Ethics in Engineering Design:

An Ethical Analysis Guideline for iGEM Teams Embarking in Bioengineering

University of Manitoba Prairie iGEM Team 2024

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1. Introduction

The most important role as an engineer is to ensure the safety and welfare of the public who will be exposed to the design or product. As students studying synthetic biology design applications, it is easy to dismiss or disregard the implications of our work, no matter at what scale. As such, it is important to review our work, correct mistakes, and ensure mistakes are not repeated to ensure public and environmental protection. By acknowledging engineering ethics helps us gain a sense of morality in our work. Ethics is the study of what is right or wrong, which can guide us in impact analysis of engineering work. Ethics in engineering is a particularly important topic as our work often has implications to our surroundings such as society and the environment. Therefore, the University of Manitoba Prairie iGEM team decided to create and share an ethical guideline to help analyze our projects impacts and ultimately, help other teams analyze their projects' impacts as well. While recognizing that there are many different sectors of engineering, ranging from mechanical to civil, electrical to computer, and even chemical and biological, as students participating in iGEM, we fall into the bioengineering category. Therefore, this guideline will be discussed in the context of our work in synthetic bioengineering.

The following guideline is sectioned into four main stages, using the iGEM's engineering cycle as a reference [1]. By doing such, we can better acknowledge the importance of creating a feedback loop within our work. At every stage of the engineering cycle, it is important to recognize any errors that should be corrected or possible improvements to be made. The four stages used in this guideline include design, build, test, and learn. The design stage is the first initial step an engineer takes in turning an idea into reality. A conceptualization should be formed within this stage that will act as the basis for the rest of the engineering cycle. Next, the concept is realized in the lab, fabrication shop, etc. The build stage allows the engineer to confirm the idea fits within the constraints of reality. Then, the test stage is used to confirm the design is functional, operational, sustainable, and safe. Critiques can be noted and then discussed in the learn stage, where any changes can be decided and integrated back into the design stage. As such, an engineering cycle is formed that allows feedback to be integrated into the conceptualization.

In addition to improving the design's features and functionalities through the engineering cycle feedback loop, one can also recognize the full lifecycle impacts of the design [2]. In other words, one can recognize the ethical implications of their work. General ethical considerations in engineering design can include public safety, resource usage, product disposal, socioeconomic effects, and environmental impact. In the context of synthetic bioengineering, major ethical considerations include biohazards and containment. As such, the following sections will act to guide the engineer or team of engineers to successfully recognize the ethical implications of their work at each stage of the engineering cycle – specifically in the context of work relating to synthetic biology.

2. Engineering Cycle

2.1 Design

The first stage in the engineering cycle followed by teams participating in iGEM is the Design stage. During this phase of the cycle, before a design can be conceptualized, an idea has to be put forward. Rather, a potential solution to a real-world problem is offered. In order to transition an idea to an actual design, one must first properly define the problem at hand. As such, a problem definition should be formed with a list of design constraints and parameters. Once a thorough understanding of the problem has been formed, one can move forward in conceptualizing the idea into a physical design or system that can be tested against the design constraints and parameters. Overall, the Design stage allows the engineer or team of engineers to develop the design before building and testing.

Within the Design stage, there are several ethical considerations the team can consider that can act to improve the development process. First and foremost, ideally, the selected problem should be in-need of a solution or in-need of optimization [2]. In the context of synthetic biology, it is important for the engineer to consider the application of their work. Rather than developing a new consumer good for the sake of profit-seeking companies, our work should sustainably enhance the wellbeing of individuals and communities. It is the responsibility of the engineer to select a problem that fulfills a purpose and benefit to society [2]. Once the engineer has identified a meaningful problem to address, it is important to properly define the constraints and parameters that may cause limitations in the development of their work. By doing so, one can either identify how to meet a design's constraints and/or parameters, or how to overcome potential limitations before further issues arise. This requires constraints and parameters that not only affect the development, building, and testing of the design but rather the socioeconomic and environmental interactions as well. Detection of potential limitations or issues within the premature design helps to foster the development process towards a more sustainable solution. Constraints and parameters can include relevant regulations put forward by government bodies, regulatory agencies, or international organizations. As such, it is important to review such regulations against the design.

The following is a list of questions that can be asked to the engineer or team of engineers to better acknowledge ethics within the Design stage:

- What problem is this design solving?
- Is this problem in-need of a solution?
- Does the solution positively and sustainably benefit society?
- How does it positively and sustainably benefit society?
- What are the design's constraints and parameters?
- Will the design be limited if the constraints and parameters are not met?
- How can potential limitations be overcome to limit negative effects to society and/or environment?
- Does the design need to follow certain regulations in-place?

2.2 Build

The second stage of the engineering cycle is the Build stage where the team works towards prototyping their design solution to then be tested against the defined constraints and parameters. This requires acquisition of several different parts, components, materials, tools, and various other resources. Using the necessary resources listed, the design is further developed into an actual conceptual product. This stage allows the team to recognize effective lab manufacturing strategies to take when developing the product. The field of synthetic biology contains numerous approaches to successfully manufacture genetically engineered products and it is valuable to recognize the most appropriate approach.

Within the Build stage, there are several ethical considerations the team can consider to improve the final outcome of their work. Given that the work of synthetic biology often is the application of genetic engineering within organisms [3], it is important to acknowledge any such biohazards associated with the storage and handling of the organisms. Given that the goal of iGEM is to tackle a real-world problem and present a potential solution, it is also valid to consider the feasibility of mass manufacturing of the product. For instance, considering the cultural or geographic context of the design solution across the world – is it internationally feasible or only in certain locations? As well, it is important to consider the economic requirements for developing this design solution and whether or not it can be accomplished in the desired region depending on the economic situation. And perhaps the most important consideration being whether or not the design solution is testable in a simulated or real-life environment to fully understand the implications of implementation.

The following is a list of questions that can be asked to the engineer or team of engineers to better acknowledge ethics within the Build stage:

- Are there any associated biohazards with the working materials?
- Are the working organisms stored and handled appropriately?
- Is the product feasible in the targeted geographic region? Internationally?
- What are the economic implications or opportunities with mass manufacturing of the product?
- Is the built design solution testable in the desired end-environment?

2.3 Test

The third stage of the engineering cycle is the Test stage, in which the design solution can be tested to verify it's functionality, operability, and most importantly, it's safety [2]. The team works with all the information gathered in the Design stage and the product developed in the Build stage to test the associated impacts and final outcome of implementation. This is done by implementing the built product in a similar, simulated, or intended end-environment of the product. As such, this stage allows the team to address limitations in the initial design and areas of improvement. This stage also gives the team the opportunity to address how responsible user-interaction can be established within the product [2].

Within the Test stage, there are several ethical considerations the team can consider to improve the feasibility of the design. The Test stage is a valuable time in the engineering cycle to recognize the end-of-life of the product, any consequences that come with employing the product, and how to manage this. In the context of synthetic biology applications, a particular major ethical concern in the field is human health in medical trials [2]. As such, any potential negative effects should be acknowledged and addressed. However, it is also important to recognize within this stage that the product's potential negative effects may not be realized in a small-scale test and may only become apparent in large scale. In addition, while the public's safety is paramount in engineering design, it is important to acknowledge that risk comes in many forms, such as socioeconomic or environmental risk. Any suspected consequential risk should be effectively communicated to the user and addressed in risk management studies of the product.

The following is a list of questions that can be asked to the engineer or team of engineers to better acknowledge ethics within the Test stage:

- How is the design going to encourage responsible user-interaction?
- Are there any potential consequences with implementation of the product?
- How will the product be responsibly managed at its end-of-life?
- Is the full potential of the product realized during testing? Or is a larger scale required?
- Is there potential risk to human health, environmental conservation, economic prosperity, etc. with deployment of the product?

2.4 Learn

The last stage of the engineering cycle is the Learn stage, in which the life cycle impacts of the current product iteration are recognized in order to identify necessary changes in the design. After a cycle of design, build, and test, the team can better understand where to improve the product and initial design. In addition to internal evaluation, this stage ideally will also involve consulting with relevant field experts, colleagues, fellow student engineers, etc. to gain further feedback. Consideration and application of internal- and external-team feedback to the design's engineering cycle is critical to ensure the product meets the parameters and constraints defined in the Design stage, as well ensures the safety and prosperity of those that will be interacting with the product.

The Learn stage in the engineering cycle is most critical in terms of recognizing and understanding any such ethical implications of the product. As discussed, the Learn stage allows the team to understand the full life cycle impacts of the product and therefore, the ethical considerations of those impacts. While it is important to integrate feedback from the Learn stage into designing, building, and testing of the product, it is also valuable to use that feedback to properly understand the overarching ethical implications that create secondary socioeconomic or environmental effects. As such, in terms of ethical analysis in the final feedback loop of the engineering cycle, it can be divided into primary ethics and secondary ethics. Primary ethics refers to the direct effects that are associated within the main stages of the engineering cycle, as discussed in the prior sections of this guideline. These effects may be consequential and if so, can be properly managed by the team with a Risk Assessment. A Risk Assessment will allow the team to identify all the potential risks associated with development, building, testing, end of life, etc. of the product and how to mitigate such risks [2]. Secondary ethics refers to the indirect effects that are associated with implementation and deployment of the product. These effects are likely to be projections of the final product, or any effects witnessed during the test stage. In order to properly predict the secondary ethics and indirect effects of the product, the team must again consider the full life cycle of the product and recognize how society, the economy, and/or the environment will be impacted by the product. Or rather, the team must recognize how the product either achieves or discounts the Three Pillars of Sustainability [4]. This will allow a meaningful and holistic analysis of the design to be made.

The following is a list of questions that can be asked to the team of engineers to better analyze the ethics of their design in the Learn stage:

- Are there any major or minor consequential effects associated within the Engineering Cycle of the design? If so, a Risk Assessment may be valuable.

- Will implementation of the product cause any negative effects to society and/or particular communities?
- Will implementation of the product cause any negative effects to the environment and/or surrounding ecosystems?
- Will implementation of the product cause any negative effects to the economy?

Once a technical and ethical evaluation of the initial design has been completed, the team can integrate potential changes back into the engineering cycle to undergo another round of review. Within engineering work, integration of positive feedback is critical to ensure the final product will not only protect society and the environment but create prosperous communities.

Bibliography

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