ABET Addendum

1. Desired Needs
    - Develop a non-invasive breast cancer prevention device that physically blocks environmental carcinogens from entering the mammary ducts while avoiding surgery or long-term pharmaceutical therapies
    - Create a waterproof, sweat-resistant, and biocompatible barrier capable of maintaining a seal during daily activities including showering, sleeping, and exercise
    - Design a reusable, comfortable, and discreet device that could be worn for extended periods without causing skin irritation or limiting mobility
2. Constraints
    a) Safety/Regulatory Affairs
        - Materials had to meet skin-contact biocompatibility requirements and align with ISO 10993 standards for irritation and sensitization
        - IRB approval preparation required informed consent documentation, safety validation, and minimal-risk classification
    b) Risks
        - Risk of skin irritation, allergic reactions, water infiltration, and device failure during extended wear
        - Potential reduction in adhesive performance during water exposure and sweating
    c) Global Impact
        - Breast cancer affects over 2.3 million worldwide, requiring affordable and accessible prevention technologies
        - Device needed compatibility across diverse anatomies, skin types, and lifestyles
    d) Manufacturability
        - Prototype fabrication had to remain within a $400 budget and one academic year timeline
        - Design constrained to rapid prototyping methods using Fusion 360, 3D printing, and commercially available silicones and adhesives
    e) Quality Control/Marketability
        - Consistent seal integrity and adhesion performance were necessary for clinical viability
        - Product needed to remain discreet under clothing and easy to apply/remove for consumer adoption
3. Engineering Standards
    - ISO 10993-1, -5, -10, -23: Guided biological safety evaluation, cytotoxicity, irritation, and sensitization testing for skin-contact materials

- ASTM F2244, ASTM F2256, ASTM F2258: Guided adhesive peel-force and mechanical adhesion testing methods
- ISO 13485 and ISO 14971: Informed quality management systems and risk analysis for future medical device development

4. Ethical, Environmental, or Societal Concerns
   - Ethical responsibility to avoid overstating preventative efficacy because definitive evidence for carcinogen entry through non-lactating mammary ducts is still under investigation
   - Importance of maintaining participant safety and informed consent during wear trials and future clinical studies
   - Environmental considerations included reducing disposable waste through semi-reusable silicone components and development of cleaning/reuse protocols
   - Societal concerns involved improving equitable access to non-invasive breast cancer prevention options and reducing reliance on invasive surgeries or long-term medications
5. Active Teamwork and Leadership
   a) Collaboration and Inclusion
      - Team members contributed diverse perspectives in CAD modeling, testing, regulatory planning, materials selection, and data analysis
      - Iterative design decisions were made collaboratively using participant feedback and weighted decision matrices
   b) Delegation of Leadership
      - Leadership responsibilities were distributed across subprojects including prototype fabrication, wear-trial coordination, IRB preparation, adhesion testing, and report writing
   c) Goals and Deadlines
      - The team used structured prototype cycles with scheduled wear trials, testing sessions, and weekly milestone meetings to maintain progress
   d) Constructive Feedback
      - Team members continuously evaluated each prototype cycle through standardized wear-trial logs and incorporated feedback into redesign decisions, improving comfort, adhesion, and waterproofing over time
6. Significant Motivating Factors
   a) Acquiring New Knowledge
      - Learning CAD design, silicone casting, adhesion mechanics, IRB preparation, and medical device regulatory standards was necessary to progress the project
   b) Being Self-Initiating

- The team independently researched breast cancer prevention gaps, engineering standards, material properties, and testing methodologies beyond classroom instruction

c) Persisting Through Challenges
   - Repeated setbacks involving water infiltration, adhesive degradation, and material defects motivated iterated redesigns across five prototype cycles
   - Limited budget, compressed timelines, and the complexity of balancing comfort with barrier performance required continuous problem solving

7. Innovative and/or ENtrepreneurial Ideas
   - Development of the first known non-invasive nipple barrier specifically intended to prevent environmental contaminant entry into mammary ducts
   - Combining a reusable silicone barrier with a replaceable adhesive system to balance manufacturability, comfort, and cost
   - Potential commercialization pathway involving improved integrated adhesive systems, standardized cleaning protocols, and patent submission
   - Using this device not only as a prevention tool, but also as a research platform to investigate environmental mechanisms contributing to ductal breast cancer development