NIST Final Summary Report
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Standards Modules for Engineering Curriculum: A Case Study Approach

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Abstract

This final report outlines the development of standards education modules based on case studies, designed for both remote and on-site learning. Specifically, we aimed to engage biomedical engineering students with technical standards through a product liability in-class activity, modeled after a moot court. In this activity, students work in teams to investigate an ambiguous case study and participate in a debate as either the prosecution or defense, persuading their peers on the role of standards compliance in the product liability case.

These modules can be seamlessly integrated into Introduction to Engineering or Senior Design Capstone curricula to enhance students' understanding of ethical approaches in engineering design and practice. The educational materials, including lesson plans, tutorials, case study narratives, and videos related to the moot court exercise, have been freely disseminated through the Open Science Framework (OSF).

Key aspects of this work include (a) the innovative positioning of the case study to teach standards in an engaging manner, and (b) the assessment of students' knowledge of standards through pre- and post-surveys. Project assessments were conducted by a third-party evaluator as well as internal cross-cutting analyses, student surveys, and self-reflective activities.

The primary objective of this project was to create comprehensive, flexible, adaptable, and customizable class materials that would facilitate adoption by educators in other design courses. A specific goal was to develop modules that encourage the consideration and use of standards in quality systems software development and cybersecurity within Senior Capstone courses.

This report details the project outcomes, lessons learned, and experiences in promoting the project's suitability and potential for adoption by other educational institutions.

Introduction

Public and environmental safety are critical components of engineering ethics that require an understanding of the engineering, business, and legal issues related to the safety concepts and are connected to standards and regulations compliance. Hess & Fore found in their 2018 study that teaching standards and regulations are increasingly popular in engineering programs [1]. However, they pointed out a lack the business and legal context, which is crucial for understanding the critical role these standards play in industry. One way to connect the interdisciplinary complexities is through product liability cases [2,3].

Product liability cases highlight the consequences of inadequate adherence to standards, emphasizing the importance of designing safe, effective, and compliant medical products. One example of the connection between standards and product liability law is the case study by Forbes & Emplaincourt [4] related to a real-life accident. These scenarios teach students to assess risks, interpret regulations, and implement industry best practices, preparing them for real-world challenges. Additionally, many biomedical engineers may be called to participate in product liability litigations as engineering expert witnesses, which represents an increasingly common aspect of the engineering profession[5,6]. Furthermore, such case studies cultivate critical thinking, problem-solving, and decision-making skills, enabling students to analyze complex situations involving multiple stakeholders, including manufacturers, regulators, and patients[7,8]. By focusing on the role of standards, students gain insight into how guidelines like ISO certifications or FDA regulations shape innovation and ensure public safety. This knowledge fosters a comprehensive understanding of the interconnectedness of design, manufacturing, and post-market surveillance.

In essence, the concept of product liability represents an excellent way to bring all aspects of safety issues to the forefront of the engineering profession because it includes the legal responsibility of developing safe products. While medical devices that reach the market through a Premarket Approval ("PMA") application are generally preempted from the product liability law[9], this does not always apply for those marketed via a 510(k) process; regardless, in both cases familiarizing biomedical engineering with the product liability concept is valuable as an exercise in engineering ethics and as an opportunity to discuss compliance with FDA regulations and industry standards. One way to teach about product liability which is increasing in popularity is through a moot court class activity.

Moot court, traditionally associated with legal education, involves simulated legal proceedings, allowing students to engage in mock trials. Moot court represents an engaging active learning technique that uses a case-based approach to solving problems and contributing to the development of student's critical thinking skills. Expanding the scope of moot court to engineering programs presents a unique opportunity to bridge disciplines and foster interdisciplinary learning mirroring the complexities they may encounter in their future engineering careers. Integrating this innovative pedagogical approach into the engineering curriculum through product liability cases provides students with a practice-based education, allowing them to apply theoretical knowledge to practical scenarios, while also learning about business and legal aspects related to engineering.

Moot court exercises have been successfully adopted by other disciplines to increase students' understanding of the legal system[10–14] , including engineering disciplines [15–18].

While developing a liability case applicable to biomedical engineering posed challenges - especially with FDA-approved medical devices - we successfully crafted fictional medical device case studies focusing on two contemporary issues: cybersecurity and the misinterpretation of commercially available wearable devices for medical use. These cases were implemented over a three-year period with the BME Senior Design courses at our institution. The assessment of the moot court class activity demonstrated success in developing students' critical thinking and problem-solving skills. Appendix A provides the highlights of the case "Agility Ace."

Method

Methodology is crucial when developing a case study as it ensures a structured, objective, and comprehensive approach to analyzing and presenting information. It provides a clear framework for gathering relevant data, identifying key insights, and maintaining consistency throughout the study. Furthermore, a structured approach enables other institutions to understand how we developed the cases and areas where they might need to adapt in their own educational settings. A well-defined methodology enhances credibility, facilitates stakeholder understanding, and ensures the findings are both accurate and actionable, making the case study a reliable resource for in-class activity.

In our project, the initial framework for development activities, which emphasized a systematic approach, proved valuable; however, the detailed steps underwent refinement over time. Conducting a case study on the standards applied in a moot court case required additional research and careful consideration. Significant time was devoted to gathering comprehensive and relevant information and ensuring its presentation was clear and concise, addressing the needs of all stakeholders—both internal and external—engaged in the process.

Our method involved 7 major steps.

1. Identify the moot court learning objectives and measurable learning outcomes. This shapes the selection of design standards to be involved in the case. For instance, the case study of the present work wanted to bring into view contemporary issues with the design of "wearables," personal fitness devices that could be interpreted as a medical device, but may not meet relevant standards. Many wearable systems feature cloud-based processing, machine learning software as a medical device (SaMD) and challenges with interface design and power budgets. Once understanding cybersecurity standards was identified as key learning outcome, case authors (a) identified the case-specific standards documents, and (b) conducted a literature search on the current legal, ethical, and product development issues that could help frame an interesting case. Ideally, at this step in the process it is beneficial to draw on experts in the field to gain insights into the standards and their application.

2. Formulate a relevant moot court product liability position: From the many different ideas created during the literature search, formulate a hypothetical legal issue such as non-conforming product, adulterated product, design failure, manufacturing failure or regulatory non-compliance. The critical path is to then weave together the legal aspect and the application of design standards. There are a multitude of moot court cases for product liability of a very general nature to guide the development of plaintiff and

defendant positions that could be taken, though critical is identifying a meaningful and substantial role of standards in the case. Appendix A provides an example case.

3. Analyze the premise of the case: Analyze the moot court case to understand how the standards were applied and how use plays a role in product liability. Identify the key arguments and positions that could be taken by the parties involved, and examine the evidence presented to support these positions. This sets the foundation for flushing out more details and issues through the development of a case outline.

4. Develop a case study outline: Based on the preliminary analysis, develop an outline for the case study. This should include an introduction that provides background information on the case, a description of the standards involved, a summary of one or two potential arguments made by the parties involved, and suggestions for highlights of the key takeaways from the case. At this point it is essential to bring in third parties for review; we found that there are a variety of law school moot court and mock trial students groups across the country that are willing to help; this is not about getting a precise legal review as much as a general "sanity check" on the overall case. A sample script is provide din Appendix B.

5. Write the case study: With the outline as a guide, write a 2-4 page case summary. Be sure to include as many details as possible, but it is helpful to leave room in the outline for the student actor team to have input and explore for themselves how standards were (or might be) applied in the case. Including hypothetical discussion points, questions or prompts will encourage students to engage with the material. Go back to your key third party opinion leaders for a review. Consider the complexity of the case in the context of how long you will plan for the actual case to be conducted; we have found that 90 minutes is adequate for an inaugural exercise.

6. Review and revise: With the revised case study in hand, review it for accuracy, clarity, and assurance that the use of standards will follow from trial arguments. Make revisions as needed to ensure that the case study effectively communicates the key concepts and insights related to the standards used in the moot court case.

7. Identify case roles and share the case study: There are a wide variety of roles that the students can play that have varying degrees of oration and argument. For instance, the plaintiff's attorney may play a prominent role in case presentation, but the bailiff a more reserved (but equally important) role. Identify roles such as judge, plaintiff, defendant, expert witnesses, and jury; it is surprising how quickly a roster will build to more than a dozen participants. Share the case study with the relevant stakeholders, deciding in advance how much latitude and creativity you want the students to have; the exercise can be a lot of fun, but the more serious nature of the role of standards in design must have centner stage.

These seven steps build out the case study that will set the stage for the student team members to take the next step and prepare for the moor court session itself. Protocols for conducting a moot court exercise abound on-line and these can be used to create your own agenda for the event that needs to fit the time-frame set aside for the case. While other considerations such as where to hold the court exercise are important, there is no need to rent a courtroom as a typical small-amphitheater classroom can work just fine.

Once the case study was developed and launched in-class, several other steps are important to keep in mind related to the success and impact of the in-class case activity. Three components – easily overlooked -- are important:

- Finalizing Educational Materials: Supporting materials such as lesson plans and tutorials need to be revisited based on the in-class experience. were developed to facilitate the learning process. These materials were designed to be flexible and adaptable for different teaching environments. It is important to take nodes during the Trail and then integrate them into the case materials before the detials are lost.

- Assessing Feedback: The case study and moot court exercise were pilot tested with a shorter versions (20 minute discussions) and expanded into full one-hour in-class cases Feedback was collected to identify areas for improvement and to ensure the materials were effective and engaging.

- Finalization and Dissemination: After incorporating feedback, the final version of the case study and educational materials was completed. These resources were then disseminated through the Open Science Framework (OSF) to ensure wide accessibility and adoption by other educators.

By following these steps, we were able to create comprehensive and impactful case studies that effectively teach the importance of standards in engineering practice.

Implementation Planning

Our initial estimate was that we could accomplish the development and testing our cases within a two-year period, as outlined in Figure 1, below, involving

1. Curriculum Development
2. Curriculum Testing and Refinement and
3. Curriculum Dissemination

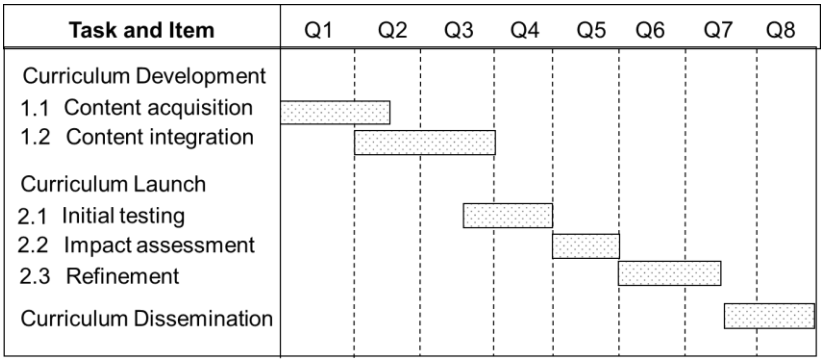

Figure 1. Overall timeline for curriculum development, launch (testing and assessment) and for dissemination. This timeline was fairly accurate except the testing and impact took much longer than originally planned and required an additional 4 months to complete the planned activity.

In Figure 2, below, we illustrate that our course curriculum development process is structured so that learning objectives are clearly derived from concepts that lead to essential questions that can be answered with specific enduring understandings. We believe this structure guides case study design to be as non-perishable as possible. The process implied in Figure 2 is a draft of one of four potential areas for which cases can be developed.

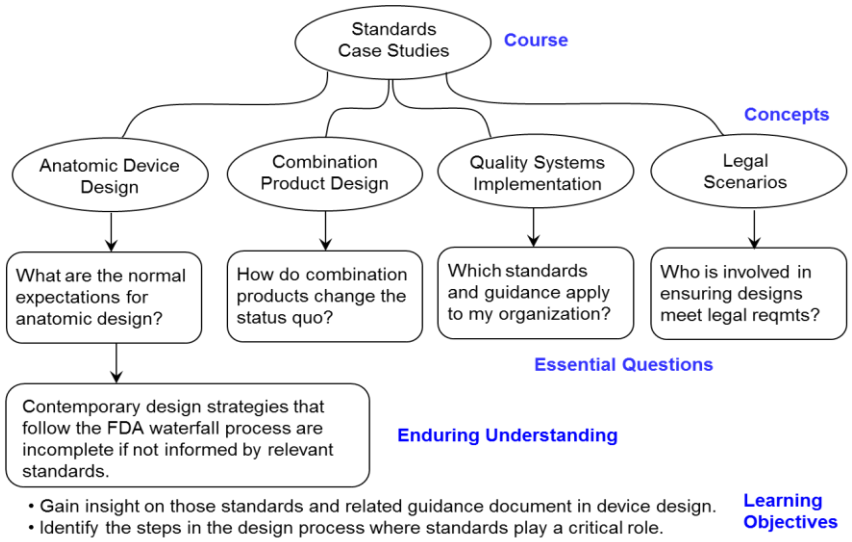

Figure 2. Curriculum development strategy, illustrating the pathway to developing learning objectives. Only one case study example is provided. A complete set of enduring understandings and learning objectives is foundational to case study success and impact.

Communication Plan

Our curriculum materials are licensed under the Creative Commons 4.0 license and made publicly available on the Open Science Framework (OSF) in a public space specially devoted to this project. Complete course materials have been posted on the OSF page as well as improved versions after assessment. This Final Summary Paper will be posted on OSF. As OSF offers means to measure the impact of the materials through downloads counts, website visit statistics, and copies made for documents, we will be able to monitor the use of these materials.

Dissemination efforts will be carried at the campus, local, and national and international levels. At the campus level, we hope to encourage CWRU faculty to integrate standards in their curriculum by sharing our experience with standards education. At national and international level, additional dissemination has taken place through presentations at conferences, such as the Biomedical Engineering Society (BMES) Annual Meetings, the Society for Standards Professionals (SES) conference, and the American Society for Engineering Education (ASEE) Annual Conference, all are premier international professional organizations engineering education, respectively.

Initial Case Development and Implementation

To date, the moot court in-class activity has been held in each of three academic years during the Fall and Spring classes of Senior Design students. For the Spring sessions, the activity was preceded by first a lecture covering an overview of standards and regulations, followed a week to two weeks later by a lecture on how to identify, access, and declare conformance to standards as part of the engineering design process. These preparation lectures serve to introduce the concepts of standards as well as establish the legal underpinnings and ramifications of regulatory affairs as they relate to Biomedical Engineering. The moot court was held a few weeks to a month after the initial introductory lecture.

The process for developing the case for the moot court activity followed the seven-point process for case study development highlighted earlier. In short, the case design starts with the identified

learning objectives, and the details are fleshed out based on actual reported events from previous liability cases and FDA recall reports. A key part of this process is getting the "legal ritual" and language correct. Working with local student moot court clubs or organizations can potentially be a critical aspect of case development – their moot court models are slightly different as they are framed though the lens of a competition, not in-class learning.. The initial case developed for this in-class exercise was intentionally designed to be multi-layered, covering aspects of product liability, cybersecurity, and the available standards applicable to these areas. These particular areas were selected as they are quite pertinent to direct-to-consumer medical devices as well as topical given the new emphasis by the FDA (as of March 2023) on the cybersecurity of medical devices.

The activity itself consisted of student volunteers serving as participants in the moot court in one of the following roles: 1) plaintiff, 2) defendant, 3) plaintiff's or defendant's lawyer (we had three for each side), 4) expert witness to provide specific technical or regulatory content (this case used four students in this role). The instructor served as the judge to maintain order - of both the court and the teaching aspects of the activity. Participants were supplied with partial scripts and topic prompts (sample provided in Appendix B) but were otherwise encouraged to "ad-lib" in the spirit of the role.

To assess the effectiveness of this activity in teaching students about standards, a pre- and post-activity survey was used to assess their understanding of standards, and how it improved as well as inquire about their overall impression of the activity itself. We initially used a third-party consultant for this activity, but soon realized we could use internal resources just as effectively, and it was clear that most consulting companies were interested in $20K engagements, not the $2K levels we were hoping for.

Collaborative Initiatives

A major component of the project was to develop collaborative efforts with other Institutions to introduce a Moot Court class activity aimed at involving engineering students in the application of technical standards. Such a collaborative approach not only allows for the sharing of educational resources but also provides an opportunity to assess the case study's effectiveness in different educational settings. In principle, the plan was for the process to promote knowledge exchange and to help refine the case study to cater to a broader audience. Challenges were often linked to the educational environment at each institution and the comfort zone of the instructor leading the case implementation. We also found that students' familiarity and comfort with standards are also critical for class participation.

Rolling out a Moot Court case study to other institutions involves careful planning and execution, and we gained many "lesson learned" along the way. We first highlight the challenges and then discuss the benefits from both the organizational and implementation perspectives.

<u>Challenges</u>

- Writing a case study is hard work, and it is challenging to be creative when trying to develop diverse and engaging case studies that cover a range of legal issues. While a diversity of cases ensures participants become exposed to different areas of law, not every institution will have engineering faculty versed in case legal knowledge, and some background information may need to be developed. Providing training sessions on how to

effectively run a Moot Court, including understanding the rules, structuring arguments, and facilitating student participation, is essential.

- Case studies need to align with the curriculum and learning objectives of different courses. Ensuring that case studies are relevant and applicable across a variety of organizations can be a challenge.
- Initial authorship and implementation of a Moot Court case is likely to be led by one organization very knowledgeable about many case details and nuances. It can be easy to overlook the need for comprehensive guidelines and resource requirements other participants may need. This includes case standards, rules, judging criteria, and any relevant legal summaries. Unless participating institutions have access to the same information it can be confusing or uncertain how to launch their own Moot court activity.
- The entertainment value of the cases has student appeal, but it is important to define the objectives and goals of the Moot Court case study. Faculty should prioritize the most critical elements to ensure students grasp the core concepts. Each institution must identify specific skills and knowledge participants gain, and how the Moot Court aligns with the educational objectives (such as ABET) for the institutions involved.
- Implementing Moot Court case studies and adapting it to specific time constraints may be challenging and may require the selection of the key aspects of the case that highlight essential standards and legal issues.
- Students may struggle to adequately prepare for Moot Court sessions, especially when facing time constraints. Implementing a structured preparation schedule and providing resources such as guidelines, templates, and sample arguments can assist students in managing their time effectively.
- Education impact assessment challenges can be difficult. Ensuring consistent and fair evaluation across different faculty members can be challenging unless clear grading rubrics are available. While time and resource-intensive, holding calibration sessions where faculty members can discuss and align their assessment criteria can help maintain consistency – this step is very difficult to implement in practice.
- Consider how feedback will be generated from participants (student and faculty), coaches, and peers that can help improve not only the case, but also student academic argument skills, celebrate their strengths, and understand areas where performance can be improved. This needs to be adaptable to the preferences (and budgets) of different institutions, in particular where in-house assessment tools are not in place (and must be contracted). Regardless of the mechanism, a thorough post-event evaluation will take time and effort but is central to process improvement.
- Collaborators typically have different levels of resources, both in terms of finances and personnel to dedicate to a Moot Court that might be viewed as an extracurricular activity. Some institutions may have dedicated staff to support a Moot Court event, while others may lack such resources.
- There might be resistance to adopting new teaching materials or methods. Faculty members may be accustomed to traditional teaching materials and may be hesitant to incorporate Moot Court cases and events into their curriculum. Faculty members may have different teaching philosophies and preferences for instructional materials. Some may prefer traditional lectures or textbooks over case studies, making it challenging to achieve widespread adoption.
- While this did not arise in the current work, copyright and intellectual property issues may come into play. Because case studies are developed by individuals or organizations, and they may be protected by copyright or other intellectual property rights. Universities

need to be mindful of legal considerations and obtain the necessary permissions to distribute and use these materials.
- The development of the case study is not static over time and communication of "lessons learned" is important. Regularly updating all participants on, for instance, changes to the case study requires a centralized platform for communication.

Benefits

Collaborating with other universities in sharing and exploring Moot Court case studies brings about several valuable benefits.

- Collaborators have unique strengths, specializations, and perspectives on engineering education and standards – exchanging ideas enabled a multi-faceted perspective on the case wherein different viewpoints identified areas of improvement in case concepts. Encouraging collaboration and knowledge-sharing among faculty members with diverse expertise can help address gaps in understanding.
- Collaborating with other universities broadens potential content variety and ideas for the development of new case studies. This diversity ensures that students are exposed to a variety of real-world situations, enhancing their ability to apply engineering standards across different contexts and industries.
- Collaborating with other universities fosters networking opportunities for both faculty and students. This interconnectedness can lead to partnerships, joint research projects, and collaborative initiatives that extend beyond the specific case studies, enriching the overall academic environment.
- Engaging with other universities allows for peer review and feedback on the Moot Court cases. This iterative process provides continuous improvement of teaching materials, enhancing their relevance, accuracy, and educational value.
- Individual institutional effort and financial burden associated with creating high-quality content may be reduced through the open sharing of the case studies documents, teaching materials, and research initiatives.

Thoughtful program design is essential when collaborating, but the investment in time, energy, and resources can enhance the effectiveness of Moot Court case studies and provide a valuable learning experience for students across varying faculty expertise levels. We continue to explore the potential for widespread adoption of Moot Court class activity for teaching technical standards across engineering programs and underscore the role of inter-university cooperation in elevating the quality of educational materials and enhancing the adaptability of teaching resources—an endeavor that ultimately yields benefits for both students and educators alike.

Results & Discussion

At our university the teaching of standards is an integral part of the Senior Design Experience. The moot court experience appears to suggest that use and application of standards had more impact on students then knowing the importance of standards and the understanding that standards are important in professional practice. In essence, the moot court activity may have been more influential on the "why" of the importance of standards versus the "what" of our conventional didactic class lectures.

Primary Lessons Learned:

Overall, students found the exercise engaging and a good vehicle for delivering content that can often be perceived as "dry" and with little context available to put into perspective its importance to engineers. Novice engineers often see their work as "design and development", ending with the launch of the product. Whatever happens in the post-market phase of the device is "not their problem", which is erroneous, as their design and the choices they make can lead directly to product liability issues. This means of presenting the impact of these decisions as legal issues that arise after the engineering work is complete does well to put this into the proper perspective.

A related result is that students were able to better appreciate the role of standards, as a concept, separate from the specific details of the standards included in the exercise. When covering standards in the classroom, instructors too often cover the technical aspects in excessive detail. This can cause students to disengage from the material and see standards as overly "wonky" with too much emphasis on the minutia. This can lead to an "if I need to know ALL this, then why bother?" type of attitude. By presenting the role of the standards at issue in the moot court exercise as well as the details, students gain a better appreciation for the former, even if they were unclear of the latter. It is this context that is too often overlooked in a lecture presentation on the topic. Similarly, this presentation style does a good job of separating the "soft skill" concepts of understanding standards with respect to product liability from the "hard skills" of the technical implementation in the device.

Of particular interest was the applicability of our example in Appendix A presented to the student audience. While standards cover a breadth of applications, it was felt that using them in the context of a software liability dispute would be more appropriate and "timely" to the student population. As the topic was familiar and approachable, it aided in engagement. It is felt that a less topical example would not be as engaging.

IRB-approved pre- and post-surveys were conducted to measure the impact of the moot court experience. Overall, students found the exercise engaging and a good vehicle for delivering content that can often be perceived as "dry" and with little context available to put into perspective its importance to engineers. A related result is that students were able to better appreciate the role of standards, as a concept, separate from the specific details of the standards included in the exercise. Of the 20 survey questions, several results suggested students gained knowledge or had a better understanding of the role of standards in design. Sample results are as follows:

1. If given a biomedical engineering issue or case, I am confident in my ability to identify the relationship between Standards and the issue presented: "Strongly Agree" increase of 14%
2. I have a strong foundational knowledge of the regulatory aspects of biomedical engineering. "Strongly Agree" increase of 27%
3. My current knowledge of Standards is very important as I complete my biomedical engineering education: Pre- and post-survey results were similar.
4. My current knowledge of Standards will be integral to my next professional or educational steps: Pre- and post-survey results were similar.

These results are only a small sample of the data collected to assess the impact of the impact of the moot court experience on standards knowledge.

As this activity involves a substantial amount of "presentation", it is important to select students who are more adept and comfortable with public speaking and acting. The first run of the moot court came across as a bit staid, while the second run the next semester with different students in key roles was much better received. While the content was mostly the same (see above) the improved performance served to make the activity more entertaining and afforded better retention of the material.

Other Lessons Learned:

Despite these successes, it should be noted that there were also a number of lessons learned about what NOT to do in this type of exercise. These are being shared as cautionary tales.

Reliance on a few volunteers to act out the case is not advised. As this was a new exercise, it was felt that we should engage a limited number of student volunteers to work through this inaugural run. While the overall activity met the desired goals, it was not without some minor hiccups. The most significant (though in hindsight illuminating) of these was the impact of people not showing up. Unfortunately, the student prepared to play the expert witness was unable to attend class at the last moment due to illness. Without this key part of the story, the overall outcome of the case was the exact opposite of the intended verdict. While an interesting demonstration of the key role of the expert witnesses in a moot court exercise, it shows that having a few students cover the required roles can lead to an unpredictable outcome and perhaps prevent the exercise from even being conducted. There was also a wide variability in the quality of the background preparation with some students being well-versed and others having done little more than read the prompt for their role.

For this reason, it is highly advised that all students in the class are assigned a role to prepare for and are expected to be able to present the material relevant to that role on the day of the exercise. Each student should be tasked with doing their own research in preparation for their part. This background research should be a graded assignment in order to compel adequate participation in developing the background. With everyone so prepared, those chosen for each role can then be either volunteers or randomly determined. This allows all students to "share the load" of preparing for the moot court but also eliminates the issue of key participants not being able to deliver their content. Better preparation will also allow for improved and more accurate and nuanced delivery of the regulatory and technical content.

With each run of the activity, we identified hiccups and missteps in the process. For example, during the first run, one of the students playing an expert witness was unable to attend class when the moot court was held. This fundamentally impacted the quality of the technical content presented - both in the moot court and the class. Having doubles (understudies) for the roles is highly encouraged.

Another observation was made that some students did not entirely follow all aspects of the moot court case. While this may have been due to some lackluster performances, it is felt that a summary discussion following the exercise would be helpful in "closing the loop" and re-covering key details that may have been missed. The timing of this discussion remains a question to be answered, however. Ideally, it would be immediately after the exercise while it is fresh in students' memories, but the moot court case already takes a full class period. The other option would be to have the review during the next class period, but this temporal disconnect

between the presentation and the discussion may impact its utility. A compromise would be if a long "lab period" were used that could provide enough time for both the moot court and review, but most Design courses are not taught during lab periods.

Finally, some technical details of the exercise itself were noticed to be issues with implementation. The room used for the inaugural run (what seems like a long time ago) was suboptimal and was not fully set up as an actual courtroom. Choosing a room that can more accurately reflect the layout of a true courtroom is felt to potentially allow for a more immersive experience. Similarly to this, having microphones for all speaking parties would also be useful as given the room size, it was at times difficult to hear all of the participants. This is a critical necessity if the exercise is being filmed as a few omnidirectional microphones did not pick up everything. On the topic of filming, while initially a key objective of the moot court exercise, the final utility is seen as less important than originally felt. Other than having the exercise available for students unable to attend for a variety of reasons, the original concept was to develop the activity, record it, and then use this video as a teaching tool for other classes, including at other institutions. While this can present the material, it eliminates the background preparation and direct participation in the exercise itself, which is one of the primary teaching aspects of the moot court. It asks the question of whether just watching the video and talking about others performing in the moot court is enough to instill an understanding of the role of standards in Design education. We feel that it would be far better for students to fully participate rather than just watch a movie and discuss.

Recognizing the appeal of the project, a collaborating university implemented the activity in their senior design class, albeit in a way we did not anticipate. The collaborative approach facilitated the sharing of educational resources, encouraged knowledge exchange, and contributed to refining the case study to cater to a broader audience.

Conclusion

The moot court activity proved to be an effective teaching tool, demonstrating significant educational benefits for participants. Notably, in our most recent case there was a 12% improvement in understanding regulatory language, which is crucial for navigating the complex legal frameworks that govern biomedical engineering. Additionally, participants showed an 11.3% increase in their grasp of how quality systems apply to labeling, an essential aspect of ensuring compliance and maintaining standards in product development. The activity also boosted overall confidence in understanding standards and their roles by 16%, highlighting its effectiveness in demystifying these often challenging concepts. More broadly, there was a 12% increase in confidence regarding the regulatory affairs environment specific to Biomedical Engineers, underscoring the activity's relevance and applicability to real-world professional settings. These improvements suggest that the moot court activity not only enhances specific regulatory knowledge but also builds general confidence in navigating the regulatory landscape. Consequently, we believe that incorporating this activity into design courses can provide substantial educational value, equipping students with the necessary skills and confidence to excel in their future careers. The positive outcomes observed affirm the merit of the moot court activity, making it a valuable addition to any curriculum aimed at preparing students for the regulatory challenges they will face as professionals in the biomedical engineering field.

About Us

Colin Drummond is Professor and Assistant Chair in the Department of Biomedical Engineering, who leads efforts in undergraduate education with a specific focus on expanding experiential design courses and professional practice preparation. Colin joined CWRU after two decades in industry and this practical experience has been an asset to his central role in teaching graduate and undergraduate design courses in the department.

Matthew Williams, Ph.D. is an Assistant Professor with a long history of teaching Senior Design Capstones and in the development of experiential education at the first-year level. Dr. Williams' experiential education activities broadly include engineering design, programming, data acquisition/processing, and fabrication. Research interests include control of prosthetics and assistive technology for stroke and spinal cord injury.

Daniela Solomon is the Research Services Librarian liaison to the Case School of Engineering. Solomon has a bachelor's degree in electrical engineering and a master's degree in library and information science. Prompted by her work experience with standards, Solomon is deliberately working towards increasing standards awareness of engineering students at CWRU by creating opportunities for students to learn and interact with standards. She initiated campus-wide on-demand purchase program for standards, collaboratively organized two successful standards education workshops on campus, and collaborated with faculty on teaching standards . She is active in several local and national professional organizations.

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Appendix A: AgilityAce Sample Case

"*Adding Hustle to your Health"*

Background

A year after losing in court that HealthMaster was not liable for her injuries, Shifra has a knee replacement after being injured while playing "paddleball" at her local senior citizen center. She is doing well overall, but her youngest daughter Katherine feels she is not active enough as per recommendations by physical therapy. Katherine decides that yet another new fitness product "AgilityAce" on the market by Phoenix Electronics will enable objective data to be collected on her mother Shifra. Katherine does not think her mother Shifra is active enough and wants to have fitness tracking data to share with Physical Therapy. Overall, the use of the device goes well except for a lot of "artifacts" and there are long periods of time when data is not collected. Determined to prove her daughter wrong, Shifra used a gel underneath the wearble device to "get better contact" just like the gels used for her recent EKG. Unfortunately, the gel not only caused a rash, but there was a slight "tingling" sensation that feel like a shock, so she stopped using the gel.

Although the gel is discontinued and the original rash went away, more recently Shifra is wearing the device 24 hrs/day and not only has a completely new rash returned, but there was blistering and an infection that required antibiotic treatment. Shifra complains that the antibiotics make her tired and she cannot exercise. Her daughter Katherine knows that AgilityAce is part of the "Internet of Things" and can track not only the number of steps, but also tracks where Shifra goes. Shifra's refrigerator is connected to the web so Katherine can monitor food in the refrigerator. Shifra is outraged that there is now data to show she is actually active enough to go the refrigerator quite frequently and is even more upset that physical therapy knows, too. Further, Gerrard, a former employee of Phoenix Electronics discovers that while the security problem has been fixed that allowed the device to be hacked (and battery life modified), he now is able to hack the "cloud" storage site and access the device data files (a cloud storage app is required to view Agility Ace data). Gerrard shares on social medica that the device is less likely to enhance active lifestyles as much as the device tracks eating; he finds it fun to post (by zip code) how many times users go to the refrigerator.

The Complaint

The family is suing Phoenix for selling a defective product since it was the source of the infection. Further, the suit claims that inadequate cloud security measures did not follow "best practice"; as a result of data leakage on social media about Shifra's eating habits, Shifra no longer feels comfortable going the senior center to play paddleball - she is increasingly depressed without her social network in place.

Changes in personnel on the case

The family was unhappy with the prior Plaintiff Attorney team, so the lead plaintiff attorney Aaron Rodrigues has a new support member, William Kaon. Shifra's oldest daughter Harshita become fascinated with cybersecurity so now works for a consulting firm and likes the pay an expert witness makes (she earns $542/hourly). It has been very difficult for the family hire expert witnesses for the plaintiffs since the family is running out of money, so they don't have a ISO10993 Biocompatability expert to suggest the standard was not followed; they are hoping Harshita has read about this on the internet and can comment in court if necessary. Harshita is happy to oblige since is pleased her younger sister is so eager to sue Phoenix again. Phoenix was happy with the defense team so has kept the same counsel. Eric has retired from being a Cybersecurity expert witness and is now the lead designer for Phoenix; he likes the comfort of an office job since working as a consultant involved long hours and interfered with golf. The lead attorney for the defense, Lauren Zukowski, plays golf, too, where she met the expert witness for FDA matters, Justin Chin, at the clubhouse. Justin has only been serving as an expert witness for 90 days and this is his first time in court - Justin makes $120/hr which is twice what he used to earn as a CAD designer. No one is very concerned since he is a member of the club and surely can be trusted. Raodatullah, the other defense attorney agrees; Phoenix has been spending a fortune on lawsuits and Raodatullah thinks Justin is a great cost-cutting measure, besides, he downloaded a paper

from the internet on product liability and has been reading it and wants to bring it to court for evidence. Lauren like the idea and is not worried overall since "we've got this in the bag."

Today in Court
The case has been underway for a week and on this Friday the case is resuming, now focused on determining whether the product design followed "best practice." There are many issues at play, but a few sentiments have arisen over the past few weeks. On the plaintiff's side, they feel this is really a consumer device that has been falsely advertised as a medical device, and simply has not been properly designed; they find it annoying that Phoenix continues to "get away with it." Further the plaintiff is annoyed that the Cloud App is not only required to subscribe to if you want to view your data, but the internet is not secure. The defense believes that court precedent will show this is strictly a recreational device; further Phoenix will argue the plaintiff and her family did not follow AgilityAce instructions for use, related warnings, and simply does not "get it" that this is just a fun fitness tracker like millions of others on the market.

Friday Moot Court Notes
We have changed the narrative a bit to give the Actors room to make a variety of arguments. Opinions may or may not always be entirely correct or sound! Unlike last semester, the Jury (audience) is to closely follow the discussion and *they* determine what is the truth.

Key concepts

- Perception of Agility Ace as a medical device (for physical therapy tracking) even though Phoenix claims it is a recreational consumer device.
- Non-compliant biocompatibility and duration of wear (ISO10993 on tests for various use duration)
- The FDA has only providing guidance on what is turning out to be a rapidly emerging consensus on IoT, so it is incumbent on the device designers know and comply with "state of the art."

The class "jury" will be writing statements about the case in "real time" and the Actors here only have to make arguments about the multiple parts of the case; the jury (audience) will determine which part of the case is most important.

Moot Court Participants

Presiding

Judge:	Instructor
Bailiff:	Daniella Solomon

Plaintiff

Plaintiff:	Shifra
Plaintiff's Daughter	Katherine
Plaintiff Lawyer A:	Aaron
Plaintiff Lawyer B:	William

Defense

Defendant:	Eric, Design Engineer, representing Phoenix Electronics
Defendant Lawyer A:	Lauren
Defendant Lawyer B:	Raodatullah

Expert Witness

Plaintiff Witness 1	Harshita	Expert Witness, Cybersecurity
Plaintiff Witness 2	Volunteer TBD	Expert Witness, Biocompatibility
Defense Witness 3	Justin	Expert Witness, FDA Guidance

Jury

Classmates in the audience.

Appendix B: Agenda and Procedural Items

Part 1 - Convene			Maximum time
3:20 pm	All	Participants take their places	
3:22 pm	Judge	• Instructions to the Jury • Call to Plaintiff's lawyer	2 min
Part 2 - Opening remarks			
3:24 pm	Plaintiff lawyer A	• Opening statement	3 min
3:27 pm	Defense lawyer A	• Opening statement	3 min
Part 3 - First Witness			
3:30 pm	Plaintiff lawyer B	• Call 1st witness: Plaintiff – Shifra • Introduce evidence "product sell sheet"	4 min
3:34 pm	Defense lawyer B	• Cross-examine 1st witness.	4 min
Allow1 minute transition if not running behind			
Part 4 - Second Witness			
3:39 pm	Plaintiff lawyer A	• Call 2nd witness: Phoenix – Eric	4 min
3:43 pm	Defense lawyer A	• Cross-examine 2nd witness.	4 min
Allow1 minute transition if not running behind			
Part 5 - Expert Witness <u>for Plaintiff</u> (Cybersecurity)			
3:49 pm	Plaintiff lawyer B	• Call expert witness: Harshita	5 min
3:54 pm	Defense lawyer B	• Cross examine	5 min
If we pick up time, Judge will ask Plaintiff attorney if there are any further questions			
Part 6 - Expert Witness <u>for Defense</u> (FDA policy on med devices & ISO10993)			
3:59 pm	Defense lawyer A	• Call expert witness: Justin	5 min
4:04 pm	Plaintiff lawyer A	• Cross-examine	5 min
If we pick up time, Judge will ask Defense attorney if there are any further questions			
Part 7 - Closing Statements			
4:09 pm	Plaintiff lawyer B	• Closing statement	2 min
4:11 pm	Defense lawyer B	• Closing statement	2 min
4:15 pm	Judge	• Call to adjourn.	

Note:

- Previously the maximum time was not used and we went a little ahead of schedule. We will have to be flexible and extent or cut off discussion depending on how things go.
- The schedule is set that whichever Attorney starts off (default "A") with Opening Remarks, their colleague ("B")will be delivering the closing statement. Please define roles in advance.

Appendix C: Moot Court participant Interview questions

1. In hindsight, what lessons have you learned from this moot court experience that you believe will benefit you in your future studies or career aspirations?
2. Were there any unexpected challenges or counterarguments presented by your peers or the judge during the moot court session? How did you respond to them? How did you handle those challenges while maintaining the credibility of your testimony?
3. Reflecting on your performance, what aspects of your presentation or argumentation do you feel particularly proud of? Is there anything you wish you could have done differently?
4. How did you collaborate with your team members, if any, to prepare for the moot court? What strategies did you employ to ensure effective teamwork and coordination?
5. As a BME student, what specific legal standards or principles did you have to learn more about to support your arguments in the moot court case? How did you prepare to ensure you understood these standards thoroughly?
6. Thinking about being an expert witness in the moot court case, what specific expertise or qualifications did you bring -- or have to prepare for -- to support your testimony?
7. Although the case was conducted several weeks ago, can you describe the key points or evidence you presented that you were most proud of during your testimony in the moot court session?
8. Expanding on the earlier question, how did you prepare for your role as an expert witness prior to the moot court session? Did you engage in any research or consult any resources to strengthen your understanding of the case and relevant standards?
9. In what ways did participating as an expert witness in the moot court session enhance your understanding of legal proceedings and the application of standards in real-world scenarios?

Appendix D: Resources

Existing resources already available to support the program highly leveraged the NIST investment. Several embedded assets remain in place and are likely present at other Institutions. We classify available resources into (1) course instructors, (2) library assets, (3) professional membership, (4) the OSF dissemination platform, and (5) MediaVision content management.

1. *BME Courses and instructors in other departments available to support module implementation*. We have existing Senior Design Capstone courses in three departments and two institutions available for testing the case studies. While our initial focus will tend to be centered around Capstone Design, we also have the first-year Experiential Learning program for engineers, as well as a well-established BioDesign program that is a platform for outreach to industry and medical professionals.

2. *Standards at the library:* Kelvin Smith Library collections available to the Case community include electronic full-text access to publications from major scientific society publishers. Additionally, the library provides online campus-wide access to a variety of engineering standards that include ASTM, IEEE, ASCE, ACI, BS ISO and facilitates access to individual standards as needed through on-demand service.

3. *Professional society membership*: CWRU faculty and staff with standards expertise and membership in BMES, IEEE, ASEE, SES. Our faculty regularly participate in national meetings and this on-going activity provides pathways for the dissemination and feedback facets of the program.

4. *CWRU's institutional OSF account*: CWRU's institutional Open Science Framework (OSF), a free open-source platform, has been used for posting all the course kits and corresponding reports. The use of OSF ensures curation and the dissemination of the curriculum materials, and provides a space project collaboration for all those interested in participating.

5. *CWRU's MediaVision Production group* offers professional production services to the faculty, staff, and students of Case Western Reserve University including event support and services, promotional video production, DVDs, academic lecture recordings, and other media production-related services. The team was a significant asset in all areas of video production of our events, from single-camera capturing to large scale media production and rich data collaborations that meet a multitude of needs and expectations.