2026 ASEE ANNUAL CONFERENCE June 21–24, 2026 | Charlotte Convention Center, NC
Host Sponsor UNC Charlotte
Paper ID #52612

SHARE: Implementing Test-Methods Standards Education in a Sophomore BME Lab

Jennifer M Hatch, Purdue University at West Lafayette (COE)

Jennifer Hatch is a Lecturer of Biomedical Engineering at Purdue University. She earned her BS and MS in Biomedical Engineering from Indiana University-Purdue University Indianapolis (IUPUI) and is currently working towards a PhD in Engineering Education at Purdue University. Her research interests center around curricular interventions to increase industry-readiness for undergraduate biomedical engineering students, and understanding the ways that rapidly changing technologies alter both the way students learn and the skills that students need to learn to be successful engineers.

Violet M Frye, Purdue University at West Lafayette (COE)

Violet Frye is an Instructional Lab Supervisor in Biomedical Engineering at Purdue University. She earned her B.S. and M.S. in Biomedical Engineering from Indiana University–Purdue University Indianapolis (IUPUI). Her work focuses on experiential education designed to help students integrate tools, methods, and theoretical concepts, building the technical confidence and professional readiness required in industrial and regulatory engineering careers.

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The primary learning outcome of this project is for students to **recognize, research, and utilize ISO and ASTM standards** as tools which may be used in the engineering design process [1], [2]. This outcome is achieved through two objectives: first, students will understand the role of standards in the development and testing of products, processes, and services, and second, students will apply standards to verification testing for medical devices. Introducing these concepts early in the curriculum gives students practical experience navigating the world of technical requirements and specifications. Prior to implementation of this project, use of standards was not addressed in our curriculum until our senior design capstone course, and then it was presented only in the context of medical device design and design controls without example of practical use. While the Accreditation Board for Engineering and Technology (ABET), in criterion 5d, establishes the use of appropriate engineering standards in culminating major engineering design experiences as an essential element of engineering education [3], we observed that delaying this subject until our senior design capstone course was often insufficient to motivate student engagement with standards in their design projects. Consequently, this project shifts the balance of engineering standards in our curriculum from theoretical compliance to practical application of standards as a foundational skill.

While the use of standards could be integrated into many lecture courses, our interest in exposing students early to the practical application of standards made our sophomore biomechanics lab the best choice. The biomechanics lab is a required one semester course taken concurrently with the biomechanics lecture. The lab explores concepts of static mechanics, leaning heavily on the use of universal testing systems (UTS) through lab modules focused on compression, tension, and bending testing. We replaced our existing compression module with a module performing industry-relevant tests used to establish the forces involved in syringe depression. In this module, lab instructors introduce students to the ISO 7886-1:2017 standards manual [4] in a pre-lab lecture, during which students are instructed on the purpose, interpretation, and implementation of standards. Student groups are then provided with access to ISO 7886-1:2017, 1 mL, 10 mL, and 20 mL syringes and all the materials necessary to set up a test complying with the standard specifications. Students are meant to interpret the constraints and requirements presented in the manual and incorporate these into their test setup, perform tests on each syringe, and report the measurements describe in Annex E of the standard manual.

To complete this lab successfully, students must assemble the testing apparatus and implement the test as described in the standard manual, appropriately placing the water reservoir and setting parameters within the UTS software before executing the test. As a post-lab exercise, students use the guidelines in the manual to present the force vs. displacement data and report the relevant force measurements defined in the standard (Fig 1D). Rather than develop and apply analyses beyond the methodology in the standard, students are asked to evaluate how well their test setup matched the requirements of the standard, indicating discrepancies in implementation and potential sources of error. During a cumulative practical examination, students' ability to apply standards to verification testing for medical devices is assessed. Students are provided with ASTM F88/F88M-09 [5], a standard they haven't studied, which describes methods for determining the seal strength of flexible barrier materials. They are given a sterile syringe in its packaging and prompted to identify and implement the correct test technique based on the seal material and type. This assessment is graded based on accurate descriptions of packaging, correct implementation of an appropriate test method, and presentation of results.

Due to the proprietary nature of the information contained in both ASTM and ISO standards, one obstacle to the implementation of this project is the availability of standards to students, though students and faculty may have access to these through university library systems, removing the cost as consideration. However, beyond the purchase of the standard protocol, implementation of this lab does not require a large financial investment. While commercial fixtures geared towards syringe testing are available from UTS manufacturers, these are cost-prohibitive for occasional use in a student lab. We developed two methods for fabricating custom fixtures either with laser-cut parts or 3D printed parts (Fig 1B, 1C, 1E) which may be shared by request. The fact that the test apparatus described in the ISO manual [4] could be trivially translated to rapidly prototyped designs realized through both additive and subtractive manufacturing suggests that fixture fabrication will not pose a barrier to entry for engineering educators. However, the ability to collect the required parameters and graphs as described in this paper does require the availability of a universal test system.

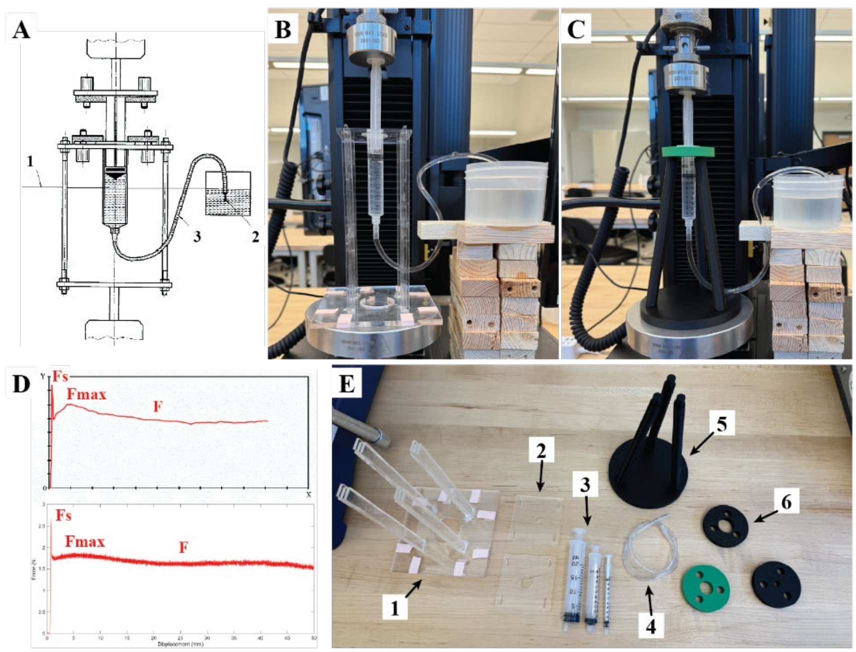

Fig 1. A) Apparatus for determining forces to operate piston [4]. 1: Water level adjusted to align with the graduation mark at 50 % of the nominal capacity of the syringe, 2: Needle [1.2 mm (18 G) and approximately 10 cm length], 3: Tubing [(2.7 ± 0.1) mm i.d. and 19.5 ± 0.5 cm in length with male and female Luer adapters at each end)]. B) Laser cut apparatus. C) 3D printed apparatus. D) Examples of graph of forces required to operate plunger. Top: Exemplary figure from standard manual [4], Bottom: Results generated using 3D printed apparatus. Fs: Force required to initiate movement of the plunger, F: Mean force during plunger travel, Fmax: Maximum force during the plunger travel [4]. E) Disassembled apparatus. 1: Laser cut apparatus base, 2: Laser cut syringe barrel holders, 3: Syringes (20 mL, 10 mL, 1 mL), 4: Syringe tubing with Leur lock adapters, 5: 3D printed apparatus base, 6: 3D printed syringe barrel holders.

While this implementation is uniquely focused on the biomechanics compression lab, with the prevalence of testing standards, the addition of standards to a mechanics lab in another program need not be limited to the compression of syringes. For example, the F88/F88M standard [5] used in our lab practical assessment would be suitable for a standards education lab built around tensile testing. The variety of test methods covered in a typical UTS-based static mechanics lab lend themselves well to implementation of standards testing modules at any point in the curriculum. Through exposure to multiple standards, students will develop understanding of the roles of standards and their applications. These outcomes are realized through completion of a standards module and reflection on post-lab assignment feedback prior to assessment during the lab practical.

This work does not use data from humans and therefore does not meet the definition of human subjects research; IRB review is not required.

References

[1] A. S. Khan, A. Karim and J. A. McClain, "The State of the Use of Standards in Engineering and Technology Education," presented at *American Society for Engineering Education Annual Conference & Exposition*, Atlanta, Georgia, United States of America, pp. 23.1233.1-23.1233.33, June 23-26, 2013, doi: 10.18260/1-2--22618.

[2] S. Kurihara, "Foundations and Future Prospects of Standards Studies: Multidisciplinary Approach," *International Journal of IT Standards and Standardization Research,* vol. 6, no. 3, 2008, doi: 10.4018/jitsr.2008070101.

[3] ABET, Baltimore, Maryland, United States of America, *Criteria for Accrediting Engineering Programs*, 2025-2026. [Online]. Available: https://www.abet.org/accreditation/accreditation-criteria/criteria-for-accrediting-engineering-programs-2025-2026/[4] *Sterile hypodermic syringes for single use - Part 1: Syringes for manual use*, ISO 7886-1:2017, Corrected version 2019-08, 2019.

[5] *Standard Test Method for Seal Strength of Flexible Barrier Materials*, ASTM F88/F88M-23, 2023.