Product Design Specification: Fetal Radiation Shield

Client: Dr. Zac Labby
Advisor: Dr. Beth Meyerand
Team: Janae Lynch, klynch8@wisc.edu (Team Leader)
Lauren Heinrich, lheinrich@wisc.edu (Communicator)
Maura McDonagh, mcdonagh2@wisc.edu (BWIG/BPAG)
Emily Knott, knott2@wisc.edu (BSAC)
Date: February 7th, 2018

Function:

Approximately 4000 women per year will require radiation therapy treatments during pregnancy in the United States. Negative effects of ionizing radiation on the fetus are moderately understood, and are generally reduced with lower fetal dose. Appropriate shielding for standard radiation would include several hundred pounds of lead held safely over the fetus during radiation therapy for brain and breast cancer. The Department of Human Oncology at UW Hospital is seeking a safe and effective shield for these purposes. The shield will need to be mobile, adaptable to a variety of treatment delivery machines and techniques, and be safe to use for all involved. This team will design, fabricate, and test the shield with clinical treatment delivery systems throughout this semester.

Client requirements:

- Must provide physical blockade of the fetus from radiation leakage from the head of the instrument and scattered photons from the collimators
- Must not pose greater risk of safety to mother or fetus than radiation itself

Design requirements:

- Must be mobile: easily moved between patient treatment rooms and stored when not in use
- Must reduce the fetal dose by 50%
- Must be compatible with women of all sizes and varying stages of pregnancy
- Must be usable with current treatment room equipment, specifically the treatment table and linear accelerator, and their respective ranges of motion

1. Physical and Operational Characteristics
    a. *Performance requirements:* Aside from the shield blocking 50% of the radiation reaching the fetus, it must have the ability to be moved around the hospital to different treatment rooms. Primary and scattered radiation can approach the patient from from a variety of angles depending on treatment plans and location of treatment site, thus the shield should cover the majority of the abdomen. The shield must possess the capability to move in the vertical direction in order to accommodate different table heights.
    b. *Safety:* This is the most important aspect of this design. In order to be used with a patient, the risk of it falling and injuring the patient must be less than the benefit that the patient may receive from the shield. A primary risk of safety will involve the mobility

of the shield for patients, technologists, and physicians. Safety standards for a medical apparatus similar to this are highly regulated by medical professionals and government agencies. The apparatus must prevent any patient-to-lead contact, which could lead to lead poisoning. Additionally, the apparatus must capable of being wiped down with common clinical cleaning reagents (ex: Cavi-Wipes) before and after each use.

c. *Accuracy and Reliability:* The apparatus must shield the fetus from 50% of incoming radiation, assessed during each treatment session. This support mechanisms of this device must stay below the yield stress of the chosen material and have a high fatigue limit.
d. *Life in Service:* The design will go through periodic cycles of use, depending on whether patients being treated require the shield. However, the apparatus will remain at the hospital permanently. Frequency and length of treatments vary greatly, ranging between 1-45 fractions, with each fraction lasting 15-30 minutes. When not in use, the apparatus will be stored away.
e. *Shelf life:* This is intended to be kept in the Department of Human Oncology to be used to aid in the treatment of pregnant patients. Lead, the primary material that will be incorporated into the design, is highly corrosion-resistant and dense.
f. *Operating Environment:* The apparatus will be utilized in radiation treatment rooms while patients undergo therapy. The rooms are surrounded by 8 foot thick concrete walls that house a linear accelerator and rotating patient bed, along with various medical instruments that assist with treatment.
g. *Ergonomics:* The shield must fit comfortably across the patient's abdomen and take into account potential different positions of the fetus and variability in patient physiology. Additionally, the apparatus must allow the patient to lay comfortably on their back during treatment sessions.
h. *Size:* The size of the apparatus must be compatible with the current treatment room set-up. The dimensions of the apparatus must be able to fit a patient up to 300 lbs. Additional measurements of the room are to be determined.
i. *Weight:* The treatment couch has a weight limit of 440 pounds, which includes the patient's weight. If the apparatus is attached to the bed or rests on the bed in any way, the weight of the apparatus must account for this as well.Additionally, the covering on the floor beneath the treatment table covers the rotating machinery- the heavy apparatus cannot stand on this cover and must be moved carefully around this location.
j. *Materials:* Lead will comprise the body of the shield of the apparatus; other materials required for support and safety will consist of aluminum, steel, and various plastics to be determined by the final design.
k. *Aesthetics, Appearance, and Finish:* This apparatus must comply with the safety standards for approval in clinical use. It must be aesthetically appealing and non-threatening to the patient and physicians in the room. The finish on this device must also be able to be wiped down per clinical standards.

2. Production Characteristics
    a. *Quantity*: Only one (1) apparatus will be fabricated.

b. *Target Product Cost*: The total cost of the project (prototyping, testing and fabrication) for the final product must not exceed $10,000 USD.

3. Miscellaneous
    a. *Standards and Specifications:* All medical devices are classified into Class I, II, or III. Each classification has certain standards that must be met before the product can be used. Most Class I medical devices are exempt from Premarket Notification 510(k), while most Class II medical devices require Premarket Notification 510(k). A Premarket Notification 510(k) must show that the device is substantially equivalent to one commercially used in the USA before it can be distributed. Class III medical devices require Premarket Approval (PMA). A PMA is a more inclusive test than the 510(k) for devices which pose a significant threat to injury or illness. Additionally, a clinical study is required to support a Premarket Notification 510(k) or PMA submission to the FDA.
    b. *Customer:* This device will be in a relatively clean environment that can also be a very uncomfortable setting for patients. As a result, the apparatus must not appear threatening.
    c. *Patient-Related Concerns*: Some of the greatest patient concerns of undergoing radiation therapy while pregnant are the associated risks of disrupted fetal development and later childhood cancer. While these risks are generally relatively low, the shield should reduce this risk without incurring another immediate risk to the fetus.
    d. *Competition:* Currently, no products of this nature are commercially available. Previously, clinics utilized table-like supports with lead draped or placed on top. This is now forbidden in clinic due to safety concerns and no way to ensure support of the heavy, dense lead. According to the client, pregnant patients seeking radiation therapy at UW Hospital are most likely referred to the Mayo Clinic, which uses a wooden bridge supporting lead bricks to shield leaked radiation. Aiming to provide a safer option, The University of Michigan developed a custom fetal lead shield. The shield was highly effective in reducing radiation, but not economically feasible. The company responsible for development went bankrupt and could not support further development.