



Designation: E 1639 – 01

An American National Standard

Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems¹

This standard is issued under the fixed designation E 1639; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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 792 Guide for the Selection of a Clinical Laboratory Information Management System²
- E 1238 Specification for Transferring Clinical Observations Between Independent Computer Systems²
- E 1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (RADT) Systems for Automated Patient Care Information Systems²
- E 1246 Practice for Reporting Reliability of Clinical Laboratory Computer Systems²
- E 1340 Guide for Rapid Prototyping of Computerized Systems²
- E 1381 Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems²
- E 1384 Guide for Content and Structure of the Electronic Health Record (EHR)²
- E 1394 Specification for Transferring Information Between Clinical Instruments and Computer Systems²
- E 1460 Specification for Defining and Sharing Modular Health Knowledge Bases (Arden Syntax for Medical Logic Modules)³

- E 1466 Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory²
 - E 1578 Guide for Laboratory Information Management Systems (LIMS)²
 - E 1633 Specification for Coded Values Used in the Electronic Health Record (EHR)²
 - E 1712 Specification for Representing Clinical Laboratory Procedure and Analyte Names²
 - E 1714 Guide for Properties of a Universal Healthcare Identifier²
 - E 1715 Practice for an Object-Oriented Model for Registration, Admitting, Discharge, and Transfer (RADT) Functions in Computer-Based Patient Record Systems²
 - E 2118 Guide for Coordination of Clinical Laboratory Services Within the Electronic Health Record Environment and Networked Architectures²
- #### 2.2 ANSI Standards:
- ANSI X3.172-1990 American National Dictionary for Information Systems⁴
 - ANSI X11.1 M Programming Language⁴
- #### 2.3 NCCLS Standards:
- NCCLS Auto Communications System, Instrument Systems⁵
 - NCCLS AUTO3-A Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices and Information Systems⁵
- #### 2.4 IEEE Standards:⁶
- 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

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

Current edition approved May 10, 2001. Published August 2001. Originally published as E 1639 – 94. Last previous edition E 1639 – 97.

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

³ Discontinued 1999. See the 1999 *Annual Book of ASTM Standards*, Vol 14.01.

⁴ Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

⁵ NCCLS, 940 West Valley Rd., Suite 1400, Wayne, PA 19087-1898.

⁶ Available from IEEE, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331.



Definition-Concept of Operations

2.5 *ISO Standard:*

ISO 11756 M Programming Language⁴

ISO 12207 Information Technology—Software Life Cycle Processes⁴

2.6 *Other Document:*

HL7 Health Industry Level 7 Interface Standards Version 2.3⁷

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 *Acronyms:*

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 Guide E 792, 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)⁸ 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 Practice E 1246). 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 Specifications E 1381 and E 1394). 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, implementors, 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 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.

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

⁸ The boldface numbers in parentheses refer to the list of references at the end of this standard.



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 Guide E 2118. The full CLIMS Domain Information Model is given in Annex A1 which is normative.

TABLE 1 CLIMS Objects

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

CLINICAL ACTIVITY:	
<i>Clinical Order/Service Request</i>	
<i>Clinical Order Result</i>	
<i>Healthcare Facility Encounter</i>	
<i>Healthcare Registration</i>	
<i>Healthcare Registration Change</i>	
<i>Record Location</i>	
<i>Release of Information Record</i>	
FACILITY:	
<i>Clin/Ancillary Service</i>	
<i>Clinical Laboratory Organizational Service</i>	
Environmental Stressor	
<i>Healthcare Treatment Facility</i>	
Laboratory	
Laboratory Workstation	
FISCAL ACTIVITY:	
<i>Account</i>	
<i>Account Receivable</i>	
<i>Account Payable</i>	
Bill for Services	
Billing Item	
Consumable Supplies	
Customer Services Account	
Equipment	
Inventory	
Invoice	
Payroll	
Purchase Order	
Stock Item	
<i>Workman's Compensation Claim</i>	
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

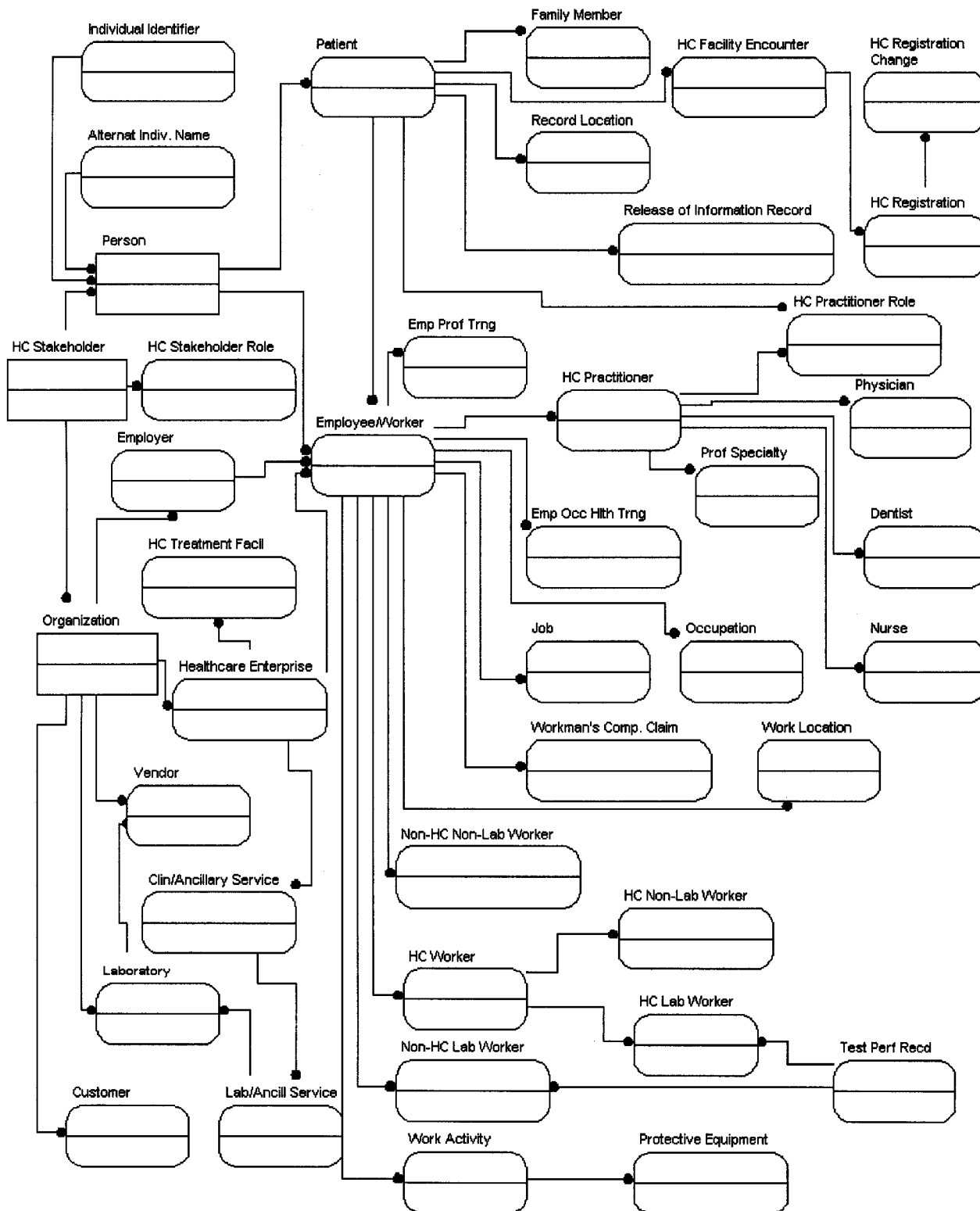


FIG. 1 People and Organization Relationships

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.

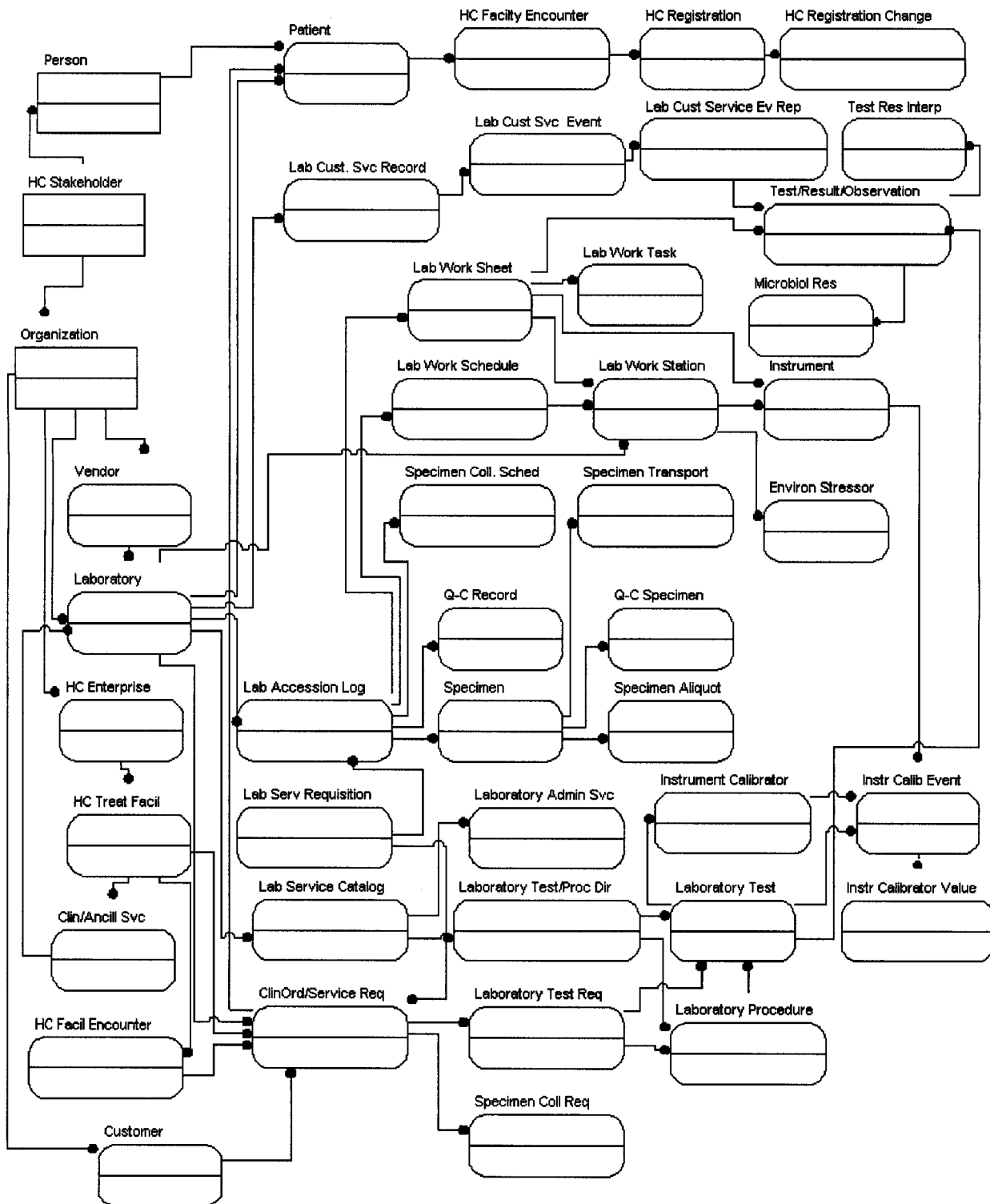


FIG. 2 Clinical Activity Relationships

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.

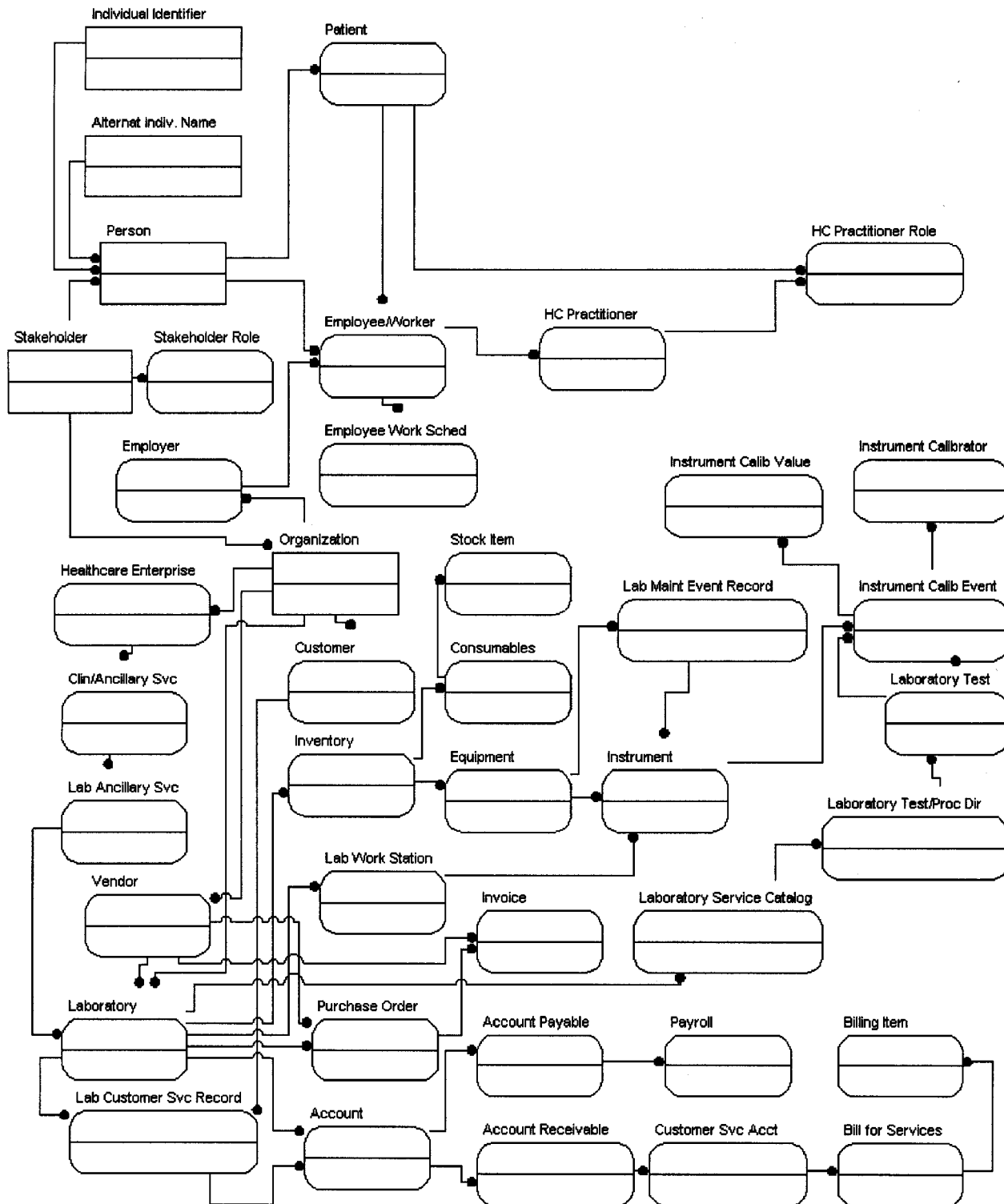


FIG. 3 Fiscal and Resource Relationships

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 Specification E 1466), 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 worklist 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 in 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*.⁹

7.4.9 *Management Functions*.⁹

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 recommen-

dation 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.

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 data base 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 data base 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.

⁹ Provided for expansion; text in development.



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 wand 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 be used for other tests, and whether there is dependence of worklist 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 Specification E 1238.

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 function.



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 Guide E 1239, Specifications E 1633 and E 1238, 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 Specification E 1238.

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