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SYMPOSIUM ON THE ENGINEERING OF COMPUTER-BASED MEDICAL SYSTEMS

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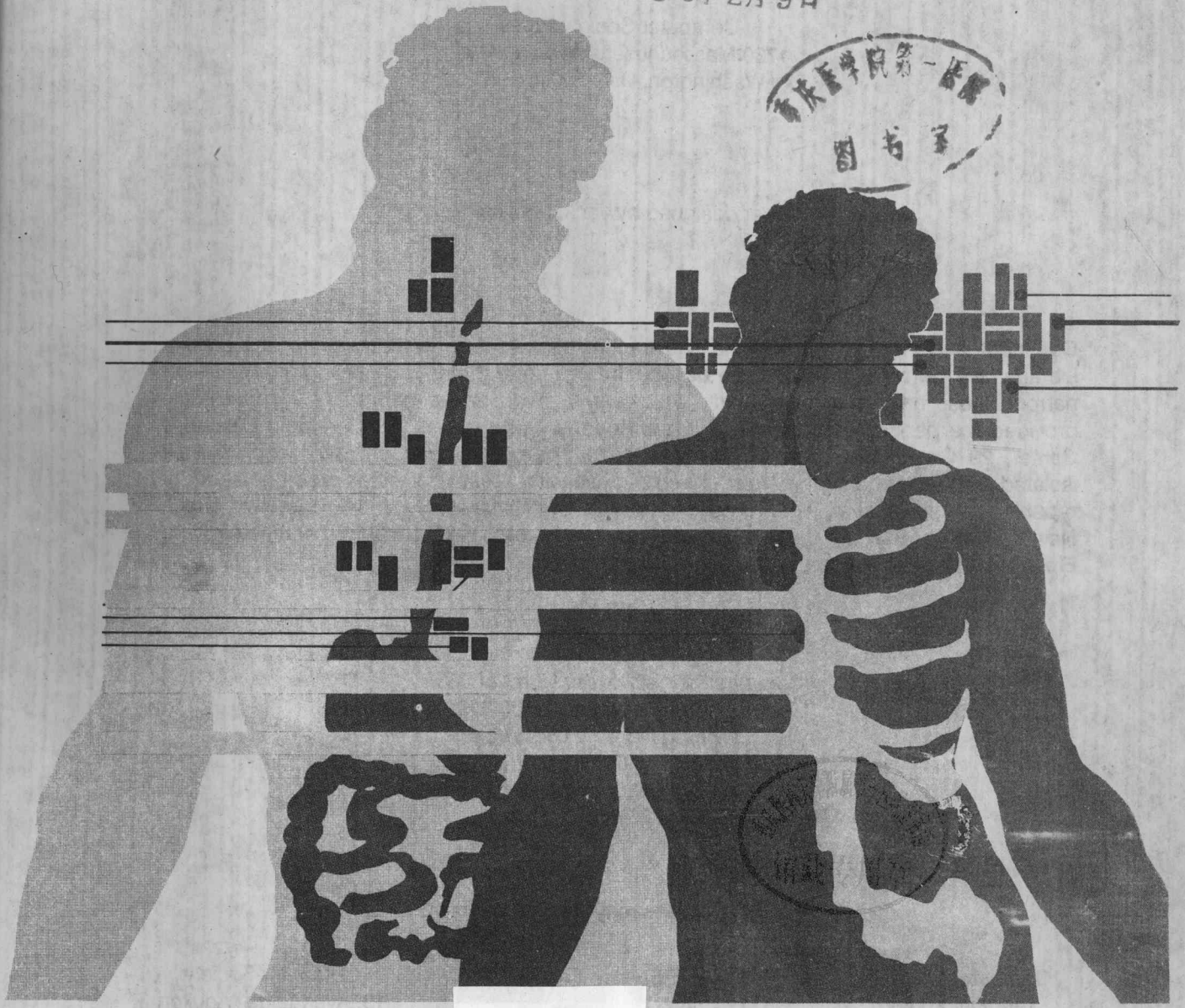

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Introduction from the General Chairman

Welcome to the first **Symposium on the Engineering of Computer-Based Medical Systems**. The name is long and doesn't seem to fit well into an acronym. Even so, it was chosen deliberately to emphasize the unique goals of our symposium.

First, this symposium is about *computer-based medical systems.* This includes all kinds of computer systems, both the hardware and software, that are designed and built for use in a medical environment. It also includes embedded computers, both hardware and software, found in medical devices. We are especially interested in systems used in conjunction with patient care.

Second, this symposium is about the *engineering* of these systems. This symposium has been developed by and for working engineers and computer scientists who are inventing, designing, developing, and implementing computer-based medical systems.

The symposium is organized into three components; preconference workshops to help you better understand the symposium papers, joint plenary sessions with WorldMed 88 and, most important, the symposium itself which includes invited and contributed papers.

There are many special and unique problems that the designers and developers of computer-based medical systems must face because they are used in a patient care setting. For this first symposium, we have chosen to emphasize these unique issues.

Regulatory Issues

Regulatory issues are a current major concern. WorldMed 88 Keynote Speaker John Villforth will discuss current FDA plans to regulate medical computer software. John F. Kunkel and Donald R. Stone will deal with these issues in a workshop on Tuesday afternoon. Finally, during the regular conference, representatives of both government and industry will debate and present papers on interesting and challenging issues related to this new regulatory area of the FDA.

Validity and Reliability

Although these concerns are not really unique to medicine, they do take on special significance in a medical environment. Actually most of the material presented in this track was developed in other environments, primarily in defense. We hope medicine can benefit from their experiences. A workshop on hardware design and reliability will be presented by Troy Nagle and David McAllister. A related workshop on software safety will also be presented by David Gelperin. We will then have a number of contributed papers that deal with these important issues.

Real World Applications and Experiences

In preparation for the papers in this area, Reed Gardner will present a workshop on the big picture of medical computing. His workshop will appeal to all of WorldMed 88. We have arranged the papers into several tracks. The emphasis on practical issues should make them valuable to the engineer/computer scientist working with medical systems.

- *Artificial Intelligence*

After a mini-tutorial, several papers will be presented that discuss how this technology is being used in medical systems.

- *Chronobiology*

A special session will cover how computers are used in chronobiology.

● *Closed Loop Drug Delivery Systems*

A session will be devoted to the design, development, and implementation of a closed loop drug delivery system. The FDA approval process, no mean feat, will be discussed.

● *Selected Applications*

We have included a few additional papers that present ideas and information that seem to be of interest to working engineers and computer scientist.

Before I stop, I must express my sincere gratitude to the other members of the Executive Committee: Dr. Al Potvin, Eli Lilly; Dr. H. Troy Nagle, North Carolina State University; and Dr. Barton Galle, University of Minnesota.

The program committee, especially the track chairmen, virtually all from industry, have been the people who have developed what I believe is an excellent symposium program. The names are listed separately as a way of highlighting their contributions. I think you will agree with me and I suggest that you let them know.

I wish to thank our financial sponsors. These are the IEEE Engineering in Medicine and Biology Society, the Computer Society, and the Continuing Medical Education Office of the University of Minnesota.

Finally, I wish to thank WorldMed 88 for including our symposium and for their many forms of support.

Enjoy the Symposium.

John M. Long, Ed.D.
General Chairman

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FDA REGULATIONS OF COMPUTER-BASED MEDICAL SYSTEMS

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ABSTRACT

A major focus of the Symposium is on the regulation of computer-based medical systems. John Villforth, Director of the FDA's Center for Devices and Radiological Health, will speak on this and other issues in an address as one of the WorldMed keynote speakers. On Tuesday afternoon, John F. Kunkel and Donald R. Stone will present a workshop on Regulatory Issues and Standards: Domestic and International.

Roger Schneider will further extend the considerations of this important issue by leading a panel discussion. As an aid in these discussions the draft FDA Policy for the Regulation of Computer Products, published in September, is reprinted below.

FDA POLICY FOR THE REGULATION OF COMPUTER PRODUCTS

PURPOSE

To the extent that computer products used in medicine are intended to affect the diagnosis and treatment of patients and are medical devices, the Food and Drug Administration (FDA) must provide reasonable assurance that these products are safe and effective. To clarify its role in this area, FDA has prepared this general policy statement on how it will determine whether a computer product is a medical device and if so how FDA will regulate it. Although the document provides general guidance on the regulatory requirements for computer products, it cannot cover all issues in advance. Manufacturers of such products are encouraged to contact FDA with questions they may have. For general information on the regulation as medical devices contact the Division of Small Manufacturers Assistance (800) 638-2041. For questions specific to computer products and their regulation as medical devices contact the Division of Product Surveillance (301) 427-8156.

AUTHORITY

FDA is responsible for assuring the safety and effectiveness of medical devices under the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic act (the act). Computer products are subject to regulation as medical devices when they meet the following definition (see Section 201(h) of the act, amended by Section 3(a)(1) of P.L. 94-295):

> ". . . an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals . . . (3) intended to affect the structure or any function of the body of man or other animals."

POLICY

FDA's device regulations and authorities do not apply to computer products used only for traditional "library" functions such as storage, retrieval, and dissemination of medical information -- functions traditionally carried out through textbooks and journals. Similarly, computer products used for general accounting or communications functions are not covered, nor are those used solely for educational purposes rather than to diagnose or treat patients.

When a computer product is a "component, part, or accessory" of a product recognized as a medical device in its own right, the computer component is regulated according to the requirements for the

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parent device (unless the component of the device is separately classified). This would include any computer product which is intended to have a direct interface with a medical device or one whose primary function is to provide input data intended to control the functioning of a medical device.

Computer products which are medical devices, and not components, parts, or accessories of other articles which are themselves medical devices, are subject to one of three degrees of regulatory control, depending on their characteristics. These products are regulated with the least degree of control necessary to provide reasonable assurance of safety and effectiveness. The manufacturers of these products could be: (A) exempt from registering and listing their products with FDA; (B) required to register and list as well as to notify FDA before marketing; or (C) required to obtain FDA approval by demonstrating safety and effectiveness before marketing a product.

The following describes each level of regulation for computer products.

A. Exemptions From Registration, Listing, and Premarket Notification

Manufacturers of the following categories of medical computer products are exempt from the requirements for registering their establishments and listing their products with FDA, for reporting adverse effects under the Medical Device Reporting Regulation, and for premarket notification. Such devices are, however, subject to the misbranding and adulteration provisions of the act. FDA can thus address public health concerns which might be posed by such devices if they should arise.

1. General Purpose Articles (21 CFR 807.65(c)). A general purpose article is a product that is not labeled or promoted for medical uses but which, by virtue of its application in health care, meets the definition of a medical device. These devices either pose little or no risk, or are appropriately the sole responsibility of the health care professionals who have used them in medical applications. A personal computer which has been programmed by a clinical chemist to display values from tests on human specimens is an example of a general purpose article. A database management system, with no medical claims, that is used by a health care professional to identify patients at risk for a given medical procedure is a general purpose article.

2. Computer Products Manufactured By Licensed Practitioners For Use in Their Practice (21 CFR 807.65(d)). This exemption applies to "Licensed practitioners including physicians, dentists and optometrists who manufacture or otherwise alter devices solely for use in their practice." A medical facility where a computer product is developed will be treated similarly, provided that the product is used only in that facility. Furthermore, if software is provided without charge to other similar medical facilities, no requirement to register will be incurred. Thus, for example, exchange of software on computer "bulletin boards" would not result in a requirement for registration or listing.

3. Computer Products Used in Teaching and Non-Clinical Research (21 CFR 807.65(f)). This exemption applies to "Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis . . ." This exemption covers research and development efforts which have not progressed to the state of human experimentation.

4. Computer Products Which Provide Opportunity for Competent Human Intervention. Computer products including, for example, many software products known as "expert" or "knowledge based" systems, that are intended to involve competent intervention before any impact on human health occurs, (e.g., where clinical judgement and experience can be used to check and interpret a system's output) will also be exempt from registration, listing, and premarket notification. This will be accomplished by FDA through the normal exemption granting procedure. New devices that are substantially equivalent to these newly classified preamendments devices will likewise be exempted. In the interim, manufacturers of such unclassified products and similiar postamendments devices will not be required to register, or list these computer products, or notify FDA prior to marketing.

B. Computer Products for Which FDA Must be Notified Prior to Marketing

1. Computer Products with Uses Excluding Competent Human Intervention. Manufacturers of postamendments and preamendments devices that are

intended to be used without competent human intervention will not be exempt from the premarket notification requirement, and will be required, under 21 CFR 807.81(a)(3), to notify FDA prior to marketing.

2. Substantially Equivalent Computer Products. Computer products not exempt from the premarket notification requirements and found by FDA to be substantially equivalent to a device classified into Class I, II, or III, will be regulated to the same degree as the equivalent preamendments or postamendments device. In these cases, the manufacturer must register with FDA, list his products, notify FDA prior to marketing, and meet all other requirements of the device's class.

C. Computer Products for Which Premarket Approval May be Required

Computer products in this category are subject to the greatest degree of regulatory control. Those devices which are not substantially equivalent to a preamendments device, or which are substantially equivalent to a Class III device, are regulated as Class III devices. The safety and effectiveness of new Class III devices must be demonstrated by the manufacturer before marketing, usually through a Premarket Approval (PMA). If a manufacturer believes that a PMA is not necessary prior to marketing to assure safety and effectiveness, FDA encourages the submission of a petition to reclassify the product to a lower class. At this time, FDA is not aware of any computer product that is not a component, part, or accessory of another device that would require an approved PMA prior to marketing.

BRIEF DESCRIPTION OF REGULATORY CLASSES

Class I devices are subject to the act's "general controls" relating to such matters as misbranding, registration of manufacturers, recordkeeping, and good manufacturing practices. An example is a program for the calculation of the composition of infant formulas.

Class II devices are those for which general controls are insufficient to provide reasonable assurance of safety and effectiveness, and for which performance standards can provide such assurance. A computer program designed to produce radiation therapy treatment plans is such a device.

Class III devices are those for which insufficient information exists to assure that general controls and performance standards will provide reasonable assurance of safety and effectiveness. Generally, these devices are represented to be life-sustaining or life-supporting, or for a use which is of substantial importance in preventing impairment to health, are implanted in the body, or present a potential unreasonable risk of illness or injury. Postamendments devices (new devices introduced into the marketplace after the Amendments were enacted May 28, 1976) which are found not substantially equivalent to a preamendments device are Class III devices, as is a postamendments device that is found to be "substantially equivalent" to a Class III preamendments device. At present, all Class III computer devices are components, parts, or accessories of other products recognized as medical devices in their own right and are regulated as such as discussed in the POLICY section, supra. An example is a device having a computerized component which measures glucose levels and based upon measured results, calculates and dispenses insulin without physician intervention.

Regulatory Issues

Chair

G. Sachs, Biomedicus

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