FDA REGULATIONS ON EMC

BACKGROUND

Since May 28, 1976, the Food & Drug Administration has been granted new authority to regulate the sale and manufacture of medical devices. The Food, Drug, and Cosmetic Act, as amended in 1976, provides three levels of regulatory control. Regulatory Class I applies to all medical devices and it involves general controls such as registration, record-keeping, and quality-control procedures. Regulatory Class II applies to those devices for which the general controls are not adequate to provide reasonable assurance of safety and effectiveness. Devices in Class II must comply with Performance Standards promulgated by the FDA. Class III devices are those for which even Performance Standards are deemed insufficient to control the hazards. Manufacturers of these devices must perform testing and seek premarket approval from the FDA.

Most FDA Performance Standards will address specific medical devices or generic classes of medical devices. However, the FDA anticipates that there will be many types of requirements which will be common to many devices and that a more effective approach would be to develop baseline standards to cover the requirements. Four such standards that the FDA has identified to date will deal with electrical risk currents, general electrical and mechanical safety, environmental performance (temperature, humidity, shock, and vibration), and electromagnetic compatibility.

When completed, these baseline standards will be promulgated as recommended guidelines; compliance will be voluntary. In the future, however, as individual medical devices are scrutinized by the FDA, these baseline standards may become mandatory for devices exhibiting problems or having potential problems in these areas.

On October 1, 1979, the FDA issued the EMC Standard. Its number is MDS-201-0004, and it is titled "Electromagnetic Compatibility Standard for Medical Devices". Copies may be obtained by writing to the:

Division of General Medical Device Standards
HFK-310
Bureau of Medical Devices
8757 Georgia Ave.
Silver Spring, MD 20910

The Technical basis for this standard was developed under FDA Contract 223-74-5246 (McDonnell Douglas Astronautics Company-East). The requirements are based upon data taken during a hospital and emergency vehicle survey program, a review of the data gathered during previous hospital measurements, EMC tests on medical devices, established EMC test methods, and discussions in public review meetings. During the eight-month survey program, tests were performed in ten hospitals and two emergency vehicles. EMC tests were performed on selected medical devices as a means of determining the practicability of the requirements and test methods contained in the standard. The EMC test methods specified in this standard are based upon established test procedures. Whenever possible, the test methods developed for military EMC Standards have been selected. The established test methods were selected in an attempt to minimize the impact of this standard upon the medical device manufacturers and the EMC test community. Most EMC test facilities should be capable of performing the tests outlined in this standard without having to purchase or rent additional test equipment.

LABELING

Because conformance to this document is voluntary (except when referenced in a regulation), manufacturers may utilize or amend the requirements and test methods of this standard in any manner which is judged appropriate for the device. However, a claim by a manufacturer that a product conforms to this standard is inherently deceptive unless certain specific additional information is supplied.

a. Unless stated otherwise, it shall be assumed that the device conforms to all of the requirements of this standard. If a manufacturer imposes only some of the requirements on his product, he must describe, in his instruction manual, which requirements are applicable and describe any deviations.

b. There are many variables in a test setup which are unique to the device and which may affect the test results. For example, a defibrillator may be far more susceptible with the paddle cables spread apart than with the cables tightly twisted together. If a defibrillator manufacturer feels that twisted cables are appropriate during a susceptibility test, it is essential that it be stated in the instruction manual.

c. For the purposes of this discussion, there are two types of malfunctions which may be manifested during susceptibility testing:
   - performance characteristics which do not meet the manufacturer's specified tolerances (e.g. - accuracy of ECG chart speed)
   - performance characteristics which do not meet implied levels of performance (e.g. - speed of raising or lowering of an electrically operated patient bed)

In the first example, it is expected that an ECG manufacturer will disclose the chart speed accuracy which the ECG will meet during susceptibility testing if it doesn't meet the normal accuracy specification.

In the second example, complete inoperability of the bed or an intermittant jerking motion is obviously a failure to meet implied levels of performance. However, if the jerking is not severe, it is conceivable that the manufacturer may consider the malfunction to be insignificant. In such situations, the manufacturer would be expected to disclose the existence of the malfunction and the conditions under which it occurs and to state that the malfunction is considered insignificant. The requirement to describe these insignificant malfucntions is imposed so that the potential device user may evaluate the impact of these malfunctions upon his particular circumstances.

EMISSIONS

The primary purpose of this standard is to establish a reasonable level of assurance that medical devices will operate safely and effectively in the electromagnetic environments expected in use. However, hardening medical devices against EMI is a

losing strategy unless some attempt is made to limit the steadily growing ambient. Therefore, emission limits were established, the desired effect being to halt the growing ambient at present levels. Since this standard is explicity intended for medical devices, it is obvious that many of the major contributors to the electromagnetic environment will remain uncontrolled. However, it is hoped that this standard will serve notice to users that electromagnetic compatibility should be considered when purchasing nonmedical equipment. Any such equipment which emits electromagnetic energy at levels in excess of the limits presented in this standard is a potential source of interference for medical devices, even if those medical devices conform to the susceptibility requirements of this standard.

SUSCEPTIBILITY

To insure that medical devices perform satisfactorily in their intended environment, it is necessary to establish device susceptibility limits. These susceptibility signal limits reflect the maximum electromagnetic interference signal levels that would be found in 99% of all medical facilities.

Degradation Criteria — One of the most troublesome problems encountered in the development of this standard concerned degradation criteria or pass/fail criteria during susceptibility testing. Without a specific device and application in mind, it is not possible to generalize as to what kinds of performance degradation should be considered unacceptable. For example, if a patient monitoring console incorporates a digital clock (time-of-day) for the convenience of the nurses, it might be unfair to say that the patient monitor has failed the susceptibility requirements if the clock malfunctions. On the other hand, if that clock is depended upon to automatically transmit patient status at regular intervals, one might say that a malfunctioning clock is reason for failing the patient monitor.

During the public reviews of early drafts, comments were made to the effect that this standard should specify degradation criteria for every medical device on the market. This suggestion is clearly not within the scope of a baseline standard. Therefore, it was decided to adopt a labeling approach which allows manufacturers to determine those malfunctions they deem insignificant and requires manufacturers to list those insignificant malfunctions in their device literature, thereby allowing users to judge the insignificance (or significance) of those malfunctions in the users' particular applications.

Within the meaning of "insignificant malfunction" are included those primary device characteristics, the performance of which may degrade beyond the manufacturer's specification but not to the extent that it represents a hazard. For example, if the manufacturer's normal specification for noise on an electrocardiograph is 50 μV, the manufacturer may feel that 100 μV noise is an acceptable degradation of performance when exposed to susceptibility testing. Therefore, that manufacturer would be required by this standard to state in the labeling that the noise specification is degraded to 100 μV under susceptibility conditions and that this is considered an insignificant malfunction. If this labeling approach is found to be inadequate for specific devices, detailed susceptibility degradation criteria may be included in the individual medical device performance standards.

In early drafts of this standard, a distinction was made between critical and noncritical parameters. Critical parameters of a device were those that could result in immediate jeopardy to the patient. When performing susceptibility tests, the test levels were significantly higher for critical parameters. This distinction was eliminated for several reasons. First, the critical/noncritical distinction was being confused with insignificant malfunctions, even after several lengthy discussions at two public review meetings. Second, it was difficult to identify device parameters that were, and always would be, noncritical independent of application. With the advent of computer aided diagnosis, many parameters that ordinarily could be considered noncritical (such as patient temperature) assume a more significant role. Third, since the susceptibility levels for noncritical parameters reflected the environment in 99% of all medical facilities, the higher susceptibility levels for critical parameters reflected levels that would be found in less than 1% of medical facilities.

Modulation

Most electronic devices are more susceptible to modulated interference signals than to unmodulated signals. The most susceptible case exists when the modulating signal is similar to a signal generated within the electronic device or to a signal the device is designed to monitor. To ensure that medical devices do not experience EMI problems, the susceptibility signal must be modulated by a sine wave within the physiological passband of the device or, for those devices that do not have a physiological passband, a 40-Hz sine wave.

In early drafts of the standard, the susceptibility signal was modulated by a "critical signal" where a "critical signal" was defined as the signal to which a device was most susceptible. This was an open-ended requirement and, theoretically, a manufacturer would have had to test at a multitude of modulation frequencies to determine the most susceptible frequency. By limiting the range of the modulating signal to a frequency within the physiological passband of the device, a limitation is placed upon the modulation signal frequency.

The modulation requirements contained in early drafts addressed the susceptibility problems peculiar to digital devices. Interference signals having characteristics similar to the clock signal can cause false data transfer within the device or from one device to another. Since greater reliance is being placed upon computer-controlled data gathering and diagnosis, it was felt necessary to ensure that the components in these systems were immune to EMI. Therefore, the modulation requirements included square-wave modulation at a prf equal to the clock frequency of the test sample. This approach ran into difficulty because of the unavailability of oscillators and modulators below 1 GHz which could be squarewave, or even pulse-modulated at high prf. The omission of square-wave modulation is somewhat justified by the infrequent occurrance of pulse-modulated signals in the electromagnetic environment below 1 GHz. Manufacturers or users of devices which are used near radar transmitters (>1 GH_Z) may derive some benefit from radiated susceptibility tests utilizing pulse-modulation above 500 MHz.

Magnetic-field susceptibility signals need not be amplitude-modulated. Within medical facilities, the magnetic-field interference is generated by high current flowing through the 60-Hz power lines. It is not likely that the ac power in the hospitals will be amplitude modulated by a coherent signal.