ABET Addendum

1. **List two to four Desired Needs of your project that led to your final design objectives. Answer in two to four bullet points or concepts within a sentence or two.**
   - The benchtop model generates 5-7.8 kPa pressure in the bladder, expels and fills with water/saline, and has a fully compressible urethra interior. The cuff iteration stops 5 kPa of pressure through the urethra and distributes pressure over surface area of 157 $mm^2$
2. **List the major Constraints on your design/project**
   a) **Safety/Regulatory Affairs** Only biocompatible, implantable materials can be used for the device. Although the goal is to prevent flow, urethra cuff pressure should not increase enough to cause tissue erosion and degradation.
   b) **Risks** Failure mode remains closed for the urethral cuff, creating a risk for infection and pain during failure.
   c) **Global Impact** Lack of literature review and data on device failures and complaints from other countries than the United States.
   d) **Manufacturability** Access to quality manufacturing facilities (silicone elastomer printer) to fabricate cuff and benchtop model components (urethra, bladder) were unavailable.
   e) **Quality Control/Marketability** Iterations to the cuff were original, however, rely on the AMS 800 pressure regulating balloon and pump button.
3. **List the major Engineering Standards on your design/project**
   a) ISO 10993: all device materials proven to be non-toxic and non-irritant (silicone elastomer)
   b) ISO 14971: risk management to medical devices to evaluate lifecycle-based hazards and identify risks.
   c) ASTM F2503: Standards for marking medical devices for safety in the MR environment
4. **Explain Ethical, Environmental, or Societal concerns for practical applications of your project.**
   **Ethical**: Improves quality of life for men affected by prostatectomies which is also a health disparity for Black men.
   **Environmental**: 3D prints and models were made of PLA which is biodegradable and more sustainable than petroleum-based plastics.
   **Societal**: Improvements to AUS improve patient quality of life.
5. **Describe Active Teamwork and Leadership in your design group**
   a) **collaboration?** Everyone was collaborative and willing to help
   b) **leadership?** Subproject (sensors, cuff design, FE) leadership roles were fairly distributed amongst members.
   c) **goals and setbacks?** Goals were commonly met, with minimal setbacks.
   d) **constructive feedback?** Feedback was respectfully given and appreciated by members
6. **What were the most significant motivating factors that led you to**
   a) **acquire new knowledge** Mentorship from Industry and Medical professionals providing insight into additional problems/ complaints
   b) **be self-initiating** Mentor support and resources at UCSD makerspaces
   c) **persist against challenges and setbacks.** Team member and teaching staff support
7. **What are your most innovative and/or entrepreneurial ideas for this project**

The development of benchtop model testing and experimental set up for pressure reading (specifically barometric pressure reading of the bladder). Cuff iteration design with 15 t-spline chambers to improve pressure distribution.