Product Design Specification: Fetal Radiation Shield

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Function:

Approximately 4000 women per year require radiation therapy for brain and breast cancer during pregnancy in the United States. The deleterious effects of ionizing radiation on the fetus can generally be reduced with a lower fetal dose. The shield used to protect the fetus during standard radiation would include about half a ton of lead held safely over the fetus during treatment. The Department of Human Oncology at UW Hospital is seeking a safe and effective shield for to mitigate the potential effects of ionizing radiation on the fetus during treatment. The shield must be mobile, compatible with a variety of treatment delivery machines and techniques and be safe to use for all involved, particularly the patient. Our team will design, fabricate, and test the shield with clinical treatment delivery system over the course of the next two semester, while focusing on designing a transportation mechanism for the shield and its support system this semester.

Client requirements:

- Must physically block radiation leakage from the head of the instrument and scattered photons from the collimators from reaching the fetus
- Must not increase health risks to mother or fetus
- The shield must be at least 5 cm thick to reduce the fetal dose by at least 50%
- The shield must be transportable between treatment suites in the hospital

Design requirements:

- Must be mobile enough to easily move between patient treatment rooms and storage
- Must reduce the fetal dose by 50%
- Must be compatible with women of all sizes and varying stages of pregnancy
- Must be compatible 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:* In addition to blocking 50% of radiation from reaching the fetus, the shield must be able to be moved around the hospital between treatment rooms and storage. Primary and scattered radiation approach the patient from a variety of angles depending on treatment plan and treatment site, therefore the shield should fully cover the abdomen. The shield must be capable of moving vertically in order to

accommodate different table heights. It is possible that the shield will also have to move laterally when the head is rotated such that it is at adjacent to the treatment table.

b. *Safety:* Safety is the highest priority for this design. In order to be used with a patient, the risk of collapse and resultantly injury of the patient, which could be fatal to the mother and/or fetus, must be less than the benefit of reduced fetal dose. A primary risk of safety will involve transporting the shield by technologists, and physicians around patients. Safety standards for this type a medical device are challenging to find due to the lack of a regulatory specific to this engineering application, but nevertheless must be rigorous. Any patient-to-lead contact, which could lead to lead poisoning, must be prevented. Additionally, the apparatus must capable of being wiped down with cleaning reagents used in a clinical environment (ex: Cavi-Wipes) before and after each use.
c. *Accuracy and Reliability:* The apparatus must shield the fetus from 50% of incoming radiation. The support and transportation systems must be of materials that can withstand stress about three times the yield stress 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. It will not be used frequently, according to the client; about one patient per year will require radiation therapy while pregnant. The apparatus will remain at the hospital permanently. When not in use, the apparatus will be stored away. Due to the massive weight of the shield and support system, it is preferable that parts in the shield-support assembly and transportation system will not have to be replaced.
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. The entire device should be designed to last indefinitely.
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, the head which rotates about 270 degrees on a gantry, a translating patient bed and various medical instruments. The shield transportation and support system must avoid a circular force plate, about 4 ½ ft in diameter, beneath the treatment table and allow for full rotation of radiation machinery to achieve all desired angles the physicians might need.
g. *Ergonomics:* ALthough patient safety is the top priority, safety of the medical personnel transporting and operating the shield assembly is also important. The transportation mechanism should not require an unreasonable amount of force exerted on the assembly to maneuver it and ideally not cause staff to strain their backs and knees. Similarly, the support system should need only minimal effort to operate and avoid strain and injury to the staff using it. The shield itself must fit comfortably across the patient's abdomen and take into account potential different sizes of pregnancy (from single to triplets) and variability in the patient size themselves. 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. The hallways through which the shield-support assembly will be transports are over 7 ft wide, however, the door to the treatment room is about 51 in--4 ¼ ft. This poses a considerable challenge to designing the support and transportation systems as the diameter of the force plate in the treatment room that must be avoided, about 4 ½ ft, is wider than the door.

i. *Weight:* The maximum load to be supported by the transportation system will be roughly 1500 lbs, with the center of mass (COM) closer to the rear of the shield and support system due to the shape of of the "Highwaisted Skirt" shield design. It is critical that the intrinsic instability of the shield due to its eccentric COM is accounted for in the transportation system design. The highest stress exerted by the shield-support assembly will be where the linear actuators interface with the transportation system toward the middle on each side. There are no industry-specific standards for the factor of safety (FoS) for hospital equipment; however, because the weight of the shield-support assembly and the expected frequency of interactions between medical personnel, patients and the equipment, and the potential for workarounds by busy hospital staff, we believe that the FoS should be between 3 and 4. Therefore, the total load that the transportation system should be able to support is 4500 to 6000 lbs.

j. *Materials:* The shield will be fabricated from lead and encased in steel, and the support system from aluminum, steel and various plastics. If wheels, particularly the caster variety, are used to transport the shield-support assembly, they must avoid scuffing and scratching the linoleum or laminate floors of the hospital and thus be made from polymers like nylon and polyurethane. However, there must also be a low coefficient of friction (stationary and kinetic) between the wheels and the floor to facilitate easy maneuvering of the assembly by hospital staff. Additionally, transport of the assembly should create as little noise as possible. The wheel mounting material should be compatible with the materials used in the support system and have high compressive strength and durability.

k. *Aesthetics, Appearance, and Finish:* The shield-support assembly and transportation mechanism should be aesthetically appealing and instill trust to the patient and medical personnel who interact with them. The shield finish and any components/moving parts in the support and transportation assemblies must safely permit cleaning per clinical standards Components of the support and transportation systems should operate smoothly and create as little noise possible during use

2. Production Characteristics
    a. *Quantity*: Only one (1) apparatus will be fabricated. At least four wheels will be required to transport the shield-support assembly.
    b. *Target Product Cost*: The total cost of the project (prototyping, testing and fabrication) for the final product (shield, support and transportation systems, electrical components) must not exceed $10,000 USD.

3. Miscellaneous

a. *Standards and Specifications:* All medical devices are classified by FDA standards into Classes I, II, or III. Each class 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. It will be necessary to follow the American Standards of Mechanical Engineers when designing the various aspects of this device. In addition, a safety engineer will have to review the design to ensure the is minimal risk of failure, which could result to harm of the patient.
b. *Customer:* Our client, Dr. Zac Labby, is associated with the Department of Human Oncology and has indicated that the shield apparatus we design and fabricate will likely not be marketed and used solely in the UW Hospital. Therefore, our goal is to design a shield that meets our client's specifications and achieves its intended purpose of reducing fetal dose by at least 50% during radiation therapy. Marketing the shield apparatus is currently not a priority.
c. *Patient-Related Concerns*: The chief concerns for a patient undergoing radiation therapy while pregnant is the risk of disrupting fetal development and the increased likelihood of childhood cancer. While these risks are generally low, the possibility of devastating effects on fetus due to radiation exposure warrant a solution. The shield should reduce this possibility without incurring additional risks to the mother and fetus. This device will also be placed over the patient during the radiation, so it is important to ensure there is no risk of the device collapsing on the patient.
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 that the dense lead is adequately supported. According to the client, pregnant patients seeking radiation therapy at UW Hospital are usually referred to the Mayo Clinic, which uses a wooden bridge stacked with lead bricks to shield the fetus from radiation leakage and scattering. The University of Michigan developed a custom fetal lead shield that was highly effective in reducing radiation, but not economically feasible. The company behind the development of the shield went bankrupt.