In the United States, the Food and Drug Administration (FDA) uses standards in order to help determine reasonable assurance of safety and effectiveness. People in hospitals feel that using standards for purchasing will result in products that are safe and effective. Manufacturers incorporate standards into their designs in order to demonstrate to both the users and the FDA that the products are reasonably safe and effective. Regulators have used standards to make judgments on the approval of new products for distribution. But, their greatest influence is economic.

As yet, no standards have been issued by the FDA. Those in use have been written by a few thousand volunteers working with around ten major associations active in writing standards. This voluntary effort, comprising a few thousand individuals, has some effect on 36 billion dollars of medical device shipments. These shipments are produced by nearly 250 thousand people employed in the medical device industry in production, design, research, marketing and service. An additional 25 to 30 thousand biomedical engineers, clinical engineers, and technicians work in hospitals supporting these products and also in research for providing new or improved devices.

The formal start of the integration of the European Community (EC) was on 1 January 1993. The directives, or laws of the EC that govern medical devices, must be met in order to export to this EC. European standards, essentially those provided by ISO (International Standards Organization) and the IEC (International Electrotechnical Commission), will have to be met in order to distribute products into the EC. As a result, there is now increased interest in international standards by manufacturers. This is beginning to impact the voluntary standards effort and the work of the associations involved in standards writing.

Recalls of products for corrective action due to problems relating to safety or efficacy were summarized for the years 1987 through 1992. There are approximately 5000 manufacturers in the US, each producing from one to several different products, that are in this data base. 49% of the recalls were said to be due to alleged deficiencies in the quality system. About 20% were claimed to be due to software design issues. Another 20% were felt to be due to hardware. Radiation and other problems accounted for the remaining 11%.

Manufacturers are required to report incidents that may have caused or contributed to death or serious injury or have malfunctioned and the malfunction would be likely to cause or contribute to death or serious injury if it should recur. About 15,000 manufacturers are subjected to these reporting requirements. For 1992, deaths averaged about 90 per month and the total number of reports averaged around 2000 per month. They come from millions of patients.

Efforts are being made to obtain product failure information that is representative of the medical device industry. At this time, no information has been made available. It is hoped that, by the time of the presentation, some data will have been found.