Environmental Controls

The Context
Device manufacturers, as part of production and process controls, §820.70(c), identify environmental conditions that could have an effect of product quality. For these conditions, the manufacturer establishes and maintains procedures to control the conditions. The term establish means to define, document, and implement. In this case, the company should determine any environmental conditions (particles, temperature, humidity, static electricity, *etc*.), define how to control them, document the method, and follow the procedure.

The Warning Letter
FDA sent this February 15, 2012 Warning Letter to Grantech Co., Ltd., a manufacturer digital and infrared thermometers located in Baoan District, Shenzhen, China. The Warning Letter was the result of an FDA inspection.

The Issue Cited
The Warning Letter included a citation related to electrostatic discharge control in which FDA says, "For example, your firm's Electrostatic Discharge (ESD) procedure … indicates that workers should wear ESD wristbands and self-test. However, during the inspection, multiple employees, including managers, at your firm were observed to be touching, holding, and repairing … in-process and reworked printed circuit boards and other electronic parts during thermometer assembly without using ESD wristbands or other means of proper ESD control. Also, those employees that were observed wearing ESD wristbands did not have the wristbands connected to the grounding rod."

The firm responded and FDA said, "We reviewed your firm's response and conclude that it is not adequate. Your firm indicated in its response that it promised to correct this observation and it provided a timeline for correction. However, in the response to this observation, your firm did not include any evidence to indicate that it has developed a corrective action plan, implemented a corrective action, and considered a systemic corrective action."

This is a situation where the firm documented the requirements in a procedure, but didn't implement it. It is particularly interesting that managers, who should set an example, were part of the problem.

The Requirement
The Quality System Regulation, in §820.70(c), requires, "Where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. Environmental control system(s) shall be periodically inspected to verify that the system, including necessary equipment, is adequate and functioning properly. These activities shall be documented and reviewed."

ISO 13485:2003 has similar requirements in Clause 6.4.b:

> If work environment conditions can have an adverse effect on product quality, the organization shall establish documented requirements for the work environment

conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1).

Note: Clause 7.5.1.2.1 provides an exception if the product is cleaned prior to sterilization or use or if the product is supplied non-sterile and cleaned prior to sterilization or use.

In ISO 13485:2016, the requirement, in Clause 6.4.1, says:

If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment.

Recommendations

During Design Transfer, identify and document any environmental conditions in the production process that could affect product quality. Possible conditions include Air pressure, Airborne contamination, Filtration, Humidity, Lighting, Microbial contamination, Pest Control, Static electricity, Temperature, Ventilation, and Water.

If a condition doesn't apply, explain the reason. If it does apply, then establish a procedure. Include your evaluation in the Design History File.

Establish the procedure, put it under document control, and add it to the Device Master Record, §820.181(b).

Identify the people who need to follow the procedure, train them, and create training records.

Include each environmental control in the internal quality audit program.