

Final Summary Paper

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

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1. Project Description and Importance

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 standards when seeking device approval with the FDA. At the University of Illinois Chicago (UIC) Richard and Loan Hill Department of Biomedical Engineering (BME), we have only one course in our curriculum that teaches standards, namely BME 410 - FDA and ISO Requirements for the Development and Manufacturing of Medical Devices). This course typically focuses solely on ISO 13485:2016 Quality Management Systems. Indeed, a large proportion of our students pursuing industry jobs upon graduation find roles as Quality Engineers due to knowledge related to this course. While this ISO standard is of the utmost importance for our students entering the medical device industry where quality assurance is key, it is a relatively poor example of a standard to incorporate into the engineering design or assessment of a new technology. While data is limited, a survey of medical device manufacturers performed by Harding and McPherson in 2010 suggested that over 80 percent of employers thought there was “a need for engineers who possess the fundamentals of standards development and the knowledge to find and apply standards prior to employment” [1]. Indeed, even our educational standards organization, the Accreditation Board for Engineering and Technology Inc. (ABET), requires that a culminating major engineering design experience incorporates appropriate engineering standards and multiple constraints [2].

Current UIC BME programming, and most of that identified in biomedical engineering education literature [3, 4, 5] introduces students to standards aiming for recognition and recall of important standards for a particular industry (e.g. ISO 13485 for the medical device industry). 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. Our project provides an approach to apply principles of Bloom’s Taxonomy to the education of standards by targeting not just the common learning objectives of recognition and application of standards, but also more comprehensive learning objectives related to reflection/revision and creation of new standards. We believe that by building domain agnostic modules at different levels of learning (i.e. recognition/understanding, application, revision, and creation), we can develop a centralized curriculum for standards education at UIC BME. With this methodology applied to different engineering/technical disciplines, we hope to establish a distinct value to UIC engineering education that employers such as Hollister Incorporated can leverage for their workforce. With

demonstrated success, we also hope to share our findings among other institutions to help reinforce standards education nationally.

2. Project Goal and Aims

The primary goal of this proposal is to enhance students' understanding of standards in engineering practice. The secondary goal of this proposal is to augment students' preparedness for careers in modern industry involving standards. This project meets these goals with curriculum modules for the teaching of standards in engineering education. 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.

This proposal is organized into two specific aims with accompanying sub-aims, as itemized below.

- Specific Aim 1 (SA1): Development of Scalable Curriculum Modules for the Teaching of Standards in Engineering Education
 - Specific Aim 1a (SA1a): Development of a curriculum module for the sourcing and appropriate selection of standards.
 - This module targets the foundational levels of Bloom's taxonomy, helping students recognize common standards across and within domains and understand how to identify appropriate standards for a given product or test case.
 - Specific Aim 1b (SA1b): Development of a curriculum module for the writing of protocols to verify standards
 - This module addresses the protocol writing component of verification testing using the viral "Exact Instructions Challenge" peanut butter and jelly video as inspiration for teaching students to check assumptions, write with clarity, and consider all viewpoints when writing protocols.
 - Specific Aim 1c (SA1c): Development of a curriculum module for the revision of standards
 - This module teaches standards revision, a skill normally learned only on-the-job, through a round-robin testing experience. Here, student teams execute the same performance standard, identify its limitations through performance discrepancies, and compile their recommendations for a revised standard to reduce discrepancies.
 - Specific Aim 1d (SA1d): Development of a curriculum module for the development of new standards
 - This module builds students' competency in creating new standards, a skill common among seasoned engineers but rarely taught, by having students write a standard for an instructor-provided product requirement. The process for creating a standard follows a multi-step process from identifying related standards through drafting, discussion, and acceptance.
- Specific Aim 2 (SA2): Pilot Implementation of Curriculum Modules for the Teaching of Standards in Biomedical Engineering with an Industry Partner
 - The modules from SA1 will be piloted across two UIC BME courses: BME Senior Design and BME 410. BME Senior Design is a required two-semester,

three-credit sequence that focuses on the FDA medical device waterfall process, principally the process between design inputs, design process, design outputs, verification, and validation. In BME Senior Design, SA1a (standards sourcing) will be incorporated into the Fall semester so teams could identify performance standards relevant to their projects and SA1b (protocol writing) will be incorporated into the Spring semester, so teams can write detailed verification protocols leveraging testing standards (e.g., a team developing a load-bearing biomaterial modeling ASTM E4/D638 for verification testing). This is BME 410 is a three-credit selective course that focuses on 21 CFR 820 and ISO 13485 compliance, culminating in a mock 510(k) submission. In BME 410, SA1a, SA1c, and SA1d will be layered onto a simulated Hollister product assessment: students will use SA1a to source standards for real ostomy/incontinence care products (with performance ISO standards pre-identified by the instructors), apply SA1c to critique another team's Product Requirement Deliverable and develop a verification protocol — including two visits to Hollister's testing lab — and finally will use SA1d to draft a new ASTM-format standard for a Hollister product requirement that lacked an established test method, working directly with Hollister representatives to translate user needs into testable criteria.

These modules represent varied curricular and didactic approaches, including active learning at multiple levels of Bloom's taxonomy, to maximally scale based on the need and experience of instructors. To disseminate this work, manuscripts will be written and module resources will be shared.

3. Project Outcomes

The project produced four curriculum modules, each targeting a distinct level of Bloom's Taxonomy (SA1), and were piloted in two UIC biomedical engineering courses (SA2): BME 410 (FDA and ISO Requirements for the Development and Manufacturing of Medical Devices) and the year-long BME 396/397 (Senior Design) sequence. Piloting proceeded iteratively from initial in Fall 2023, to second in Spring 2024, and then again in Fall 2024 and Spring 2025. All module materials have been made freely available at our module repository:

<https://uofi.box.com/s/476ibec32ysju4jfg5ny3d2pv49hwyxu>

Module 1 — Sourcing and Selecting Standards

Our first module creates resources for sourcing and reading and standards. This module was integrated into both BME 410 and BME Senior Design for general education on finding standards. 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 is meant to be introduced to learners as a tool and can be paired with basic definitions and knowledge about consensus standards. This module also provides 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 the “**Module 1: Searching for Standards**” repository folder. This module is highly adaptable and can serve as an introduction to standards in any entry-level engineering course.

Module 2 — Writing Protocols to Verify Standards

Our second module incorporates consensus standards into both design inputs/product requirement definition (via identification and brief proposing of protocols) and the verification phase (via standards-based protocol development and execution) of device design. This module is integrated across both BME Senior Design courses. 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 and class slides for verification protocols can be found in the “**Module 2: Writing Protocols for Standards**” repository folder. 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.

Module 3 — Revising Standards through Round-Robin Testing

The third module uses a custom-built benchtop tensile testing apparatus for round-robin testing during an in-class activity in BME 410. 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. 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. Details from implementing this module, designs of components, and relevant curricular materials have been previously published [6] and can be found in the “**Module 3: Revising Standards (Round Robin Tensile Testing Curriculum)**” repository folder. A brief summary of the methodology from the publication is provided below.

Custom-built benchtop tensile testing devices (Figure 1) and a mock standard, “ASTM BME410-24,” adapted from ASTM D412, were developed for the module. The device itself was designed for easy adoption and was made from common materials/components, 3D printed parts (the

design files were made available), and common manufacturing methods. To facilitate the educational objectives related to discrepancy in results during round-robin testing, the standard was modified from the original version for class testing purposes. During piloting, several testing devices were deliberately adulterated in one way (e.g., measurement resolution, spring constant, or material sourcing) to ensure discrepancy in results. Thus, as teams conducted testing according to the standard, they would generate notably different data with their tensile testers. During round-robin data evaluation, the students were instructed to identify discrepancies in data, the experimental and/or equipment basis for these discrepancies, and to propose a revision to the mock standard to eliminate the sources of discrepancies.

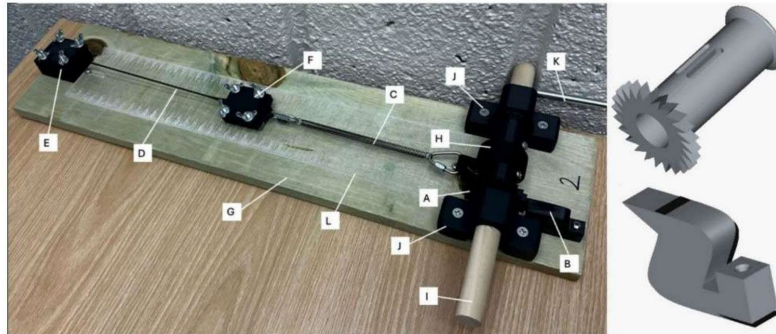


Figure 1. The custom tensile testing device used in Module 3. Adapted from Nunnally et al.[6]

Module 4 — Creating New Standards

The fourth module reaches Bloom’s highest levels of learning, challenging students to create new standards *de novo* 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 BME 410. The instructor begins the class sessions with a monologue about a fictitious “Billy Boingz” who has recently died in a tragic pogo-stick activity. 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. 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. 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. 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). On 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. The deliverable is intended to 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. All curricular materials can be found in the “**Module 4: Creating Standards**” repository folder.

In addition to the modules, the PIs recruited an MS graduate student (Chara Nunnally) to coordinate work under Aim 1c (module 3). Chara defended her thesis on that work in Spring of 2025.

4. Evaluation, findings, and lessons learned

Module 3 — Revising Standards through Round-Robin Testing

Module 3 was evaluated in a formal study (UIC IRB STUDY2025-0353, determined exempt) involving 28 students across eight teams in BME 410. This report has been published by Nunnally et al.[6] Major findings are provided below.

Student teams actively identified relevant parts of the mock standard to perform, characterized the Young’s elastic modulus of their material, and effectively applied round-robin methodology to identify sources of error between teams. After round-robin testing, teams authored a Standard Revision Report to propose modifications to the mock standard to eliminate sources of potential error. Students also completed a post-module survey to assess their understanding of module content. The learning objectives of the module were formulated to span all of Bloom’s Taxonomy. Learning objectives of the module included: 1) define round-robin standards assessment process (levels 1 and 2), 2) interpret and apply a consensus standard (levels 3 and 4), and 3) revise a consensus standard (levels 5 and 6).

The first learning objective was assessed using the individual definitions of round-robin testing from the post-module survey. The Microsoft Copilot summary of round-robin testing definitions indicated themes of consistency, accuracy, collaboration, comparison, reliability, and reproducibility. These themes are consistent with appropriate definitions of round-robin testing. However, the definitions were scored at 0.4 ± 0.5 (out of 1), corresponding to an average of 40%. Thus, on average, students could supply approximately half of the expected definition. The discrepancy between the Microsoft Copilot assessment and our own may be attributable to our searching for exact components, which is less flexible than an overall summary. Nevertheless, 17/28 students (63%) could supply at least partial definition, and including the more holistic assessment from Microsoft Copilot, we feel confident the students reasonably met the first learning objective.

The second learning objective was assessed using the summary of elements from the mock standard that students determined were useful for their own tensile testing (Table 1). From the composite scores of the summaries, the mean and standard deviation were 2.5 ± 0.5 (out of 3), corresponding to an average score of 83%. From this assessment, all teams but one score full points in the preparation and testing performance categories. The evaluation of testing was the lowest scored category, with two teams scoring no points. We suspect this discrepancy in

scoring between categories is related to the ability of the teams to identify relevant elements from the mock standard that immediately reflected what they had in front of them (i.e., preparation and testing reflecting the device and materials they received) rather than what would be required after testing (i.e., evaluation of performance). From these data, we feel confident the students met the second learning objective. Identification of correct adulterations was not required for the activity to be efficacious and for students to meet learning objectives. Instead, we considered consistency between identified adulterations (even if incorrect) and the revisions to the mock standard to be more important. Nevertheless, it was useful to assess the ability of teams to correctly identify adulterations as it provides an opportunity to reflect on their relative difficulty to identify (primarily a pragmatic consideration for the sake of learning in this module), which may drive changes to the adulteration selections in future module implementations. From the standards revision report, six of eight teams (75%), at least in part, identified an adulteration, with three teams scoring 2.5/3 (Table 2). Though, the mean and standard deviation adulteration score was 1.3 ± 1.1 (out of 3), corresponding to an average of 42%. Of the adulteration sources, the adulterated spring constant was seemingly the easiest for groups to identify, while the material adulteration proved to be the most challenging. These results suggest that while students demonstrated a reasonable ability to detect adulterations in general, their ability to correctly identify an adulteration varied based on the adulteration type and the group's interpretation of the provided standard. Notably, each of the three teams that scored 2.5/3 identified an issue with the supplied material. Specifically, they observed that some material sets had striations perpendicular to others suggesting an anisotropy of the material. As such, these were not incorrect observations, but the teams did not easily identify that they were labeled as being manufactured by different vendors. This variability in group performance, as reflected in the differing scores for adulteration identification, underscores the need for more structured guidance during the early stages of the module, such as guidance of more detailed notes on the worksheet, to ensure a uniform understanding of expected testing outcomes and critical evaluation techniques. Moreover, different adulterations to the devices may be considered to enhance performance and facilitate the connection between adulteration and standard revision.

Table 1. Scoring of the Standard Revision Report for summary of elements from the ASTM BME410(24) mock standard that were useful for customized tensile testing. Scores for the categories were as follows: 0=missing or neither correct requirement, 0.5=one correct requirement, or 1=both correct requirements. An average and standard deviation for each category and the summary score are provided. Reproduced from Nunnally et al.[6]

Device and Team Number	Adulteration	Summary of Preparation for Testing	Summary of Testing Performance	Summary of Evaluation of Testing	Total Summary Score
1	None	1	1	1	3
2	None	1	1	0	2
3	Resolution	1	1	0	2
4	Resolution	1	1	1	3
5	Spring	1	1	0.5	2.5
6	Spring	1	0.5	0.5	2
7	Sourcing	0.5	1	1	2.5
8	Sourcing	1	1	1	3
		0.9 ± 0.2	0.9 ± 0.2	0.6 ± 0.4	2.5 ± 0.5

Table 2: Scoring of the Standard Revision Report for identification of the alterations to the tensile testing devices. Scores were as follows: 0 =not identified, 0.5=partial identification, and 1=complete identification. An average and standard deviation for each category and the summary score are provided. Reproduced from Nunnally et al.[6]

Device and Team Number	Adulteration	Identification of Resolution Adulteration	Identification of Spring Adulteration	Identification of Material Adulteration	Total Adulteration Identification Score
1	None	1	1	0.5	2.5
2	None	0	0	0	0
3	Resolution	1	1	0.5	2.5
4	Resolution	0	0	0	0
5	Spring	0	0.5	0	0.5
6	Spring	0	0.5	0	0.5
7	Sourcing	1	1	0.5	2.5
8	Sourcing	0	1	0.5	1.5
		0.4±0.5	0.6±0.4	0.3±0.3	1.3±1.1

The third learning objective was assessed using the modifications made to the standard (Table 3). From the composite modification scores, the mean and standard deviation were 1.5 ± 0.5 (out of 2), corresponding to an average score of 75%. All teams scored points in the alteration category, and all but one team scored points in the new section category. These results indicate general consistency and quality in the modification of the mock standard. Notably, this section was scored according to the team's identified adulterations, so even if they did not accurately identify an adulteration, it did not preclude quality work in the modification of the standard.

Table 3. Scoring of the Standard Revision Report for modification of the ASTM BME410(24) mock standard. Scores were as follows: 0=missing, or inconsistent with adulterations and did not demonstrate quality/thoroughness, 0.5=consistent with adulterations or demonstrated quality/thoroughness, or 1=consistent with adulterations and demonstrated quality/thoroughness. An average and standard deviation for each category and the summary score are provided. Reproduced from Nunnally et al.[6]

Device and Team Number	Adulteration	Alteration of Standard	New Section of Standard	Total Modification Score
1	None	1	0.5	1.5
2	None	0.5	0	0.5
3	Resolution	1	1	2
4	Resolution	1	1	2
5	Spring	0.5	1	1.5
6	Spring	0.5	0.5	1
7	Sourcing	1	1	2
8	Sourcing	0.5	1	1.5
		0.8±0.3	0.8±0.4	1.5±0.5

Though most of it was not assessed as part of the learning objectives, the post-module survey was an important opportunity for us to reflect on the efficacy of the module in general as well as collect useful feedback about its implementation. Analysis of the post-module survey Likert-Scale responses indicates a generally positive reception of the module, with students expressing moderate to high confidence in their ability to apply consensus standards. In particular, students reported higher confidence in extracting product requirements and applying standards to general use cases compared to customized use cases. Here, we probed the understanding of following a standard “verbatim” (i.e. in the general case with a device that one would claim full compliance with the standard) compared to customized use cases where one must identify appropriate portions of a standard which require compliance. The lower confidence in customized use cases suggests that additional instructional time or supplementary materials might be necessary to build advanced skills in adapting standards to unique contexts. The open-ended question portion of the survey offered an opportunity for capturing critical feedback and responses highlighted the

importance of precision, collaboration and reproducibility when applying consensus standards. These responses mirrored those to the Likert-scale questions and students shared that the module could be enhanced by providing more time and detailed instructions.

Though most of it was not assessed as part of the learning objectives, the post-module survey was an important opportunity for us to reflect on the efficacy of the module in general as well as collect useful feedback about its implementation (Tables 4 and 5). Analysis of the post-module survey Likert-Scale responses indicates a generally positive reception of the module, with students expressing moderate to high confidence in their ability to apply consensus standards. In particular, students reported higher confidence in extracting product requirements and applying standards to general use cases compared to customized use cases. Here, we probed the understanding of following a standard “verbatim” (i.e. in the general case with a device that one would claim full compliance with the standard) compared to customized use cases where one must identify appropriate portions of a standard which require compliance. The lower confidence in customized use cases suggests that additional instructional time or supplementary materials might be necessary to build advanced skills in adapting standards to unique contexts. The open-ended question portion of the survey offered an opportunity for capturing critical feedback and responses highlighted the importance of precision, collaboration and reproducibility when applying consensus standards. These responses mirrored those to the Likert-scale questions and students shared that the module could be enhanced by providing more time and detailed instructions

Table 4: Likert-scale questions from student survey to assess confidence in certain skills after completion of the module (1=Very Unconfident, 2=Somewhat Unconfident, 3=Not sure, 4=Somewhat Confident, 5=Very Confident), average score, standard deviation, and number of responses (N). Reproduced from Nunnally et al.[6]

Question Number	Summarized Question Content	Average $\pm$ Standard Deviation (N)
1	Rank your confidence in using appropriate tools to identify an appropriate consensus standard for a given technology or process	3.9 $\pm$ 0.63 (28)
2	Rank your confidence in extracting product requirements/specifications from consensus performance standards for a given technology or process	4.1 $\pm$ 0.45 (28)
3	Rank your confidence in applying consensus standards in general use cases (i.e. when a standard applies to a process or procedure)	4.1 $\pm$ 0.54 (28)
4	Rank your confidence in applying consensus standards in customized use cases (i.e. when not all of the standard applies to your concept)	3.6 $\pm$ 0.78 (28)
5	Rank your confidence in identifying potential limitations in consensus standards	3.9 $\pm$ 0.62 (27)
6	Rank your confidence in applying consensus standards for conducting verification testing	3.9 $\pm$ 0.63 (28)
7	Rank your confidence in conducting round-robin testing of consensus standards	3.6 $\pm$ 0.79 (27)

Table 5: Likert-scale questions from student survey to reflect on the round-robin standards testing learning module (1=low;5=high), average score, standard deviation, and number of responses (N). Reproduced from Nunnally et al.[6]

Question Number	Summarized Question Content	Average $\pm$ Standard Deviation (N)
8	Rank your perception for how the Round-Robin Testing module helped prepare you to apply your knowledge of consensus standards in industry	4.3 $\pm$ 0.76 (28)
9	Rank how effective you found the Round-Robin Testing module in preparing you to assess a standard for use in verification testing.	4.3 $\pm$ 0.59 (28)
10	Rank your enjoyment of the Round-Robin Testing module (activity and deliverable)	4.1 $\pm$ 1.0 (28)

There were several limitations to the study. First, the sample size was relatively small with only 28 students across eight teams, which may limit the characterization of the study’s findings. Additionally, the module was implemented within a single BME course and further research is

necessary to assess its applicability across diverse engineering disciplines and institutions. Given the nature of the curricular module, longitudinal assessment of the module on career preparedness was precluded. Second, there was a wide scoring and performance distribution among teams, particularly in the ability to identify adulterations. The teams that scored higher overall (teams 1, 7, and 8, compared to teams 2 and 6) were those that also attended the two optional days of the activity, highlighting the importance of participation and collaboration during the activity to maximize learning outcomes. Anecdotally, the higher scoring teams were typically composed of higher performing students who self-assembled into teams via their seating proximity. In contrast, some teams that scored lower misinterpreted the goals of the activity and did not leverage the opportunity for collaboration on the two additional testing days. Deliberate team assignments in future module implementations may help to avoid large deviations in performance between teams. Third, a pre-module survey was not administered. This would be useful to evaluate the differential responses between the pre- and post-module survey and assess the effects of the module. Lastly, there was no capacity to evaluate the effect of the module on the careers of the students. Future studies to explore long-term impacts of the module beyond the course (e.g. in industry roles) would be useful to gauge efficacy and serve as an opportunity for respondents to reflect on the feedback they originally provided.

As a result of these limitations and our findings, there are several general modifications and considerations for future implementation. First, integration of consensus standards across engineering curricula improves fundamental understanding of consensus standards as observed by Rooney et al.[4] Second, within the module, students may benefit from extended duration (e.g. increasing from structured 2- to 4-day activity) and more explicit instructions (e.g. specifying to review supplier information, explicitly sharing which sets of tensile testing machines were adulterated similarly), consistent with student feedback. Third, integrating additional complex tasks aimed at higher levels of Bloom's Taxonomy (e.g., writing a new standard without predicate, a consensus standard draft from the entire class) could further enhance student capabilities in customized and innovative applications of standards. To fully address student open-ended comments, it would likely be helpful to provide better guidance in loading samples and setting up the tensile testing system while also providing more context for why elastic modulus calculations are important.

This work was also presented as the thesis work of Chara Nunnally (MS in BME).

Modules 1, 2, and 4

Modules 1, 2, and 4 were assessed less formally, primarily through classroom conversation and instructor observation across pilot iterations. In general, these modules were found to be strong active learning opportunities. Module 1 was successful in generating a resource that describes standard, the types of standards (and equivalency), and how to search for them and identify them. We have employed module 1 in both BME 410 and BME Senior Design. BME 410 relies on standards interpretation and so module 1 is an indispensable foundational curricular component for that class. In BME Senior Design, module 1 has been similarly indispensable given standards are a requirement now for both design inputs and verification testing. The incorporation of module 1 has substantially decreased the barrier to entry for students to incorporate engineering standards into their design process.

For module 2 in BME Senior Design, we ordinarily split the verification protocol into two stages (proposal and execution) with both occurring after the module. However, in Spring 2025, to evaluate the effect of module 2 more specifically, we moved module 2 activity until after the proposal stage. This ensured students would benefit from the module only at the execution stage (wherein the protocol is performed and verification is rendered). In this semester, there was a significant difference in verification protocol assignment scores between stages (i.e., before and after the module), with scores on the proposal document at 82.6 ± 05.75 and scores on execution document at 86.8 ± 3.88 ($p=0.001$, paired t-test, $N=12$ teams). However, in comparison to the Spring 2024 semester, where module 2 was performed before the proposal stage, there was also a significant difference between assignments at the stages 83.6 ± 6.03 and 92.3 ± 5.42 ($p<0.001$, paired t-test, $N=12$), respectively. These findings suggest that module 2 alone did not significantly improve performance on verification protocols between proposal and execution stages. We reason this is because performing a verification protocol forces students to be more considerate in their work than an interactive module alone can achieve, no matter how engaging. Of course, differences in projects among the compared semesters may also contribute to the perceived effects of the module.

Students engaged well with Module 4 activities and reported enjoying the innovative, active learning approach they participated in. Though each session necessitated extended activity time and some simplification of technology to facilitate in-class discussion more rapidly.

5. Suitability and Potential for Adoption in Other Settings

The modules were designed from the outset for reuse beyond their originating courses. While we piloted our approach in biomedical engineering courses concerning medical devices, the teaching modules can be repurposed across education level (K-12 to graduate school) and transferable to other technical domains with varying complexity. For example, module 1 provides a basic introduction to standard and tools for their identification, which doesn't necessitate a particular technical domain. Similarly, module 2 can be used as an introductory exercise to any protocol writing process. Even the other modules, which are positioned in medical devices, are scalable to other domains like mechanical engineering or civil & materials engineering - any engineering discipline that benefits from materials characterization and utilizes consensus standards.

6. Public Availability of Project Results

The works of this project are designed to enhance workforce preparedness in quality engineering and R&D roles. Towards this purpose, all educational contents are made freely available at our Box weblink: <https://uofi.box.com/s/476ibec32ysju4jfg5ny3d2pv49hwyxu>. We hope that these materials may aid others in building a better foundation for students to interrogate, use, and improve consensus standards. Three manuscripts were published on the work from this project, as listed below (all publicly available):

- Browne, M. G., & Felder, A. E., & Defante, A. P. (2024, June), *Work-in-Progress: Development of a Domain-Agnostic Standards Curriculum in Partnership with a Medical Device Manufacturer* Paper presented at 2024 ASEE Annual Conference & Exposition, Portland, Oregon. 10.18260/1-2—48534

- Link: <https://peer.asee.org/48534>
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7. Conclusion

The goal of this project was to enhance students' understanding of standards in engineering practice and to prepare them for standards-related careers. Over a three-year period, we developed, piloted, refined, and publicly released four curriculum modules spanning the full range of Bloom's Taxonomy, grounded in an authentic partnership with a medical device manufacturer. The goal now is for these publicly available, domain-agnostic modules to aid others in building a better foundation for students to interrogate, use, and improve consensus standards.

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