities than those described for general LIMS. Moreover, it is recognized that the move to EHR System **(1)**[7] and CLIMS is a signal that CLIMS reliability must be very high and will require software quality management. Therefore, the trends toward computerization of the various other functions within health care institutions will continue (see LIS6). There is now, and will continue to be, increasing pressure for these computerized functions to be interrelated and mutually supportive as part of the move to quality management of health care information systems. For example, more or less the same patient demographical information is needed by nearly all functional units such as the laboratory, pharmacy, dietary, medical records, and the like. Also, computer functions for many of these entities need access to the same relatively fixed information, such as lists of names and addresses of physicians or other practitioners, and the organization of beds in an in-patient facility into convenient collection and distribution lists. These functions need to be described in a common way. Finally, there are many more specific interactions, such as the need for the laboratory to know patient problems and medication profiles in order to help explain test results and the importance of patient appointments in order to avoid scheduling conflicts. The issues of point-of-care testing must be addressed in a consistent fashion, but neither the management issues nor the technical conventions that define data structures, properties of objects, or data representation may be complete in the first version of this guide.

4.2 Some institutions have elected to provide these information services to the various departmental units by acquiring a large central computer in which software components are installed for the various functions. Others have decided to use separate smaller computers for each of the different functions and to meet the demand for shared information with computer networks. In either case, there would be advantages to both the buyers and sellers of such systems if the various component parts and their interfaces were standardized. For example, the interfaces between clinical laboratory instruments and CLIMS have recently been standardized (see LIS1 and LIS2). Sellers would then have the advantage of a more clearly defined target for their design. Buyers would also benefit from a more likely availability of a second source for software and hardware components.

5. Significance and Use

5.1 This guide assists in the process of developing such standardization by defining a model for the general capabilities set forth for LIMS (see Guide E 1578) and the minimum functionality of a CLIMS laboratory component. To be useful in the above context, the functionality of other ancillary systems supporting the EHR must also be defined using the same model. The interfaces, data interchange, and other communication conventions among such components must then be defined (see Guide E 1340 and IEEE 830, 1058 and 1362. Therefore, this guide can only be viewed as one step in the desired standardization process.

5.2 It is recognized that developments in the application of information science to health care are still proceeding rapidly. This guide is not intended to limit any advancements that are still to be made. Instead, it should be viewed as a common definition of the minimum essential functionality that all users can expect when they purchase a CLIMS as an application package for any host computer. Also, this guide does not define the way in which the required features are to be implemented. Indeed, it is expected that competition between vendors will take the form of improved software design for efficiency, cost, and reliability to meet the basic requirements of a laboratory system. It is also expected that vendors will add special enhancements and extra features to make their commercial product better than the competition. As these new features are recognized and included in this guide, a common convention for the attributes of that function will be available to vendors, implementers, and users alike. The application of these conventions will be different in reference laboratories than in a hospital or other within-facility laboratories. However, the functions selected should produce similar handling of that function. The commonly

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

specified data elements should be present. There will also be unique data elements and special data representations for functions for which a common convention does not yet exist.

6. Models

6.1 A model is an intellectual construct that aids the understanding of the systematics of a process or entity. Guide E 1578 gives several models for the basic capabilities of a LIMS. Because health-care data interchange standards are already using an object model approach and because object models extend the conventions of entity-relationship models **(2)**, this guide for CLIMS uses object models **(3, 4)** to depict the basic logical structure of a CLIMS. Data Flow modeling **(5)** is used to depict the dynamics in addition to the use of services/messaging within object models. While object models for a reference laboratory may be different than that for a hospital or care facility clinical laboratory, the objects and their attributes should have the same relationships and inheritance, but the dynamics will obviously differ.

6.2 *Domain Information Model*—A Domain Information Model for the clinical laboratory is intended to be composed together with a more general health care model that includes the Electronic Health Record (EHR). Those aspects which deal with the EHR are given in LIS9. The full CLIMS Domain Information Model is given in Annex A1which is normative.

TABLE 1 CLIMS Objects

NOTE 1—Objects in common with Practice E 1715 in italics.

CLINICAL ACTIVITY:
Clinical Order/Service Request
Clinical Order Result
Healthcare Facility Encounter
Healthcare Registration
Healthcare Registration Change
Record Location
Release of Information Record
FACILITY:
Clin/Ancillary Service
Clinical Laboratory Organizational Service
Environmental Stressor
Healthcare Treatment Facility
Laboratory
Laboratory Workstation
FISCAL ACTIVITY:
Account
Account Receivable
Account Payable
Bill for Services
Billing Item
Consumable Supplies
Customer Services Account
Equipment
Inventory
Invoice
Payroll
Purchase Order
Stock Item
Workman's Compensation Claim
LABORATORY ACTIVITY:
Employee Work Schedule
Instrument
Instrument Calibration Event
Instrument Calibrator
Instrument Calibrator Value
Laboratory Accession Log
Laboratory Admin Services
Laboratory Customer Service Event
Laboratory Customer Service Event Report
Laboratory Customer Service Record
Laboratory Maintenance Event Record
Laboratory Procedure
Laboratory Service Catalog
Laboratory Service Requisition
Laboratory Test
Laboratory Test Request
Laboratory Test/Procedure Directory
Laboratory Work Schedule
Laboratory Work Sheet/Load List
Laboratory Work Task
Microbiology Result
Q-C Record
Q-C Specimen
Specimen

Specimen Aliquot
Specimen Collection Request
Specimen Collection Schedule
Specimen Transporter
Test-Result/Observation
Test-Result/Interpretation

ORGANIZATION:

Customer
Employer Company
Healthcare Enterprise
Healthcare Stakeholder
Healthcare Stakeholder Role
Organization
Vendor

PERSON:

Alternate Individual Name
Dentist
Employee Occupational Health Training
Employee Professional Training
Employee Work Schedule
Employee/Worker
Family Member
Healthcare Practitioner
Healthcare Practitioner Role
Individual Identifier
Job
Laboratory Worker Test Performance Record
Nurse
Occupation
Patient
Person
Physician
Professional Specialty
Protective Equipment
Work Activity
Work Location
Worker, Healthcare
Worker, Healthcare, Laboratory
Worker, Healthcare, Nonlaboratory
Worker, Nonhealthcare, Laboratory
Worker, Nonhealthcare, Non Lab

6.3 *The CLIMS Object Model*—The model for a CLIMS is dependent upon a model for the patient registration functions (see Practice E 1715). The objects making up the CLIMS Object Model are shown in Table 1. The objects are organized into object groups that reflect the basic activity areas of the clinical laboratory. The relationships, a static property, are shown graphically in Figs. 1–3. The object properties and attributes are listed in Annex A1. The dynamic properties, documented separately, are given in data flow diagrams in terms of the inter-object message/service names.

7. Functions of a Clinical Laboratory Information Management System (CLIMS)

7.1 *Purpose*—In addition to the purposes of a general LIMS, the main purposes of a Clinical Laboratory Information Management System are:

7.1.1 To guide the practitioner in requesting laboratory services by facilitating the communication of a laboratory clinical order and posting this request in the patient's record (EHR).

7.1.1.1 Condition patient and relevant laboratory service data relating to the laboratory clinical order in a manner that facilitates the practitioner's decision about the services to be requested.

7.1.2 To manage the laboratory data regarding patient specimens and the tests conducted upon these samples, including:

7.1.2.1 Reducing manual paperwork.

7.1.2.2 Keeping more accurate, up-to-date records.

7.1.2.3 Reducing missed tests and specimens.

7.1.2.4 Speed result reporting, including posting to computer-based patient record systems.

7.1.2.5 Reduce clerical costs.

7.1.2.6 Improving quality control at each workstation.

7.1.2.7 Produce operating statistics and other management reports.

7.1.3 To aid in interpreting the test results in terms of the clinical objectives identified in the clinical order requesting laboratory services.

7.1.3.1 Facilitate the return of not only the requested measured values but also appropriate interpretive information.

7.1.3.2 Compose the requested measurement values into a context appropriate to the clinical objectives to contain conditions representing referential and patient context information to assist the practitioner in clinical decision making.

7.2 *Laboratory Information Management Processes*—The processes that the typical CLIMS provide are:

7.2.1 Assistance to the practitioner in not only stating his clinical objectives but also in ordering the most effective tests essential to achieving those objectives.

7.2.2 The clerical tasks of accounting for the specimens scheduled and drawn, including the ability to report the status of processing and results for each test.

7.2.3 The scheduling of the tests requested on these specimens and assignment to appropriate workstations.

7.2.4 The input, evaluation, and acceptance of analytical results for each test on each specimen.

7.2.5 The scheduling of appropriate quality control operations, and the acceptance, storage, and analysis of the results of such quality control.

7.2.6 The production of reports or the posting of results for each patient and reporting location, composed in an appropriate format for physician offices, hospital medical records, clinics, and other users.

7.2.7 Aiding the task of the laboratorian in interpreting the test results in consultation with the attending physician as those results relate to the clinical objectives stated in the test request. Diagnostic, prognostic, or clinical management decisions will be made by clinicians who use laboratory data produced as a result of the requested services. However, laboratorians must also consider any complementary subjective clinical data relating to the interpretation, when that may be available, and must interpret its laboratory impacts (interferences, precision, accuracy, etc.) in terms of both the available clinical data and the clinical objectives.

7.2.8 Managing the laboratory resources, including personnel, funds, equipment, supplies, work allocation, regulations, certifications, licensure, and other administrative tasks.

7.3 *Laboratory Utilization Aids (see 7.1.1)*—CLIMS assistance to the clinician in utilizing the laboratory is still in the early stages of functional evolution. This function is dependent upon access to individual patient data from the clinical record and it must use the clinical order submission process as the formal means of communicating the decisions about the most appropriate laboratory services for the patient from the practitioner to the laboratory. Because definitions of the clinical order submission process in general, and the request for laboratory services in specific, are still in the formative stages, and because the specification of the links between the CLIMS and Patient Care Record Systems is still also in the formative stages, full statements of specification for this capability cannot yet be given; therefore, the following general requirements are noted:

7.3.1 Guidance regarding the most appropriate laboratory services must first be based on a means of representing clinical goals and objectives for a given patient. These goals must be linked to particular diagnoses or problems from the patient care record (see Specification E 1460). The general terminology to be used and the source of the specific data elements in the care record have yet to be specified.

7.3.2 The linkage between the clinical goals and patient data acquisition activity and the laboratory test data must be made through entries associated with the test data file which will evaluate the attributes of both the test and the goals/patient data to establish the appropriateness of the requested test and provide the needed guidance.

7.3.3 The composition of the test request to include the defined patient attributes appropriate to the test (posture, diet, smoking habits, etc.) shall be conducted by the Clinical Order Submission function. The completed request shall be stored both within the CLIMS and in the CPR System.

7.3.4 The CLIMS shall maintain an updated status on each request that is appropriate to the priority, and it must be capable of exchanging status information with the requesting patient care information system regarding all incomplete requests. Data on completed requests may be purged or archived on a schedule determined by the laboratory without having any affect on the patient care record system.

7.4 *Description of Clerical Functions (see 7.1.2)*—Most current clinical laboratory data systems address a rather common sequence of functions. These are outlined as follows:

7.4.1 The first major function that shall be addressed by most clinical laboratory data systems is the registration or admission of patients, or both, and the recognition of their identifiers. This function is described more completely in a separate standard (see Guide E 1239 and Practice E 1715 for R-ADT specification) which details the R-ADT capability for all systems. These general capabilities will not be further addressed here. In most systems now existing, only the clerical process supporting internal operations have been addressed in a major way in systems presently implemented.

7.4.2 Following the test selection procedure (7.2.1), which is addressed in 10.3, the next major clerical function is the coordination of test orders with sample collection orders. The specimen collection activity is followed by verification that the samples were actually collected as per order and, if not, warnings must be sent to the test order originators that the sampling did not take place. Another element of the test and sample collection order is the originator and result-destination information, particularly, but not limited to, the designation of other automated information packages into which the laboratory system may transfer information. Manual systems of information distribution require multiple copies of printed reports for distribution to the appropriate clinical locations so that

charting can be done by hand. Nevertheless, the identifiers of these locations must be input at the time of the order to ensure the timely arrival of results at the desired location.

7.4.3 Following the collection of specimens, each specimen shall be:

7.4.3.1 Assigned a systematic tracking number keyed to the master list of tests ordered (accessioning).

7.4.3.2 Aliquoted, if required, after preprocessing for distribution to workstations.

7.4.3.3 Work lists created that can be checked against specimen racks during processing.

7.4.4 These steps must be carried out as part of the cross checking required for sample accountability, which shall take place. The process shall be so organized that during an analysis, immediate (STAT) samples can be inserted into the sample stream in a systematic fashion. This process cannot perturb the normal sample flow other than to briefly delay the processing time. It is desirable to validate the sample sequence, mechanically or electronically, by reading an identifier, such as a bar code (see LIS7), on each sample as it passes into the process stream. Alternately, systems may check the sequence of samples by counting the number in a batch, and if the total number of samples check, assume sample correspondence of the sample sequence with the work list sequence. This is much less desirable than an actual verification. It is likewise desirable to have a clear but flexible process for recognizing standards and quality control check samples in each batch or stream, and if possible, to have an automatic verification that their result values are included within the limits of acceptance before proceeding with patient samples.

7.4.5 Following the analysis of samples and acceptance of the results by the analyst, a process shall exist to update the test status flags in the accession log and to file the results under patient indexes for use in the result reporting and inquiry capability. This shall occur prior to either the scheduled reporting process or the patient record updating processes. For tests (such as microbiological or immunologic incubations) requiring considerable time in progress, a reminder procedure must exist to alert the staff about scheduled processing steps and completion time and to cross check sample accountability, thereby preventing delayed results or lost samples.

7.4.6 The reporting function may happen in a variety of ways, depending upon the needs of the institution. The eventual means will involve posting of the finished results to the automated patient care record; the current means uses printed reports. If printed reports are used, one way includes reports of the days' ordered tests, a seven (or other) day period profile of tests for a given patient, and summary reports of results on all patients in a functional unit (for example, ward or clinic) for the nursing and other staff use. With printed reports, multiple and color-coded copies may optionally be produced for charting or physician-copy purposes, or both. It is imperative that reporting is an integrated general functional unit of the system and that it be capable of flexibility and quickness in changing the number and layout of reports. The printed reports shall be used in a complementary fashion to inquiry capability, depending on institutional policy; posting of results to the electronic care record will make inquiry the primary means of communication from the laboratory to the clinician. In either mode the rapid reporting of grossly abnormal results shall be expedited.

7.4.7 *General Structure*—In order to provide the above capabilities and exhibit transportability of function and modularity, clinical laboratory data systems shall possess the following general attributes: high-level language, code modularity, flexibility, data-driven independence of function, access to other files, different levels of access, access time-outs, and data acquisition by instrument microprocessors rather than by mainframe computer and posting interfaces. Machine-readable data entry devices (barcode/OCR where possible) should be in parallel with keyboard entry.

7.4.8 Quality Control Functions.[8]

7.4.9 Management Functions.[8]

7.5 *Laboratory Data Interpretation Aids (see 7.1.3)*—The interpretation of laboratory result data depends upon the nature of the requested services, the patient clinical goals, and available patient data, as well as the desires of the requesting practitioner. These data are communicated to the system with the request as noted in 7.3. When the data have been completed and certified, the interpretation functions are invoked to provide the appropriate interpretation prior to reporting or posting the data to the care record. One of the interpretations that might be given, depending upon the policies of the laboratory, the capabilities of the system, and the desires of the practitioner, is the recommendation of subsequent tests consistent with the clinical goals of the practitioner. The form that this recommendation should take in the reporting process is noted in 9.2.7. The types of interpretation that might be provided include:

7.5.1 The interpretations of patterns, test batteries, or profiles, including those for single tests producing multiple analytes such as body fluid protein electrophoresis patterns, chromatography patterns, cell population statistics (urine sediment or blood cell differentials).

7.5.2 The interpretations of multiple specific tests ordered to achieve a specified clinical objective such as an organ panel or a screening battery ordered to rule in/out a diagnosis or to detect a specific clinical condition, such as phenylketonuria or galactosemia, in a focused population.

[8]Provided for expansion; text in development.

7.5.3 The interpretations of results that call attention to interferences or potential effects on the reported results caused by missing or aberrant patient data present in the request.

8. General Concepts of Data Structuring

8.1 *Fields, Records, and Files*—In the descriptions that follow, it is assumed that information within a clinical computer system can be stored in fields that are collected, structured, and described as records. Records are grouped together to make files. This process may generate a logical data structure with several levels of hierarchy. A field contains a particular piece of information, and it may contain simple or complex subfields. A record may be structured in one of several ways and may be thought of as a collection of fields. A record may be considered to have both a logical structure and a physical structure. The purpose here is to refer only to the logical structure of the fields or data elements. Within a file, each record or entry is considered to be similar with regard to the types, meanings, and structure of the fields it contains. The structure may be hierarchical, network, or complex. Generally, one record will hold the information on one entity, such as one patient, one physician, or one test method. A file is then a collection of like records such as all patients, all physicians, or all test methods.

8.2 *Implementation*—These concepts are not intended to limit the actual implementation that embodies the physical data structure. The concept of fields, records, and files does not imply any particular kind of database or filing scheme, contiguous or noncontiguous data storage, or even the actual sizes of allocated storage space. For example, whether or not the size of a field varies with the amount of data to be stored or remains fixed at the maximum permissible size for that field is a decision left to the designer.

8.3 *Keys*—In the descriptions that follow, some of the fields are marked as keys or cross-reference fields. It is assumed that one or more records of information can be retrieved from the database through the use of these key fields. This implies that a search mechanism exists to locate all the records at a designated level of structure that have a specified value of this key field. The search program shall be given the file or level of the structure to search, the name of the field to be examined, and the value, range, or contents of the key field to be sought.

8.3.1 One field in every record for every file is designated as the primary key. It is always required and always unique for that record or level of structure. Most filing systems use this key (through one of a variety of algorithms) to actually place and retrieve the information in the data storage unit.

8.3.2 It is also assumed that records can be located through additional keys, called secondary keys. In the following descriptions, fields listed as keys, but not labeled primary, are considered to be secondary keys. Some of these secondary keys are unique, meaning their use will always retrieve no more than one record. Others will be nonunique and may be used to locate a set of records that meet a given specification. Some fields are not used as keys at all. They simply contain information related to the purpose of the record. In the data base description, some secondary keys are marked required and others optional. The required types are more commonly used in clinical laboratory settings and their absence seriously limits usefulness of the computer system. The optional keys are considered valuable enhancements but are not required for the bulk of normal routine activities.

8.3.3 It is important to note that keys for access to records are always ordered in some fashion or sorted. This capability has traditionally been very useful, especially for report generation. For example, sometimes lists of retrieved records are to be printed in alphabetical order by patient name, sometimes by physician, or sometimes by location in the hospital. Any of the keys can be designated as a sort key. This means that a mechanism is provided to retrieve a set of records from a file in an order based on the value of the key. Sometimes this order will be alphabetical, sometimes numerical, and sometimes by some other special sequence. Some sort keys are designated required and some optional for the same reason there are optional and required retrieval keys.

9. Capabilities

9.1 *Utilization of Laboratory Services*—In order to carry out the utilization functions, the system must possess the following capabilities:

NOTE 1—The capabilities of patient care information systems are still being defined. Specifications for these capabilities are not yet available.

9.2 In order to carry out the clerical functions, the system shall possess the following capabilities:

9.2.1 *Test and Sample Order-Entry*:

9.2.1.1 Test requests or the test request/sample receipt function shall be able to be carried out not only by terminal entry in the laboratory, but also from a hospital system order-entry module (if an interface exists), by manual means (backup), or by special reader equipment such as barcode/OCRA wanding or mark-sense reading from reader devices operating either in stand-alone mode or in parallel with CRT terminals.

9.2.1.2 The order-entry process should recognize coded or mnemonic identifiers for tests.

9.2.1.3 Patients must be identified either in an included registration function (see 10.1) or in a separate registration system that can be accessed by the laboratory system. In order to handle in-patient specimens, in-patient

admissions, discharges, and transfers shall also be handled in addition to ambulatory patients, and the appropriate system accessed by the laboratory. Even with a separate registration system, local copies of data elements concerning patient registration may be handled within the laboratory system for short periods of time and frequently checked, particularly at sample receipt and reporting times. Extensive, long-term, or complete clinical record patient file capability will not be carried out within the laboratory system, nor will those files or records be retained for rapid access that do not contain immediately useful data elements required for sample processing or result dissemination.

9.2.1.4 The system should be able to accommodate the checking of patient ID against system patient registration or admitting files during test ordering, specimen collection, and receipt by means of machine readable ID codes (as in 9.2.1.3).

9.2.1.5 The rejection at test ordering time of tests not presently offered that cannot be handled by simple comments should refer the orderer to the laboratory management (that is, clinical pathologist or clinical chemist).

9.2.1.6 The ability to correct or cancel requested tests should be present. This includes the ability to add or delete test requests before specimen collection or after its delivery to the laboratory, as well as to add test requests to samples already collected, perhaps even after some results for the specimen have been reported.

9.2.2 *Sample Collection*:

9.2.2.1 For samples ordered for collection, the system should be capable of producing collection lists and attendant labels organized either by collection location or by any other criteria, such as organizational unit at any time (that is, STAT, as well as established times). The minimum set of priority categories are: Routine, Same-day, and STAT (immediate).

9.2.2.2 The system should be capable of directing the preprocessing and aliquoting activities for each specimen received, such as type and time of spinning, decantation, and storage. This may be based on the tests ordered and the number and types of collection containers. Recording of conditions of collection should also be possible at the time of receipt (see Section 10). It should be possible to record the time of receipt of each specimen in the laboratory, as well as the draw and the order times.

9.2.2.3 The system should set up recollect lists for samples not drawn (with notification to the orderer) or should cancel the specimen collection request (with stated reasons).

9.2.3 *Accessioning Function*:

9.2.3.1 The system should generate specimen accession numbers (based upon specified intervals) for each specimen during the preprocessing and aliquoting of that specimen.

9.2.3.2 The accession numbers should be capable of reflecting functional subsections of the laboratory, and the accession log for each laboratory section should be displayable or printed.

9.2.3.3 Notes and observations made during sample collection, and any assignments to recollection lists should be part of the accession entry.

9.2.3.4 The estimated completion time of results should be calculable and entries for each test entered into the accessioning log.

9.2.3.5 The aliquots taken, their locations, status, movement after analysis, whether the aliquot is to used for other tests, and whether there is dependence of work list positions or specimen rack positions on to-be-delivered aliquots shall be indicated in a tabular but flexible storage file that prompts the analyst regarding special actions to be taken. For example, a particular test may use the aliquot remaining after a previous test review of this table should clearly depict sample status (see Section 10).

9.2.3.6 The system should automatically produce machine-readable specimen aliquot identifying labels at accessioning time. The number and type of labels will depend upon the institution.

9.2.3.7 The ability to request additional tests on specimens collected but not yet analyzed shall be present.

9.2.3.8 The system shall be able to independently generate multiple labels for specimen aliquots and for specimen retention storage procedures.

9.2.4 *Worklist Functions*:

9.2.4.1 The system shall be capable of producing worklists indexed by workstation based on the tests to be performed, and keyed to the aliquot storage location tables. The worklist printing function shall be capable of being activated on demand as well as at scheduled times.

9.2.4.2 Worklists shall be structured so that it is possible to cross-check these lists against accession numbers, status, sample storage location tables and, when required, patient result files. The sequence of specimens on the list should not be a critical factor in matching the analytical result to the correct specimen. Either automatic sample ID sensing or special result matching procedures may be used. STAT samples should be able to be inserted into the processing stream without reordering the list. The results for these samples shall then be checked against sample identifiers during the result accountability checks required for each worklist.

9.2.4.3 The system, during processing of a worklist, should have available, upon inquiry by the analyst, those process-step prompts regarding either the chemical analysis protocol or the required instrument function checks.

Specimen identifiers and a summary of the information available about the sample should be included in these displays. This might include observations at collection, patient diagnosis, or tests that have been ordered.

9.2.4.4 Data checks on the immediate results should be made to reveal large changes that may reflect either potential artifactual or emergency level results.

9.2.5 *Result Entry Routines*:

9.2.5.1 Results shall be able to be entered by automated procedures from instrument batches, by keyboard, or by barcode/OCR. Terminal entry should be programmed to take advantage of a terminal's separate numeric key-entry pad for counting situations at the microscope (like hematology or urinalysis).

9.2.5.2 Special instruments providing data directly into the system should have a microprocessor-controlled interface with established formats and, where possible, alternate keyboard formats for backup in case of malfunction.

9.2.5.3 The system should have the ability to calculate derived values as a test result (when constituent results are available) and also to display the needed missing constituent values. For example, urinary creatine output is calculated from urinary creatine concentration and 24-h urine volume.

9.2.5.4 The ability to enter a comment line about each specimen shall be present; abnormal values should be displayed and flagged at the time of entry so that they can be certified and commented upon, if necessary.

9.2.5.5 A certification process shall exist allowing the analyst to sign-off specimens from a given worksheet either individually or in batches.

9.2.5.6 Results of antimicrobial resistance patterns should allow not only the entry of concentrations of antimicrobial standards or test organisms by several different methods, but also the entry of zone sizes by several alternate methods. The system should then be able to calculate either the resistance patterns or the antimicrobial concentrations of the sample by standard algorithms and display the calculated results before the analyst accepts them. A check of the calculated resistance patterns against tables of known patterns for organisms should be carried out in order to either estimate the identity of the organism or detect inconsistencies.

9.2.6 *Data Review, Correction, Retention, and Record Archiving*:

9.2.6.1 The capability shall be present to correct any certified posted result (without destruction of the original's recorded value) with an identification of the corrector and the date/time.

9.2.6.2 Patient data files should be retained for a period determined by laboratory policy, even if posted to a patient record system, and the record should be archivable (in whole or in part) after that period. Entries in special files, for example, microbiology culture records, anatomic pathology, cross-reference files, and such should be retained on-line for a specified period.

9.2.6.3 Archival routines should be able to retrieve any patient off-line record of laboratory values back to any arbitrary date and then be able to reload it into an on-line status within a relatively short period of time. A separate capability for extracting data from archived records for use in statistical procedures also should be present.

9.2.7 *Reporting*:

9.2.7.1 For printed reports, a wide variety of laboratory data report formats, of data elements, and of times and places for these reports to be available are required in any health-care facility. Therefore, a powerful general report generation module shall be available that can define the parameters of all needed system reports, except inquiry formats, shall exist. This report generator module should be able to define heading data elements and their layout, the reported data elements, and the organizations of footing data elements and their layout. Each report should be identifiable by name. Several common varieties of reports that currently need to be accommodated are:

(1) Ward Report—Includes patient name, number, location, physician, collection time, completion time, specimen number, tests requested, and results. Reports may be cumulative from the time of last report.

(2) Specimen Report—Includes patient name, number, location, physician, date/time of requests, date/time of completion, tests requested, and their results.

(3) STAT Report—Printed automatically, same form as specimen report but on a designated printing device.

(4) Patient Cumulative Report—Includes designated inclusive dates (including any specified past date to the present), patient heading data, test identifiers, and the results in chronological order earliest to most recent. The ability to designate a list of desired tests to be printed should be available.

(5) Pathology Report—Containing both test and coded or codable diagnostic keys shall be available.

9.2.7.2 Reports should include for each test:

(1) The normal ranges (allowing for age, sex, posture, race, meal-status, smoking/alcohol-status, medications, and the test methodology) in addition to the result. Panic (2-SD) and absurd (3-SD) flags should be printed along with notification/acknowledgment instructions appearing that are also based on any delta values.

(2) Flags denoting inconsistencies between the given test and certain other tests shall also be displayed. Complex interpretations of the data in the report can be found in 9.3 on data interpretations.

(3) Additional patient data elements that may appear on reports are address(es), phone number, age, sex, race, doctor of record, attending or admitting, status, location, doctor's service/clinic, and admitting diagnoses.

(4) The following laboratory data may appear on the reports arranged in arbitrary format: date/time, test ID's, date/time ordered, date/time drawn, date/time received, results, units, normal ranges and panic values, and test status.

9.2.7.3 Results that correct previous results shall be specifically flagged as such. Complete reports should be automatically produced when all outstanding procedures or results are reported, even though the patient may have been discharged.

9.2.7.4 Inquiry procedures should be able to retrieve the patient laboratory result data entry by name, SSAN, accession number, or location indices.

9.2.7.5 Microbiology section reports should be capable of displaying both the partial results and the time that a final result is expected. Microbiology reports for laboratory use, in addition, should display tables by patient location, specimen type, sensitivity pattern, pathogen and anatomic site, those organisms causing nosocomial infections, and a listing of rare organisms. Such results should be posted to the Infectious Disease Control System for more detailed analyses.

9.2.7.6 Results to be transmitted to another system should be formatted and sent according to LIS5.

9.2.8 *Quality Control Reports*—The system shall be able to:

9.2.8.1 Report available tests pending (by laboratory section or overall).

9.2.8.2 Report abnormal results by patient, test, instrument.

9.2.8.3 Produce Levy-Jennings plots, Shewhart, Cum-Sum charts, Bull algorithm **(6)** and other plots **(7)**.

9.2.8.4 Produce demographic tables by test (age, sex, race, posture, alcohol/smoking status).

9.2.8.5 Produce descriptive statistics of selected subsets.

9.2.9 *Management Statistics/Administrative Data*—The system should be able to:

9.2.9.1 Display utilization of a test by physician, clinic or ward, service, or patient diagnosis.

9.2.9.2 Derive from the supply modules a materials cost accounting by test. Derive personnel time from test time and load value.

9.2.9.3 Keep an administrative activity log recording: user-ID, access port, functions used, start time, stop time, and duration.

9.2.9.4 Manage payroll.

9.2.9.5 Conduct billing, general ledger, and other business functions.

9.2.10 *Instrument Maintenance*—The system shall be able to establish and automatically report instrument preventive maintenance schedules based on both fixed times and on the workload of an instrument.

9.2.11 *Laboratory Supplies*—The system shall be able to account for supplies ordered. Each supply item required for a test procedure should be keyed to that procedure for cost-accounting purposes.

9.2.12 *Population Statistics/Normative Values*—The system shall be able to utilize parametric and non-parametric methods in describing patient populations for each test with selection of data by patient attributes. Graphic or scattergram plots will be required.

9.2.13 *Utility and Dictionary Maintenance*—In order to carry out interactively the translation of codes and lexicons, system file capabilities shall be present (see Note 2).

9.2.14 *Personnel*—The system shall be able to:

9.2.14.1 Record extent and type of work by each analyst and record time worked at specific functions.

9.2.14.2 Keep a record of employee work history, permissions, salary, and other activities.

9.2.14.3 Keep a record of employee training, experience, past experience.

9.2.14.4 Manage staffing and scheduling of times and workstations.

9.2.15 *Work Force Medical Surveillance Monitoring*.

9.2.16 *System Maintenance Utility Functions*.

9.3 *Interpretation Functions*—In order to carry out the result-interpretation functions, the system shall possess capabilities (see Note 2).

NOTE 2—The capabilities of patient care information systems are still being defined. Specifications for these capabilities are not yet available.

9.4 *General System Structure*—In order to allow the system to adapt to new laboratory functions, the following general attributes shall be present:

9.4.1 A standardized high-level language shall be used. Examples are MUMPS (ANSI X11.1, ISO 11756) for data management functions, and newer ALGOL-like (PASCAL, C, MAINSAIL, FORTH, MODULA, ADA) languages for complex numeric functions.

9.4.2 For maximum flexibility, the system shall be table-driven, whenever possible, with coded values translated into readable terms for input/output. New functions shall be able to be quickly and reliably implemented using standardized software libraries where possible.

9.4.3 The system shall be modular so that new functions in an expanded system can be implemented independently of existing functions.

9.4.4 Instrument process control functions shall be handled either by separate microprocessor modules or by microprocessors contained within instruments.

9.4.5 In order to avoid loading the system due to external functions the system should be dedicated to laboratory functions and have appropriately buffered interfaces largely to isolate the laboratory operations from dependence upon or undue support of other major functions, even though integrated with other major information systems. The laboratory system may exist in a variety of overall system architectures.

9.4.6 The system should interface easily with other complementary single-function subsystems, for example, registration, ADT, medication profile, diet orders, and such.

9.4.7 The system terminals should be able to be individually logged in for specific workstation functions, but each shall have the general ability to be used for all laboratory functions, if required. The terminal will be timed out if left unattended.

9.4.8 Each individual accessing the system and each system function will have a level-of-access code that may be used in a number of ways in accessing files and performing tasks.

10. Data to be Manipulated

10.1 For each capability noted in 9.1–9.3, the data requirements supporting that capability are developed in terms of the logical data structures required and in terms of the objects identified in Section 6.

10.1.1 *Physician*—Physicians should be identified as described in Specification E 1633.

10.1.2 *Ward/Clinic/Location*.

10.1.3 *Device Description*.

10.1.4 *Test Description*—Test names should be identified.

10.1.5 *Report Description*.

10.1.6 *Input Format and Data Element Description*.

10.1.7 *Exceptions (Specimen, Test Requests, Unusual Results)*.

10.2 *Laboratory/Registration Patient Data File*—The system registration file will contain all essential demographic patient information. It may exist as a separate system. Whether stand-alone or as a module of the clinical laboratory computer system, each record is created by laboratory personnel at the time the individual is recognized by the laboratory or by direct communication with a Registration Admission-Discharge-Transfer (RADT) system (see NCCLS document LIS5, ASTM Guide E 1239, Specification E 1633, and Practice E 1715, and HL7v2.3), which registers a patient when a new patient enters the healthcare facility. A patient record is archived to an inactive status when all record activity conditions for purging from the active file have been met. The laboratory patient registration file, however managed, will contain the following data elements defined in Guide E 1384:

10.2.1 *Patient Name*—(Index: 01001, Required key/required sort). First and last names are stored in a way to permit flexible input format and better checking.

10.2.2 *Primary Identifying Number*—(Index: 01015 Primary key/optional sort). This entry is sometimes called the hospital number, unit number, or medical number. The identifying number is checked when the record is first created to determine if (*1*) a record for the patient already exists or (*2*) two different patients have been assigned the same number. (See Guide E 1714.) The key may be alphanumeric and its format specified differently for each institution. The following format characteristics are permitted:

10.2.2.1 *Length*, (up to 10 characters).

10.2.2.2 *Letter, Number, Either, or Special Mark*—At each position.

10.2.2.3 *Internal Check*—The last character may be specified as an internal check character. If so, it is generated by this system or the hospital ADT computer when the record is first created and checked whenever the key is specified.

10.2.3 *Record Numbers*—(Index: 01016, 01020, unique optional key/optional sort). Additional patient identifiers are allowed; at least two should be provided. They are sometimes called the billing code, social security number, or the like. They may be used to help the system conform to existing practice in hospitals that use more than one identifying number for each patient. They have the same format and checking features as the primary key (see 10.2.2) and may be used to locate the record.

10.2.4 *Physicians*—(Index: 04001, Required key/required sort). This field identifies the physicians responsible for the care of the patient. The values are assigned according to the following scheme: Each physician is identified by a name and an eight-character alphanumeric code. Up to five physicians may be specified and are assigned the ranks of primary, secondary, consultant 1, consultant 2, and consultant 3. Retrieval may be limited to any one or combination of the three ranked entries.

10.2.5 *Patient Date of Birth*—(Index: 01032). This is a numeric field for date of birth that may optionally be used instead to store the patient's age. In the latter case, the system should be capable of calculating the date of birth. Provision is also required to allow for age in days or months in the case of pediatric service.

10.2.6 *Patient Sex*—(Index: 01040). This entry consists of a one letter code with the legal values of F = female, M = male, and U = unspecified.

10.2.7 *Patient Race*—(Index: 01042). This entry consists of a coded set of values with the values assigned according to the list: A = Asian, N = Black, C = Caucasian, I = American Indian.

10.2.8 *Family Member Linkage*—(Index: 01090). The parents of a child are identified here for genetic and legal functions. The names are characterized by the attributes of each individual (01090.02–01090.27 as described in Guide E 1384; at the minimum the father and mother shall be characterized.

10.2.9 *Patient Type*—(Index: 14001.A002). A two-letter code designates the patient type, such as in-patient, outpatient, employee, student, etc. The values are assigned according to the codes shown in Specification E 1633.

10.2.10 *Patient Location*—(Index: 14001.A136, Required sort). An alphanumeric character code of up to eight characters identifies the patient location such as ward number, outpatient department, intensive care unit. It also specifies the bed number for in-patients. This field is indexed in a way that permits reports to be generated by patient care area in a sequence that permits easy distribution to patient charts (see 9.2.7.1).

10.2.11 *Warnings*—(Index: 14001.A143). This field is to record a warning when special care or procedures are required for the patient or for handling any samples that come from that patient. It is used to print warning messages on collection lists and worklists. Examples include hepatitis or tuberculosis.

10.2.12 *Diagnoses*—(Index: 14001.A166 for in-patients). If known, diagnoses are entered to assist the laboratory with regard to interpretation of unusual results. Any special drug treatments that may affect test results may also be recorded here. The entry consists of either codes (ICDA, SNOP, SNOMED) or free text.

10.2.13 *Day of Admission*—(Index: 14001).

10.2.14 *Confidentiality Code*—(Index: 14001.A004). A code is used to mark some records as particularly sensitive and requiring a higher level of security. It is used in case of celebrities, police cases, unwed mothers, hospital staff, etc. The values are assigned according to the codes shown in Specification E 1633.

10.2.15 *Blood Type*—(Index: 01165). The patient's blood type is important if blood bank records are included in this system.

10.2.16 *Patient Home Address*—(Index: 01095). The patient's permanent address is recorded here. Additionally, the current temporary address (Index: 01105) may also be recorded.

10.2.17 *Responsible Administrator*—Some instructions provide an ombudsman or the equivalent to help improve service. This individual is recorded here.

10.2.18 *Other*—(Index: 01205). Some institutions record additional information to help reduce mistakes. An example is mother's maiden name.

10.2.19 *Free Text*—There are always special cases, and a place to add additional clarifying text is needed.

10.2.20 *Date of Discharge*—(Index: 14001.F040). This field gets filled in after discharge for in-patients but while the record may still be active because of pending test results. It is also needed when the information is moved to permanent archives.

10.3 *Test Method File*—The test method file is the most important file regarding the internal workings of the laboratory. This file identifies and describes all tests and test aggregates (panels, profiles, batteries) that are processed by the laboratory. This file is used by the system to process test requests, prepare work schedules, prepare reports, and perform quality control. A record is entered in this file for each test method with which the computer system shall deal and the measured entities (analytes) that result from these test methods. Any additions, changes in tests, or deletions can be entered by the laboratory management. There are two general types of tests that are included in this file: single tests and test batteries. The following minimal information is maintained in the test method file:

10.3.1 *Full Name*—This should be a unique test name that defines a test or test battery (see Specification E 1712).

10.3.2 *Single Test or Battery*—If this is a single test, the remaining fields of the record are used. Otherwise, only the codes of the individual tests that are a part of the battery are given in this field.

10.3.3 *Abbreviated Name*—An mnemonic alphanumeric code for the test is specified by this field. It describes the test in a shorthand notation for personnel who use the system regularly and do not wish to type the full name. For example, the sodium test may be designated as “Na.”

10.3.4 *Test Identifier or Code (Primary Key)*—A unique code identifies each test. This number may be used by hospital personnel to identify a test, but its primary function is to provide for computer access. The scheme to be used is as follows: Requests for a record from this file by other nodes will normally identify the record by its code.

10.3.5 *Revision Number*—The revision number is assigned by the computer and is not normally used directly by laboratory personnel. In the event of an alteration to a test procedure, the system for a time may have results by both the old and new methods. The revision number is used to associate the correct normals with the actual version of the test used.

10.3.6 *Specimen Type*—A code is used to specify legal specimen types. Examples include urine and blood. The values are assigned from the list of codes in LIS5.

10.3.7 *Specimen Container*—This field identifies the type of container to be used to transport the patient specimen. Examples include various sizes of tubes and bottles.

10.3.8 *Special Requirements*—A free text field is used to inform the person entering the test or collecting the sample about any special conditions that shall be met to satisfactorily assay the specimen. Examples include messages that the sample shall be packed in ice for this test or that it is preferable that the specimen only be drawn during the day.

10.3.9 *Department*—A reference is made to the laboratory department file to define where the specimen is to be analyzed.

10.3.10 *Volume*—The volume of specimen required for analysis is given here. It is used in conjunction with the department code to decrease the number of samples required. If more than one test is required in a given department on a sample with the same specimen container and special requirements, this field allows the computer to determine if one collection will provide enough material for all tests.

10.3.11 *Allowable Draw Time*—This field contains a code that indicates the desirable time of day to draw the sample for this test. It may be overridden for special cases, but is provided to reduce situations where a sample is drawn at a time that is deleterious to the assay. An example of this is HAA antigens.

10.3.12 *Result Type*—This field defines the type of result and how it is entered into the test result file. There are four primary types of results. Some tests may require combinations of these four. An example is creatine phosphokinase, which has a numeric, calculated, and textual result. In addition, it may use a menu-driven entry. The four types are as follows:

10.3.12.1 *Numerical Result with Possible Alphanumeric Comment*—This type is the usual result in chemistry and hematology. A single comment is sometimes needed to better define the result. These comments are generally abbreviations. In addition, provision for a free text comment is needed, although it may rarely be used.

10.3.12.2 *Calculated Result*—This is also a numeric result with a possible comment and occurs primarily in chemistry. An example is creatinine clearance. Such a result necessitates inputting several parameters that are used to calculate a result. In some cases, a free text comment is appropriate.

10.3.12.3 *Text Entry*—A short text entry result usually consists of single or multiple comments chosen from a menu that describe the test result. Examples of this are microbiology or cytology entries. The statements are English text, and although the individual results are well defined, the latitude of these results necessitates an open-ended result entry. Unlike 10.3.12.1 and 10.3.12.2 results, multiple specimen identifiers are necessary. For example, a urine culture may have a single entry of "unsatisfactory" or may have a microscopic analysis that includes several organisms and corresponding antibiotic sensitivities.

10.3.12.4 *Word Processor Entry*—This type takes two forms. One is used in surgical pathology. The length and content of the entry is impossible to define in advance. Another application for a word processor entry is the generation of interpretative results.

10.3.13 *Default Value*—Some tests, like screening procedures, might frequently produce the same result, such as "negative." This field allows the result to be given as a default test result. It can be changed by the technologist in those cases where the result is different.

10.3.14 *Result Definition*—This field includes the units used to report the result and the maximum allowable size and format of the result. It is used primarily for Type A and B results.

10.3.15 *Normal Range*—This is an age- and sex-stratified normal range and is used to check if the specimen is normal. It is defined for each revision number of the test.

10.3.16 *Panic Value*—This field defines numerical result values that, if exceeded, indicate severe abnormality. In these cases, the computer gives immediate warning so the attending physician can be immediately notified.

10.3.17 *Supervisor Check*—When a numerical test result exceeds the limits of this field, supervisor attention is required. The supervisor shall give approval before this result can be released.

10.3.18 *Absurd Check*—Numerical values outside of the limits in this field are inconsistent with life and probably indicate an entry mistake, a malfunctioning instrument, or a faulty procedure. This field helps maintain quality control by rapidly bringing such situations to the attention of the laboratory.

10.3.19 *Delta Check*—The delta check compares the result that has just been generated with the previous result if it was obtained within a user-defined time period. If this criterion is satisfied, a check occurs in one of two ways. Either the system will check for an absolute numeric change greater than a user-defined level or to see if the value has exceeded a certain percentage change. This field will provide for quality control checks on specimens and also can be used to alert the physician to a significant change in the patient's condition. The technologist is alerted if the delta check is significant. This field specifies the type of delta check, the significance level, and the time limit needed for valid comparison.

10.3.20 *Specimen Priority*—This field defines how and when specimens can be assayed. It defines whether a test may be scheduled "emergency," "important," or "routine." If high priority is permitted and requested, the test occurs near the beginning of worksheets and results are dispatched to the requestor as soon as they are available. The field is also used to notify test requestors of illegal requests for priority status.

10.3.21 *Minimum Time Between Orders*—This field is also called the interval time. It provides a means of alerting the person ordering the test if a duplicate order already exists. It defines the minimum time that shall elapse before a new order for the test is considered logically valid. This check is advisory and helps contain costs by alerting personnel about possible unnecessary duplication. As an example, endocrine or tumor marker tests requests are not normally repeated frequently.

10.3.22 *Advance Order Time*—This time specifies how far in the future each test may be ordered. It is used to help reduce the problem of excessive tests ordered too far in advance.

10.3.23 *Scaling Factor*—This numeric entry is similar to the calculated result and provides for uniformity of a reported result of the same entity but from different methodologies. An example is when one instrument measures an analyte per liter and another measures per deciliter. It may be desirable to recalculate one of these results for consistent display on reports, thereby allowing physicians to better monitor the progress of their patients.

10.3.24 *Billing Codes*—This field is used to save up to five billing codes, which each consist of a reference to the billing code file. The five codes allow the charge for the test to be computed on the basis of the work actually performed and consist of the categories: phlebotomy charge, analysis charge, special priority charge, special handling charge, and professional charge. This feature allows more exact billing for actual work. Any given analysis may result in a bill that is composed of several charges.

10.3.25 *Turnaround Time*—The turnaround time defines the time that the laboratory would normally take to complete the test and report the results. If after this time period a result has not been released, the test request appears on an overdue test report.

10.3.26 *Specimen Site*—The specimen site is used in some departments, such as microbiology and cytology, rather than test name. The field should contain an English text description of the site as well as a site code abbreviation to be used in the test requests and results file. The site code may be a standard code like SNOMED (see LIS3).

10.3.27 *CAP Workload Units*—The current value of the CAP workload unit assigned to this test and the date it was determined are saved. Intermediate values and dates may also be saved.

10.4 *Clinical Orders and Requests for Laboratory Services*:

10.4.1 Each request for laboratory services will be part of a clinical order recorded in the primary record of care and attributed to a practitioner supervising that patient's care. Each request will involve at least one specimen upon which at least one, but possibly many measurements will be made. On each specimen received, the following minimal information should be collected:

10.4.1.1 Specimen identification (ID) in a specified form.

10.4.1.2 Date/time of order.

10.4.1.3 Date/time of collection.

10.4.1.4 Place of collection (if not a received sample).

10.4.1.5 Date/time of log-in or receipt.

10.4.1.6 Tests ordered.

10.4.1.7 The name of the requesting practitioner.

10.4.2 The system establishes a specimen status during the subsequent accession process for samples received directly at the laboratory.

10.4.3 Samples that are ordered for collection can have the request stored for later printing out to the collecting team at the time of specimen collection. This collection request for use by the collecting team includes the following information: patient name, patient location, age, sex, specimen ID assigned, ordering physician, date/time ordered, date/time to be collected, place to be collected, tests ordered, special handling or sampling instructions (such as meals, medications, etc.), amount to be collected, and container type. The orderer's clinical objectives should be recorded, if available, so that the laboratory can advise the orderer if all laboratory criteria provide a result that is consistent with these objectives. The following should also be recorded at the time of collection: patient rejection, meal status, smoking, alcohol in the status, sample drawing difficulties, patient posture, time of actual collection, and the identity of the drawer. Based upon the clinical order and test request, at the time of receipt the system must display preprocessing and aliquoting information and provide adequate labels at the time of specimen log-in, aliquoting, and accessioning. The following should be entered at this time: time of receipt, preprocessing problems/aliquoting inadequacies, identity of sample racks, the location of existing aliquots (sample racks should have a systematic identifier), and any designation for sample recollection notification flags.

10.4.4 During the accessioning, an accession number set should be assigned based on the tests (laboratory departments or sections) ordered followed by the preprocessing information plus any changes in processing priorities. The entry to this function should allow orders that are additions of tests to an already collected sample to modify the accessioning status table by identifying sample aliquot locations, new tests requested, and their priority.

10.4.5 *Work Management and Specimen Flow*—Worklist generation requires entry of the following data: analyst identifier, test identifier (prescheduled times and locations may be generated based on laboratory policy or workload, or both are displayable at this point). The pending worklist or sample lists for this test should be displayed

with locations of specimen storage racks and other special requirements for conducting the test (several options of material to be presented here should be available). The ability to change the order of samples or insert new specimens at this point should exist. This entails entry of worklist sequence numbers or specimen and sequence numbers. The insertion capability implies modifying data in the accessioning table by some process in order to maintain a master status of the workload. This data should be enterable at any time up to result entry time. Data available on the worksheet that is to be used at result entry time should be displayable to the analyst, either routinely or on command, and should contain drawing and preprocessing problems, patient diagnosis, and prior results values upon this test and other tests ordered on this aliquot/sample.

10.4.6 The results may be entered either directly by keyboard or from another microprocessor-controlled device. If entered by machine interface the interface specification given in LIS1 and LIS2 should be used and the result validated by the operator. Data supplied by these instruments cannot be designated here as they will be device dependent even when the above specified transfer format is used. Therefore, the minimal data to be transferred by those devices to the main system will be stated. Direct entry, either by keyboard or digitally from an instrument, will have the same general requirements. Each test will have specific requirements that should be contained either in an instrument or CLIMS system table, including validity (range and pattern) requirements. Results may be entered by several parallel methods (keyboard, UCR/barcode, digital transfer, and the like), but each result shall pass the validity and data element checks in order to be accepted by the operator as a valid patient result before proceeding. Following this, the delta checks on any previous patient results should also be displayed (either batch or individually) to the analyst and the opportunity offered for comment on any sample. Finally, a certification procedure that includes a date/time and analyst, if not already so identified, is performed.

10.4.7 Tests requested that are, in fact, derived values from other measurements shall be displayed as a separate worksheet, and the resulting calculated values produced (along with display of the constituent variables) for those specimens for which the constituent test values are available, certified, and posted. The system should leave on the uncompleted derived-values worksheet those values where one or more of the constituent values are incomplete. The status or value of all of the constituent values shall also be displayable. Tests that have interim results shall be able to display the interim result, its date/time, and the time of the expected final result. Results that constitute a constellation of values (described in the test description table) should also be able to be displayed as a constellation (for example, electrolytes).

10.5 *Test Request and Result File*—The requirements for this data differ from the simple structure needed for other files because it requires repeating groups or logical subfiles for data elements of a record. Moreover, test requests must be linked to the clinical order submission system (see Specification E 1633). The information for the fields described below must be repeated for each test ordered for each patient. One conceptual implementation is to create separate test request (10.4.3) and result files for each patient with pointers to the appropriate record of the patient registration file. Each record in one of these patient result files then corresponds to a test request and its results. This file can get large for patients who need extensive laboratory work and can be very small for others. The following information should be associated with each test result:

10.5.1 Specimen identification number (primary key).

10.5.2 Ordering physician.

10.5.3 Date and time of order.

10.5.4 Date, time, and place specimen is to be or was collected. Also, special collection conditions (diet, smoking, alcohol, drawing difficulties, posture). Special instruments to be used. Special handling or routing instructions, preprocessing problems, recollection flag.

10.5.5 The individual who collected the sample.

10.5.6 Date, time, and accession number when sample was received by the laboratory.

10.5.7 Date and time when results are released.

10.5.8 Test method identification code (see 10.3.4).

10.5.9 Code for the type of result (see 10.3.12).

10.5.10 *Specimen Result*—This entry might include the result itself, codes for appropriate standard comments, or references to text files for more lengthy results.

10.5.11 Code of responsible person(s) (see 10.3).

10.5.12 *Printed Flag*—A flag is used for each type of report that may be printed to indicate if the result has been previously listed on that type report. It may be used to highlight data that is being reported for the first time.

10.5.13 *Interim Flag*—This field will indicate whether additional information for this test is still expected. The available partial results may be beneficial to the physician and can be released earlier than the final data.

10.5.14 *Charges*—This field indicates which combination of the five separate charges listed in 10.3.24 are to be applied for this test.

10.5.15 *Billed Flags*—Five flags indicate that the five billing codes in 10.3.24 for this test have been reported once to the hospital financial office responsible for collections. It is assumed the laboratory computer will not be responsible for repeat billings of uncollected debts.

10.6 *Accession Number File*—This file is used to account for each specimen and cross-check that each requested result is reported. It is also used to account for specimens assigned to sections of the laboratory and to identify whether the sample was aliquoted and where the aliquots are stored. It includes the following items:

10.6.1 Laboratory accession number (primary key).

10.6.2 Section/division accession number (secondary key).

10.6.3 Specimen ID.

10.6.4 Patient name (secondary key).

10.6.5 Date and time received.

10.6.6 Aliquot ID's and locations.

10.6.7 Tests requested, aliquots, date and time results released, pending flags, abnormal flags.

10.7 *Laboratory Personnel File*—The laboratory personnel file is used to maintain information about individuals working in the laboratory. It can be used to define authorized system users and also allow only certain members of the laboratory access to sensitive data files. Finally, the code for the person responsible for a specimen result is defined by this file. The information to be made available on all laboratory personnel includes: name, SSAN, date employed, salary, permissions, workstations, certification code number, work shift/schedule, insurance, etc.

10.7.1 Display of this data by inquiry depends upon permissions of the inquirer. The following list of access, optionally selectable, will govern:

10.7.1.1 Laboratory director (all).

10.7.1.2 Technician.

10.7.1.3 Supervisor (each section).

10.7.1.4 Technician (own record) name, SSAN, date employed, salary, permission, central work shift.

10.7.1.5 Clerk, name, work-shift/schedule.

10.7.2 The personnel file contains the following information:

10.7.2.1 *Person's Name*—Both the first and last name should be stored as both may be used to identify people in the laboratory. This field is also used when the name of the responsible person is to be included in the report.

10.7.2.2 *Person's Code(s)*—This code is entered in the test request and result file to assign responsibility for a test result.

10.7.2.3 *Password*—One or more codes are assigned for password protection.

10.7.2.4 *Telephone Number*—The telephone number of each employee allows the laboratory management to contact personnel.

10.7.2.5 *Home Address*—This field helps identify each employee and provides a central location of important information on employees.

10.7.2.6 *Employee Position*—This field defines the job category of the individual, possible pay status, and responsibilities within the laboratory.

10.7.2.7 *Social Security Number*—This field helps to uniquely identify the employee and adds to the central store of information for each person.

10.7.2.8 *Privileges*—This field shall contain the codes denoting the permitted functions the user has on the system.

10.8 *Billing File*—The billing file, if not part of an external system, is used to prepare billing information from the internal billing codes. The file provides translation data to convert the internal billing code into one of eight external codes or to the dollar amount of the charge. Multiple-billing codes are required for the same work if bills are to be sent to different third-party payers, such as Medicare/Medicaid, or used for the billing system of the hospital. When a patient bill is prepared, the appropriate external code or dollar charge (determined by the intended recipient of the bill) is obtained from this file for every previously unreported charge listed for every test on this patient. Each record in this file describes the charges and codes for a single internal billing code. The entries are:

10.8.1 The internal code (primary key).

10.8.2 The dollar charge.

10.8.3 Up to eight external billing codes.

10.9 *CAP Workload File*—The CAP workload file will be used to provide accurate information on the productivity of both departments and laboratory personnel. The file is used to store raw workload counts, CAP workload factors, and corrected workload units. This file is used to produce a final workload report. Entry may be automatic from on-line instruments or manual, which is particularly important at manual workstations where the computer is unable to provide on-line monitoring of the work in progress. A final workload recording-unit printout includes the listing of a station, a test, the number of raw units, the number of controls, any other information such as dilutions and repeats, the CAP workload unit value, and finally the calculated totals. The CAP workload file contains the following information:

10.9.1 *Type of Test*—This provides the information regarding how the CAP workload units are generated. Workload units may be recorded for each of the following ways:

10.9.1.1 *When Each Specimen is Received into the Department*—This would reflect the time and effort expended in collecting the sample.

10.9.1.2 *When a Single Result for a Specimen is Signed Out*—This records the work done in producing that result.

10.9.1.3 *When a Quality Control Sample is Run*—CAP workload units generally allow for the input of additional quality control numbers and use these to generate additional CAP workload units.

10.9.1.4 *When Certain Multiple Analyzer Instruments are Run*—When a sample is analyzed by these instruments, a fixed number of workload units are generated regardless of the number of tests ordered on the specimen.

10.9.1.5 *By Additional Manual Input*—Certain specialty tests, particularly in surgical pathology and microbiology, require the input of additional identifying information. For example, in surgical pathology workload units are generated by specimen with additional units for number of special stains and number of slides.

10.9.2 *Raw CAP Workload Units*—These workload units correspond to each type of test or procedure that is used to generate corrected CAP workload units.

10.9.3 *Responsible Person for Generating the CAP Workload Units*—This responsible person could allow for productivity studies of either personnel within the department or entire departments.

10.10 *Department File*—The department file is used to divide up the laboratory into logical sections. This can be used in the generation of productivity figures, worklists, and quality control data. In addition, such activities as proper sample splitting and allocation of specimens to portions of the laboratory are enhanced. It may also be necessary to divide the larger departments into subdepartments. This may occur in departments such as chemistry, where a section such as electrophoresis, toxicology, or routine chemistry is necessary. The department file contains the following information:

10.10.1 *Full Name of Department*—This is an uncoded name for the department and may be used to generate the heading on any of the major administrative documents, maintenance logs, or other necessary paper output.

10.10.2 *Code of Department*—This is in alphanumeric code used to define the department in the files. This is particularly applicable in the test code file section.

10.11 *Workstation File*—The workstation file is used to identify either on-line instruments or manual stations. It provides information about the specimens required for an assay. It includes what tests or specimen sites, or both, are analyzed at this station. The workstation file contains the following information:

10.11.1 *Name of Workstation*—This is an alphanumeric name of the station that will exist on the top of workstation forms.

10.11.2 *Department*—This is the code of the department in which the workstation exists.

10.11.3 *Test or Site, or Both*—In most cases, samples are sent to a workstation for a particular type of analysis available at that station. However, in some departments, such as microbiology or cytology, workstations may more often be designed to handle samples originating from particular specimen sites. This field identifies the test available, and if appropriate, the specimen site.

10.11.4 *Default Station*—This would be used at major workstations in case of failure. If a workstation was not functioning, the specimens or tests, or both, designated to this station would automatically be routed to the default workstation listed in this field.

10.11.5 *Linearity Check*—This field is particularly useful in the chemistry section. It is used to alert the technologists if a certain test result has exceeded the usable or calibrated range of the instrument.

10.11.6 *Number of Available Spaces*—This field defines the number of specimens that can be utilized in one run. It is used to help prepare worklists or instrument load lists.

10.11.7 *Quality Controls*—This field defines the usual number, location, and identity of the quality controls needed for a run at this workstation. It is used to help prepare the worklists or load lists. Systems would most likely provide the technologist with the ability to override any of these parameters.

10.11.8 *Replicates*—In some analyses, such as radioimmunoassay, specimens may be run in duplicate. This field specifies the usual number of replicates.

10.11.9 *Other Results*—If other results are required at a workstation, this field specifies which other results may be displayed in determining a derived value. An example of this is the need to see a patient's MCV from hematology at a station that assays iron or vitamin B-12.

10.12 *Physician File*—The physician file, which may be accessed in concert with other systems, contains the names, codes, and other attributes of all doctors who have patient admission privileges within the hospital. This file is used to check the validity of the physician field in the administrative data file when a new patient is entered into the system and permits mailing labels when reports or other information are to be mailed. It must be coordinated with the file maintained for the patient care record system (see Guide E 1384). It contains the following information:

10.12.1 *Full Name of Physician or Physician Group*.

10.12.2 *Physician Code (Primary Key)*—This alphanumeric code is used to identify the physician or group in the patient file.

10.12.3 *Group Reference*—This field permits a given entry to be for an individual physician or a physician group. If the record is for an individual, this field identifies the association of this physician with a group, if any.

10.12.4 *Addresses of Physician*—The working addresses of the physician are entered here and are used to mail information.

10.12.5 *Office Telephone Number*—This field is used to contact the physician in the event of an emergency.

10.12.6 *Other Number*—This could be a home telephone number or a paging number to be used if the physician is not at his office.

10.12.7 *Speciality*—The physician speciality would be used to further identify the physician and may be used to generate reports specifically tailored to a speciality group. For instance, hematologists may request all information pertinent to red cells and white cells be placed at the beginning of the report.

10.13 *Bed File*—The bed file, which is maintained by the registration, admitting, discharge, and transfer system (see Guide E 1239), is used for two major reasons. The first is to check for an illegal or already occupied bed during the administrative entry. The second is to provide sequence information for the printing of patient reports, including cumulative and interim reports and blood drawing lists. The bed file contains the following information:

10.13.1 *Bed Number*—This is an alphanumeric entry that gives the bed codes.

10.13.2 *Occupied Flag*—This flag is set when the bed is occupied.

10.14 *Quality Control File*—Quality control files are the primary assurance of precision and accuracy in the department. It is necessary, however, to provide more than the traditional forms of quality control that accept and check only numeric input from either an assayed or unassayed quality control specimen. The computer can provide additional information and checks on such points as routine instrument maintenance and temperature checks. In addition, extraction of normal patients from the daily specimen runs can provide vital data points. The following data elements may appear in quality control reports. The exception report of out of normal range on either panic–patient values or on quality control samples may be printed. By test, a plot of the quality control samples' values by date/time should be able to be displayed. Cum-Sum plots **(7)** of daily control samples results may be requested, or the log of all quality control samples' values for each test, or both. Each entry should identify accession number, worksheet batch and cup number, and date/time. The running and daily means and S.D. may be printed. Daily means may also be subject to Cum-Sum plots **(7)**.

10.14.1 Normative values will be produced from patient attributes: age, sex, race, posture, diagnosis, height, weight, and test values. The patients selected may be designated by means of several methods such that the time of data capture may be designated, and during that time the attributes will be written to a statistical file as they are received. It may also be designated that selected values may result from a retrospective search of the existing patient file. The output form of the statistical results may be in the form of percentiles, histograms, or parameters of the distribution as desired.

10.14.2 The files are divided as follows:

10.14.2.1 *Full Name of File*—This is an alphanumeric descriptor of the file that is used as a heading whenever the information is displayed or printed.

10.14.2.2 *Abbreviated File Name*—This is a cryptic, numeric, or alphanumeric code that describes the control for materials which contain multiple analytes (for example, sodium, potassium, and CPK). This code may be common to several files, in which case the name that will make this field unique is the name of the individual test.

10.14.2.3 *Department*—This refers to a record in the department file to which the quality control file applies.

10.14.2.4 *Workstation*—This references a record in the workstation file to which the quality control file applies.

10.14.2.5 *Test*, if appropriate, for which the quality control file is used. This is the final delineation of what result will be stored in this quality control file. The tests will either be obtained from the test code file or from the site file.

10.14.3 *Type*—The quality control file type can exist as one of the following:

10.14.3.1 *Quality Control Material*—This is the standard type of quality control function in which the input consists of numeric input and the output includes charts, the mean, the standard deviation, the coefficient of variation, and a listing of all points.

10.14.3.2 *Patient Data File*—This would contain a defined range, usually the normal range, of values for an instrument. This would again be used to provide quality control for a specific workstation for a particular analyte. This file would be numerical in nature and produce Shewhart charts, means, coefficients of variation, standard deviations, and a listing of all results placed in the file.

10.14.3.3 *Text Entry Checks*—This would be in two main forms. The files would either be numeric or alphanumeric in nature and would not present data in Shewart **(7)** chart form. This type primarily would be used where charts are not important and numeric reduction is unnecessary. The two main uses of this would be as maintenance logs and numeric answers. Maintenance logs, such as refrigerator temperature and analysis of blood bank material would have the result stored along with the time and date and the code of the responsible person.

10.14.3.4 *Other*—The last type of quality control would be used when results are normally expected to be alphanumeric. The quality control of a test such as VDRL may only require a textual answer along with the time and date and code for the responsible person.

10.14.4 *Scheduled Time Interval*—This is useful to provide reminders when instrument maintenance is to be done at regular intervals.

10.14.5 *Check and Verify Against Outliers*—This would permit the user to be notified if an inappropriate response was received. The system may either force the user to verify the response or simply not allow the value to be stored in a file.

10.14.6 *Expected Range*—These responses will determine several conditions. In the case of quality control material, it will alert the operator that a result for a quality control material is out of range. In the case of patient data, this entry is used to select the normal range patients, which are age and sex stratified, that will become a part of the normal statistics as used in 10.14.1. They are defined here and are not the same as the normal ranges held in the test code file, since the ranges for the patient-type quality control files may have a separate and distinct range. Two types of expected range or response are allowed:

10.14.6.1 *Mean, Standard Deviation, Coefficient of Variation*—These would be for numeric input and would be used for either the quality control material or for the patient data files.

10.14.6.2 *English Phrase*—This would be used for text entry checks and would be the required response. For example, the response "yes" is appropriate for maintenance processed on an instrument.

10.14.7 Once this data has been saved, additional mathematical manipulation can occur. This would include skewness, kurtosis, and standard deviation index. With a specific criteria identified, monthly summary reports can then be generated as well as comparison of different methodology with Youden plots. The maintenance log files can be printed separately and would again fulfill many of the CAP and regulatory agencies requirements.

10.15 Laboratory management data or administrative information may require the entry or recording of the following data by the system: For each test, a table containing the ordering physician, the location of the patient, the service, the patient's diagnosis, the laboratory station conducting the test—these will be printed later. A periodic printout of the user's log containing the following data elements for each entry: use ID, port or station, times logged on and off, duration functions used will be created to monitor system usage. A log of each workstation and the tests conducted will be created; each entry shall contain date/time, started and finished, the number of tests conducted (standards and controls separately identified) and technician identifier during that session. These logs will be designed to operate with test-reagent/resource description files and the laboratory chemicals and supplies files to estimate the cost per test. The test description files shall contain codes and amounts of chemical reagents and supplies (corresponding to identifiers in the laboratory supply files) used in each test; instruments shall be identified by workstation and average time per test.

10.16 *Instrument Maintenance*—Instrument projected maintenance files will be constructed that contain the following information: the instrument identifier, workstation code, a list of maintenance intervals and procedure codes that are to be accomplished at the end of that interval, the date and cycle of last maintenance, a list of procedural steps for each instrument to be serviced, and the cycle step to be carried out. Daily, weekly, and monthly printed segments of this table are required. When each step is accomplished an updated entry, including the identifier of the maintenance person and the date and time, is entered in the record for that instrument, including full test comments.

10.17 *Supplies Inventory*—A file of all supplies ordered and inventoried by the laboratory will be maintained. This file will contain records on each item identified by a key related to that used by supply service and that can be used in the next test reports/resources file. Each record will contain the date/time of inventory, amount on hand, amount on order, total amount utilized during current fiscal period, tests or procedures that this item is used for, cost/unit, relevant invoice/P.U. numbers, and relevant inventory control numbers.

11. Keywords

11.1 capabilities; clerical functions; CLIMS; data structures; laboratory utilization; object model; requirements; result interpretation

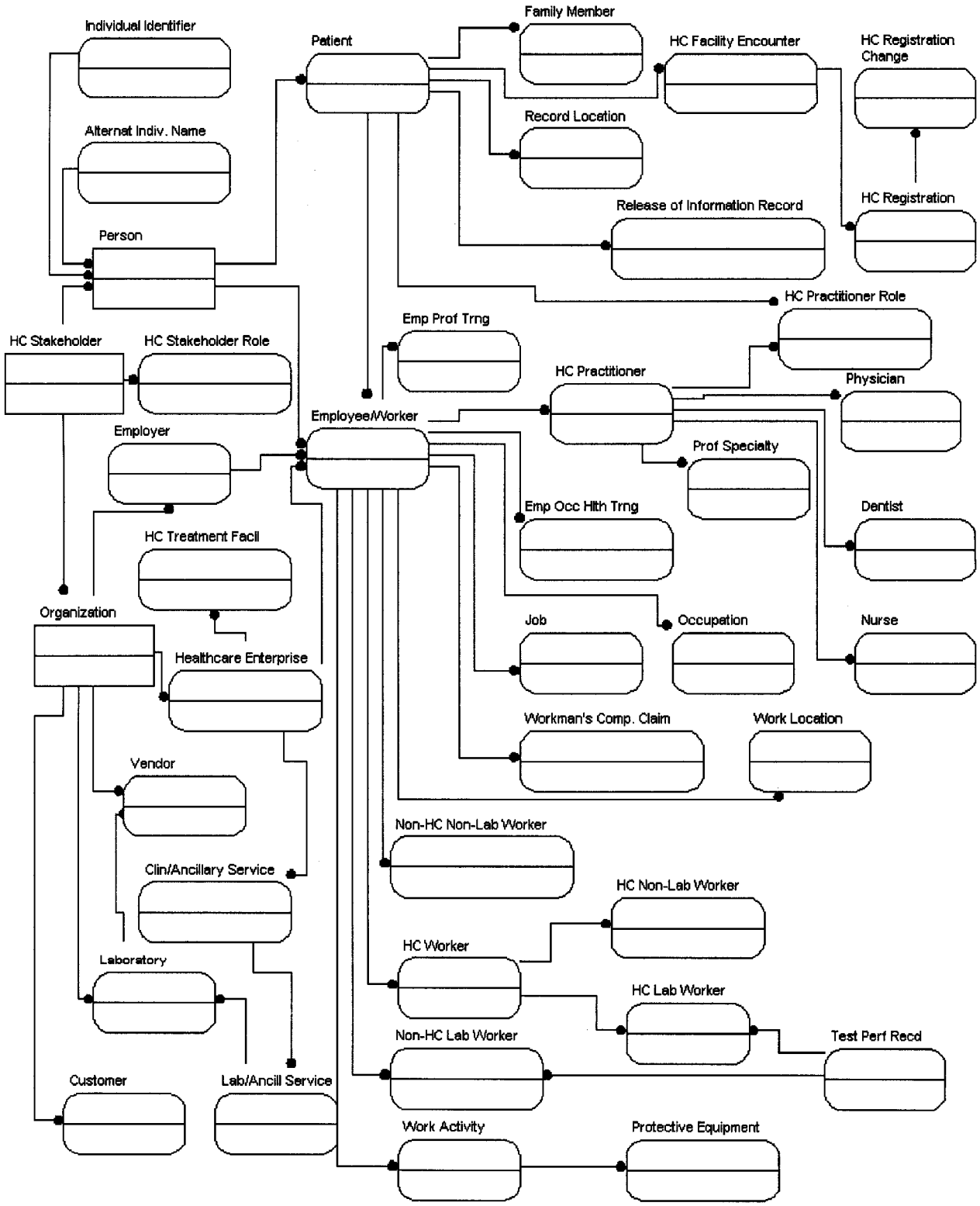

FIG. 1 People and Organization Relationships

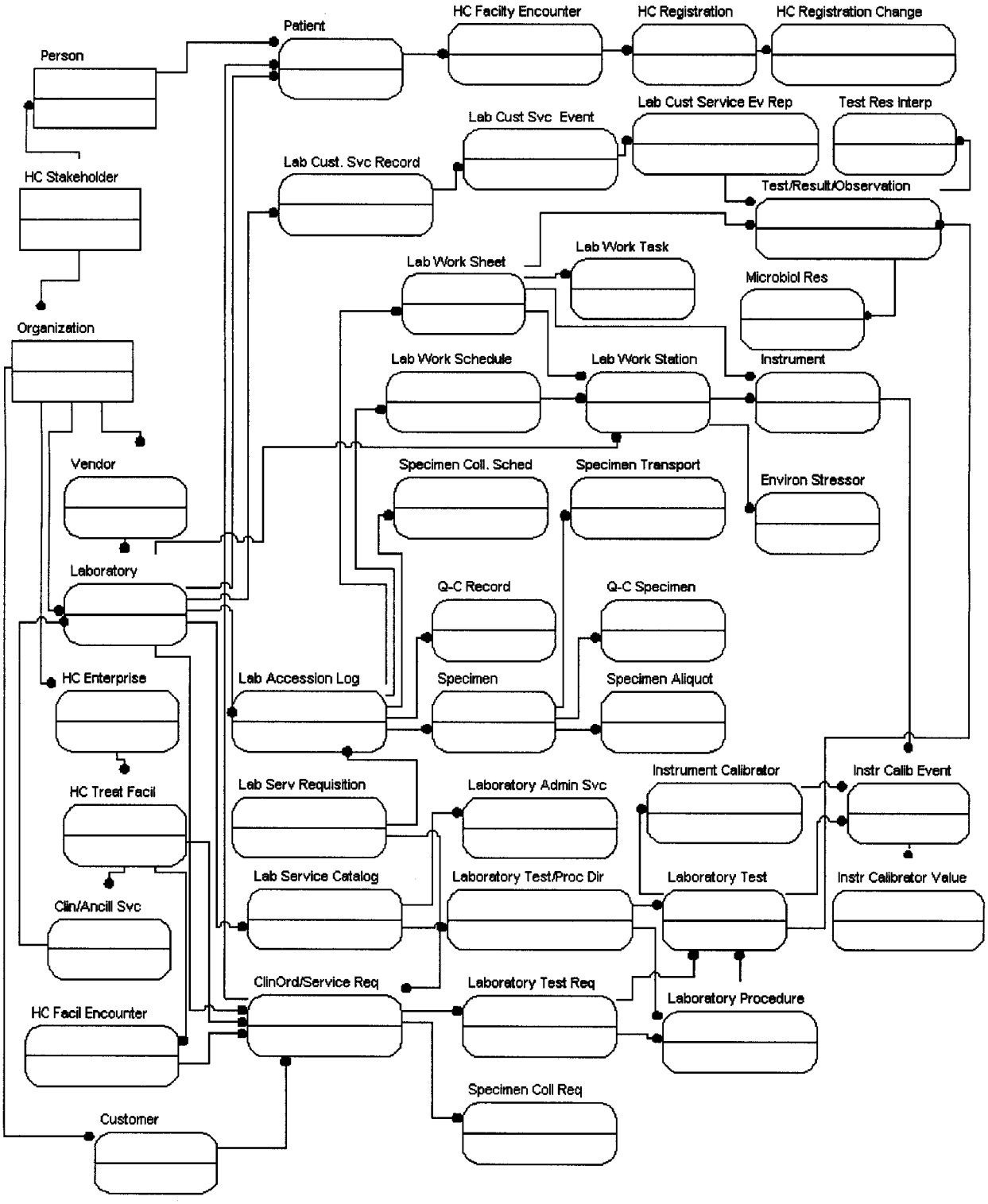

FIG. 2 Clinical Activity Relationships

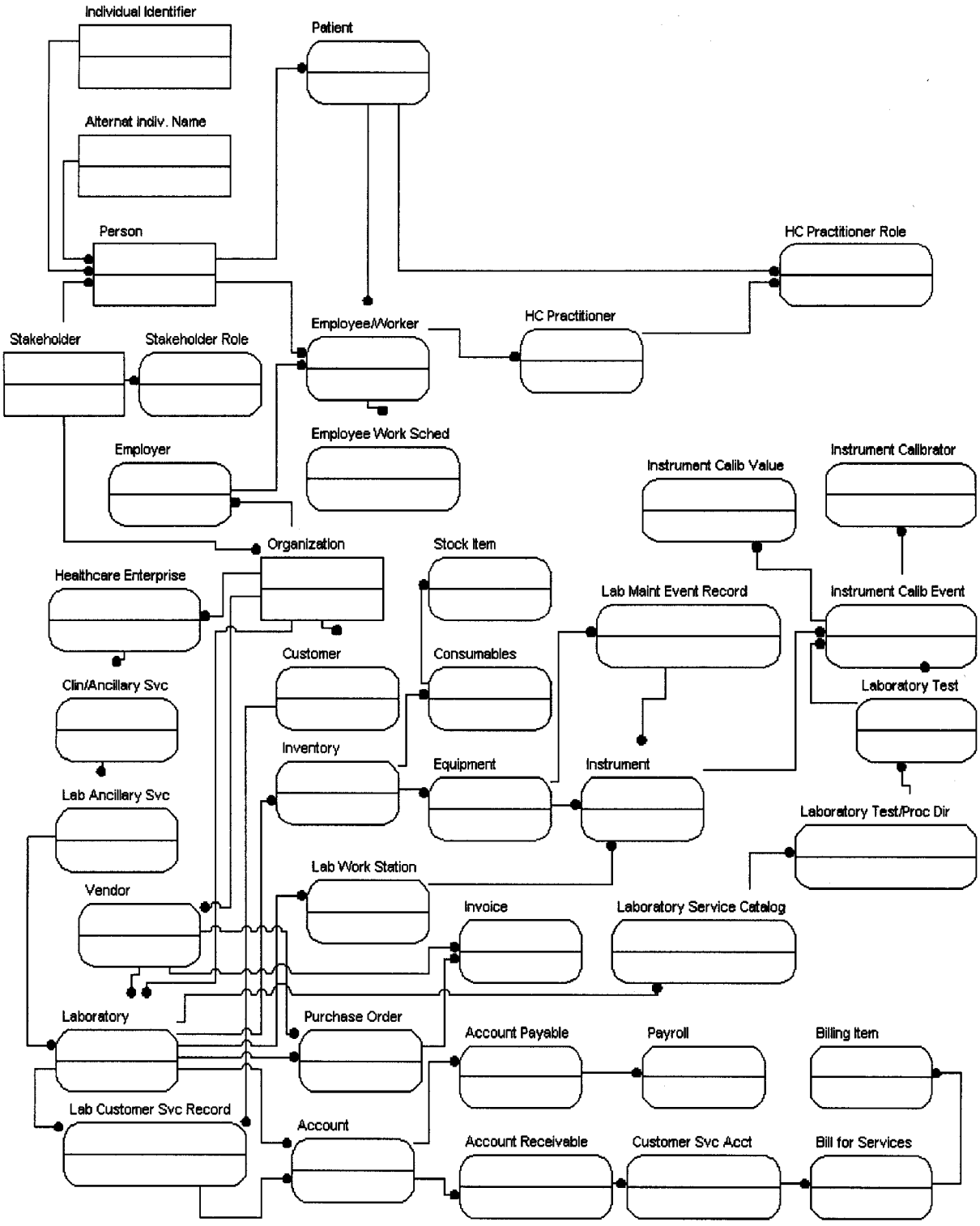

FIG. 3 Fiscal and Resource Relationships

ANNEX

(Mandatory Information)

A1. OBJECT MODEL PROPERTIES

Component of Model: CLIMS Laboratory

GENERAL SUBJECT/OBJECT GROUP: CLINICAL ACTIVITIES

CLINICAL ORDER/SERVICE REQUEST		OBJECT & CLASS
	RELATIONSHIPS:	
	is a component/member of: Emergency Room Activities	
	is a component/member of: Healthcare Ambulatory Visit Activities	
	is a component/member of: Inpatient Activities	
	INHERITANCE:	
	Person	
	Patient	
	Healthcare Stakeholder	
	Organization	
	Healthcare Enterprise	
	Healthcare Treatment Facility	
	Healthcare Facility Encounter	
	Healthcare Facility Encounter Activities	
	Emergency Room Activities	
	Healthcare Visit Activities	
	Inpatient Activities	
	This object encompasses the general properties of a clinical action message, or “Clinical Order.” It characterizes the properties common to all types of Clinical Orders by identifying the addressee, the subject, the circumstances and the control properties of the action ordered. It does not include those special properties of the addressee specialty.	
	ATTRIBUTES:	
10001	CLIN ORDER ID NUMBER	
10001.002	CLIN ORDER PATIENT STATUS	
10001.009	CLIN ORDER DATE-TIME OF ORDER	
10001.010	CLIN ORDER TYPE	
10001.013	CLIN ORDER ACTION	
10001.015	CLIN ORDER PRIORITY	
10001.017	CLIN ORDER PRE-ADMIT STATUS	
10001.019	CLIN ORDER ORIGIN	
10001.021	CLIN ORDER PARENT ORDER	
10001.022	CLIN ORDER MULTIPLE SEQ STATUS	
10001.023	CLIN ORDER RELATED ORDERS	
10001.025	CLIN ORDER USER	
10001.027	CLIN ORDER USER SIG	
10001.029	CLIN ORDER NURSE ID	
10001.031	CLIN ORDER NURSE SIG	
10001.033	CLIN ORDER ORDERING PRACTITIONER NAME	
10001.035	CLIN ORDER ORDERING PRACTITIONER SIG	
10001.037	CLIN ORDER COUNTERSIGNING PRACTITIONER NAME	
10001.039	CLIN ORDER COUNTERSIGNING PRACTITIONER SIG	
10001.041	CLIN ORDER NURSE SIG NEEDED STATUS	
10001.043	CLIN ORDER NURSE SIG NEEDED DATE-TIME	
10001.045	CLIN ORDER PRACTITIONER SIG NEEDED STATUS	
10001.047	CLIN ORDER PRACTITIONER SIG NEEDED DATE-TIME	
10001.049	CLIN ORDER COUNTERSIG NEEDED STATUS	
10001.051	CLIN ORDER COUNTERSIG NEEDED BY DATE-TIME	
10001.052	CLIN ORDER DISCONTINUED BY PRACTITIONER NAME	
10001.053	CLIN ORDER DISCONTINUED PRACTITIONER SIG	
10001.055	CLIN ORDER CONFIRMATION RECD DATE-TIME	
10001.057	CLIN ORDER ACTIVE/PENDING FLAG	
10001.059	CLIN ORDER ACTIVE STATUS	
10001.061	CLIN ORDER PENDING STATUS	
10001.063	CLIN ORDER INACTIVE STATUS FLAG	
10001.065	CLIN ORDER START STATUS	
10001.067	CLIN ORDER EXECUTION FREQUENCY	
10001.069	CLIN ORDER DURATION OF SERVICE	
10001.071	CLIN ORDER LATEST STATUS CHG DATE-TIME	
10001.073	CLIN ORDER REACTIVATION DATE-TIME	
10001.075	CLIN ORDER REQ FM ANCILLARY	
10001.077	CLIN ORDER ANCILLARY ACTIV DATE-TIME	
10001.079	CLIN ORDER RESULT EXPECTATION DATE-TIME	
10001.081	CLIN ORDER TELEPHONE RESULT FLAG	
10001.083	CLIN ORDER TELEPHONE TO REQUEST DESTINATION	
10001.085	CLIN ORDER REQUEST SCHEDULED FLAG	

10001.087 CLIN ORDER REQUESTED APPT TIME
10001.089 CLIN ORDER APPT TYPE
10001.091 CLIN ORDER APPT TRANSPORT STATUS
10001.093 CLIN ORDER APPT STATUS
10001.095 CLIN ORDER ASSIGNED APPT TIME
10001.097 CLIN ORDER HEALTH SERVICE ORDERED
10001.099 CLIN ORDER PRINCIPAL PROBLEM
10001.100 CLIN ORDER FULL TEXT
10001.102 CLIN ORDER LOCATION OF SERVICE
10001.104 CLIN ORDER FREQ ORDERED SVC
10001.106 CLIN ORDER MODIFY STATUS
10001.108 CLIN ORDER MODIFICATION REASON
10001.110 CLIN ORDER NON-MODIFY FLAG
10001.112 CLIN ORDER INSTRUCTIONS
10001.114 CLIN ORDER SECONDARY ORDERS
10001.116 CLIN ORDER MESSAGE
10001.123 CLIN ORDER DATE-TIME ORDER COMPLETED
10001.140 CLIN ORDER Q-A WARNING DATE-TIME
10001.140.1 CLIN ORDER Q-A WARNING TEXT
10001.140.2 CLIN ORDER Q-A WARNING DISPOSITION
10001.140.3 CLIN ORDER Q-A WARN OVERRIDE PRACTITIONER
10001.140.4 CLIN ORDER Q-A WARN AUTHORIZED BY PRACTITIONER
10001.140.5 CLIN ORDER Q-A WARNING OVERRIDE JUSTIFICATION
10001.160 CLIN ORDER Q-A REVIEW DATE
10001.160.01 CLIN ORDER Q-A REVIEW EVENT TYPE

CLINICAL ORDER RESULT OBJECT & CLASS

RELATIONSHIPS:
Is a result of: Clinical Order/Service Request
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Healthcare Facility Encounter Activities
Healthcare Facility Encounter
Clinical Order/Service Request
Recorded observation or action that is the direct result of a clinical order/service request
ATTRIBUTES:

10001.120 CLIN ORDER RESULT ACKNOWL DATETIME
10001.120.01 CLIN ORDER RESULT SHIFTCARE PLAN DATE
10001.120.02 CLIN ORDER RESULT RETURN FLAG
10001.120.03 CLIN ORDER RESULT RETURN STATUS
10001.120.04 CLIN ORDER RESULT RETURN DATETIME
10001.120.05 CLIN ORDER RESULT RETURN ACKNL BY
10001.120.06 CLIN ORDER RESULT RETURN COMMENT

HEALTHCARE FACILITY ENCOUNTER OBJECT & CLASS

RELATIONSHIPS:
Is a component/member of: Healthcare Encounter Activities
Is a component/member of: Patient
is a component/member of: Healthcare Episode
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Healthcare Encounter Activities
Person
Patient
This object contains general data about every event between a PATIENT and a PRACTITIONER in the health-care domain. It includes all events that result in an observation being made in the Primary Record of Care for any purpose, including telephonic and consultative conversations between PRACTITIONERS that have any implications for the patient.
ATTRIBUTES:

14001 DATE-TIME ENCOUNTER/ADMISSION
14001.A001 TREATMENT FACILITY NAME
14001.A002 ENCOUNTER TYPE
14001.A003 ENCOUNTER ID
14001.A006 ENCOUNTER TYPE
14001.A013 TREATMENT FACILITY TYPE
14001.A010 ENCOUNTER STATUS
14001.A004 ENCOUNTER SECURITY PROTECTION
14001.A050 DATE-TIME OF PHYSICAL EXAMINATION
14001.A060 ENCOUNTER COMMENTS
14001.A053 ENCOUNTER PROBLEM
14001.A100 AGE

HEALTHCARE REGISTRATION OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Healthcare Facility Encounter
is a component/member of: Patient
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Healthcare Encounter Activities
Healthcare Facility Encounter

Person
Patient
Healthcare Facility Encounter
Patient
This object characterizes the process of recognizing and characterizing the PATIENT to the health-care system. It includes gathering a demographic data set and other general information, such as permissions for care and resources to support the care that may be planned.
ATTRIBUTES:
01197 REGISTRATION REVIEW DATE
01200 REGISTRATION INFORMANT
01205 REGISTRATION COMMENT
01210 DATE RECORD TRANSF TO STORAGE

HEALTHCARE REGISTRATION CHANGE OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Healthcare Registration
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Healthcare Registration
Healthcare Facility Encounter
Patient
Person
This object characterizes the changes due to the process of recognizing and characterizing the PATIENT in the health-care system. It includes changes to the demographic data set and other general information, such as permissions for care and resources to support the care that may be planned.
ATTRIBUTES:
01195 DATE REGISTR RECORD UPDATED
01195.02 PERSON INITIATING/UPDATING

HEALTHCARE PRIMARY RECORD OF CARE LOCATION OBJECT & CLASS
RELATIONSHIPS:
Is a component of: Patient
INHERITANCE:
Patient
Person
Healthcare Stakeholder
Is a physical site where data concerning care received by a patient is stored.
ATTRIBUTES:
01027. RECORD HOLDING LOCATION ID
01027.1 DATE OF EARLIEST ENTRY
01027.2 DATE OF LATEST ENTRY

RELEASE OF INFORMATION RECORD
RELATIONSHIPS:
is a component/member of: Patient
INHERITANCE:
Healthcare Stakeholder
Patient
Person
This object characterizes the properties of each release of information from the primary record of care.
ATTRIBUTES:
02100 RELEASE OF INFO RECORD ACTION DATETIME
02100.02 TYPE OF RECORD ACTION
02100.04 REL OF INFO TYPE OF INFO
02100.06 REL OF INFO PERSON RELEASING
02100.08 REL OF INFO RELEASED TO
02100.10 REL OF INFO PURPOSE
02100.12 PERSON AUTHORIZING RELEASE

GENERAL SUBJECT/OBJECT GROUP: FACILITIES

CLIN/ANCILLARY SERVICE OBJECT & CLASS
RELATIONSHIPS:
is a component/member of a Healthcare Treatment Facility
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
This object characterizes the organizational component that is directed and specialized functions such as direct care specialities or supporting indirect specialties for diagnosis or treatment (called ancillary services). It is an included organizational component of the HEALTHCARE TREATMENT FACILITY and sponsoring ORGANIZATION.
ATTRIBUTES:
ORGANIZATIONAL SERVICE IDENTIFIER
ORGANIZATIONAL SERVICE NAME
PROFESSIONAL SPECIALTY IDENTIFIER

CLINICAL LABORATORY ORGANIZATIONAL SERVICE OBJECT & CLASS
RELATIONSHIPS:
is a special case of: Clinical Ancillary Service
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clin/Ancillary Service
This object characterizes the properties of the Clinical Laboratory function. It includes all sections of the laboratory that relate to gathering specimens, providing diagnostic services, or giving administrative support to those activities.

ATTRIBUTES:
ORGANIZATIONAL SERVICE IDENTIFIER
LABORATORY IDENTIFIER (M)

ENVIRONMENTAL STRESSOR OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Laboratory
is a component/member of: Laboratory Workstation
INHERITANCE
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Laboratory Workstation
Laboratory
Employer/Company
This object characterizes the properties of substances or forces (chemical, biological, physical or radiological) that cause stresses to an EMPLOYEE/WORKER in the workplace.
ATTRIBUTES:
STRESSOR IDENTIFIER
STRESSOR NAME
STRESSOR CODE SYSTEM (M)
CODE VALUE

HEALTHCARE TREATMENT FACILITY OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Healthcare Enterprise
INHERITANCE:
Healthcare Stakeholder
Organization
HEALTHCARE ENTERPRISE
This object characterizes the properties of a location that is used for any aspect of providing healthcare to PATIENTS. It includes those properties that are general to the function of the facility and exclude those properties that characterize the hostelry or residence properties of the facility. It may include those attributes that are utilized for both resident and non-resident PATIENTS.
ATTRIBUTES:
HEALTHCARE TREATMENT FACILITY IDENTIFIER
ORGANIZATION IDENTIFIER
HEALTHCARE TREATMENT FACILITY NAME
HEALTHCARE TREATMENT FACILITY CLASS

LABORATORY OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Organization
is a component/member of: Laboratory Ancillary Service
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical Ancillary Service
Laboratory Ancillary Service
This object characterizes the special properties of the organization that relate to its ability to provide laboratory services. It excludes those properties that are general to the laboratory function or those specific to particular components of the laboratory. It includes those attributes that apply to each of the components.
ATTRIBUTES:
LABORATORY IDENTIFIER
HEALTHCARE TREATMENT FACILITY IDENTIFIER
LABORATORY NAME

LABORATORY WORKSTATION OBJECT & CLASS

RELATIONSHIPS: I
is a component/member of: Laboratory
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical Ancillary Service
Laboratory Ancillary Service
Laboratory
This object characterizes the properties of each laboratory location used to conduct analysis procedures in the laboratory. INSTRUMENTS may be located at a location, but not mandatorily.
ATTRIBUTES:
LABORATORY WORKSTATION IDENTIFIER
LABORATORY IDENTIFIER
WORKSTATION LOCATION IN LABORATORY
ASSIGNED EQUIPMENT/INSTRUMENT IDENTIFIER (M)

GENERAL SUBJECT/OBJECT GROUP: FISCAL

ACCOUNT OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Laboratory
is a component/member of: Laboratory Customer Service Record
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Treatment Facility
Clinical Ancillary Service
Laboratory Ancillary Service
Healthcare Enterprise

Laboratory
Laboratory Customer Service Record
This object contains the general identifying data concerning a financial record about an entity in the healthcare domain. Such data are common to all financial records.
ATTRIBUTES:
ACCOUNT IDENTIFIER

ACCOUNT PAYABLE OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Account
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Customer Service Record
Account
This object characterizes monies to be paid for services received.
ATTRIBUTES:

ACCOUNT RECEIVABLE OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Account
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Customer Service Record
Account
This object characterizes monies to be received in payment for services rendered.
ATTRIBUTES:

BILL FOR SERVICES OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Patient account
is a component/member of: Laboratory Customer Service Record
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Customer Service Record
Account
Patient Account
This object characterizes the properties of the document that requires payment for services requested and delivered to the requestor. It includes properties general to the requesting ORGANIZATION and the request and excludes properties unique to BILLING ITEMS.
ATTRIBUTES:
BILL IDENTIFIER
VENDOR IDENTIFIER
PURCHASE ORDER IDENTIFIER
PURCHASE ORDER DATE
BILL DATE
BILLING ITEM (M)

BILLING ITEM OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Bill for Services
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Laboratory Ancillary Service
Laboratory
Laboratory Customer Service Record
Bill For Services
This object characterizes the properties unique to each item in the bill. It excludes general properties included in the BILL FOR SERVICES.
ATTRIBUTES:
BILLING ITEM IDENTIFIER
BILLING ITEM NAME
BILLING ITEM CHARGE

CONSUMABLE SUPPLIES OBJECT & CLASS

RELATIONSHIPS:
is special case of: Inventory
INHERITANCE:
Healthcare Stakeholder
Organization

Healthcare Enterprise
Healthcare Treatment Facility
Clinical Ancillary Service
Laboratory Ancillary Service
Laboratory
Inventory
This object characterizes the properties of an INVENTORY item for a LABORATORY that relate to its consumable nature during business operations.
ATTRIBUTES:
STOCK ITEM IDENTIFIER (M)

CUSTOMER SERVICES ACCOUNT OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Account Receivable
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical Ancillary Service
Laboratory Ancillary Service
Laboratory
Account
Account Receivable
This object identifies the services component of an account for a laboratory.
ATTRIBUTES:
SERVICE IDENTIFIER

EQUIPMENT OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Inventory
INHERITANCE:
Healthcare stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical Ancillary Service
Laboratory Ancillary Service
Laboratory
Inventory
This object characterizes the properties of INVENTORY items for a LABORATORY that relate to its nonconsumable nature.
ATTRIBUTES:

INVENTORY OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Laboratory
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
This object class includes components of EQUIPMENT and CONSUMABLE SUPPLIES which constitute the entire inventory. The building structures are not included. The properties of the Items in the inventory are contained in the specific objects. The general properties are attributes of this object.
ATTRIBUTES:

INVOICE OBJECT & CLASS

RELATIONSHIPS: I
is a component/member of: Vendor
INHERITANCE:
Healthcare stakeholder
Organization
Laboratory
Vendor
Purchase Order
This object characterizes that part of the VENDOR that lists the particular goods (STOCK ITEMS) or services supplied by the VENDOR as a result of a specific event.
ATTRIBUTES:
INVOICE IDENTIFIER
INVOICE DATE
INVOICE VENDOR IDENTIFIER
STOCK ITEM IDENTIFIER (M)
NUMBER SHIPPED

PAYROLL OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Account Payable
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Account
Account Payable

This object characterizes the financial record that calculates the pay to be received by the EMPLOYEE/WORKER for work in the LABORATORY.
ATTRIBUTES:
EMPLOYEE IDENTIFIER
PAY CLASS
TIME UNITS WORKED
TIME UNIT

PURCHASE ORDER OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Laboratory
is a component/member of: Vendor
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Vendor
This object characterizes the properties of the document provided to a VENDOR by a LABORATORY which describes the goods (STOCK ITEMS) or services which the LABORATORY desires to purchase from the VENDOR.
ATTRIBUTES:
PURCHASE ORDER IDENTIFIER
PURCHASE ORDER DATE
PURCHASE ORDER VENDOR IDENTIFIER
STOCK ITEM IDENTIFIER (M)
NUMBER ORDERED

STOCK ITEM OBJECT & CLASS
RELATIONSHIPS:
is a special case of: Consumable Supplies
is a special case of: Equipment
is a component/member of: Vendor
INHERITANCE:
Healthcare stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical Ancillary Service
Laboratory Ancillary Service
Laboratory
Inventory
Consumable Supplies
Equipment
Vendor
This object characterizes the properties of an item that is either used by a LABORATORY for business operations or is offered by a VENDOR for purchase.
ATTRIBUTES:
STOCK ITEM IDENTIFIER
STOCK ITEM NAME
STOCK ITEM CLASS
STOCK ITEM PRICE

WORKMAN'S COMP CLAIM OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Employer/Company
INHERITANCE:
Healthcare Stakeholder
Organization
Employer/Company
Record of facts relating to on-the-job illness or injury
ATTRIBUTES:
03001 WORKMANS COMPENSATION CLAIM DATE

GENERAL SUBJECT/OBJECT GROUP: LABORATORY ACTIVITIES

EMPLOYEE WORK SCHEDULE OBJECT & CLASS
RELATIONSHIPS
is a component/member of: Employee/Worker
INHERITANCE:
Healthcare Stakeholder
Organization
Employer/Company
Person
Employee/Worker
This object characterizes the time and places where the employee is scheduled to do his/her job.
ATTRIBUTES:
EMPLOYEE IDENTIFIER
WORK DATE
WORK PERIOD (M)
WORK DURATION

INSTRUMENT OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Equipment
is a component/member of: Laboratory Workstation
INHERITANCE:
Healthcare Stakeholder
Organization

Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Workstation
This object characterizes the time and places where the employee is scheduled to do his/her job.
ATTRIBUTES:
EQUIPMENT/INSTRUMENT IDENTIFIER
EQUIPMENT NAME
EQUIPMENT SERIAL NUMBER
EQUIPMENT MFR NAME
DATE INSTALLED
DATE LAST MAINTENANCE
LABORATORY MAINTENANCE EVENT REPORT IDENTIFIER (M)

INSTRUMENT CALIBRATION EVENT OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Instrument
is a result of: Laboratory test
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Treatment Facility
Laboratory
Laboratory Workstation
Instrument
Laboratory Test
ATTRIBUTES:

INSTRUMENT CALIBRATOR OBJECT & CLASS
RELATIONSHIPS:
is used by: Instrument calibration event
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Laboratory
Laboratory Work Station
Instrument
Reference Material for Calibration
ATTRIBUTES:

INSTRUMENT CALIBRATOR VALUE OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Instrument Calibration Event
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Laboratory
Laboratory Workstation
Instrument
Instrument Calibration Event
Reference Value for the constituent involved in a Lab Test
ATTRIBUTES:
INSTRUMENT CALIBRATOR IDENTIFIER
INSTRUMENT CALIBRATOR MANUFACTURER
INSTRUMENT CALIBRATOR DATE OF MANUFACTURE
INSTRUMENT CALIBRATOR ANALYTE IDENTIFIER
INSTRUMENT CALIBRATOR ANALYTE PROPERTY VALUE

LABORATORY ACCESSION LOG OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Laboratory
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Laboratory
Instrument
This object identifies all specimens received and their assigned characteristics
ATTRIBUTES:
RECEIVED SPECIMEN ACCESSION NUMBER
DATETIME RECEIVED

LABORATORY ADMIN SERVICES OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Laboratory service catalog
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory

Laboratory Service Catalog
This object characterizes all of those services that are not direct test procedures that have direct observed measurements. It includes those properties that create derived values from other measurements, manage the identification or handling of the specimen, or conduct other processes not related to the analysis for constituents.
ATTRIBUTES:
ADMIN SERVICE INDENTIFIER
ADMIN SERVICE NAME

LABORATORY CUSTOMER SERVICE EVENT OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Laboratory customer service record
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Customer Service Record
This object characterizes each laboratory service event. It includes those attributes that are general to the event and excludes those properties that comprise the entries in the specimen collection request and the SPECIMEN COLLECTION SCHEDULE, the LABORATORY TEST REQUEST, or the LABORATORY TEST SCHEDULE objects.
ATTRIBUTES:
LABORATORY CUSTOMER SERVICE EVENT IDENTIFIER
LABORATORY CUSTOMER SERVICE EVENT DATE-TIME
LABORATORY CUSTOMER SERVICE EVENT TYPE
LABORATORY CUSTOMER IDENTIFIER
LABORATORY PROCEDURE IDENTIFIER (M)

LABORATORY CUSTOMER SERVICE EVENT REPORT OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Laboratory customer service event
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Customer Service Event
Laboratory Customer Service Record
This object characterizes the attributes of the report of the service event made to the customer.
ATTRIBUTES:
LABORATORY CUSTOMER SERVICE EVENT IDENTIFIER
REPORT DATE
PATIENT IDENTIFIER

LABORATORY CUSTOMER SERVICE RECORD OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Laboratory
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
This object characterizes the services rendered to customers. It includes those attributes that are general to all services for a customer (patient in clinical systems) and excludes the details of specific events which are characterized in the LABORATORY CUSTOMER SERVICE EVENT object.
ATTRIBUTES:

LABORATORY MAINTENANCE EVENT RECORD OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Equipment
is a component/member of: Instrument
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Equipment
Instrument
This object characterizes that part of an INSTRUMENT or EQUIPMENT which relates to the properties of the maintenance events conducted thereon.
ATTRIBUTES:
LABORATORY MAINTENANCE EVENT IDENTIFIER

LABORATORY PROCEDURE OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Laboratory Test/Procedure Directory
INHERITANCE:
Healthcare Stakeholder
Organization

Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Service Catalog
Laboratory Test/Procedure Directory
This object characterizes those properties of a test that comprises a complicated functional procedure involving several analytical steps, multiple specimens or multiple analytes but which results in a single reported value or value set.
ATTRIBUTES:
LABORATORY PROCEDURE IDENTIFIER
LABORATORY PROCEDURE NAME
ICD–10 PCS CODE

LABORATORY SERVICE CATALOG OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Laboratory
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/ancillary service
Laboratory ancillary Service
Laboratory
This object characterizes the general properties of all service items offered by the LABORATORY. It includes both administrative services and test/procedures but not the specific attributes of each of those dependent objects.
ATTRIBUTES:
LABORATORY SERVICE IDENTIFIER
LABORATORY PROCEDURE IDENTIFIER
LABORATORY ADMIN SERVICE IDENTIFIER

LABORATORY SERVICE REQUISITION OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Laboratory
is a component/member of: Customer
is a component/member of: Patient
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Customer
Laboratory
Person
Patient
This object characterizes the request by the customer, or in clinical situations by the customer's surrogate, the practitioner, for services from the laboratory. It includes those attributes that characterize all services of all types and excludes those relating to specific types of services, such tests or specimen collection or administrative functions. Batteries or composite functional tests or preparative procedures are included but the specific test components are excluded as they are represented by other specific objects.
ATTRIBUTES:
LABORATORY SERVICE REQUISITION IDENTIFIER
LABORATORY TEST REQUEST IDENTIFIER (M)

LABORATORY TEST OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Laboratory Test/Procedure Directory
is a component/member of Laboratory Test Request
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Test/Procedure Directory
Laboratory Test Request
This object characterizes the properties of the analytical procedures used to measure the analytes requested in the LABORATORY SERVICE REQUISITION.
ATTRIBUTES:
LABORATORY TEST/PROCEDURE IDENTIFIER
LABORATORY TEST NAME
LABORATORY OBSERVATION IDENTIFIER (M)

LABORATORY TEST REQUEST OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Laboratory Service Requisition
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory

Laboratory Service Requisition
This object characterizes the properties of the test procedure portion of the LABORATORY SERVICE REQUISITION. It may include a single or many tests or it may utilize the name of a fixed aggregate of tests.
ATTRIBUTES:
LABORATORY TEST REQUEST IDENTIFIER
PATIENT IDENTIFIER
CUSTOMER IDENTIFIER

LABORATORY TEST/PROCEDURE DIRECTORY OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Laboratory service catalog
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
LABORATORY SERVICE CATALOG
This object characterizes the properties of the tests, procedures and test batteries offered as services by the LABORATORY. It does not include the administrative services such as derived values which are composed of the measurements resulting from several tests or procedures.
ATTRIBUTES:
LABORATORY TEST/PROCEDURE IDENTIFIER
LABORATORY PROCEDURE CHARGE

LABORATORY WORKSHEET/LOAD LIST OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Instrument
is a component/member of: Laboratory Accession Log
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Instrument
Laboratory Accession Log
This object characterizes the properties of the LABORATORY WORK TASKS and INSTRUMENTS contained in the ACCESSION LOG. It also relates to observed TEST RESULT/OBSERVATIONS' general properties.
ATTRIBUTES:
LABORATORY WORKSHEET IDENTIFIER
RECEIVED SPECIMEN ACCESSION NUMBER

LABORATORY WORK TASK OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Laboratory work sheet/load list
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Work Sheet/Load List
This object characterizes the properties of the analytical task assigned to provide the requested services in the ACCESSION LOG. Each task will take place at a LABORATORY WORK STATION.
ATTRIBUTES:
LABORATORY WORK TASK IDENTIFIER (M)
LABORATORY WORK LIST IDENTIFIER

MICROBIOLOGY RESULT OBJECT & CLASS
RELATIONSHIPS:
is a special case of: Test/Result/Observation
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Accession Log
Laboratory Worksheet/Load List
Test Result/Observation
This object characterizes the properties of a microbiological TEST RESULT/OBSERVATION
ATTRIBUTES:

Q-C RECORD OBJECT & CLASS
RELATIONSHIPS:
is a component/member of Laboratory Accession Log
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise

Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Accession Log
This object identifies the specimens utilized for Q-C and their characteristics
ATTRIBUTES:
Q-C SPECIMEN IDENTIFIER

Q-C SPECIMEN OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Specimen
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Accession Log
Specimen
This object characterizes those properties of a specimen that has known values and is used for checking the accuracy and precision of the analytical process.
ATTRIBUTES:
Q-C SPECIMEN IDENTIFIER
Q-C SPECIMEN LOT
Q-C SPECIMEN MFR

SPECIMEN OBJECT & CLASS

RELATIONSHIPS:
is a component/member of Laboratory accession log
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Accession Log
This object characterizes the properties of the specimen which is being presented to the LABORATORY for analysis according to the LABORATORY SERVICE REQUISITION.
ATTRIBUTES:
SPECIMEN IDENTIFIER
PATIENT IDENTIFIER
DATE-TIME SPECIMEN COLLECTED
COLLECTOR EMPLOYEE IDENTIFIER
SPECIMEN CONTAINER EMPLOYED
SPECIMEN VOLUME/MASS
MODE OF TRANSPORTATION IDENTIFIER

SPECIMEN ALIQUOT OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Specimen
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Specimen
This object characterizes the properties of the sub-specimen taken within the LABORATORY for conduct of the requested LABORATORY TEST or LABORATORY PROCEDURE.
ATTRIBUTES:
SPECIMEN ALIQUOT IDENTIFIER
SPECIMEN IDENTIFIER
ALIQUOT CONTAINER
ALIQUOT VOLUME

SPECIMEN COLLECTION REQUEST OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Laboratory Service Requisition
is a component/member of: Clinical Order/Service Request
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Service Requisition
This object characterizes the activities surrounding the gathering of the appropriate specimen for analysis by the LABORATORY.
ATTRIBUTES:
SPECIMEN COLLECTION REQUEST IDENTIFIER
CLINICAL ORDER IDENTIFIER

TIME OF COLLECTION REQUESTED
PLACE OF LOCATION REQUESTED

SPECIMEN COLLECTION SCHEDULE OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Laboratory Accession Log
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Accession Log
This object characterizes the properties of the time list of events for collecting specimens relating to a LABORATORY SERVICE REQUISITIONs. It includes attributes detailing times, places, and actions to be taken to deliver a SPECIMEN to the LABORATORY.
ATTRIBUTES:

SPECIMEN TRANSPORTER OBJECT & CLASS
RELATIONSHIPS:
is a component/member of : Specimen
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Specimen
This object characterizes the properties of the actions involved in transporting the specimen from the collection site to the LABORATORY.
ATTRIBUTES:
SPECIMEN TRANSPORTER IDENTIFIER
SPECIMEN IDENTIFIER
DATETIME DEPARTED

TEST-RESULT/OBSERVATION OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Laboratory work sheet/load list
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Accession Log
Instrument
Laboratory Worksheet/Load List
This object characterizes the properties of the measurement/observation itself.
ATTRIBUTES:
RESULT IDENTIFIER
OBSERVATION IDENTIFIER
OBSERVATION NAME
LOINC CODE
LABORATORY PROCEDURE IDENTIFIER
RESULT NAME
RESULT CURRENT NORMATIVE RANGE
RESULT VALUE
RESULT UNIT

TEST-RESULT INTERPRETATION OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: test result/observation
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Clinical/Ancillary Service
Laboratory Ancillary Service
Laboratory
Laboratory Accession Log
Instrument
Laboratory Worksheet/Load List
Test result/observation
statement of meaning by performer
ATTRIBUTES:

GENERAL SUBJECT/OBJECT GROUP: ORGANIZATION

CUSTOMER OBJECT & CLASS
RELATIONSHIPS:
is a special case of: Organization
INHERITANCE:
Healthcare Stakeholder
Organization

This object characterizes those aspects of an organization that relate to its activities as a purchaser of goods and services.
ATTRIBUTES:
CUSTOMER NAME
CUSTOMER TYPE
ORGANIZATION NAME
PERSON NAME

EMPLOYER/COMPANY OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Organization
INHERITANCE:
Healthcare Stakeholder
Organization
This object characterizes those aspects of an ORGANIZATION that involve its responsibilities and benefits deriving from having individuals work formally for the organization for pay.
ATTRIBUTES:
ORGANIZATION IDENTIFIER
EMPLOYER IDENTIFIER
01075 PRESENT EMPLOYER NAME
01077 WORK ADDRESS
01080 WORK (BUSINESS) PHONE

HEALTHCARE ENTERPRISE OBJECT & CLASS

RELATIONSHIPS:
Is a special case of: Organization
INHERITANCE:
Healthcare Stakeholder
Organization
This object is a business entity that delivers health care services. It may also be a practitioner, which is a separate object containing data on the professional attributes of the provider/practitioner relationship. This object, however, contains only those attributes relating to the business function of a practitioner's practice.
ATTRIBUTES
04001 PROVIDER/PRACTITIONER NAME
04001.03 PROVIDER ADDRESS
04001.05 PROVIDER TYPE
04001.07 PROVIDER ID NO.
04001.07.01 PROVIDER ID AGENCY

HEALTHCARE STAKEHOLDER OBJECT & CLASS

RELATIONSHIPS:

INHERITANCE:

Organization
This object is a business entity that delivers health care services. It may also be a practitioner, which is a separate object containing data on the professional attributes of the provider/practitioner relationship. This object, however, contains only those attributes relating to the business function of a practitioner's practice.
ATTRIBUTES:
STAKEHOLDER IDENTIFIER

HEALTHCARE STAKEHOLDER ROLE OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Healthcare Stakeholder
INHERITANCE:
Organization
This object is an entity that has a health care role. It may be a person or an organization
ATTRIBUTES:
STAKEHOLDER ROLE IDENTIFIER
DATE STAKEHOLDER ROLE BEGAN
DATE STAKEHOLDER ROLE ENDED

ORGANIZATION OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Healthcare Stakeholder
INHERITANCE:
Healthcare Stakeholder
This object contains general data about any social entity which is organized for any purpose relating to a societal function. It includes those ORGANIZATIONS offering services in the health-care domain and those ORGANIZATIONS consuming or supporting such services, such as insurers, suppliers, manufacturers, etc. It excludes those nonbusiness entities that are solely related to individuals and have no implications for the health-care domain.
ATTRIBUTES:
ORGANIZATION IDENTIFIER
ORGANIZATION NAME
ORGANIZATION ADDRESS
ORGANIZATION CONTACT PHONE
ORGANIZATION CLASSIFICATION

VENDOR OBJECT & CLASS

RELATIONSHIPS:
Is A Special Case of: Organization
INHERITANCE:
Healthcare Stakeholder
Organization
This object characterizes the properties of an ORGANIZATION which relate to its offering of goods or service to be purchased by other organizations.
ATTRIBUTES:
ORGANIZATION NAME
VENDOR IDENTIFIER
VENDOR CLASS (M)

GENERAL SUBJECT/OBJECT GROUP: PEOPLE

ALTERNATE INDIVIDUAL NAME OBJECT & CLASS

RELATIONSHIPS:
is a component/member of PERSON
INHERITANCE:
Healthcare Stakeholder
Person
Characterizes additional names for a PERSON
ATTRIBUTES:
INDIVIDUAL ALTERNATE NAME
INDIVIDUAL ALTERNATE NAME END DATE
INDIVIDUAL ALTERNATE NAME START DATE
INDIVIDUAL ALTERNATE NAME USAGE

EMPLOYEE OCCUPATIONAL HEALTH TRAINING OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Employee/Worker
INHERITANCE:
Healthcare stakeholder
Person
Employee/Worker
Organization
Employer/Company
This object characterizes the properties of an EMPLOYEE which relate to those aspects of his job that impact his health or safety while on the job.
ATTRIBUTES:
DATE-TIME OF OCCUPATIONAL HEALTH TRAINING
LOCATION OF OCCUPATIONAL HEALTH TRAINING
TOPIC OF OCCUPATIONAL HEALTH TRAINING
DURATION OF OCCUPATIONAL HEALTH TRAINING
ACCREDITATION OF OCCUPATIONAL HEALTH TRAINING
ATTENDEE EMPLOYEE INDENTIFIER (M)

EMPLOYEE PROFESSIONAL TRAINING OBJECT & CLASS

RELATIONSHIPS:
is a component of: Employee/Worker
INHERITANCE:
Healthcare Stakeholder
Person
Employee/Worker
Organization
Employer/Company
This object characterizes the training received in the employee's professional discipline. It does not include any training received in workplace-specific issues or safety-on-the-job topics.
ATTRIBUTES:
EMPLOYEE IDENTIFIER
DATE OF TRAINING
SUBJECT OF TRAINING
DURATION OF TRAINING
COMPETENCY MEASURE OF SUBJECT
CURRENT POSITION
APPLICABLE JOB (M)

EMPLOYEE/WORKER OBJECT & CLASS

RELATIONSHIPS:
is a special care of Person
INHERITANCE:
Healthcare Stakeholder
Person
Employer/Company
This object characterizes those individuals who formally work for, and are paid for their work by, an ORGANIZATION. Being formally employed confers certain benefits and responsibilities on both the employee and the employer. The properties that characterize those aspects of an individual reside in this object.
ATTRIBUTES:
EMPLOYEE IDENTIFIER
EMPLOYER IDENTIFIER
POSITION TITLE
PRIMARY OCCUPATION OF POSITION

FAMILY MEMBER OBJECT & CLASS

RELATIONSHIPS:
Is a component of: Patient
INHERITANCE:
Healthcare stakeholder
Person
Patient
This object contains those attributes of a patient's family members, including parents and all ancestors and their characteristics, that relate to care of the patient. This includes the ability to render or assist in care and the known causes of death and major health problems of ancestors, and it includes the profile of the known genes possessed by those family members or ancestors. These attributes are not inclusive and may be extended in the future when the need for additional attributes can be justified. The inherited characteristics of family members and ancestors is highly confidential and must be protected from to any but those who have the highest priority need-to-know.
ATTRIBUTES:

01090	FAMILY MEMBER NAME
01090.02	FAMILY MEMBER SSAN
01090.03	FAMILY MEMBER RELATIONSHIP
01090.05	FAMILY MEMBER MALE PARENT
01090.07	FAMILY MEMBER FEMALE PARENT
01090.09	FAMILY MEMBER SPOUSE

01090.11 FAMILY MEMBER SEX
01090.13 FAMILY MEMBER DOB
01090.15 FAMILY MEMBER DATE OF DEATH
01090.17 FAMILY MEMBER HEAD OF HOUSEHOLD STATUS
01090.19 fAMILY MEMBER PRIMARY CAREGIVER STATUS
01090.21 FAMILY MEMBER LOCATION
01090.23 FAMILY MEMBER OCCUPATION
01090.25 FAMILY MEMBER MAJOR DIAGNOSIS/CAUSE OF DEATH

HEALTHCARE PRACTITIONER OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Employee/Worker
is a component/member of: Healthcare Treatment Facility
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Person
Employee/Worker
Healthcare Treatment Facility
This object contains those attributes of a PERSON that characterize the individual's role in delivering health-care services, either directly or indirectly to PATIENTS. It includes those individuals having some professional education, competence, and certification or licensing attesting to competence to engage in such activity. It excludes HEALTHCARE WORKERS, who are those individuals not possessing such special competence, but not those PRACTITIONERS who, at some time, are engaged in a non-PRACTITIONER role. PRACTITIONERS are categorized with respect to their level of responsibility and their area of specialty.
ATTRIBUTES:
NATIONAL PROVIDER IDENTIFIER
HEALTHCARE PRACTITIONER NAME
EMPLOYEE IDENTIFIER
EMPLOYER IDENTIFIER

04001.10 PRACTITIONER NAME
04001.12 PRACTITIONER SSAN
04001.15 PRACTITIONER'S UNIVERSAL ID NO
04001.20 PRACTITIONER'S PROFESSION
04001.25 PRACTITIONER'S ADDRESS
04001.30 PRACTITIONER'S PHONE
04001.35 PRACTITIONER LICENSE NO
04001.40 PRACTITIONER LICENSE STATE
04001.50 PRACTITIONER SPECIALTY
04001.45 PRACTITIONER CURRENT ROLE
04001.45.01 DATE PRACTITIONER ROLE BEGAN
04001.45.02 DATE PRACTITIONER ROLE ENDED
04001.60 PRACTITIONER SIGNATURE

HEALTHCARE PRACTITIONER ROLE OBJECT & CLASS

RELATIONSHIPS:
exists for: Patient
INHERITANCE:
Healthcare Stakeholder
Person
Patient
Employee/Worker
Organization
Healthcare Practitioner
This object characterizes those individuals who are not PRACTITIONERS but whom work in health-care settings. These individuals are also EMPLOYEES and inherit properties from the EMPLOYER.
ATTRIBUTES:
ROLE NAME
ROLE RESPONSIBILITY (M)

HEALTH CARE PRACTITIONER, DENTIST OBJECT & CLASS

RELATIONSHIPS:
Is a special case of: health care practitioner
INHERITANCE:
Healthcare Stakeholder
Organization
Employee/Worker
Healthcare Enterprise
Healthcare Treatment Facility
Person
Healthcare Practitioner
This object is characterized by the attributes concerned with the education, training, and licensing of dentists as special cases of practitioners.
ATTRIBUTES:

HEALTH CARE PRACTITIONER, NURSE OBJECT & CLASS

RELATIONSHIPS:
Is a special case of: Health Care Practitioner
INHERITANCE:
Healthcare Stakeholder
Organization
Employee/Worker
Healthcare Enterprise
Healthcare Treatment Facility
Person
Healthcare Practitioner

This object is characterized by the attributes concerned with the education, training, and licensing of nursing personnel at all levels. It includes all aspects of general nursing but excludes those aspects of nursing specialties.
ATTRIBUTES:

HEALTH CARE PRACTITIONER, NURSE PRACTITIONER OBJECT & CLASS
RELATIONSHIPS:
Is a special case of: Healthcare Practitioner
Is a special case of: Healthcare Practitioner, Nurse
INHERITANCE:
Healthcare Stakeholder
Organization
Employee/Worker
Healthcare Enterprise
Healthcare Treatment Facility
Person
Healthcare Practitioner
This object is characterized by those attributes that concern the special education, training, or licensing of nursing personnel that provide the competence to provide limited primary care.
ATTRIBUTES:

HEALTH CARE PRACTITIONER, PHYSICIAN OBJECT & CLASS
RELATIONSHIPS:
Healthcare Practitioner
INHERITANCE:
Healthcare Stakeholder
Organization
Employee/Worker
Healthcare Provider
Healthcare Treatment Facility
Person
Healthcare Practitioner
A physician object is characterized by the attributes concerned with the education, training, and licensing of physicians and osteopaths as special cases of practitioners.
ATTRIBUTES:

INDIVIDUAL IDENTIFIER OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Person
INHERITANCE:
Healthcare Stakeholder
Person
ATTRIBUTES:
INDIVIDUAL IDENTIFIER
INDIVIDUAL IDENTIFIER END DATE
INDIVIDUAL IDENTIFIER START DATE
INDIVIDUAL IDENTIFIER ISSUING ORGANIZATION
INDIVIDUAL IDENTIFIER STATUS

JOB OBJECT & CLASS
RELATIONSHIPS:
is a component of: Employee/Worker
INHERITANCE:
Healthcare Stakeholder
Organization
Employer/Company
Person
This object characterizes the work that an individual does for an EMPLOYER/COMPANY and an ORGANIZATION. The properties of a job are the general activities and responsibilities of the work assigned.
ATTRIBUTES:

08070	JOB START DATE
08070.01	JOB EMPLOYER
08070.03	JOB FULL/PART-TIME STATUS
08070.05	JOB STATUS
08070.07	JOB TITLE
08070.09	JOB CODE
08070.11	JOB CLASSIFICATION
08070.13	JOB EMPLOYEE NUMBER
08070.15	JOB PROCESS/ACTIVITY
08070.17	JOB TERMINATION DATE
08070.19	JOB COMMENTS
08070.21	JOB WORK ACTIVITY
08070.23	JOB PROTECTIVE EQUIP
08070.25	JOB STRESSORS EXPOSED TO

LAB WORKER TEST PERF RECORD OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Worker, Healthcare, Laboratory
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Healthcare Treatment Facility
Laboratory
Person
Employee/Worker
Worker, Healthcare
Worker, Healthcare, Laboratory
This object characterizes those properties of a LABORATORY WORKER which relate to his/her performance on known value test specimens used for measuring the accuracy and

precision of certain test procedures.
ATTRIBUTES:
LABORATORY WORKER IDENTIFIER
PERFORMANCE MONITORING MEASURE (M)
PERFORMANCE MEASURE DATE (M)
MEASUREMENT VALUE

OCCUPATION OBJECT & CLASS

RELATIONSHIPS:
is a component of: Employee/Worker
INHERITANCE:
Healthcare Stakeholder
Organization
Person
This object characterizes the general nature of a person's work skills, education combined with a generally recognized generic requirement of EMPLOYERS. The properties of an OCCUPATION reflect the skills and preparation for a general domain of JOBs without necessarily being specific for any one JOB.
ATTRIBUTES:
01062 CURRENT WORK STATUS
01065 CURRENT OCCUPATION
01070 PREVIOUS OCCUPATIONS
01070.01 DATE COMPLETED OCCUPATION

PATIENT OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Person
INHERITANCE:
Healthcare Stakeholder
Person
Organization
Healthcare Enterprise
Employer/Company
This object characterizes the special properties of an individual that surround the process of seeking health care from a practitioner. It excludes the general properties of the individual found in the PERSON object.
ATTRIBUTES:
PATIENT UNIQUE IDENTIFIER
PERSON IDENTIFIER
01007 ADOPTED?
01015 PATIENT NO.
01016 UNIVERSAL PATIENT HEALTH NO.
01025 ARCHIVE DATA
01030 LOCATION OF CHART
01035 MULTIPLE BIRTH MARKER
01037 BIRTH ORDER
01045 ETHNIC GROUP
01047 RELIGION
01050 MILITARY SVC/VETERAN STATUS
01058 PATIENT'S LANGUAGE
01062 CURRENT WORK STATUS
01087 NUMBER IN HOUSEHOLD
01090 FAMILY MEMBER NAME
01110 EMERG. CONT. (REL/FR.)
01112 EMERG. CONT. RELAT.
01120 PATIENT GUARDIAN NAME
01125 PATIENT GUARDIAN ADDRESS
01130 PATIENT GUARDAN STATUS
01135 LNOK NAME
01137 LNOK RELATIONSHIP
01140 LNOK ADDRESS
01142 LNOK HOME PHONE
01005 PARENTAL MARITAL STATUS
01058 INTERPRETER REQ
01067 CURRENT VOCATIONAL STATUS
01070 PREVIOUS OCCUPATIONS
01070.01 DATE COMPLETED OCCUPATION
01085 USUAL LIVING ARRANGEMENT
01115 EMERG. CONT. ADDRESS
01117 EMERG. CONT. H. PHONE
01119 EMERG. CONT. B. PHONE
01097 PATIENT COUNTY/CEN TRACT
01150 R/L HANDED?
01155 COLOR EYES
01160 COLOR HAIR
01165 BLOOD TYPE
01175 BUILD
01185 PATIENT RECORD ACTIVITY STATUS
01190 CONFIDENTIALITY PROTECTION
01262 CLERGYMAN'S NAME
01265 CLERGYMAN'S ADDRESS
01267 CLERGYMAN'S PHONE
01170 HEIGHT
01180 WEIGHT

PERSON OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Healthcare Stakeholder
INHERITANCE:
Healthcare Stakeholder

This object contains data common to all human beings identified within the healthcare domain.
ATTRIBUTES:
PERSON IDENTIFIER
PERSON NAME
PERSON ALIAS (M)
DATE OF BIRTH
GENDER
RACE
ETHNICITY
OCCUPATION (M)
START DATE OF OCCUPATION
END DATE OF OCCUPATION

01001	PATIENT NAME
01002	PREVIOUSLY REGISTERED NAME
01010	ALIAS
01020	SSAN
01055	CITIZENSHIP STATUS
01032	DATE-TIME OF BIRTH
01033	BIRTHPLACE
01040	SEX
01042	RACE
01052	MARITAL STATUS
01060	EDUCATIONAL LEVEL
01065	CURRENT OCCUPATION
01075	PRESENT EMPLOYER NAME
01080	WORK (BUSINESS) PHONE
01015	PATIENT'S TEMPORARY ADDRESS
01095	PATIENT PERMANENT ADDRESS
01099	FOREIGN RESIDENCY
01100	HOME PHONE
01097	PATIENT COUNTY/CEN TRACT
01077	WORK ADDRESS

PROFESSIONAL SPECIALTY OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Healthcare Practitioner
INHERITANCE:
Healthcare stakeholder
Organization
Healthcare enterprise
Healthcare treatment facility
Person
Employee/worker
Healthcare practitioner
ATTRIBUTES:
PROFESSIONAL SPECIALTY IDENTIFIER
PROFESSIONAL SPECIALTY NAME
CERTIFYING PROFESSIONAL SOCIETY

PROTECTIVE EQUIPMENT OBJECT & CLASS
RELATONSHIPS:
is a component/member of: Work Activity
is a component/member of: Work Location
INHERITANCE:
Healthcare Stakeholder
Organization
Employer/Company
Person
Employee/Worker
Work Location
Work Activity
This object characterizes the properties of the equipment used in WORK ACTIVITIES for protection against environmental STRESSORS.
ATTRIBUTES:
PROTECTIVE EQUIPMENT IDENTIFIER
PROTECTIVE EQUIPMENT NAME
IDENTIFIER OF STRESSORS PROTECTED AGAINST (M)

WORK ACTIVITY OBJECT & CLASS
RELATIONSHIPS:
is a component/member of: Employee/Worker
is a component/member of: Employer/company
INHERITANCE:
Healthcare Stakeholder
Organization
Employer/Company
Person
Employee/Worker
This object characterizes the activities and procedures conducted by the EMPLOYEE during the workday.
ATTRIBUTES:
WORK ACTIVITY IDENTIFIER
WORK ACTIVITY NAME
STRESSOR IDENTIFIER (M)
PROTECTIVE EQUIPMENT IDENTIFIER

WORK LOCATION
RELATIONSHIPS:
is a component/member of: Employee/Worker
is a component/member of: Employer/Company

INHERITANCE:
Healthcare stakeholder
Organization
Employer/company
Employee/Worker
Person
This object characterizes the physical location in which the EMPLOYEE works. It includes properties of the equipage of the workplace and all devices located therein. It excludes the attributes of the activities conducted at that location.
ATTRIBUTES:
WORK LOCATION IDENTIFIER
WORK LOCATION AREA
WORK LOCATION DESCRIPTION

WORKER, HEALTHCARE OBJECT & CLASS

RELATIONSHIPS:
is a component/member of: Healthcare Enterprise
is a special case of: Employee/Worker
INHERITANCE:
Healthcare Stakeholder
Organization
Healthcare Enterprise
Person
Employee/Worker
This object characterizes those individuals who are not PRACTITIONERS but whom work in health-care settings. These individuals are also EMPLOYEES and inherit properties from the EMPLOYER.
ATTRIBUTES:
EMPLOYEE IDENTIFIER
STRESSORS EXPOSED TO (M)

WORKER,NONHEALTHCARE,LABORATORY OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Employee/Worker
INHERITANCE:
Healthcare Stakeholder
Organization
Employer/Company
Person
Employee/Worker
This object characterizes a PERSON and EMPLOYEE who works in a Laboratory of any type and, for Clinical Laboratories, is differentiated from a HEALTHCARE WORKER by this work location because of the special conditions existing there.
ATTRIBUTES:
EMPLOYEE IDENTIFIER
LABORATORY IDENTIFIER
STRESSOR (M)

WORKER, HEALTHCARE, NON-LABORATORY OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Worker, Healthcare
INHERITANCE:
Healthcare Stakeholder
Organization
Employer/Company
Healthcare Enterprise
Person
Employee/Worker
Worker, Healthcare
characterizes a PERSON and EMPLOYEE of an ORGANIZATION who works in a HEALTHCARE ENTERPRISE
ATTRIBUTES:

WORKER, NON-HEALTHCARE, NON-LABORATORY OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Employee/Worker
Inherits from:
Healthcare Stakeholder
Organization
Employer/Company
Person
Employee/Worker
an individual worker not in healthcare and not in the laboratory
ATTRIBUTES:

WORKER, HEALTHCARE, LABORATORY OBJECT & CLASS

RELATIONSHIPS:
is a special case of: Worker, Healthcare
Inherits from:
Healthcare Stakeholder
Organization
Employer/Company
Person
Employee/Worker
characterizes those HEALTHCARE WORKERS who work in healthcare Laboratories
ATTRIBUTES:

APPENDIX

(Nonmandatory Information)

X1. GENERIC LIMS WORK FLOW

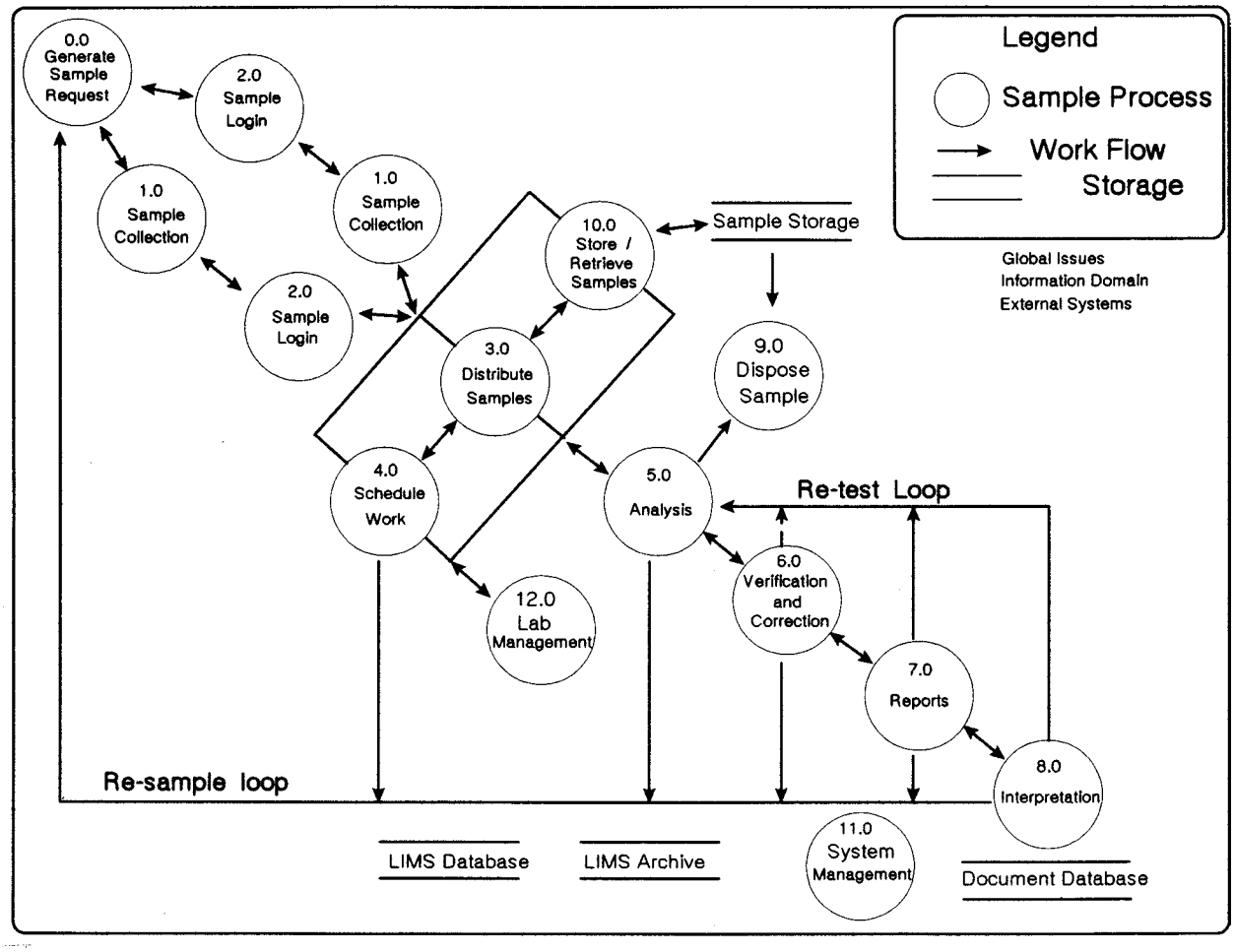

FIG. X1.1 Generic LIMS Work Flow

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NOTES

NOTES

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