Medical Device Software Regulation: An Industry Perspective

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I. INTRODUCTION

The Health Industry Manufacturers Association (HIMA) is a national trade association representing over 700 manufacturers of medical devices, *in vitro* diagnostic products, and medical information systems. Many HIMA member companies manufacture computer-controlled medical devices, software accessories to medical devices, and stand-alone software systems that are used in a medical environment. The Association is vitally interested, therefore, in any regulatory initiative affecting these products. To this end, we have formed a Medical Software Task Force to work with the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) and other interested parties to create a reasonable regulatory framework for medical software.

HIMA commends CDRH for making this process an open one. Openness is an important feature of this dialogue, especially considering the difficulty of the undertaking and its potential impact on both technological innovation and patient care. It is clear that CDRH recognizes the complexities of medical software regulation, as acknowledged in some of the innovative proposals put forth by the Center for consideration. FDA released "discussion points" papers on this topic,[1] and these documents helped to frame the issues and provided some much needed insight into FDA's current thinking. Although an in-depth analysis of the discussion points has not been conducted, HIMA here proffers a few comments on the subject that are worth considering. The Association's Medical Software Task Force will be submitting detailed recommendations to CDRH within the next few months.[2]

II. DEFINITIONS OF TERMS

Providing clear definitions of terms is key to the process of constructing a regulatory scheme. The definitions provided by the agency in the Background Information section of its discussion points papers[3] are well thought-out, and the examples that

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[1] In preparation for the Public Workshop in September 1996, and as announced in FDA's notice of the meeting (61 Fed. Reg. 36,886 (July 15, 1996)), FDA made the following documents publicly available on August 2, 1996: 1) FDA Regulation of Medical Software (Background), 2) Classification and Risk-Based Criteria, 3) Commercial Distribution, and 4) An Alternative to Current Premarket Notification (Software Quality Audit) [hereinafter FDA Discussion Points Documents]. These documents were provided as background and topics for discussion at the workshop.

[2] HIMA's Medical Software Task Force is in the process of developing two sets of recommendations. One addresses how medical software should be classified and the type of regulatory submission that should accompany it. This will be submitted in the Spring of 1997. The second recommendation will address how and when a software quality audit could be used to replace the parts of the regulatory submission pertaining to software. This will be submitted to FDA in late 1997.

[3] FDA Discussion Points Documents, *supra* note 1, at 4-6.

accompany some of them are very helpful. In addition, participants in the process may want to consider the following suggestions.

The differences between "software accessories" and "stand-alone software" should be further clarified. As presented, some stand-alone products appear to be software accessories, even though stand-alone and accessory software are addressed in different sections in the Background Information. With this in mind, it might be helpful to evaluate first the specific function that the software is performing. If it is a stand-alone product that is an accessory, then it should be categorized in the accessory section, perhaps under a subsection devoted to stand-alone accessory software.[4] It also would be beneficial to give examples of software that perform simple calculations, general accounting, and communications functions. Further defining communications functions will be useful, because a significant number of stand-alone products will be included in this category.

HIMA agrees that the term "competent human intervention" has proved to be one of the most misunderstood aspects of the 1989 draft policy.[5] The agency is legitimately concerned that this exemption has been misapplied, and it sometimes may be difficult to administer this criterion. HIMA believes, however, that this can be a clear-cut and appropriate criterion to exempt from active regulation the large number of stand-alone software systems whose only function is to transmit test results from one location to another. Provided that these systems do not use algorithms to manipulate incoming data, they certainly can allow the opportunity for competent human intervention. Actually, such test result transmitter systems replace manual recordkeeping systems only; they do not in any way diminish or replace the caregiver's role in the decisionmaking process. HIMA recommends that FDA retain the competent human intervention criterion while providing additional clarification and examples. Also, software that performs recordkeeping functions should be exempt from regulation, with the exception of a general prohibition against adulteration and misbranding. Recordkeeping in this context means software that replaces pens, papers, and manual filing systems, but does not manipulate incoming data.

To many in the software industry the term "library function" refers to software that performs an archiving function. In light of this interpretation, HIMA recommends that FDA's definition for library function in the 1989 draft policy[6] remain the same, with the term "library function" deleted.

III. REGULATION OF BLOOD BANK SYSTEMS

With regard to medical information systems, the impact of FDA regulation is evident in the blood bank area. The Center for Biologics Evaluation and Research (CBER) is in the process of regulating blood bank software via the premarket submission process.[7] CBER's review of this software has been a long and arduous operation. As the next versions of their software become available, many companies are unwilling to

[4] HIMA has since concluded that the distinction between software accessories and stand-alone software should be eliminated because it is unnecessary and confusing. Instead, software should be regulated according to its intended use in patient diagnosis or treatment and its risk.

[5] *See* Food and Drug Admin., FDA Policy for the Regulation of Computer Products (Draft) (Nov. 13, 1989) [hereinafter FDA 1989 Draft Policy].

[6] FDA 1989 Draft Policy, *supra* note 5, at 1.

[7] *See* Div. of Blood Applications, Off. of Blood Research and Review, CBER, FDA, Draft Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software (issued Apr. 12, 1996).

submit a new version to the agency when its predecessor version has not yet received CBER clearance. This nonsubmission of upgraded software has had two major ramifications: the enhanced version is not being distributed to the users, and manufacturers are less inclined to enhance their software because many of these enhancements will have to be cleared by CBER before the software can be marketed. Experience in using software teaches that enhancements are part of the process of continuous quality improvement. If a manufacturer is not permitted to release enhancements in a timely manner, then there is room to question whether the current system of software review is in the best interests of the public health.

If we are to avoid these situations in the future, FDA policies must utilize good manufacturing practice (GMP) requirements, coupled with design controls, to ensure that blood bank systems have been adequately designed, developed, and manufactured.

IV. MEDICAL SOFTWARE

A. *Medical Software Classification*

HIMA supports the concept of a risk-based classification scheme for medical software, and requests that such a scheme contain as little ambiguity as possible. Some form of qualified medical judgement is almost always involved with patient diagnosis and treatment, and this will affect the level of risk. This situation is recognized in the criteria listed at the end of FDA's discussion points document on classification, item 2 of which addresses the time available before medical intervention is provided based on the results of the software.[8]

Related to that criterion, HIMA proposes that this workshop's participants consider another risk criterion that will address the occasions when a patient's test result almost always is evaluated by a medical professional in context with a physical examination and other test results before a diagnosis is made or treatment initiated. An example of this would be the result of a test as displayed by a laboratory information system; it would be extremely rare for a medical professional not to compare the test result to all of the other available patient information prior to treatment or diagnosis.

B. *Medical Software Distribution*

One item that HIMA's Medical Software Task Force came to agreement on immediately was that the distinction between source code and executable code will not work well in determining when a finished device exists, and thus when regulatory control must be exercised. This is because source code is sometimes sold to a user who then converts it to executable code.[9]

In lieu of this criterion, some of the workshop discussion should contemplate the linking of the regulatory control of distribution to the requirements established for classification (i.e., the intended use of the software and the level of risk that the software poses). For example, the distribution controls associated with diagnostic devices would be different than those involved with devices for disease prevention.

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[8] FDA Discussion Points Documents, *supra* note 1, at 11.

[9] "Source code" is computer instructions that must be translated into executable code via an assembler, compiler, or other translator. "Executable code" is computer instructions that can be assessed immediately by the user without the use of a translator.

C. *Medical Software Quality Audit*

HIMA supports the concept of regulating medical software by the use of GMPs, design controls, and standards, in lieu of product submissions. The Association's experience to date with blood bank systems submissions has demonstrated that that regulatory construct is not practical and does not work. GMPs with design controls are a more sensible approach.

Manufacturers already are subject to multiple inspections and audits (e.g., for the European Community (CE mark), International Organization for Standardization (ISO) compliance, Underwriters' Laboratories, the Canadian Standards Association, GMPs, and in some cases, by their customers). In many cases, the manufacturer must pay for the audit. In addition, the audit and inspections processes themselves consume company resources. Requiring another separate audit for software, which must be paid for by the manufacturer, will add another cost burden and this will be passed on to the patient. As an alternative, HIMA recommends that FDA and workshop participants devote some discussion time to the concept of manufacturer self-certification according to agreed-upon standards and requirements. Compliance with these requirements could then be ascertained as part of a routine FDA GMP inspection. HIMA member companies are willing to work with the agency to set up a pilot program to test this concept.

If a separate software quality assurance audit is adopted, it should not be product-specific. This would be extremely expensive and may delay the introduction of products to the market. Also, this audit should be performed on a periodic basis, similar to the ISO 9000-3 assessment.[10] The acronym "SQA" should not be used to refer to this audit because it will be confused with Software Quality Assurance as defined by the American National Standards Institute and the Institute of Electrical and Electronics Engineers.

D. *Consistency of Medical Software Regulatory Requirements*

HIMA urges that the new medical device software requirements be used consistently among all FDA Centers that perform reviews of medical devices.

V. CONCLUSION

In conclusion, I would like thank CDRH for giving me the opportunity to speak on behalf of HIMA member companies. We look forward to working with the agency and workshop participants to effect a practical approach to medical software regulation.

[10] *See* ISO 9000-3 1991 Quality Management and Quality Assurance Standards — Part 3: Guidelines for the Application of ISO 9001 to the Development, Supply and Maintenance of Software.