Email from Dr. Eugene Chabot regarding Standards for Medical Devices

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After digging through some of my notes, I've run across a few pointers on the medical standards. First off, a few brief lists of standards can be found at the following addresses:

http://www.doctordevice.com/genstds.html
http://www.doctordevice.com/stdnote.html#iec601240

I would not consider them exhaustive, but it gives you a feel for some of the types of professional standards related to commercial products and medical devices. For example, project specific standards may exist like when using electromyogram you could do a quick search on the IEC website to find IEC 60601-2-40 which is titled "Particular requirements for the safety of electromyographs and evoked response equipment."

Other general standards that I've run across in the past are as follows:

IEC 60812:2006 ANALYSIS TECHNIQUES FOR SYSTEM RELIABILITY – PROCEDURE FOR FAILURE MODE AND EFFECTS ANALYSIS

ISO/IEC 14971:2007 Medical devices — Application of risk management to medical devices

IEC 61010-1:2001 Safety requirements for electrical equipment for measurement, control, and laboratory use

IEC 61326-1:2005 ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE – EMC REQUIREMENTS

ANSI/AAMI/IEC 62304:2006 Medical device software— Software life cycle processes

Lastly, a site the students may find interesting to read on the FDA process is http://www.manufacturingcenter.com/dfx/archives/0504/0504rules.asp. It gives a brief overview of the FDA rules that need to be followed.

For next year (or perhaps next semester), I could probably put together a presentation on some of the standards that covers how they relate to industry and what importance they have to practice. The more general practices (i.e. development process) would be applicable to all projects.

Eugene