Design Objectives

Clinical Laboratory Management System (CLMS)
Program Number 5718-H12

CLMS is a system of files and procedures designed to satisfy the basic information processing requirements of clinical laboratories in modern hospitals. Utilizing the Clinical Laboratory Data Acquisition System (CLDAS) program product (5718-H11) or its equivalent for the data acquisition function, CLMS provides a broad base for an information management system. CLMS, with its unique file approach, directs and controls the flow of information from receipt of the initial requisition for a test until the final result has been developed and is ready for reporting.

CLMS processing revolves around a Master Log File which maintains the status of each test as it progresses through the laboratory cycle. Initial entries in this file are created from test requisitions entering the laboratory. The system generates the printed master log and the worklists for the various work stations. As the test runs at the work stations are completed, the system prints quality control listings to permit verification of the final test results before they are made available for reporting. Upon verification, these results are placed by the system into the Master Log. Periodically, the Master Log can be reviewed and a patient report printed for the completed tests. Entries into a charge file may be made at various points in the processing.

The Master Log contains work status indicators which are maintained by the system. These indicators show when a specimen has physically entered the laboratory and is ready for testing, when is has been placed on a worklist for a test run, and when a result has been obtained and is ready for reporting. These indicators are used by the system to direct the laboratory work flow. They are also available to the user for real-time response to inquiries on the status of tests.

The Master Log, in the normal course of processing, collects data on most aspects of the laboratory operation; the type and number of tests performed, the technologists performing them, the devices and procedures used, etc. This information is available to the user for the preparation of statistical and other special reports of value in managing the laboratory and planning for its future.

For a description of the laboratory, CLMS utilizes a set of internal files. These files are created by the system from punched cards containing operational data specified by the user. By respecifying the operational data, the user may at any time modify the system to reflect additions, deletions, or rearrangements in his test procedures.

CLMS utilizes the card reader, printer, and console typewriter as its principal means of communication with the user. However, all input and output functions of CLMS originate or terminate in a system file. These interfacing files simplify the incorporation of other input-output devices into the system. The user is responsible for any additional device support programs. A knowledge of the 1800 and its programming languages is required to write these additional device support programs.

CLMS uses an internal file, the Patient ID File, for patient data such as name, location, birthdate and sex. The user is responsible for providing the data for the creation and the procedure for maintenance of this file.

CLMS is a series of background batch process programs designed to operate concurrently with the data acquisition function. The user must provide CLDAS or its equivalent for the direct monitoring of his laboratory instruments.

Availability

The Clinical Laboratory Management System is planned for availability on July 31, 1970.

Programming Systems

CLMS operates under the IBM 1800 Time Sharing Executive System (TSX). Both IBM 1800 FORTRAN and IBM 1800 Assembler Languages are used in the system.

System Configuration

The TSX system has minimum system requirements for Systems Generation as outlined in "IBM 1800 Time Sharing Executive System Concepts and Techniques Manual" (C26-3703). CLMS requires that the 1801 Processor-Controller have at least 16K core storage (a

minimum of 5.8K of variable core is required in the TSX system). A 1443 Printer, 1442 Card Read Punch and an 1816 Console Typewriter are required. An 1810 Disk Storage Model A2 is also required. (While the Model A2 will normally provide adequate storage capacity, it is possible that laboratory volumes could be large enough to necessitate a Model A3. The Application Description Manual* will have guidelines for determining disk storage requirements.) The user's method of executing the data acquisition function will dictate the IBM 1800 Process I/O features required on the system.

Programming Service Classification: B

The programming service classification assigned to any licensed program may be changed by IBM in accordance with the terms of the license agreement for IBM program products. Some reclassification may constitute a discontinuance of service.

* See your marketing representative for availability.

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Program Product

GH20-0715-0

IBM Clinical Laboratory Data Acquisition System (CLDAS) Application Description Manual

The IBM Clinical Laboratory Data Acquisition System applies the capabilities of the IBM 1800 Data Acquisition and Control System to the problems of the clinical laboratory. The system is designed to monitor laboratory instrumentation, convert raw instrument readings into the final determinations, and present these results to the technologist in a printed report. It is intended primarily for the continuous flow type of single and multiple channel automatic analyzers; however, its modular design facilitates the incorporation of other instruments into the system. It is an online data acquisition and analysis system which provides a firm base for the development of a laboratory information system.

The purpose of this manual is to provide a general description of the application, to outline the system advantages and to provide information useful in planning for installation of the application.

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First Edition (December 1969)

Significant changes or additions to the information contained in this publication will be reported in subsequent revisions or Technical Newsletters.

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INTRODUCTION

During the last 20 years the value of the clinical laboratory in the practice of medicine has greatly increased. This increase will continue and accelerate, if one may judge from recent trends. The doubling of laboratory workload every five years is a currently accepted phenomenon. This results not only in increased requirements on the laboratory as a diagnostic and therapeutic aid to the physician, but in correspondingly greater responsibility on the laboratory—responsibility for both performance of more work and improved reliability.

Other trends accentuate the need for more efficient laboratories. Medical research is daily contributing new and more informative tests which are often time-consuming. The growth in insurance coverage for a large part of the population will enable more people to seek medical care. Routine admission tests involving more than ten clinical chemical determinations in addition to routine blood work and serology have been introduced in several medical institutions. Meanwhile, medical technologists remain in short supply, and all of the usual personnel problems associated with training, supervision, and frequent replacement of highly skilled technicians continue to take up a great deal of time. Pathologists, hospital administrators, and others who are rightly concerned over rising hospital costs, have reason to be pleased that the costs of laboratory work have not risen to impossible heights. Automated analytical instruments, nonexistent ten years ago, may be seen in most laboratories today. It is in fact not at all uncommon to find laboratories in which over 75% of all chemical and 50% of all hematological data is obtained via automation. The real value of automation has been its ability to free trained technical personnel from time-consuming routine tasks and thus increase both the quality and quantity of laboratory output.

Nevertheless, today, even in advanced laboratories, medical technologists still spend an estimated 30% of their time on clerical work. It often takes three times as long to do the necessary paperwork as it does to perform the test. Results of tests that are completed in minutes may not reach the ward for hours.

Efforts to further reduce this clerical function with its attendant delays and errors have led laboratories to consider a computer as part of the automation process.

Computers have already demonstrated their capability to automatically acquire data from a variety of instruments, to perform countless calculations without error, and to present the results of their efforts in a myriad of ways. The IBM Clinical Laboratory Data Acquisition System applies these capabilities of the IBM 1800 Data Acquisition and Control System to the problems of the clinical laboratory.

Specifically, the system is designed to monitor laboratory instrumentation, convert raw instrument readings into final determinations, and present these results to the technologist in a printed report. It is intended primarily for the continuous-flow type of single and multiple channel automatic analyzers; however, its modular design facilitates the incorporation of other instruments into the system. It is an online data acquisition and analysis system which provides a firm base for the development of a laboratory information system.

GENERAL DESCRIPTION

IBM 1800 DATA ACQUISITION AND CONTROL SYSTEM

The IBM 1800 Data Acquisition and Control System offers a broad variety of data processing capabilities. The Processor-Controller, through its input devices, can accept information from punched cards, punched paper tape, and from keyboards of various types. As auxiliary storage during processing it can utilize magnetic disk storage and magnetic tape storage. Its output can be presented on typewriters, plotters, or printers. In general, the IBM 1800 has all the standard data processing capabilities required in the clinical laboratory application. Of particular importance to the laboratory, however, are the process control abilities of the IBM 1800.

The IBM 1800 is designed to operate in an environment where many different dynamic processes require continuous measurements to be made, analyses to be performed, and action to be taken. The process control features of the 1800 facilitate this type of operation. The 1800 can accept a wide range of electrical signals in both analog and digital form directly from analytical instruments. It can collect these signals by scanning input lines at regular intervals controlled by internal clocks and programming or it can collect data from given lines in response to external requests at irregular intervals. These two modes of operation may be intermixed as required to tailor the system to the specific data acquisition requirements of its environment.

The data acquisition function in a clinical laboratory normally requires only a small portion of a computer's capability but it requires it continuously over extended periods of time. The internal logic of the IBM 1800, recognizing this characteristic, is designed such that other functions and programs may proceed simultaneously with the monitoring function.

IBM CLINICAL LABORATORY DATA ACQUISITION SYSTEM

The IBM Clinical Laboratory Data Acquisition System is an online data acquisition and data reduction system for monitoring automated instrumentation in the laboratory. The system operates within the Time Sharing Executive System (TSX) on the IBM 1800 Data Acquisition and Control System. It supports both the peak and plateau types of continuous flow automatic analyzers.

The overall functioning of the system can be best described by referring to Figure 1. Step 1 is accomplished at the time the system is initially installed for operation. Portions of Step 1 will be repeated but only when new instrumentation or new procedures are added to the system. The purpose of this phase is to describe to the system the instrumentation and the procedures it is expected to service. The definition is accomplished by entering punched cards with the pertinent data. Typical parameters are type of device (peak or plateau), number of channels (pen recorders), test name, test units, number of standards, standard values, and so on. This information is organized by the system into a procedures file which is then referenced during the daily processing cycles.

The remainder of the steps in Figure 1 describe the sequence of events which occur for each test run during the day.

Step 2 is the beginning of the cycle. As the work enters the laboratory it is organized and distributed for processing. When the technologist has a number of specimens for a given test, she advises the computer via the keyboard of the test or group of tests to be

run and the number of specimens on that run. She then begins the preprocessing leading to the loading of the trays for the automated device.

Step 3 is the system response to the notice given it in Step 2 above. It refers to that portion of the procedure file that contains the operational data on the test requested and using that data creates a work list file for the requested test run. The work list file contains all the fixed information for the test run obtained from the procedure file and provides space for the storage of the test results as they are developed during the test run.

When the technologist has the automated device loaded for the test run, she advises the computer through the keyboard (Step 4) to activate the appropriate work list file. This, effectively, logically attaches the automated instrument to the system and starts the monitoring process described in Step 5.

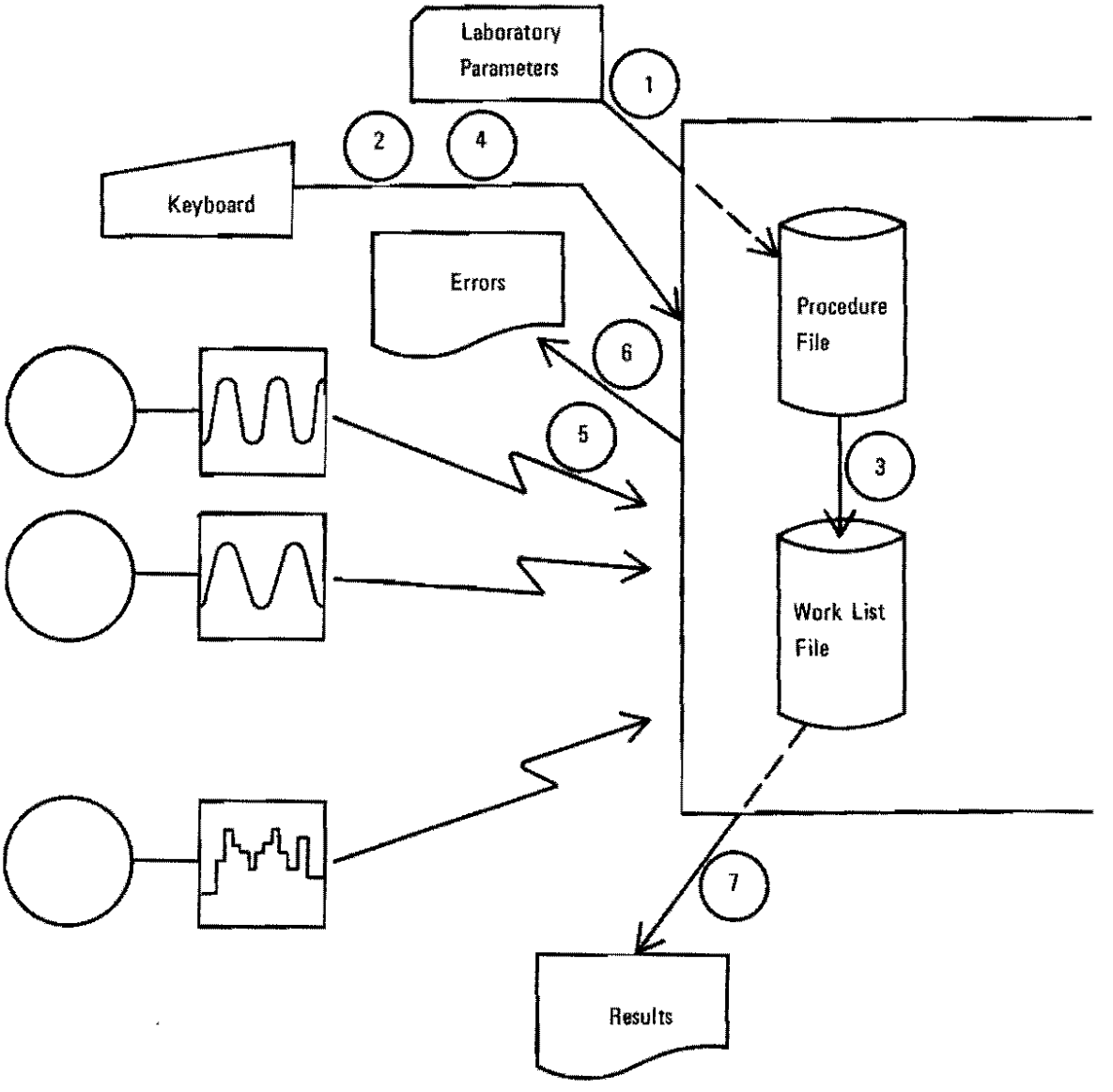

Figure 1. Schematic of system operation

Step 5 is an automatic process which proceeds under the control of the system. There are several distinct steps involved:

1. A basic data acquisition routine scans all input lines at preset intervals, converts the electrical signals to their digital equivalents and stores the values in a core storage buffer. At prescribed intervals, the data from each "active" input line is turned over to the appropriate analysis routine for processing.

2. The analysis routines are device oriented. There will be a different one required for each type of device attached to the system. The peak type analyzer routine inspects the newest data points from the automatic analyzer to determine if a peak has been developed. If so, the peak value is transfered to another buffer for further processing. If no peak has occurred, the routine stores certain data elements and prepares itself to accept the next set of data points.

   The plateau type analyzer routine operates in a similar fashion; however, it checks to see that a plateau has been established instead of a peak.

   In both routines, peak and plateau, certain error conditions can be detected as indicated in Step 6.

3. Periodically, the raw peak and plateau values are transfered from the buffer to the appropriate work list file where they are stored until the work list is completed.

As indicated above, certain error conditions can be detected during the monitoring process. As shown in Step 6 these errors are communicated back to the technologist as they occur—while the run is still in process. Examples of the types of possible errors or malfunctions which are reported are:

Narrow peak

Pen off scale

Shoulder

Washout

Appropriate corrective action in each case is left to the discretion of the technologist in charge of the instrument.

Step 7 represents the final phase of the process. As each work list is filled indicating that the test run is complete, the raw readings are converted into final determinations and a report of the results is printed out for the technologist to review.

Figure 2 pictures the report generated for a four-channel automatic analyzer set up to run the electrolytes. A brief explanation of the items on this report follows:

WORK LIST NUMBER — a unique number assigned for each work list generated by the system.

DATE — the date of the test run.

TEST NUMBER — the numeric code assigned to identify a test (101 for Sodium, etc.).

NAME — abbreviated test name.

CODE — a code number identifying the type of specimen in that rack position, i.e., - 1 indicates a calibration standard, - 2 indicates a drift standard and 0 is a specimen for testing.

ACCESS NUMBER — sequential location in rack.

DILUT FACTOR — dilution factor for that particular specimen.

The remaining four columns are headed by test units and contain the final calibrated results for each of the four electrolytes.

ANYTOWN HOSPITAL - DEPARTMENT OF CLINICAL CHEMISTRY

WORKLIST NUMBER - 1
DATE - 4/14/70

TEST NUMBER -			101	102	103	104
NAME -			NA	K	CL	CO2
CODE	ACCESS NUMBER	DILUT FACTOR	MQ/L	MQ/L	MQ/L	MQ/L
-1	1	1	100.00	2.00	92.00	10.00
-1	2	1	120.00	4.00	104.00	20.00
-1	3	1	140.00	6.00	116.00	30.00
-1	4	1	160.00	8.00	128.00	40.00
-2	5	1	120.55	4.27	104.47	20.86
0	6	1	142.36	4.21	103.90	13.52
0	7	1	155.34	5.55	122.81	4.47
0	8	1	148.19	4.17	106.14	15.07
0	9	1	140.66	4.13	98.89	21.47
0	10	1	141.41	3.66	99.41	27.97
0	11	1	127.31	5.26	95.15	15.83
0	12	1	137.46	4.10	99.52	23.20
0	13	1	132.96	4.05	92.50	22.26
0	14	1	139.26	3.59	104.96	22.44
0	15	1	141.09	4.05	97.62	33.01
-2	16	1	118.22	4.10	104.23	20.63
0	17	1	130.65	4.30	100.65	14.32
0	18	1	141.48	4.49	106.62	22.72
0	19	1	144.29	3.13	98.41	30.94
0	20	1	136.29	2.99	98.37	24.61
0	21	1	127.48	3.64	86.63	22.20
0	22	1	143.73	3.63	104.83	23.84
0	23	1	132.71	4.46	98.71	21.30
0	24	1	138.62	5.07	92.38	33.20
0	25	1	138.47	2.18	92.23	29.33
0	26	1	137.40	4.76	94.43	30.18
-2	27	1	119.79	4.10	104.61	20.55

Figure 2. Clinical chemistry work list

System Advantages

The IBM Clinical Laboratory Data Acquisition System in combination with the IBM 1800 Data Acquisition and Control System provides several benefits for a clinical laboratory.

Increased technologist productivity. Perhaps the most important immediate benefit is an increase in the productivity of the technologists performing the automated tests. This is accomplished primarily in two ways. The first is in the monitoring process itself. The system is continuously monitoring the instrument output and advising the technologist of any apparent problems, hence constant attention is no longer required. The time gained may be spent to more casually monitor a larger number of instruments and on other procedures requiring a technologist's skills. The second gain occurs at the end of the test run. The system automatically develops the calibration function and converts all readings to final determinations. The technologist is completely relieved of all chart manipulations and calculations. Again, the time saved may be spent on other tasks.

Improved control. The Clinical Laboratory Data Acquisition System will enhance the overall quality of the results reported from automated procedures. Elimination of the chart handling and manual calculations in calibrating instrument readings removes a potential source of errors in the process. The system also applies its set of rules uniformly in determining all peaks and plateaus. Variations due to different chart interpretations by different technologists are removed. Consistency is assured.

Improved laboratory responsiveness. A reduction in the time required to complete tests coupled with an increase in the productivity of the technologists enables the laboratory to respond more quickly to the demands placed on it. By ensuring a high level of quality in the process, the system expands the capacity of the laboratory permitting it to more readily handle the steadily increasing workload.

System Growth Potential

The preceding section outlined those benefits that immediately result from the installation of the IBM Clinical Laboratory Data Acquisition System. Of equal or greater importance are the benefits that can be realized over a period of time by utilizing the IBM Clinical Laboratory Data Acquisition System as a base upon which to build a laboratory information system. The base design is highly modular in nature. This permits the user to create additional program modules and extend the system as dictated by the needs of his particular laboratory. This tailoring may proceed in many different directions. This section discusses some of the more obvious extensions that a user might wish to consider for the system. Included is a description of how a laboratory information system might be developed by the user with the IBM Clinical Laboratory Data Acquisition System as its base.

Adding instruments to system. The data acquisition routine of the system is designed to accept data from a large number of input lines (instruments). To attach an entirely new type of instrument it is necessary first to ensure that the voltage level requirements are met. Then a device analysis routine (such as the peak type analysis and plateau type analysis) must be written and the procedures file must be modified to reflect the characteristics of the new instrument. To attach another device of the same type already being serviced, only an extension to the procedure files is necessary.

Extension of reporting system. The system supplies the technologist with a complete listing of the final calibrated results for each test run. It maintains a duplicate of this report in a file on the disk storage unit (work list file). If the patient's name and location are entered into the system by punched cards or by keyboard this information can be merged with the test results in the work list file and a report generated for the patient's chart.

Laboratory information system. Many different approaches to data processing are being employed in laboratories today. All have one thing in common. They have as an ultimate goal some form of a "Laboratory Information System". A major objective in the design of the Clinical Laboratory Data Acquisition System was that it provide a firm base for the development of a more comprehensive system. This objective has been attained with a highly modular system of programs and files. This same modular philosophy readily carries over into the design of a laboratory information system. The following system discussion illustrates how a flexible system can be developed using this modular approach. For convenience, the information processing within the laboratory is considered in ten distinct steps.

Entry of Test Request

Development of Master Log

Generation of Collection Schedule

Verification of Collection Process

Generation of Work List

Entry of Test Results

Verification of Test Results

Reporting of Test Results

Inquiry Response

Production of Statistical Information

The general processing approach and the files utilized in each step are discussed in the following sections.

Entry of Test Request: The entire process starts with the entry of the initial request for a test. It is in this area particularly that a system must have a great deal of flexibility. Not only may several methods be used in an initial system design (i.e., cards for normal requisitions, keyboards for entry of stats) but it is in this area that advances in technology promise great things (terminals, CRT's, optical readers, etc.). Hence a system must allow the use of various types of input devices and for changes in these devices but at the same time must consolidate all request data for the next processing phase.

This can be accomplished by establishing a test request file which is to contain all the pertinent information from a request such as patient ID number, specimen ID number, test code, type of specimen, etc., and a standard input programming module which will load this file from requisition information in the bulk storage of the system. As shown in Figure 3 programming submodules can then be created for the transfer of information from a given device to bulk storage where the standard input module assumes control. With this approach the remainder of the processing is dependent only on the content and

format of the test request file and changes in input devices have only a minimal impact on the system.

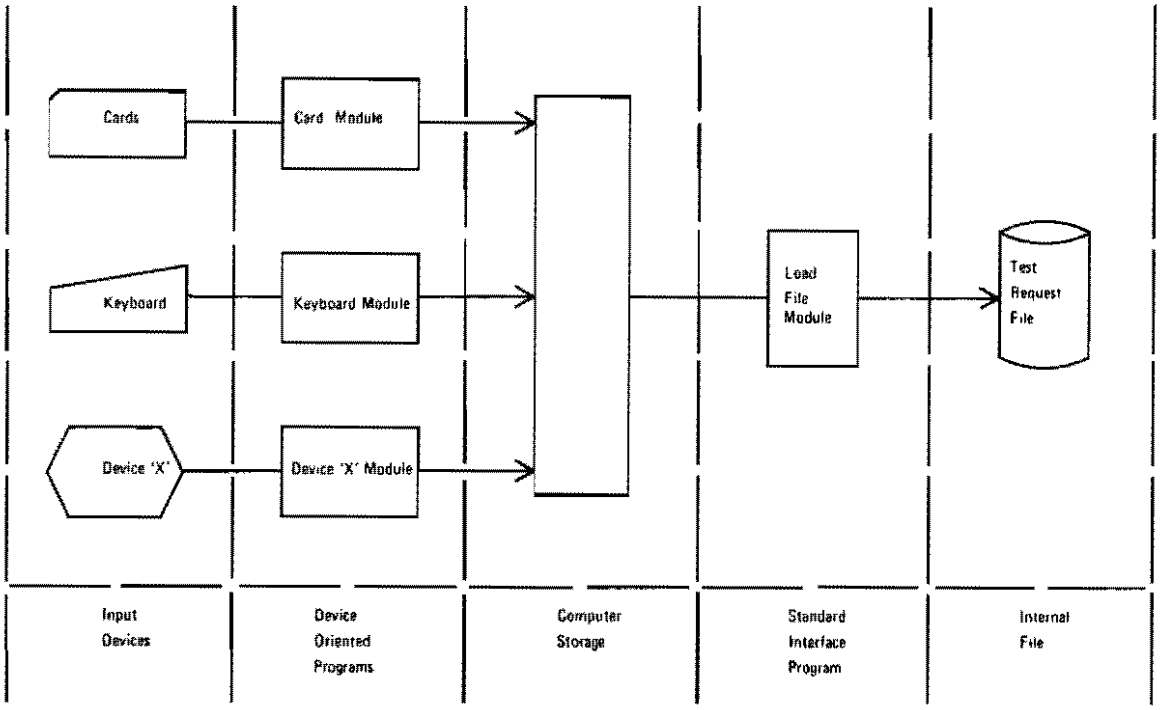

Figure 3. Entry of test request

Development of Master Log: The key file around which the total system revolves is the master log file. This file contains an entry for each test requested on each patient and reflects the status of that test as it progresses through the cycle. This file is created by matching the entries in the test request file with the pertinent entries in a patient ID file and a clinical lab master file as indicated in Figure 4.

All information in the test request file becomes a part of the master log file. In addition, the patient ID number is used to access the patient ID file for additional information such as name, ward, room, bed, birth date, sex, race, etc., which is incorporated into the master log file. (The patient ID file is essentially a census file which is updated by admissions, discharges, transfers, etc.) Next, the test code is used to access the clinical lab master file. This file is organized by test and contains complete collection information, normal test limits, and work station procedures information. This data is also transfered to the master log file. It is at this time that accession numbers are assigned. The master log can now be published either as a unit or subdivided according to the various labs or sub-labs.

Generation of Collection Schedule: Each entry in the master log file carries an indicator specifying whether or not that specimen has been collected. The next step is to process the master log file and generate collection schedules for those specimens requiring collection. These schedules are ordered by patient location and contain the accession numbers to be assigned to each specimen.

Verification of Collection Process: After the collection process has been completed, it is necessary to verify that the specimens are available. Essentially this step involves

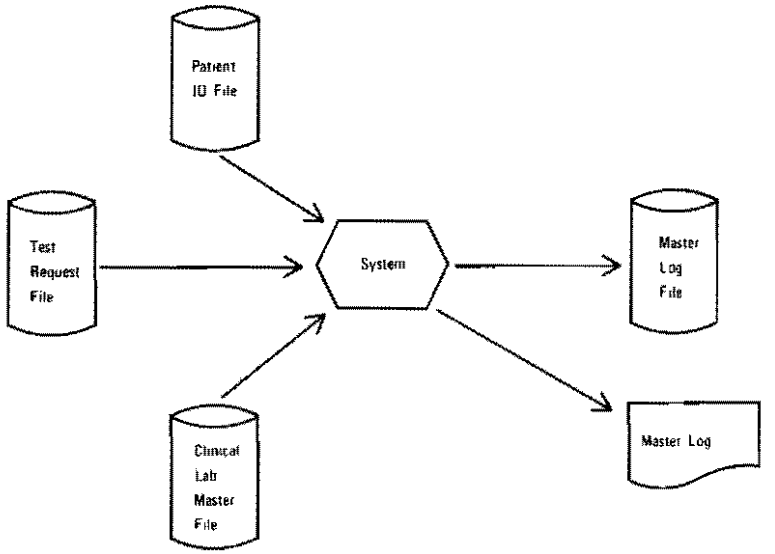

Figure 4. Development of master log

notifying the system of those items not collected so that followup action can be taken and work lists will be generated for only those items actually in the laboratory.

Generation of Work Lists: The next phase is to generate the work lists to be used in performing the tests. This is accomplished by again using the master log file, this time in conjunction with a procedures file as shown in Figure 5. The procedure file, as in the Clinical Laboratory Data Acquisition System, contains an entry for each laboratory procedure which might be requested. It identifies the work station with which that procedure is associated and itemizes the detailed requirements for the work list associated with that procedure. The output of this step is a printed work list for a given work station listing in correct sequence all calibration standards, unknowns by accession number, drift standards, etc. for that batch of tests. Copies of these work lists are uniquely numbered and stored internally as work lists files. It is these files that will be utilized in the reporting of results to the system.

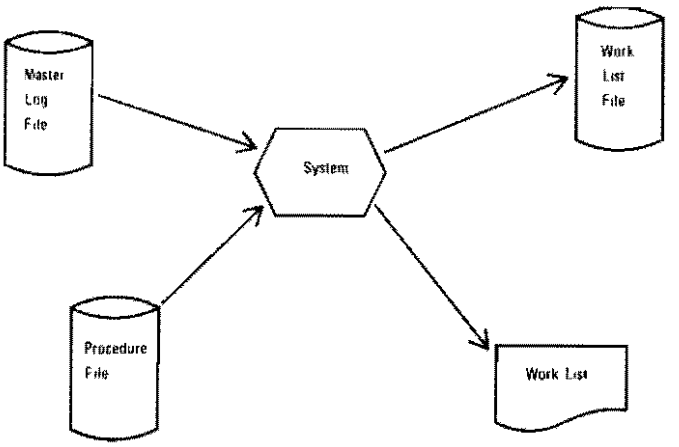

Figure 5. Generation of work list

Entry of Test Results: From a data processing viewpoint the procedures utilized in the performance of the test can be divided into two categories: (1) those where the test results are obtained online, i.e., from the Clinical Laboratory Data Acquisition System, and (2) those where the results are recorded in some form for later batch entry into the system. The functioning of the Clinical Laboratory Data Acquisition System has been described earlier, hence, only the second case will be discussed here.

In the manual procedures, the technologist accumulates the results for a work list recording the values either on the printed work list or on cards prepared for that purpose. When the work list has been completed these values are then entered into the system and filed in the appropriate work list file. Thus, as each work list is completed in the lab, the appropriate work list file reflects those results.

Verification of Test Results: The work list files now contain the test results with one major assumption — that the work was performed in the sequence indicated on the work list. Quite often this is not the case so the next step is to print out a quality control report with the reported results. Means and standard deviations can be reported at this time. This list is analyzed and the necessary changes entered into the system. These changes may reflect deletions, additions, interchanges, etc. When satisfied that the results are acceptable, the system is notified and the results are then transfered into the master log file and are ready for reporting back to the ward.

Reporting of Test Results: Two levels of reporting can be used to transmit the results of the testing process back to the wards. The first, which should be considered an interim report, is called a ward summary report. It is prepared for each ward showing for each patient in that ward all tests requested and the results of those completed at that point in time. The master log file, which is being updated continually throughout the day as results are reported in, provides the necessary information. The ward summary report is published at scheduled intervals and is to be retained at the nurses' station for reference. It is not entered into the patient's chart.

The second level, the patient summary report, is the document that becomes part of the patient's medical record. It contains the results of all tests requested on a patient over a specified period of time, usually a week. The results are grouped by test and printed in the chronological order in which they were requested. This report is generated at the close of the day's operation and is placed in the patient's chart. The ward report summaries may be discarded at that time. The information for this report is obtained by merging the completed entries in the master log file into a patient history file which contains all test results from previous days.

At the same time that the patient summary reports are generated, the master log file is also reviewed to determine those tests still outstanding. These are then printed out for followup. They may either be canceled at this time or reentered into the system for processing in the next work cycle.

Inquiry Response: One major type of inquiry, determining the status of a stat, should be expedited since stats are so identified in the system and cause a notice to be generated whenever they are completed. Other inquiries can be satisfied by immediate reference to the master log file which contains the status of all test requests.

Production of Statistical Information: Quite often overlooked in the design of a day-to-day laboratory information system is the fact that various types of statistical information are required for effective management of the laboratory. Various workload analyses, financial

analyses, and quality control functions must be performed. In this instance, this type of information is available as a byproduct of the normal processing cycle. The master log file entries establish relationships between all the pertinent parameters such as patient, test, result, work station, technologist, etc. This same information can also be made available for educational and research projects.

In summary then, a laboratory information system might be viewed as in Figure 6. Those elements within the enclosure represent the data flow as manipulated by the data processing system while those around the periphery depict the basic forms of communication that exist between the system and laboratory personnel.

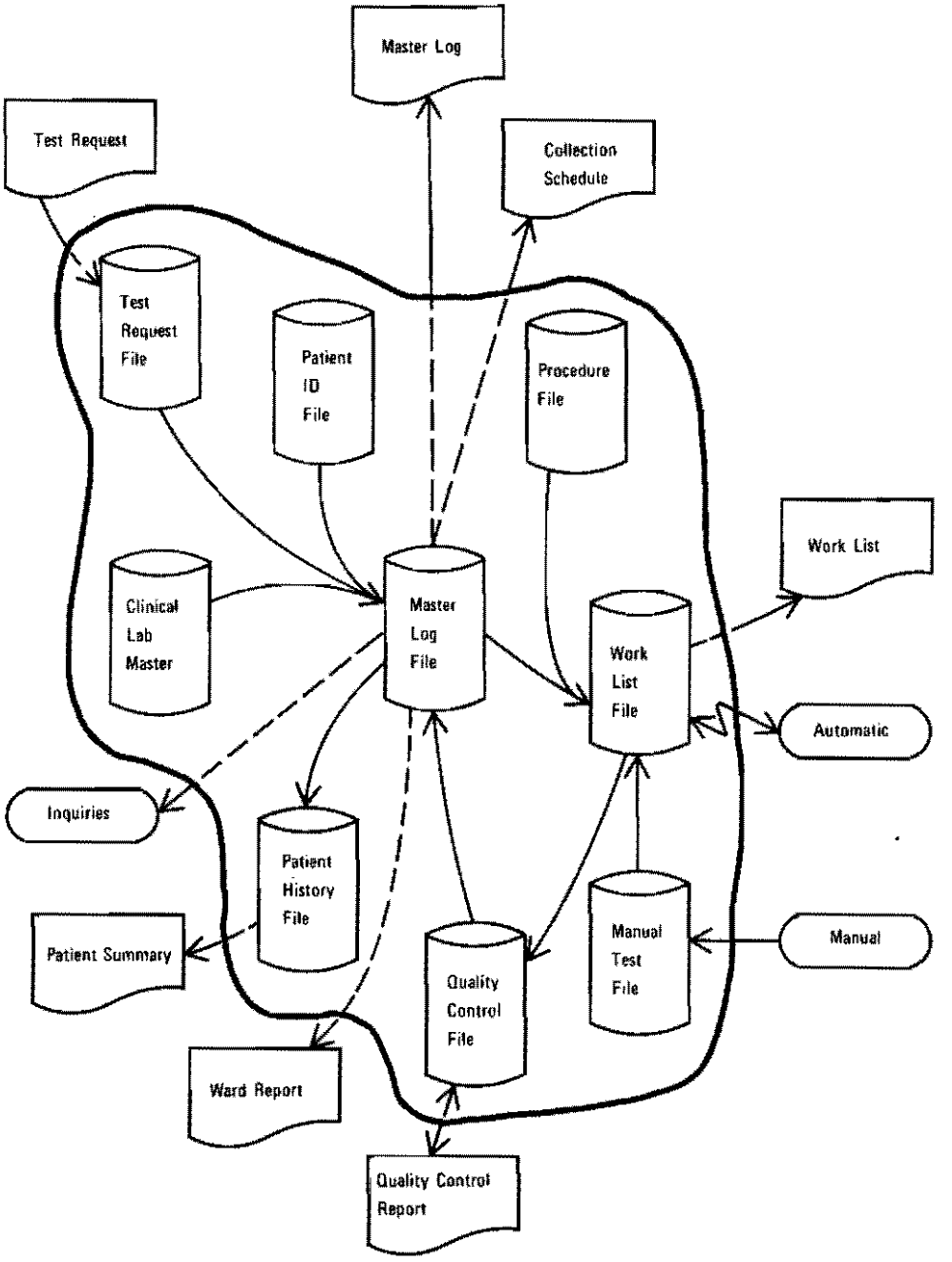

Figure 6. Laboratory information system