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Summer 2014 Experience at Ethicon Endo-Surgery (Johnson & Johnson)

My hometown is Las Cruces, New Mexico, and I have always pictured myself as an Aggie. I chose to join the New Mexico State chemical engineering program after former CHME undergraduates (now alumni) visited my high school chemistry class. It was clear that these students had camaraderie amongst each other. An aptitude for mathematics and enthusiasm for chemistry also contributed to my decision in joining NMSU chemical engineering. I have most recently completed heat and mass transfer (CH E 306) during the fall semester of 2013 before accepting the Sterilization Engineer Coop position at Ethicon Endo-Surgery in Albuquerque, New Mexico.

The cooperative education experience at Ethicon Endo-Surgery in Albuquerque, New Mexico is quickly coming to a conclusion. (The final day of employment is August 8th, 2014.) The Sterilization Engineer Coop position has provided an invaluable understanding of both how engineering processes function, as well as how one's quality of work can affect society; Ethicon Endo-Surgery's top priority is its patients and their families who are impacted by surgical procedures. The sterilization facilitator and sterilization scientists assigned a variety of projects and tasks over the course of the coop. The department's objectives were to allow cooperative education students to gain insight on engineering and scientific operations in an industrial setting. These objectives have been met through successful completion of the following: a capacity report that details the amount of run time and downtime of two cobalt-

60 irradiators; the implementation of an industrial labeling application for alanine dosimeters; collaboration with a sterilization scientist to ensure sterility of various endoscopic surgical products; assistance in calibrating a new weigh scale; communication with a project engineer from DePuy Synthes (located in Monument, Colorado) and a production engineer from Ethicon Juarez; evaluation of various ISO standards to ensure the sterilization associates and technicians are properly trained.

A weekly capacity report was generated in order to quantify product volume and illustrate the amount of time the cobalt irradiators processed Ethicon products. This was accomplished by analyzing routine reports that include dosage classification (timer settings) and number of totes processed. Timer settings are broken down into dose classes using the NATO phonetic alphabet (i.e. alpha, bravo, charlie). Given the dose classes, the number of totes processed per hour, and the number of hours per week, the weekly run time and downtime can be determined. This allows Sterilization Sciences to determine if a larger overall volume of product can be irradiated, and allows management to make decisions on how to appropriate funds, as cobalt-60 is replaced annually at a steep price. Sterilization technicians currently update the capacity reports on a weekly basis.

As mentioned above, the cobalt-60 source is replenished annually. One of the two irradiators receives new cobalt every two years so that production on the other machine will not be brought to a halt. The resourcing of cobalt requires that test protocols be performed. This is to ensure that the cobalt-60 decay is providing consistent ionizing radiation. Phantom materials, which simulate various densities, were utilized in the resourcing procedures. In order

to quantify the amount of radiation received at a particular location within a tote, alanine dosimeters were placed at predetermined areas within the totes. I was given the task of labeling approximately 1200 dosimeters using a label application called LabelRight. Communication with the sterilization technicians was essential, as they knew how the labels would best fit without being disturbed in the irradiator cell. Labeling and organizing dosimeters was tedious, but the resourcing activities proved to be successful, as gamma radiation to the phantom material was uniform; the data analysis validated this, as there were no coefficients of variance greater than 2%.

Audits, both periodic and unexpected, from organizations such as the United States Food and Drug Administration (FDA) and the Nuclear Regulatory Commission (NRC), prompt all associates to have accurate and up-to-date documentation. One form of such documentation includes dose class memos. These provide information on various products (density, product code) and serve as verification as to which dose class is necessary for a particular product or instrument. I was given the task of confirming the appropriate dose class for individual product codes. Effective communication between a sterilization scientist and myself resulted in organizing numerous dose class memos and meeting an important deadline that included the memos.

A countless number of special request materials and research products come to the Albuquerque plant from Cincinnati, Ohio or Somerville, New Jersey to receive a special amount of radiation. These products are not assigned a specific dose class, but are rather fit into one based on its density. The Sterilization department determined that a new weigh scale would be

necessary for such processes. Many individuals are responsible for the successful implementation of the weigh scale: the calibration specialist, the environmental health and safety expert (EH&S), the facility engineer, and the head of facility resources. The calibration specialist and I discussed what the proper parameters for the scale was, resulting in a plus/minus value that is acceptable for the weigh scale, as well as a value that determines when the equipment is out of tolerance. The EH&S expert reviewed and approved the safety changes that result from implementing the weigh scale. The head of facility resources, facility engineer, and myself discussed how to best fit a table in the sterilization department on which the table was to be placed. The table was also modified so that it did not pose a safety threat by protruding out into a walking area. Numerous steps were taken to ensure that the scale was properly calibrated and that it was safe for all associates within the facility. Overall, the scale implementation was successful.

Communication between engineers from other plants that work with Ethicon Endo-Surgery and myself took place during the summer term. Email, telecom, instant messaging, and direct phone calls were the means by which communication took place. I spoke with a project engineer from DePuy Synthes about variable density products- Synthes had pushed back their schedule and sent the products to a plant in California in order to be validated. Ethicon in Albuquerque will then receive the products in late September/October. While dose mapping did not occur, I did manage to receive sample shippers and devise a potential tote configuration. This will hopefully eliminate that step of the sterilization process and allow processing to occur much quicker.

I also communicated with a production engineer from Ethicon Juarez regarding the draft of a training procedure (TR) I had composed during the spring term. The document's purpose is to determine a controlled manufacturing environment's (CME) bioburden limits. Bioburden are the microorganisms present on the surgical devices. Sources of microorganisms vary, but the most common are found from human skin (Staphylococcus epidermidis). Ethicon is seeking to have all bioburden calculations in Minitab by 2015 so that the Albuquerque and Juarez plants use the same application.

The most recent assignment has been reading and transferring various ISO standards into Microsoft Word documents for gap assessments. A gap assessment is an analysis of what an associate may or may not know- in this case they were radiation dosimetry standards. ISO/ASTM standards 51400:2003(E) "Standard Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory", 51261:2013(E) "Standard Practice for Calibration of Routine Dosimetry Systems for Radiation Processing", 51607:2013(E) "Standard Practice for Use of an Alanine-EPR Dosimetry System", and 51707:2005(E) "Guide for estimating uncertainties in dosimetry for radiation processing" were evaluated and placed into gap assessments. Completion of the gap assessments will ensure that associates utilizing dosimeters or practicing dose mapping will be properly trained.

Workplace safety is a top priority at Ethicon Endo-Surgery, as all machines, desks, tables, and workstations have specific tape on the floor with labels indicating where each item belongs. All associates are required to wear steel-toed shoes wherever there are large objects being moved; safety glasses are required upon entering the controlled manufacturing

environment, as mechanical and electrical parts are constantly in operation. Safety was observed everyday: I have multiple pairs of glasses, all objects conform to labeling procedures, and steel-toed shoes are worn every day.

Communication skills have proven to be crucial to this job, as there are a plethora of associates who are knowledgeable in one area or another. Effective communication is necessary for accomplishing any task. The means of communication varied from speaking directly, phone calls, telecom calls, email, written notes, and instant messaging (which featured a useful screen sharing feature). Clearly, an engineer must be able to work with others and convey his or her ideas in a manner in which others can understand. While scientific and engineering principles are the building blocks of the industry, being an effective communicator is the most important part of being an engineer, as thoughts and ideas must be able to come to fruition.