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**COMMENTS TO THE PROPOSED RULE:**

**Medical Devices; Refurbishers, Servicers, and "As Is" Remarketers of Medical  
Devices; Review and Revision of Compliance Policy Guides and Regulatory  
Requirements; Request for Comments and Information**

**DOCKET NO. 97N-0477**

**Presented to:**

**Dockets Management Branch  
Food and Drug Administration**

**by:**

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### Qualifications of Author

I have been employed as a medical device servicing person in a community hospital in Minneapolis, Minnesota for 18 years. I am currently enrolled in a baccalaureate degree program at the University of Minnesota in **Health Technology Administration**. I have written hundreds of technical testing procedures, and have read and followed hundreds of manufacturers testing procedures. I am fully conversant with national and international standards in calibration and metrology, as well as Joint Commission on Accreditation of Hospital Organizations (JCAHO) standards.

### Background Information

Servicers of medical equipment routinely attempt to assure that devices meet manufacturer's published specifications during the post-marketing and use phase of their life-cycle. Unfortunately, certain specifications are not routinely published that would allow safe, effective, and efficient calibration assurance practices.

The two types of failure that occur with medical equipment are: **1) random**; and, **2) failure associated with parameters that fail to meet specifications due do a time-related function (sometimes known as “drift”, “loss of calibration”, or “uncertainty growth”)**.

Currently, hospitals, third-party service organizations, original equipment manufacturers, and accreditation agencies such JCAHO lack *consistent* policies regarding the frequency of routine testing of medical devices. **Organizations are left to establish their own policies, frequently without regard to accepted metrological practices. This results in heuristic systems that are inconsistent, often ineffective, and usually inefficient.** Consistent methods need to be employed, and consistent specifications should be made available to all users and servicers of equipment.

**All calibration systems that assure the integrity of medical measurements should employ methods similar to those set forth in national and international standards such as ISO GUIDE 25, ANSI/NCSL Z540-1, NASA 5300.4, or U.S. DOD MIL-STD-45662A.** These standards require periodic intervals and methods be established to maintain acceptable accuracy and measurement reliability. Measurement reliability is defined as: *the probability that the equipment under test and the measurement standard will remain in-tolerance throughout the established interval.* This kind of system is designed to be both effective and efficient at addressing the needs of uncertainty growth.

#### **Post Market Safety and Effectiveness**

The majority of Class 2 and Class 3 medical devices either make a measurement of a clinical parameter or deliver some kind of energy, drug, or bio-material to a patient. Thus the intrinsic safety and effectiveness of the device is compromised in the post-market use period if the device does not meet manufacturer's specifications or clinically acceptable specifications. If the calibration of these devices cannot be assured, then the clinical endpoints and patient benefits upon which the regulatory approval was granted cannot be assured.

The concept becomes clearer when one realizes that the effectiveness, or the use of the device under ordinary circumstances, is currently suspect due to poor or non-existent documentation, various levels of training by medical device users, servicers, and developers of the calibration and quality system, inconsistent practices in the field, and accreditation bodies that do not have expertise in metrology or calibration systems.

## Comments

**COMMENT #1:** In addition to current GMP requirements, manufacturers should be required to deliver servicing information with the delivery of the device. The information should recommend procedures and intervals based upon premarket and ongoing testing, as well as the following four statistics: **1) the parameter tolerance limits; 2) a specified period of time over which value will be contained within the tolerance limits; 3) the *probability* that parameters will be contained within the tolerance limits for the specified period of time; and 4) mean time between random failure.**

Items 1 - 3 above address uncertainty growth and gives servicers a starting point for which to establish testing intervals for necessary parameter testing. Item 4 addresses random failure, which can be used to establish maximum testing interval length.

**COMMENT #2:** All refurbishers, rebuilders, reconditioners, servicers, and remarketers should be required to employ calibration systems that meet the above mentioned national or international standards, especially on the basis of *measurement reliability*. Measurement reliability is the one standard that can provide consistency between all servicing organizations.

**COMMENT #3: :** All refurbishers, rebuilders, reconditioners, servicers, and remarketers could be required to report reliability to the original device manufacturer. Although the concept has some justification on the basis that the large amount of data collected could generate highly efficient interval analysis. However, the individual environment of use may provide enough difference in data to make the analysis invalid. Therefore, organizations should aggregate data according to the particular use environment, and create their own measurement reliability data for the safest and most effective calibration intervals.

## **Benefits**

The benefit of regulating these parameters can be demonstrated by projecting the amount of resources currently utilized in unnecessary testing, which would occur when reliability is high and testing intervals are too frequent. Conversely, when reliability is low and testing intervals are too infrequent, **the integrity of the clinical measurement system, and thus the safety, effectiveness, and quality of patient care, is jeopardized.**

Further benefit is achieved by if servicers are required to report to manufacturers, data distinguished as random or time-related, thereby uniquely identifying the kind of manufacturing adjustments or periodic maintenance needs that might be necessary.

## **Specific Examples**

In my 18 years as a medical device servicer, I have **frequently** encountered either no service information, or a **lack** of service recommendations and statistics that enable developing a proper calibration system. This occurs on all types of devices, but unfortunately, even high-risk devices such as blood warmers, ventilators, and lithotriptors are subject to these abuses. This happens too frequently, and leaves the medical device servicer to “make-up” a test procedure.

Blood warmers are an excellent example, where the thermostats can drift out of calibration if not subject to a rigorous calibration program. I have recently been presented new state-of-the-art blood warmers with no servicing information! This has also happened recently with life-sustaining ventilators!

On the other hand, many devices maintain their accuracy and reliability over long periods of time. Most microprocessor-based instruments fall into this category. The maximum testing interval in this case can relate to mean time between random failure, which is often very long. The amount of needless testing may be staggering. If all hospital based servicing departments could cut testing by 2000 hour per year, it would save approximately \$240,000,000 in needless testing alone!

Perhaps the most serious problem that post-market device servicers face is that hospital administrators and JCAHO compliance surveyors are not trained in the practice and philosophy of bench testing and measurement systems. Therefore, devices are routinely accepted for use with inadequate testing, documentation, and training, even though standards would seem to imply that these issues are considered.

The standards that I suggest be implemented and regulated would provide a consistent methodology for attacking these problems, as well as prevent ambiguities that still exist in this industry.

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