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## Inspections, Compliance, Enforcement, and Criminal Investigations

### The Computer in FDA Regulated Industries - Part II Computer Hardware

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#### **ITG SUBJECT: THE COMPUTER IN FDA REGULATED INDUSTRIES - PART II COMPUTER HARDWARE**

This is the second of a series of ITGs dealing with computers and computer operations in FDA regulated industries. This ITG is written to familiarize investigators with digital computer hardware and its integral relationship in a computer system. As mentioned in ITG 23, there are two basic types of computers: analog and digital; while a third type called a hybrid computer employs techniques of both the analog and digital computers.

Equipment used in digital computer systems is usually referred to as the "hardware". The digital computer is comprised of three basic hardware components: Input, Output, and Central Processing Unit (CPU, i.e. Mainframe). Devices used for Input and Output are occasionally referred to as "peripheral equipment".

The Input component of most digital computers consists of a "reader". This reader is a device which translates external information (usually on a punched card) into electrical pulses which the computer can understand. Other Input data sources used are punched tapes, magnetic tapes, Optical Character Recognition (OCR) devices (which allow the reading of special alph-numeric characters by a light sensor for input), light pens, and microfilm. A light pen is a light detector shaped like a pencil which is used to take data directly from a Cathode Ray Tube (CRT) screen by detecting changes in light levels (light modulation), allowing for instant data changes. A Cathode Ray Tube screen is similar to a television screen and can be used to display both alphanumeric and graphic information.

The reader may be located in the same room as the computer or thousands of miles away. When a reader is not located in the computer room, it is referred to as a "remote" reader while the reader in the computer room is called a "local" reader. All FDA district offices are equipped with remote readers. Highly sophisticated computer operations using one or more remote readers can be found in the large food, drug, and device firms. These remote readers may transmit incoming raw materials data to update materials inventory maintained by a main computer.

The printer, which provides a hard copy printout, is a common Output component of the computer system. There are local printers and remote printers. Printer speeds were once measured in characters per minute and progressed to speeds measured in lines per minute. Recent innovations, such as laser Output devices, print at rates measured in pages per minute.

The CRT previously mentioned is another Output device which can be used to display both alphanumeric and graphic information. The CRT display may be used in production areas as a quick reference for locating a part number in a list of materials, quantity of raw materials on hand, etc. Other Output devices include interactive terminals, plotters, audio devices, and magnetic tape. When magnetic tapes are used as an output medium, the data may be stored for later use. At a later date, reports may be made from data stored on the tape to provide plant activity information. It is important to note that when tapes are used, a back-up copy should be provided. A back-up is a duplicate copy of the master and is used, for example, when water pipes burst and shower the main tape room ruining the master tapes. Proposed GMPs for device manufacturers would require "a duplicate copy of computerized information... and stored in a separate geographical location."

The third basic computer hardware component is the Central Processing Unit (CPU). Simply stated, the CPU consists of "memory", "arithmetic and logic", and "control" units. In the past, most large computer memories consisted of magnetic cores or tiny rings (few hundredths of an inch in diameter) of magnetic material. Programmers often refer to the computer memory as "...the core..." The computer memory operates in a binary mode, i.e., a light bulb is ON or OFF, voltage potentials are PRESENT or ABSENT, or the core is magnetized in one direction or in an opposite direction. Each condition represents a "bit" of information. The memory contains operating instructions for executing stored programs and may contain data from the stored programs to act upon. The instructions are executed by the control unit to operate on data or to modify instructions to fit new conditions that arise during processing.

Magnetic cores are arranged in planes, and each plane is stacked in an array. Cores may be arranged with a density as high as 6500 cores per square inch. In the computer room, the magnetic core memory is normally enclosed in a configuration similar to filing cabinets.

Other types of memories may be constructed of metal film, called "Thin Film Memory". A metal dot on a thin glass plate replaces the core. Recently, microelectronics technology has created the Metal Oxide Semiconductor (MOS) storage or "chip" storage. Thousands of bits of information may be stored on each tiny chip which may be no more than a few thousandths of an inch in area. MOS technology is commonly used in hand-held calculators. The latest advances in memory deal with magnetic "bubbles" which are tiny magnetized areas in a thin film of material such as garnet crystal. These areas can be moved about electronically to store and access data. A bubble package about half the size of a pack of cigarettes can be used to store up to 280,000 bits of information.

The computer "arithmetic and logic" section is as its name implies. The basic operations are addition, subtraction, multiplication, division and certain logic operations. Arithmetic operations are expressed in speeds ranging from milliseconds (.001 of a second) to nanoseconds (.000000001 seconds).

The computer "control" section interprets or decodes instructions from memory and signals or initiates action in, or operation of, other system components, such as the readers, printers, or the arithmetic and logic.

Numerous computer applications are found in medical device instrumentation. For example, computers can be used in non-invasive techniques for patient ECG monitoring. One procedure uses a pressure cuff which monitors sounds of blood flowing through blood vessels under the cuff and converts the sound to "digital" signals. To change the sound signal into a digital signal, an Analog to Digital (A/D) converter is used. The converter breaks a continuous signal into small discrete signals, readable by the computer. Using the converter, a continuous signal is said to be "digitized". The information can then be processed by the computer and displayed on a CRT. Electrical impedance of the thorax and patient temperature are other patient parameters which can be monitored by the computer.

Many food, drug and cosmetic firms use computers for inventory control and financial operations. Drug firms may use the computer to locate a specific raw material (according to vendor's lot number, raw material storage bin location, etc.) to be used in production, basing its selection on previously submitted data (potency, arrival date, expiration date, etc.). Printouts provided to production management contain a computer-determined batch number with a list of corresponding raw materials, raw material lot numbers, vendor codes and quantities of each raw materials to be used.

Another method allows use of the computer to continually update the system during production. A series of pre-punched cards for raw materials storage, manufacturing, quality control, and distribution areas, containing only preliminary information (e.g., product name and batch number), are packaged and sent to the first area of production....raw materials storage. Here the raw materials storage card is completed (e.g., vendor's code, vendor's lot number, raw materials code, quantity) and sent to Automatic Data Processing (ADP) for further keypunching and later for system's updating. The remainder of the package is in turn completed during various phases of production and then inputted into the system.

These methods can easily allow firms to search their computer files in event of a recall. For example, a raw material found to be substandard could be traced to final product lot numbers incorporating its use. Conversely, if a final product is substandard, raw materials and their lot numbers could be retrieved from the computer. Subsequently, raw materials and their lot numbers could be retested.

The main computer, with this accumulated data, can also perform a trend analysis of rejected and accepted

components, thereby determining acceptability of a supplier.

Proposed GMPs for device manufacturers would require manufacturers that use automated quality control measurement equipment to (1) determine the validity of the automated test and determine whether the method will produce results directly applicable to the device being tested; (2) insure that QC test devices are compatible with each other; (3) verify computer programs used and to document the testing of the program, and (4) have a routine calibration program with appropriate records.

#### References:

1. Biomedical Instrumentation, 1973, WEISS, Chilton Book Co.
2. Hardware and Software, 1974, Civil Service Commission

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