Work-in-Progress: Development of a Domain-Agnostic Standards Curriculum in Partnership with a Medical Device Manufacturer

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Introduction

The medical device industry is widely considered one of the most highly regulated industries and, as a result, medical device manufacturers rely heavily on various types of consensus standards when seeking device approval with the FDA. At the University of Illinois Chicago (UIC), we are only aware of two classes in the college of engineering which actively teach standards to engineering students. One such course is Introduction to Engineering Design, a sophomore-level course offered by the Department of Mechanical Engineering which introduces standards related to fasteners and detailed drawings. The other course, FDA and ISO Requirements for the Development and Manufacturing of Medical Devices (BME 410), is offered by the Department of Biomedical Engineering (BME) and historically has focused predominantly on ISO 13485:2016 Quality Management Systems. Similar to many institutions, incorporation of this standard into the curriculum has fulfilled the ABET requirement that a culminating major engineering design experience incorporates appropriate engineering standards and multiple constraints [1]. Indeed, a large proportion of our students pursuing industry jobs upon graduation find roles as Quality Engineers utilizing the knowledge from this course and standard. While ISO 13485 is of the utmost importance for our students entering the medical device industry, it is also a relatively poor example of a consensus standard to incorporate into the technical design or assessment of a new technology. Further, a 2010 survey of medical device manufacturers performed by Harding and McPherson suggested that over 80 percent of employers desire an applicant pool of engineers with fundamental knowledge of finding, applying, and developing standards [2].

Our study design is functionally an approach to apply principles of Bloom's Taxonomy to the education of consensus standards. All current standards curricula at the UIC, and most of that identified in biomedical engineering education literature [3, 4, 5] focuses on recognition and understanding (i.e., the lowest levels of Bloom's Taxonomy). Capstone design courses may require the incorporation of standards during the design process or verification testing but approach and standard rigor can be widely varied. Recognition of appropriate standards is quite valuable for engineers entering industry, but recognition only represents base knowledge acquisition based on Bloom's Taxonomy principles. Here we describe a set of curricular modules to enhance students' understanding of standards in engineering practice that reflect learning at all levels of Bloom's Taxonomy (i.e. recognition/understanding, application, revision, and creation). The modules and their implementation will enhance students' understanding of standards, including 1) searching and identifying appropriate standards, 2) writing appropriate protocols for the verification of standards, 3) proposing revisions to standards, and 4) developing new standards. With this methodology applied to different engineering/technical disciplines, we hope to establish a distinct value to engineering education that employers can leverage.

Methods

This work was determined to be exempt from further review by UIC Institutional Review Board. To date we have piloted all four modules in Fall 2023 while a second pilot is underway in Spring 2024. Modules were piloted between our BME 410 and our year-long BME senior design course

(BME 396/397). Final iterations of all four modules are planned for Fall 2024 and Spring 2025, wherein curricular materials will be recorded and disseminated publicly.

Module 1: Sourcing and appropriate selection of standards. Partnered with our university engineering librarian in Fall 2023 and Spring 2024, we gave a short lecture introducing standards organizations (e.g. ISO, ASTM), the structure of consensus standards, and the creation of technical product requirements from performance standards paired with a live workshop on searching for standards via ASTM Compass. This fundamental module was implemented into both BME 410 and BME 396. Student teams in each class focused on specific medical technologies were tasked to identify appropriate performance standards from our institutional ASTM Compass license which includes a majority of ISO standard equivalencies. Further, they extracted quantifiable product requirements to guide design efforts as an assessment of student capacity for sourcing standards (Blooms Taxonomy levels: recognition and understanding).

Module 2: Writing of protocols to comply with standards. This module was prepared with inspiration from the viral "Exact Instructions Challenge" peanut butter and jelly sandwich video [6]. In the video, a father asks his children to write instructions to make a peanut butter and jelly sandwich. He literally interprets the instructions (e.g. rubbing jar of peanut butter on a piece of bread) resulting in failed examples of a sandwich. This elegant example demonstrates the need to clarify assumptions and consider all factors and viewpoints when writing protocols for use by others. This module was implemented into BME 397 where we begin our session with a live demonstration of the peanut butter and jelly sandwich "Exact Instructions Challenge" to demonstrate common deficiencies in protocol preparation in an engaging way. We supplemented the activity with a lecture on best practices for protocol writing then leveraged our longitudinal design project to assign a group homework to assess student capacity for protocol writing with the additional opportunity to complete said protocol (Blooms Taxonomy level: application).

Module 3: The revision of consensus standards. Modeled after industry panels to revise consensus standards, we have piloted an in-class activity for different stakeholders to collectively propose and write standard revisions. In BME 410, we provided students with ISO 15971 In vitro diagnostic test systems: Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus for review. Students were then placed into five teams representing different relevant stakeholders (e.g. medical device manufacturers, standards organizations). Similar to the popular "Murder Mystery Party" game, each team was provided with special "proprietary" knowledge that was designed to induce biased perspectives. The teams then negotiated proposed changes to the standard to improve device safety and efficacy before drafting edits to the standard (Blooms Taxonomy levels: analyze and evaluate).

Module 4: The creation of new consensus standards. Creating standards is a complicated task for an inexperienced engineer, though it is ultimately a common practice for experienced engineers needing to set product requirements (internal to an organization) or to develop testing protocols. Nevertheless, general competencies in how standards are developed and how decisions are made in standard development for a junior engineer would greatly improve their efficacy as an engineer in product development and verification testing [2]. Through preliminary pilot testing, we created an in-class activity where students collaborated to create a new performance standard titled "ISO Standard for Appropriate Use of Generative AI in Biomedical Engineering Coursework". Students were tasked with defining key elements of a consensus standard in the ISO format including scope, normative references, and definitions but encouraged to create the

remaining sections through negotiation and discussion. Building from Module 3, Module 4 was also implemented into BME 410 and a group-based homework assignment was used to assess student capacity to create new standards (Blooms Taxonomy levels: evaluate and create).

Discussion

Our curricular effort is intended to develop a multifaceted approach to improve engineering undergraduate student understanding of how consensus standards are used, modified, designed, and tested. We aim to create an engaging learning experience for content which is otherwise challenging to incorporate into existing curricula.

We found many positive outcomes and opportunities with our pilot of our new standards curriculum in Fall 2023 and are actively revising content this Spring 2024 before preparing our "final" sharable versions in Fall 2024. In particular, we have seen considerable improvements in the verification methods performed by our BME 396 Senior Design teams by integrating testing standards in their approaches (Module 2). Students engaged well during Module 3 and 4 activities and reportedly enjoyed the sessions. Each session necessitated extended activity time and some simplification of technology to facilitate in-class discussion more rapidly.

During summer 2024, we plan to prepare a new consensus standard revision (Module 3) approach using an activity-based round-robin testing methodology. Round-robin testing asks stakeholders to each conduct a protocol for the evaluation of a standard and to collaboratively discuss discrepancy among findings in the revision of the standard. Round-robin testing has been used extensively across numerous disciplines and for varied testing purposes such as dental material wear simulators [7], for shear-bond characterization in building materials [8], or for the transition temperature of materials like polystyrene [9]. Here, we envision a teaching exercise where teams of students follow a mock ASTM Consensus Standard to test a set mechanical property (e.g. peel strength). Mechanical properties are useful to nearly every engineering domain. Unknown to students at the start of the exercise, each test setup will accommodate different "adulterations" leading to different results (Appendix Figure 1). This method is intended to outline the potential limitations associated with following a consensus standard or protocol. The goal for the students is precise execution of the mock standard and identification of associated flaws in the device or material selection. Leveraging results, the class will then complete an assignment to revise the mock standard to resolve identified issues. Accordingly, this will also facilitate the update of standard revision (Module 4) to the proposed "Murder Mystery Party" methodology which we expect will enhance learning outcomes at the top tiers of Blooms Taxonomy.

Ultimately, we hope to generate materials which, given their domain-agnostic nature, can be integrated into numerous engineering departments at UIC and be freely shared for other institutions or professional organizations to improve learner competencies in standards.

Appendix

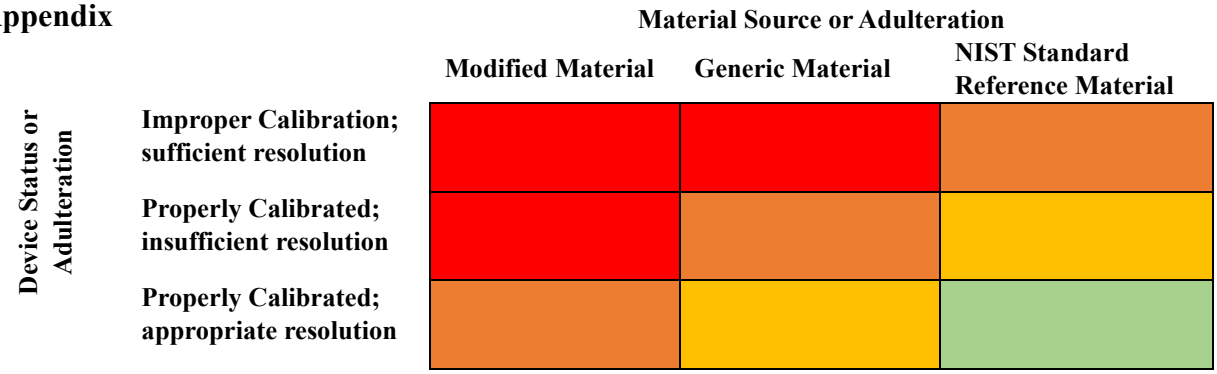

Figure 1: Example adulterations of both Test Materials and Mechanical Testing Device to demonstrate the potential pitfalls of a poorly written standard or protocol. This proposal could be assigned to any type of testing equipment.

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