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## Inspections, Compliance, Enforcement, and Criminal Investigations

### The Computer in FDA Regulated Industries

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#### ITG SUBJECT: THE COMPUTER IN FDA REGULATED INDUSTRIES

This ITG is the first of a series of ITGs intended to aid the Investigator in understanding computerized operations. The approach will be a simplified explanation of the basic principles of the computer with later ITG issues covering such areas as programming and details of computer operation and specific applications.

Computerized operations are now common in FDA regulated food, drug and medical device firms. Small "mini-computer" systems are being used, sometimes in conjunction with larger computers, to control batching operations, maintain formula files and inventories, monitor process equipment, check equipment calibration, etc. The medical device industry is presently utilizing automatic test sets controlled by computers. In this application the computer is relied upon to make the decision as to whether a particular test parameter is within a specific tolerance. The operator does not see the values of the parameters measured, but merely receives a green or red light indicating a GO-NO-GO situation. Products are accepted or rejected on this basis. In order to evaluate and/or report the adequacy of similar computer controlled processes or tests, the basics of computer construction and operation must be understood.

A computer is a machine and like all other machines is normally used because it performs specific tasks with greater accuracy and more efficiency than people. Computers accomplish this by having the capacity to receive, retain and give up large volumes of data and process it in a very short time. An understanding of computer operation, and the ability to use a computer, does not require a detailed knowledge of either electronics or the physical hardware construction. An overall view of the computer organization with emphasis on function is sufficient.

There are basically two types of computers, analog and digital. The analog computer does not compute directly with numbers. It accepts electrical signals of varying magnitude (analog signals) which in practical use are analogous to represent some continuous physical magnitude such as pressure, temperature, etc. Analog computers are sometimes used for scientific, engineering and process-control purposes. In the majority of industry applications used today, analog values are converted to digital form by an analog-to-digital converter and processed by digital computers.

The digital computer is the general use computer used for manipulating symbolic information. In most applications the symbols manipulated are numbers and the operations performed on the symbols are the standard arithmetical operations. Complex problem solving is achieved by basic operations of addition, subtraction, multiplication and division.

A digital computer is designed to accept and store instructions (program), accept information (data) and process the data as specified in the program and display the results of the processing in a selected manner. Instructions and data are in coded form the computer is designed to accept. The computer performs automatically and in sequence according to the program; i.e., add, write, store, stop, etc.

The computer is a collection of inter-connected electro-mechanical devices (hardware) directed by a central control unit. The central control unit is the controlling device that supervises the sequence of activities that take place in a

parts of the computer. Classically, the hardware consists of the mainframe (computer) for computation, storage and control, and peripheral devices (input-output devices) for entering raw data and printing or displaying the output. Input data may be entered into the computer by teletypewriters, magnetic tape, punched tape, card readers, etc. Output may be displayed in the form of a hardcopy printout, magnetic tape, cathode ray tube (CRT), etc. The two units of input and output are often joined and referred to as input/output or simply I/O. A computer terminal with a CRT display is an example of a combined Input/Output device.

Equally important as hardware in the effective use of the digital computer is the software. The numerous written programs and/or routines that dictate the process sequence the computer will follow are called software. A computer can be programmed to do almost any problem that can be "defined". Defined means that the solution of a problem must be reduced to a series of steps that can be written as a series of computer instructions. In other words, the individual steps of the problem must be set up, including the desired level of accuracy, prior to the computer processing and solving the problem. The computer must be directed or commanded by a precisely stated set of commands or program. Until a program is prepared and stored in the computer memory, the computer knows absolutely nothing, not even how to receive input data. The accuracy and validation of the program is one of the most important aspects of computer control.

Physical quantities are especially adaptive to binary digital techniques because most physical quantities can be expressed as two states: switches are on or off, a quantity level is above or below a set value, holes in cards are punched or not punched, electrical voltage or current is positive or negative or above or below a preset value. For such applications as process control, the digital computer makes decisions by comparing input data to a predetermined value. The computer takes a course of action dependent on whether the input data is greater than, equal to, or less than the predetermined value. The predetermined value and course of action the computer follows is in the form of a program stored in the computer memory. So, actually the computer does not make decisions, but merely follows written program instructions. A printout or display of the actual values measured may be included as a part of the program. Verification of proper computer operation may be accomplished in this example by applying known inputs, greater, equal to and less than the predetermined value and subsequently reviewing the results.

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U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
Ph. 1-888-INFO-FDA (1-888-463-6332)

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