Updated Codes and Standards

Team 314: Abbott Reusable RF Probes

Introduction

In order to ensure our research is following the correct rules and specifications for the methods and the materials utilized in our testing, we ensured our work followed the proper codes and standards to satisfy the rules set by different entities such as ANSI, AAMI, ASME, FDA, UL, and ISO among others. However, due to the researched-based nature of the project, most of our standards apply to the construction and testing of our prototypes. Listed below are several codes and standards directly related to the procedures followed during our stress testing. Specifically, our work with the autoclave (table 1) for heat and pressure-induced stress testing has several standards related to the equipment. The other standards (table 2) relate to the quality assurance of our prototype.

Codes and Standards

Table 1. Technical Standards of the Autoclave Machine

Standard Code	Description
ANSI \ AAMI – ST55: 2010 Table Top steam sterilizer	This standard establishes minimum construction and performance requirements for small tabletop steam sterilizers that use saturated steam as the sterilizing agent and that have a volume less than or equal to 56.63 liters (2 cubic feet).
ASME Code section I and section VIII. Div.I	This Division of Section VIII provides requirements applicable to the design, fabrication, inspection, testing, and certification of pressure vessels operating at either internal or external pressures exceeding 15 psig.
FDA 510(k) Cleared	A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act).
UL 61010-1	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
UL 61010-2-040	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials

Table 2. ISO Standards

Standard Code	Description
ISO 9001	Quality Management Systems (QMS) to continually improve processes, production, reduce costs and errors, and satisfy customer needs
ISO 10993	Biocompatibility Testing-materials and residuals from the medical device do not have adverse side effects when in contact with patient body/skin

Design Incorporation

Because of the nature of our project, the main incorporation of standards into our design is through the testing of the materials. The equipment we are using follows standards set by the manufacturer. The autoclave machine follows technical standards:

- ANSI \ AAMI – ST55: 2010 Table Top steam sterilizer
- ASME Code section I and section VIII. Div.I
- FDA 510(K) Cleared
- UL 61010-1
- UL 61010-2-040

The description for these can be found in table 1.

Table 2 refers to International Organization for Standardization (ISO) regulations followed in both the prototyping and the testing stages of the project. Radel® PPSU was chosen for the material switch of the hub in the new prototype and complies with ISO 10993 when in contact with the body for less than 24 hours. This was taken into consideration when choosing a material for our model since the procedure will take less than 24 hours and will be safe for the patient. ISO 10993 refers to biocompatibility and was important to keep in mind since the hub will be used in close contact with the human body during the procedure. ISO 9001 was followed as the hub prototype testing occurred in the lab. Our team made the commitment to continually improve our testing process. We found that it was best to designate tasks to certain people in our team to make our process quicker. This standard allowed us to keep our customer needs at the forefront of our priority when making decisions in our design/testing process. Our team was constantly improving our techniques in the lab to obtain accurate results and minimize mistakes.

Public Safety and Other Factors

RF ablation is a minimally invasive surgery that, in our project scope, is used to treat chronic nerve pain along the spinal column. The procedure has been approved by the FDA and has medical-grade standards, allowing it to treat patients suffering from chronic pain effectively. Our design uses polyphenylsulfone (PPSU) as the hub material, which is the primary change made compared to Abbott's current design. The PPSU material we are using has an ISO 10993 biocompatibility rating, meaning that it is safe to use in the medical field and allows us to use it in our selected concept. Selecting a biocompatible

material replacement for the hub is essential for assuring that public health, safety, and welfare are positively affected by our design. On a global, cultural, and social level, increasing the reusability of the electrodes while also keeping the cost down will increase patient access to the procedure. Considering economic and environmental impacts, our design will lower the cost passed down to the consumer while also reducing on how often consumers must restock units, depending on supply. In turn, this will decrease the need to ship new units cross-country and will positively impact the environment.