Inspections, Compliance, Enforcement, and Criminal Investigations

Reliability of Manufactured Products

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DEPT. OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION *ORA/ORO/DEIO/IB*

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ITG SUBJECT: RELIABILITY OF MANUFACTURED PRODUCTS

During World War II, a Navy survey revealed that its electronics equipment was not operative 30% of the time. Similar experience by the other services made it evident that reliability must be designed into their field equipment. The early Vanguard satellite had a probability of mission success of only 64%. With each launch costing $6 million, it was obvious that there is financial importance to reliability. With the Apollo Man-On-The-Moon project, reliability became a central consideration in the design, for humanitarian considerations as well as for national prestige. Now in the area of medical devices with their increasing sophistication and reliance on electronics, material science, and other space age technologies, the considerations of reliability are part of FDA's concerns in reference to their safety and effectiveness.

The reliability of a manufactured product is defined as the probability that it will perform satisfactorily for a specified period of time under stated use conditions. "Probability" means, in the mathematical sense, a number between 0 and 1 (with 1 representing 100%) indicating the likelihood of occurrence.

Not performing satisfactorily implies failure of one or more components of the product. In all manufactured products there is a measure of reliability called "failure rate." This can be the number of malfunctions occurring per unit time for continuously operating products or the number of malfunctions after a number of uses for on-off products. A concept related to failure rate (its mathematical inverse) is often used to more clearly specify or measure reliability. This concept is called the "mean time between failures" (MTBF). This is the average time that the product will operate before a failure will occur. Do not confuse MIBF with life of an item. MIBF does not include or represent any wear-out phenomena, only random failures.

The failure rate varies in a predictable manner over the life of the product and can be considered as occurring in three different periods of the life of the product. This variation forms what has been called a "bath-tub" curve because of its shape. This curve is illustrated in Figure 1.[4]

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FIGURE 1 Variation in the failure rate of a manufactured product throughout its "life."[6]

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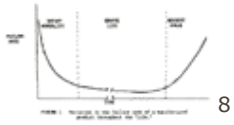

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During the first period, so called "infant mortality" failures are usually initially high and decrease rapidly. The causes o these failures are such things as weak components, manufacturing flaws, etc. A "burn-in" period is often necessary so that these early failures do not occur during the use of the product. Burn-in is a screening technique and has been described in a previous ITG (#19).

The second period is the useful life of the product. During this period the failure rate is relatively constant and failures are caused mainly by stress. Depending on the make-up of the product in question, stress can be temperature, voltage, torque, humidity, etc. Obviously to be considered reliable some products must not fail at all during their useful life. A pacemaker, for example, is expected to perform without failure during its useful life. Essentially this means designing and constructing the product such that its mean time between failures (MTBF) is much greater than its expected time of use. Statisticians have developed tables which indicate the level of confidence one can have that no failures will occur during a product's use.

The third period in the life of the product is the wearout stage. The failure rate again climbs rapidly and is caused by the general physical and/or chemical deterioration with time or use of one or more of the principal components, or the general degradation of them all, such that the functioning of the product is unacceptable, e.g., my old car.

The reliability of a product can be considered to be an important end product of the quality control considerations of its production. An investigator during a GMP inspection should have the product's reliability in mind. (Please note that this ITG does not apply to in vitro diagnostic nor single use devices.)

The following considerations with respect to reliability are important in a manufacturing operation:

Master Record

The designer's overall plan for the product is contained in the Master Record. This includes the design, product specifications, manufacturing plans, procedures for manufacture and testing, quality assurance requirements and labeling.

The actual use reliability of a product can be no better than its potential reliability level. Potential reliability is the built-in MTBF that can be expected from the finished product by virtue of these design plans. This reliability, may be adequate, but it can easily become less so by poor manufacturing practices or use.

Control of Components

Most electronic products contain many components. In a reliability sense, components can be treated as fractions o the product and in most cases links in a chain. The failure rate of a product is equal to the sum of the failure rates o its components. The more components used in a product, the more reliable each one must be. Therefore, for a reliable product, defective, weak or out of specification components must be weeded out. This is done by functional testing, stress testing and by burn-in, i.e. time testing till past the infant mortality period. The adequacy of the testing procedures and the conformance to them, personnel training, and the equipment used all affect reliability.

Equipment

Measuring equipment used in component or product testing, which is not producing accurate data, can result in poor reliability by permitting defective components to be used in the product, causing incorrect adjustments of the product or permitting unfit products to be shipped. The design, construction, maintenance, adjustment, calibration, and use of measuring and of manufacturing equipment are factors which impact on the reliability of the product.

Manufacturing materials used with the manufacturing equipment, if not removed, can in time lead to corrosion and electrical or mechanical malfunctioning. An ITG series (#26, 27, and 28) has been written on this subject.

Manufacturing Process

The actual construction of the product should be observed for conformance to procedures, as well as for the workmanship and care of the workers. Reprocessed components or products should be reviewed so that the reason for the reprocessing is known and corrected and no other factors are degraded below acceptable specifications by the reprocessing.

Product Evaluation

The product should be tested for all possible variations in its use, at least in its final form. Any consistent deviation from specifications should be investigated to determine what is wrong and how it should be corrected.

Failure Investigation

Without failure information the manufacturer does not know what defects his product has or what caused them. All failures in the factory or the field should be analyzed to determine if the product failed because of problems with design, components, manufacturing, testing, shipping, installation, maintenance, or use. A failure reporting and analysis system is vital to the manufacturer's continued control of his operation as well the maintenance or improvement of the reliability of the product. The system for the handling of rejects by quality control because of workmanship or testing is an example of the manufacturer's failure reporting scheme during manufacturing. The complaint files or other feedback from the field, such as is found in failure logs, is a failure reporting system for products in use.

A manufacturer, who recognizes the value of reliability, will have performed an analysis of his product which will indicate the effect on the product of the failure of each and every component. This is known as Failure Effect Evaluation.

Use

Even if a product is reliable when it leaves the manufacturer, what happens to it after that can reduce or destroy its reliability. A principal control a manufacturer has (if he doesn't install the product himself) on these items is the instructions for use which are part of the labeling. It is essential that these instructions be clear and include information on installation, maintenance, storage and any special conditions of the product's use.

[Phone Cardiovascular Devices CDRH]

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