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SHARE: Materials to Enhance Consensus Standards Student Competencies in Engineering Education

Dr. Michael Gordon Browne, Cook Medical

Current research and development engineer bridging upstream needs evaluation with design efforts. Prior teaching professor engaged in educating engineering design, medical device quality and regulatory processes, innovation, and entrepreneurship. My goal has always been helping students engage in industry-realistic experiences to prepare them for careers in the medical device industry. Now, my new role is allowing me to engage with academic partners from industry to work on methods to best identify and meet unmet clinical needs.

Dr. Anthony E. Felder, University of Illinois at Chicago

Anthony's current focus is on engineering education and its restructuring to better meet the diverse needs of students and industries. Anthony is also active in ophthalmology research for the multimodal imaging of retinal oxygenation and novel medical device design.

Prof. Kristyn Caragher, University of Illinois at Chicago
Adrian P. Defante

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A vast amount of technologies require approval through a regulating body prior to market entry. The Food and Drug Administration (FDA), for example, regulates medical devices while the National Highway Traffic Safety Administration (NHTSA) aids in regulating the automotive industry. These bodies rely heavily on consensus standards from organizations (e.g., ISO, ASTM, IEC) that consolidate best practices regarding safety and effectiveness. Consensus standards are mutually agreed upon performance expectations established by expert stakeholders for a given technology or testing method. These standards are generally voluntary and represent best practices derived from experience and data. For example, when an engineer purchases a Grade 5 ¼"-20 hex-head bolt, they know it fits tolerances defined by ANSI/ASME B1.1. Because of this predictability and reproducibility, engineers across the design cycle use consensus standards widely. However, while content regarding consensus standards is required under ABET, many engineering programs superficially cover the use of consensus standards—if addressing them at all—resulting in graduates learning these skills on the job.

Here, we provide a multipronged approach to improve student competencies in modules that evoke a deep understanding of when, how, and why consensus standards are used in the design cycle. While founded in the regulation-intense field of medical device development, our four modules are independently designed to teach engineers across disciplines and learning levels how to 1) source appropriate standards, 2) write and execute protocols from standards, 3) revise consensus standards, and 4) create new consensus standards. Modules are each designed to be applicable together or independently in courses. Materials to aid in performing these four modules can be found at https://uofi.box.com/s/476ibec32ysju4jfg5ny3d2pv49hwyxu. **Bolded** items throughout refer to Module folders or underlying documents therein.

In collaboration with the engineering librarian, to support standards information literacy, our first module consists of a standards research guide to aid educators and students with resources to identify and source appropriate consensus standards. Resources include free-to-use websites such as the FDA's Standards Database (helping guide what standards are helpful and/or necessary for a given medical device) and license-based tools like ASTM-Compass (a tool for acquiring standards). This research guide and much of its content is introduced to students by our engineering content specialist librarian in the first few weeks of an elective course (BME 410) titled ISO Requirements for the Manufacturing and Design of Medical Devices. After learning fundamentals of consensus standards, we distribute an assignment to source standards relevant to a chosen Class II medical device and to extract requirements therein. The assignment and a link to the university research guide for technical standards can be found in **Module 1: Searching for Standards**. This module is highly adaptable and can serve as an introduction to standards in any entry-level engineering course.

Our second module incorporates consensus standards into both the pre-concept phase (via product requirements) and the verification phase (via standards-based protocol development and execution). This module is integrated across both semesters of our BME Senior Design 2-semester course sequence. Namely, sourcing performance standards is part of an early deliverable in Senior Design 1, where quantitative product requirements must be extracted from relevant ASTM or ISO standards. Leveraging these quantitative requirements, standards-based testing is fundamental to verification testing of functional prototypes in Senior Design 2. This module contains two parts: 1) a traditional lecture on protocol writing, and 2) a dynamic activity where the class writes and executes a protocol together. The lecture is designed to occupy a single class (75 minutes) and covers expectations, purpose, and examples of a properly written protocol. The activity is inspired by a popular Youtube video "instructions challenge" to make a peanut-butter and jelly sandwich . In this classroom, students write out steps (i.e. a protocol) to make a peanut-butter and jelly sandwich. Instructors then take a few examples to make a complete protocol and execute it verbatim. The resulting demonstration is typically messy and ineffective at creating an edible sandwich, but demonstrates the need for thorough and highly specific protocols. The remainder of class time involves discussion of the assignment and sharing of some particularly well written verification protocols. Assignments for both semesters as well class slides can be found in **Module 2: Writing Protocols for Standards**. This module was designed for use in capstone design courses during verification and validation testing but is also useful for a lab course with well-defined protocols and data analysis techniques.

The third module uses a custom-built benchtop tensile testing apparatus for round-robin testing during an in-class activity in the same BME 410 class as Module 1. Over multiple sessions, teams characterize tensile properties of a given material and use the round-robin methodology to identify limitations and propose revisions. Notably, materials, device, and protocols include deliberate adulterations enabling student teams to identify discrepancies during round-robin testing, which serve as motivation to modify the standard. Details from this effort have been previously published by Nunnally et. Al. and relevant curricular materials can be found in **Module 3: Revising Standards (Round Robin Tensile Testing Curriculum)** [1]. This module was designed for an upper-level standards-based course but is also adaptable to active learning in lab courses where erroneous protocol steps are intended to serve as nuclei for critical thinking. Moreover, this module can also be adapted into courses with literature review, as a means for students to critique or cross-evaluate protocols against standards.

Lastly, our fourth module reaches Bloom's highest levels of learning, challenging students to create new standards and consider ethical challenges in consensus standard development. Learning objectives related to this module were for students to be able to apply the consensus standards development process by simulating stakeholder negotiation, drafting technical performance criteria, and navigating trade-offs among safety, performance, regulatory, and commercial constraints. This capability should help students transitioning into industry understand why standards are written as they are and how to develop standards internal to a company. To do so, the activity is modeled after a real standards panel fictionalized using a murder mystery party design. This 2-day activity paired with a deliverable was the final assignment in the same BME 410 course as Modules 1 and 3. The instructor begins the class sessions with a monologue about a fictitious "Billy Boingz" who has recently died in a tragic pogo-stick activity (**Instructor Day 1 Introduction** and **Student Information Sharable Day 1**). Student groups of 5-6 are assigned to one of numerous fictitious companies (e.g. 12 companies) who have been invited to the standards panel to create a new standard regarding pogo stick safety and efficacy (examples in **Standards Panel Companies and Organizations**). Each company has private hidden details (e.g. technologies in development, corporate goals) which are intended to guide the company's approach at the panel (examples in **Company Details – Private to Companies**). Individual students are also expected to assume the role of a specific individual at each company, each given a fake name, background, and role within a company (examples in **Individual Student Personas**). After introducing the case and getting students oriented with their personas and companies, Day 1 progresses to attendees negotiating which sections of the standard will be written as part of the panel. To more accurately emulate real standards panels, individuals are then divided among each section such that a focus group is comprised of individuals representing multiple companies with potentially competing interests (e.g. students A, B, & C from Company 1 each go to focus group sections I, II, and III, respectively, alongside students D, G, & T from Companies 2, 4, & 7). Upon the start of Day 2, each focus group must collaborate to outline then ultimately write a detailed section of the standard. Moderated discussions in class help build out high-level content to be completed by students as an assignment. Each "Company" group of students submits a final deliverable compiling sections from each of their focus groups written into a cohesive, full standard (deliverable available in **Standard Creation Deliverable**). The deliverable is intended to both give deep understanding of the process associated with standard creation, demonstrate the complexities of how standards can be ethically produced, and encourage active creation of detailed standards to ensure the highest level of understanding feasible at this level.

This paper outlines the curricular content of these modules, provides access to course materials, and demonstrates how these modules fit into two biomedical engineering (BME) courses. We found that each Module guided instructors to different key takeaways. Regarding Module 1, to effectively provide the materials related to consensus standards beyond those commonly discussed (i.e. ISO 13485), it is imperative to involve university libraries in early stages. Module 2 is, perhaps, the simplest to include in a Capstone design course with subtle changes, if any, required for many programs. Module 3 requires equipment and planning but may fit well into other courses such as a mechanics of materials course. Module 4 requires a willingness to be flexible and adapt materials on the fly as the tangible outcomes are, in many ways, less important than engagement in the in-class activity. We hope that these materials may aid others in building a better foundation for our students in how to interrogate, use, and improve consensus standards.

References

[1] D. A. B. M. F. A. Nunnally C, "Developing a Round-Robin Module For The Integration Of Consensus Standards In a BME Course Using a Custom Tensile Testing Device," *Biomed Eng Educ,* vol. 6, no. 1, pp. 83-95, 2026.