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Moot Court Cases: Bringing Standards to Life

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Abstract

Biomedical engineering instructors teach the medical devices design theory and practice following the recommendations derived from the FDA regulations included in 21CFR820 and portraying it as less of a choice but the designer's obligation to uphold laws intended to reduce medical device design risk and protect the general public from defective goods. Although product liability cases are frequently adjudicated in a court of law, many students have only a vague notion of the link between design and product liability issues, and furthermore the important role that standards play in everyday design practice. To give real-life context for the connection between product liability and the benefits of using standards in design, we are aiming to develop moot court case studies that will offer engineering students the opportunity to investigate the viewpoint of various stakeholders and to bring arguments in support of their position.

Our work-in-progress is part of a larger effort to reduce the barriers to standards adoption by engineering programs by creating a complete set of educational materials for educators based on specific case studies that foster consideration and use of standards in quality systems (ISO 13485:2016), and cyber-security in medical device design (ISO/IEEE 11073). Materials include lesson plans, content, and homework assignments that will be delivered as videos, tutorials, case study narratives, and Canvas modules. Our preliminary efforts have encouraged the continuation of the development of content, though our efforts will benefit from other educator participation - this paper is a "Call to Action" for collaborators.

Introduction

The National Academy of Engineering identified ethical issues and responsibilities as the major challenges for engineers in the 21st century.[1] Practicing engineers are expected to adhere to the National Society of Professional Engineers' Code of Ethics[2] and engineering students are expected to "recognize ethical and professional responsibilities in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts."[3] The result was an increase in interest in engineering ethics, which are defined as "the field of applied ethics that is concerned with the decisions and actions of engineers and the consequences of these actions and decisions, both individually and collectively."[4] As a central concept to engineering ethics, public and environmental safety bring forth engineering, business, and legal issues.[5]

Engineering issues are related to product design and manufacturing. Engineering design should "meet the desired needs and specifications within constraints."[3] While the manufacturing should follow established processes to ensure product quality and safety. The design constraints may include "accessibility, aesthetics, codes, constructability, cost, ergonomics, extensibility, functionality, interoperability, legal considerations, maintainability, manufacturability, marketability, policy, regulations, schedule, standards, sustainability, or usability."[3] Legal issues stem from the Product Liability Law [6] or compliance with regulations. Business issues relate to the successful launching of a product on the national or international markets, which depends on the product's ability to meet market access (regulations) and acceptance (industry standards and norms) requirements.

One industry that poses potentially very high risks to public and individual safety is healthcare. Medical devices are essential throughout all healthcare areas, and their safety and performance standards are fundamental to the healthcare industry. That is why healthcare in general, and medical devices in particular are highly regulated, making it critical for healthcare professionals, including biomedical engineering students, to be familiar with applicable laws and regulations. An essential part of this regulatory environment is the Food and Drug Administration (FDA), which acts as the regulatory agency for medical devices and controls medical devices market access.

As technical standards, codes, and regulations are a common thread for safety issues, there is no surprise that including them in engineering programs is very common.[7] These activities can take various forms such as lectures, curricular modules, or case studies. Moot court, a less common type of activity for engineering programs, offers a different type of team-based active learning exercise that develops critical thinking skills in a close-to-reality scenario and offers an inter-professional perspective on the engineering responsibility in designing safe products by connecting it to the potential legal liability due to accidents, injuries or even death of the users.[8–10]

This work-in-progress reports on our plans to use moot court exercises built around relevant case studies related to medical devices. This work is part of a larger effort at our institution to create educational materials that would contribute to building students' enduring understanding of standards and regulations in professional and legal contexts. These materials will be created

under the Creative Commons license and made available to other institutions interested in facilitating standards integration into the curriculum.

Moot Court Case Educational Attributes

As an educational exercise, participation in a moot court case has a number of benefits over a more traditional "read and recite" type of assignment. A moot court exercise provides real-world applicable attributes including immersion, self-direction, teamwork, and critical thinking. Each of these has been shown to improve retention and understanding of concepts compared to more passive assignments.[11–14] The combination of these attributes will instill in students not just knowledge of the material but also understanding of its significance, and help to hone their critical thinking skills.

At its core, a moot court exercise is an immersive experience. From learning languages to gaining hands-on skills, the act of doing, creating, and living through the experience has been shown to improve retention, understanding, and overall utility of learned material.[11,12] By engaging in this "role play" exercise, students will be engaged in active learning and will develop an intuitive understanding of the concepts involved.

Another aspect of this exercise is that it is self-directed and involves a high degree of creative learning. Students will be asked to prepare for the moot court by researching and developing arguments for and against the subject of the case. This exercise will lead students to develop not only an understanding of the main issue to be resolved but also the surrounding and supporting issues involved. Engaging with a moot court exercise will afford students a breadth of knowledge of the many topics related to the case. Additionally, because the knowledge gained was their own discovery and not dictated by the instructor, students are more likely to internalize the concepts and perceive their applications to other situations.[13]

Finally, moot court cases are one of the best examples of a team-based critical thinking skills development exercise. Students must take the core concepts presented in the class (didactic learning) and engage in research (dialectic learning) and then perform synthesis in order to determine the relevance and application of the learned knowledge. In the end, students will need to make specific judgments regarding the information presented during the exercise. The cases will be designed to be somewhat ambiguous, without a unique "right" or "wrong" answer, and it will be up to the students to discern the overall outcome based on the arguments presented. In this way, the moot court exercise teaches not just the specific topics involved, but also how to approach and learn new topics.[14]

When put together, participating in a moot court exercise goes beyond preparing students for any possible legal situations they may find themselves in during their engineering careers. It will encourage the understanding of topical knowledge and will help develop critical thinking skills used throughout their time as biomedical engineers. As a particular form of "case study" exercise, Moot court exercises present one of the optimum means of instruction in that it provides a rich experience but is still structured enough to constrain the overall effort and focus on the intended learning objectives.

Implementation

The implementation of this exercise is intended primarily for upper-level engineering students (ideally, senior design students) who have had not only the technical but also some exposure to the business and regulatory aspects of their field throughout their undergraduate careers. In addition to this background, students will have access to the pertinent standards as part of the course. While the "primary players" in the exercise will be senior students, younger students would be encouraged to attend the full moot court (point 3, below). Their participation will not only introduce them to the topic but will also help to prepare them for their own moot court experience later in their program. Younger students may also be asked to participate as "jurors" in deciding the outcome of the case.

While the aim of this work is to provide moot court exercises intended for biomedical engineering students, the overall framework and approach are applicable to other fields of engineering as well. All branches of engineering are prone to legal and regulatory entanglements, and having some experience with the concepts involved would benefit all novice engineers. For those exercises, cases could be modeled from this approach, but with different situations and pertinent standards and regulations applied.

The process of introducing moot court cases into the classroom is characterized by several levels of intended student engagement. We have established the following three-step process (see Fig 1):

1. Introduce a very narrow view of the case during a typical 50-minute class session, providing specific guidance on the possible standards that might apply. Students must identify the relationship between the standards and the issues presented.

2. Provide a one-page description of the case as a so-called "Grand Challenge" in the spirit of Michaelson's Team-Based-Learning (TBL) methodology.[15] This structured process builds critical thinking skills and has been well established to facilitate the skill of crafting a hypothesis. This case would take a full class period, and we usually use this at our Senior Design Friday Recitation classes.

3. Move to a full "moot court" scenario where students are given several days to understand more of the nuances of the case and how issues like "defective manufacture" could result from an incomplete FMEA. This is a multi-day event and is co-curricular.

Note that the short in-class session and the full recitation class of the same cohort of students are each presented with a *different* case.

Despite being at the beginning of the process, we learned valuable lessons from Steps 1 and 2. For instance, in Step 1 we learned that students get very involved in discussing standards, and many times students are very anxious to know the case outcome.

In Step 2, the teamwork aspect creates a "safe space" to think about the questions and the case. The students, who have already been trained on the Michaelson TBL approach, work as a team on the quiz and the excitement of working in small-group sessions fosters an environment of sharing, especially on some aspects of a case where the verdict is not always clear.

Forum	Intent	Case Study	Setting
In-class Vignette	Highlight standards as guidance documents	One-paragraph case summary	Small group in-class discussion w/faculty moderation Takes 15 minutes.
Team-Based Learning	Student-led exploration of issues illustrating the role of standards	One-page summary with greater context of the situation to introduce ambiguity	Recitation-based in-class discussion lead by students. Takes one hour
Moot Court Session	Student-role arguing point/counterpoint on detailed points from research.	Detailed case with some sample evidence documents to analyze.	Trial-like atmosphere in mock courtroom with third-party actors. One Day

Figure 1. The three-step process for the introduction and refinement of moot court cases.

The full moot court session in Step 3 requires more involvement, and we are in the progress of building a team of professionals to write the case and develop supporting materials.

Sample Case

The contemporary case of interest is a so-called "cross-over" product development case. A crossover product development strategy presents a challenge to both commercial entities and the medical community they seek to serve. Those new to medical device design might be inclined to emphasize "speed to markets" or a cost-effective strategy of "substantially equivalent" devices. While consideration of cost and speed might make for a competitive product from a commercial perspective, this overlooks the role and value of standards and regulations in the medical product development and launch process. It is often underappreciated that the creation and subsequent growth in the regulatory power of the FDA throughout its brief history has frequently been a direct result of individuals harmed by mislabeled, untested, adulterated, or toxic products that were well-marketed, but not well-tested. Anticipating that most medical devices need to be cleared or approved by the FDA prior to being marketed for sale in the US, the advantages of low-cost devices are irrelevant if the device cannot be presented to the marketplace due to failed regulatory compliance. Formalized and intentional clinical studies embrace the context of FDA regulation from several perspectives since it was the unanticipated consequences of new technology – and the way the technology was brought to market – that spurred the modern

medical device regulatory framework. The integrity of product development processes permits no shortcuts if the intention is for a device to be as good as or exceed existing standards of care. Many of the processes described in the standards document are essential in the product development process.

A case we have written involves a small company with long-standing sensor and wireless capability that is looking to cross over into the wearables device market for health monitoring. The company has been successful in food service, so is already somewhat familiar with the FDA, but not specifically for medical devices. They are somewhat savvy about quality control but not entirely in the context of the element of FDA's 21 CFR Part 820 Quality System Regulation. This case also features a somewhat "laissez-faire" approach to potential cybersecurity risks, underestimating how wearables, like many wireless medical devices, can be vulnerable to security breaches. This case centers on the issue of a battery going dead without warning to the user resulting in a failed alarm to the patient. The company assumes that the instructions they provide to check the battery daily were adequate.

Summary and call to action

The development of case studies that could lead to a moot court experience puts a refreshing twist to the discussion of standards in engineering programs. Curriculum materials developed for these moot court exercises will be made available under the Creative Commons license on the Open Science Framework site. This paper is a "call to action" for other engineering departments to join us and co-develop a set of case studies that will enhance the awareness, knowledge, and importance of industry standards.

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Appendix

Phoenix Electronics – FMEA Case Study

For two decades Phoenix Electronics successfully launched products with increased durability and smaller size in service to the industrial foodservice industry. As a small private firm with 50 employees, the company president Theodore "Ted" Massey was proud of the way the company kept up with sensor system advances in the industry. In addition to simple temperature and flow controls, they were building competencies in areas like gas sensor analysis to detect acetone (for spoiled meat). While the foodservice market has been a good business for Phoenix, Ted felt it was time to expand into new markets, especially since the Internet of Things (IoT) was a hot new area in foodservice monitoring. Rather than follow his competitors, Ted thought the time was right to use their electronics miniaturization and wireless expertise in a totally new way: fitness monitoring. The new product development team (NPD) at Phoenix liked the idea. The NPD manager, Rahul Asani was anxious to run with this project and his team came up with a plan to have a prototype wrist-worn within 6 months. While Ted was concerned about risks with an expedited product development process, Rahul was more confident. As he explained "we are making a simple wrist monitor and is not a medical device, so we don't need to worry about the hassle of FDA regulations. In addition, we are already making miniature wireless systems, so this is more of a new technology integration than a new technology creation project.

Product development went as planned, but an unexpected aspect of adding temperature measurement and pulseox features on top of heart rate monitoring was battery life. When operated continuously the system would last up to 3 days, but it was important to check the battery level every day. To keep the product launch on schedule, the decision was made to update the user manual with detailed instructions on charging. Instructions were clear that the system

should be placed on the induction charging pad nightly and the user would need to press the middle-status button on the side of the watch to be sure the watch was on the pad the right way and was being adequately charged. The watch has a simple green/yellow/red indicator system, where green suggested the system was charged adequately for use the next day.

Internet sales of the new Phoenix HealthBuddy device were encouraging and after a consumer trade show featuring fitness vendors, things got better. A large pharmacy chain picked up a contract with Phoenix to supply 10,000 devices for a national launch. This was a classic "hang on the hook" on display case where other items such as thermometers and low-cost finder pulseox devices were sold.

Hazel Harris was a 72 year-old living alone at home who was generally active and felt she was in pretty good health. Once in a while, though, she felt dizzy after working in the garden, but that was about it. While she felt her heath was not an issue, her family was concerned since her two daughters could not always check in on her. Hazel's oldest daughter Ann purchased a HealthBuddy as a gift and Hazel was reluctant to use the wrist-worn device, but agreed to use it if it made her daughters more comfortable. Hazel became used to checking the device to be sure if was charged every day, but since she would sometimes forget to charge at night, she was glad the HealthBuddy tended to last two days on one charge. Hazel liked the idea of spending more time in the garden and was more confident of her safety knowing the HealthBuddy would send an alarm to her phone if she became dizzy since her oxygen saturation dropped below a safe level.

Hazel was encouraged that the device made her feel safe, but after a long weekend in the garden, she felt extremely tired, and that Sunday afternoon she felt very faint, lost her balance, and fell, hitting her head. Her daughter had not heard from her for their normal Sunday check-in, went to the home and found her mother confused, but seemed to be OK. Her daughter checked the watch to see why it did not alarm and found that the batter was dead. The family sued Phoenix for negligence in design since the fitness watch did not automatically warn the user of a low battery. Phoenix argued the instructions for maintenance were clear and the user was negligent in use. What is the verdict?