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ABET Assessment Part 1: Standards

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ABET Assessment Part 1: Standards

This paper describes outcome assessment tactics for ABET

by Douglas Lyon, Ph.D.

Abstract

This is the first in a multi-part series of papers that establish an assessment framework for compliance with the general ABET criteria for standards, realistic constraints and major design experience. In this part 1 of the series, we focus on the assessment of standards. We have found that some schools use interdisciplinary-teams in their senior projects. When the outcomes from interdisciplinary teams are co-mingled it triggers ABET issues as the outcomes are not program specific. Moreover, some schools use the senior project (i.e., capstone) as their only means of providing evidence of a major design experience, evidence of student understanding of standards and the application of realistic constraints. This creates problems for programs as the program evaluators (PEVs) find it difficult (or impossible) to separate the assessments by program, resulting in issues during an ABET visit.

1. Problem Statement

ABET (formally known as the Accreditation Board for Engineering and Technology) makes use of a curriculum criterion known as *Criterion 5*. The curriculum criterion requires that programs provide evidence of "a culminating major engineering design experience that 1) incorporates appropriate engineering standards and multiple constraints, and 2) is based on the knowledge and skills acquired in earlier course work."

How do we know when we are compliant with the "major engineering design experience" with "appropriate engineering standards and multiple constraints" criterion? Where should the standards and constraints outcomes be measured? How can we have program-oriented measurement of these things when we have interdisciplinary teams? Direct examination of student work is only effective on a team-basis when the team is from the same program. Thus interdisciplinary teams confound program-oriented evaluation and yet provide intrinsic value that programs have embraced.

We are motivated to study this problem because it impacts 4,361 programs accredited at 850 institutions in 41 countries. More than 970 of these are located outside of the U.S., accounting for over 20 percent of all ABET-accredited programs in the 2020-2021 time frame. Thus, this is an international and widely felt problem [ABET].

2. Approach

The term “culminating major engineering design experience” is often interpreted to mean a senior project or a capstone experience. While standards may be introduced into early courses, if they do not result in a “major engineering design experience” the student outcomes will not be criterion compliant. For example, a fundamentals of engineering course taken by our freshman does address standards, however, it does not have a culminating engineering design experience and thus the standards covered lack criterion compliance. Thus, we devise assessment instruments that focus on senior project outcomes, as this is the “culminating major engineering design experience”. Our multi-faceted approach includes semi-automatic assessment via our course management system (*Blackboard*) as well as manual assessment of essays written by individual students, grouped by program. We do not assess interdisciplinary teams when providing evidence of compliance because this would result in comingled data. Thus, our program-oriented assessment of student work that provides evidence of compliance with curriculum criterion.

3. Summative Assessment of Standards

Our *Blackboard* system enables the creation of summative assessment instruments that can be automatically graded. We have devised an instrument, along with an answer key to facilitate automatic grading. Sample questions appear below:

1. (True/False) ISO is a standard (International Standard Organization)
2. (True/False) A norm (i.e. a social norm) can be a standard
3. (True/False) A method of development can be standardized and thus be a standard
4. (True/False) The waterfall model of software engineering is a standard design
5. (True/False) Patterns of engineering design are never standards.
6. (True/False) Standards are everywhere, from electrical connectors, to standardized page sizes, to power requirements, to nuts and bolts, etc. We are surrounded with standards and they enable us to have interchangeable parts and design from known specifications.
7. (Multiple Choice) Which are considered a "proper" standard
   (Answers)
   - Meters
   - a specification is a technical standard
   - a generally accepted test method
   - all of the above
8. (Multiple Choice) Standards are important to
   (Answers)
   - Software development
   - Engineering
   - Manufacturing
   - all of the above
9. (Multiple Choice) Standards can be characterized by
   (Answers)
   - Title
   - scope over which class(es) of items, policies, etc. may be evaluated,
   - date of last effective revision and revision designation
   - all of the above
10. (Multiple Choice) Quality management systems generally require

(Answers)
- reference to most recent test method validation
- person, office, or agency responsible for questions on the test method, updates, and deviations
- significance or importance of the test method and its intended use
- all of the above

11. (Multiple Choice) Where do standards come from?
(Answers)
- standards organizations
- professional societies
- trade associations
- All of the above

12. (True/False) ASTM is the American Society for Testing and Materials. ASTM is a developer of international voluntary consensus standards.
13. (True/False) ISO stands for the International Organization for Standardization, an independent, non-governmental, international organization that develops standards to ensure the quality, safety, and efficiency of products, services, and systems
14. (True/False) SAE formerly stood for the Society of Automotive Engineers, a United States-based, globally active professional association and standards developing organization for engineering professionals in various industries.
15. (True/False) ANSI stands for the American National Standards Institute, a private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system.
16. (True/False) OSHA stands for the Occupational Safety and Health Administration of the United States Department of Labor, formed by the Occupational Safety and Health Act of 1970. “CSHO” is an abbreviation for an OSHA Compliance Safety and Health Officer or. Compliance Officer.
17. (True/False) OSHA has standards for the prevention of infectious disease spread
18. (True/False) OSHA has standards for fall protection
19. (True/False) OSHA has standards for worker safety
20. (True/False) OSHA provides standards that employers must use to protect their employees from hazards
21. (True/False) FDA stands for the Food and Drug Administration and is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.
22. (True/False) The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.
23. (True/False) Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA
24. (True/False) The HL7 Individual Case Safety Report (ICSR) is a standard for capturing information needed to support reporting of adverse events, product problems and consumer complaints associated with the use of FDA regulated products.
25. (True/False) FDA Regulated Product Submission Release 1 (RPS) is a Health Level Seven (HL7) standard to facilitate the processing and review of regulated product information.
26. (True/False) Not all medical standards come from the FDA, some come from ISO

27. (True/False) ISO 15197:2013 is a standard for In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
28. (True/False) 802.11 is an ISO standard
29. (True/False) The FCC has regulatory standards
30. (True/False) When citing standards, use proper references with URLs that show when the standards were last accessed, for example: [68] "CFR - Code of Federal Regulations Title 21." [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr /CFRSearch.cfm?fr=820.1. [Accessed: 08-Oct-2019].
31. (Matching) Please match the below choices to the area where it seems to below
    - A. standard content - Terminology and definitions to clarify the meanings of the test method
    - B. standards are important to - software development, engineering, science, manufacturing, and business
    - C. standards test methods are scrutinized for - validity, applicability, and accuracy
    - D. standards can be associated with - Certified reference materials Data analysis, Design of experiments Document management system, EPA Methods Integrated test facility Measurement systems analysis, Measurement uncertainty Metrication, Observational error Replication (statistics) Sampling (statistics) Specification (technical standard),Test management approach Verification and validation
32. (True/False) For many fields of design, there are design standards
33. (True/False) The implementation of design standards ensures that the goals and values of the community are reflected in facilities that impact the public
34. (True/False) One standard can impact the look and feel of an entire downtown. For example: buildings designed with completely flat façades and monotone color schemes are not permitted. All buildings are required to have horizontal and vertical façade variations such as pop-outs, bays, recesses, arches, banding, columns, or similar features. Such features are required at least every 30 feet along all exterior wall planes.
35. (True/False) A standard can increase costs; For example, unfinished concrete block is not permitted as a surface material
36. (True/False) Standards can impact the public safety. For example: Microwave Oven Safety Standard A Federal standard (21 CFR 1030.10) limits the amount of microwaves that can leak from an oven throughout its lifetime to 5 milliwatts (mW) of microwave radiation per square centimeter at approximately 2 inches from the oven surface.

In addition to questions on standards, students are assessed on their understanding of realistic constraints.

4. Formative Assessment of Standards

This section described the formative assessment instrument administered to each student in order to provide evidence of standards. Each student is required to submit an essay that enables a demonstration of their level of understand of standards and how it relates to their project.

Please list your:
Name;
Major;
Project Title:
And 5 standards in the format:

1. exact standard title, standard number, and standard publication year

This is not a group assignment, each student submits their own work describing why the standard is important, how it impacts the design and how the standard relates to the major of the student. So, a EE may look into IEEE standards, FCC standards, etc. A biomedical engineering may look at FDA regulations and related standards, etc. These submissions are manually assessed.

5. Sample of Student work

This section describes examples of student work that provide a model to the student so that they can know what to expect. For example:

Our Blood Glucose Measurement project is impacted by the accuracy standards of the FDA; it's clear the Agency is taking meter accuracy seriously. Interestingly, the glucose meter field has seen a decline in new FDA clearances over the past few years: from a high of 61 clearances in 2012, only 35 were cleared in 2015, and only 17 have been cleared in 2016 so far. This guidance will raise the bar for getting a new meter to market [1].

[1] ISO 15197:2013 In-vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

Another example:

The International Organization for Standardization (ISO) and the U.S Food and Drug Administration (FDA) provide specifications and guidelines for products to ensure quality, safety and efficiency for the global consumer [62] [63] . In order to ensure safety and success, multiple design standards set forth by the ISO and FDA were taken into consideration during the fabrication of this device.

The team's device abides by the standards specified in ISO 13485, which regulates medical devices to ensure their quality and safety [64] . The potential risks were also evaluated according to ISO 14971 standards, which focus on the application of risk management for medical devices. This standard assesses the risk associated with a certain device and monitors the effectiveness of the device during its entire life cycle [65] . In addition, the biocompatibility of the device is crucial to prevent any harm to the patient and ensure the success of the surgery, thus the team has considered the ISO 10993 standards [66] . Along with biocompatibility, the sterility of surgical devices are fundamental to minimize patient risk. With this in mind, the standards included in ISO 11737, which regulate the enumeration and characterization of viable microbial populations in healthcare products, were followed [67] .

Since safety is a priority for both patients and manufacturers, the standards included in FDA 21 CFR 820 were applied to warrant the safety of the device and the fulfillment of the quality system requirements for manufacturing processes. As stated in Section 820.1, "The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use" [68] . Finally, ISO 16142

was used as a guide to assess and determine standards that when met will indicate that the device follows essential principles of safety and fulfills its purpose [69] .

[62] "ISO - Standards." [Online]. Available: https://www.iso.org/standards.html. [Accessed: 08-Oct-2019].
[63] "About FDA | FDA." [Online]. Available: https://www.fda.gov/about-fda. [Accessed: 08-Oct-2019].
[64] "ISO - ISO 13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes." [Online]. Available: https://www.iso.org/standard/59752.html. [Accessed: 08-Oct-2019].
[65] "ISO - ISO 14971:2007 - Medical devices — Application of risk management to medical devices." [Online]. Available: https://www.iso.org/standard/38193.html. [Accessed: 08-Oct-2019].
[66] "ISO - ISO 10993-1:2018 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process." [Online]. Available: https://www.iso.org/standard/68936.html. [Accessed: 08-Oct-2019].
[67] "ISO - ISO 11737-1:2018 - Sterilization of health care products — Microbiological methods —Part 1: Determination of a population of microorganisms on products." [Online]. Available: https://www.iso.org/standard/66451.html. [Accessed: 08-Oct-2019].
[68] "CFR - Code of Federal Regulations Title 21." [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.1. [Accessed: 08-Oct-2019].
[69] "ISO - ISO 16142-1:2016 - Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards." [Online]. Available: https://www.iso.org/standard/63939.html. [Accessed: 08-Oct-2019].

6. Rubric for Assessment

Each student writes about the impact and importance of the standards upon their project. We make use of the "safe-assign" (an automation system for screening for plagiarism). Blackboard enables off-line grading via a spreadsheet, however it does not show the students major. That is inserted, by hand, for the purpose of program-oriented assessment.

Figure 6-1 shows the summative assessment of student outcomes related to standards for the Biomedical, Computer Science, Electrical and Mechanical programs. Our standard of performance is met when students score above an 80.

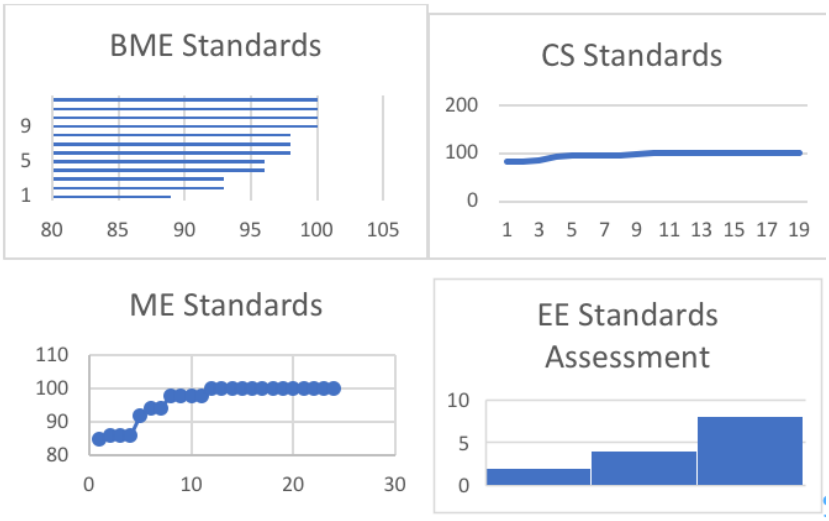

Figure 6-1. Summative Standard Assessment for 4 programs

We have selected different chart styles for each of the programs depicted in Figure 6-1 in order to further emphasize program-level assessment without co-mingling data.

7. Evaluation

ABET defines evaluation as a process for interpreting assessment data and determining the extent to which student outcomes are being attained. The evaluation results in decisions and actions regarding program improvement. We have a wrap-up session in our program that makes use of the assessment data and then makes changes to our program so that we can close the loop. The evaluation and resultant actions are the direct result of our evaluation of student performance and documented in the meeting minutes.

8. Summary

ABET compliant assessment of program-level curriculum requires measurable outcomes for students within the curriculum. Assessing and evaluating the outcomes enables continuously adjusting to improve the curriculum. Skills in the area of standards, realistic constraints and design are required of all programs and assessing these items in the capstone seems like a logical (and indeed prevalent) thing to do. Continuous improvement is a process that involves both assessment and evaluation. This paper shows one way to identify, collect and prepare data to evaluate the attainment of student outcomes in the area of standards. We use direct quantitative and qualitative measures to meet the ABET definition of assessment. Out process for evaluation is centered on the capstone course and is similar to the approach described by McCullough, except that we have shown how to single out assessment data so that it is program-based [McCullough]. Part 2 of this series presents assessment of the realistic constraints in the Capstone class.

9. References

[ABET] Private e-mail sent to ABET Program Evaluators on December 20, 2021.

[McCullough] C. L. McCullough, “A Plan to Assess All the New ABET Outcomes Using Only Three Courses,” ASEE Southeastern Section Conference, 2018.

10. Author information

Douglas A. Lyon received the Ph.D., M.S. and B.S. degrees in computer and systems engineering from Rensselaer Polytechnic Institute (1991, 1985 and 1983). Dr. Lyon has worked at AT&T Bell Laboratories at Murray Hill, NJ and the Jet Propulsion Laboratory at the California Institute of Technology, Pasadena, CA. He is currently a Professor of Electrical and Biomedical Engineering at Fairfield University, an ABET Commissioner, a life member of the IEEE and President of DocJava, Inc., a consulting firm in Connecticut. Dr. Lyon has authored or co-authored four books and over 50 journal publications. Email: lyon@docjava.com. Web: http://www.DocJava.com.