

Practical Ideas from Professors: Standards Education in Your Courses

# Teaching Standards in Biomedical Engineering



## About the College of Engineering at Marquette University

The College of Engineering at Marquette University offers undergraduate, graduate, and doctoral programs. Students in the Biomedical Engineering program participate in cross-disciplinary activities that integrate engineering sciences with the biomedical sciences and clinical practice.

### Using Standards in the Engineering Program

Incorporating standards into the capstone design course can be an effective way of demonstrating the value of standards to the design process and helping students learn about standards. Students become aware that standards provide many benefits not only to practicing engineers but also to capstone design teams. In my capstone design course, I focus on two major benefits of standards and present two opportunities for students to incorporate them into their projects.

First, identifying the need to comply with specific standards early in a project can help avoid costly design changes and schedule delays as the project progresses. For this reason, students are urged to identify all customer needs and design requirements as early as possible. Early in their projects, along with a patent search, students are required to conduct a standards search to determine if standards exist that apply to their design projects. When writing the Customer Needs Document, students ask their project sponsors if compliance with particular industry standards is a requirement. Standards are often used to develop performance requirements to be included in a team's Target Product Specifications Document. For example, a team developing an



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As a capstone design course instructor with fourteen years of product development experience in the medical device industry, my goal is to prepare students for professional engineering practice. I share my experiences as a project engineer and engineering manager, and focus on topics that are important to professional practice, such as standards. I discuss the role and value of standards in design and how they are developed, and present examples of various medical device standards.

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electronic device might include requirements for minimum allowable leakage current specified in an applicable standard.

Second, standards often define test procedures to be used to determine if the performance of a product complies with the standard. Towards the end of the capstone design project, after construction of a working prototype, teams often use standards for design validation. The Experimental Verification Document requires teams to develop a set of experiments or tests to determine if the design performs as required (meets target specifications developed earlier in the project). Teams must conduct the tests and analyze the results to determine if specifications have been met. Students are encouraged to use test procedures described in applicable standards (if they exist) instead of developing their own set of test procedures. They learn that using standards saves them time, provides them with a set of technically valid, industry-approved test procedures, and allows for direct comparison between competitive products tested per the same standard, not only for their capstone design projects but also for projects they will work on in industry.

To make standards more relevant to students, I show them examples of standards for familiar products. I then show them *ISO 594-1: Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other*

*medical equipment -- Part 1: General requirements*, and explain that compliance to this standard ensures that hypodermic needles and syringes made by different manufacturers will be interchangeable, a design feature that can save lives in medical emergencies. This example drives home the importance and value of standards in design.

### Resources

Affordable access to standards is necessary if we want students to incorporate them into their design projects. I maintain an up-to-date library of ASTM and AAMI (Association for the Advancement of Medical Instrumentation) standards for medical devices in my office, along with a few popular ISO standards, for students to use. ASTM International allows students or faculty to purchase ten ASTM standards for \$10. Some ISO and ANSI standards can be obtained at no charge at [www.standardslearn.org](http://www.standardslearn.org).

A helpful resource for conducting standards searches can be found at [www.nssn.org](http://www.nssn.org), and [www.standardsboost-business.org](http://www.standardsboost-business.org) discusses the value of standards. ASTM International offers learning modules on standards for use in the classroom ([www.astm.org](http://www.astm.org)) and several of their standards contain links to videos that show how to conduct test procedures included in the standards. Independently produced YouTube videos showing how to use specific standards are also available.

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