Equipment Maintenance

The Context
Device manufacturers must maintain production equipment to ensure the equipment is capable of meeting manufacturing specifications. The manufacturer produces a maintenance schedule and inspects the maintenance records to ensure schedule adherence.

The Warning Letter
FDA sent an April 13, 2015 Warning Letter to New King May King Plastic, Ltd. A massager manufacturer located in Shenzhen, Guangdong, China. The Warning Letter resulted from an FDA inspection.

The Issue Cited
The Warning Letter included a citation for failure to follow the company's maintenance schedule for some production equipment.

The Warning Letter says, "Your firm's 'Machine, Equipment Maintenance, and Repair Procedure' requires that machinery and equipment must be inspected and maintained daily by the operator. However, the review of the 2013 and 2014 daily maintenance records for [redacted] used in manufacturing the Verseo Wrap-A-Leg Air Massager revealed that your firm did not perform the daily maintenance activities for approximately 140 days in 2014, and approximately 215 days in 2013".

The company responded to the 483, but FDA didn't evaluate the response because the company did not provide an English translation.

The Requirements
§820.70(g)(1) requires, "Each manufacturer shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented."

§820.70(g)(2) requires, "Each manufacturer shall conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules. The inspections, including the date and individual(s) conducting the inspections, shall be documented."

Recommendations
Consider the QSR requirements as a set of steps to implement.

- Identify the equipment that needs maintenance
- Determine the maintenance activities and how often they should be conducted
- Establish and maintain a maintenance schedule
- Develop a form for the maintenance record including what was done, who did it, and when
- Develop a program to inspect the records to verify the maintenance

- Develop a form for the inspection including who did it and when

Because this firm didn't conduct the inspection, they were, presumably, surprised that the employees were not performing the required daily maintenance. Under the (generous) assumption that plant runs 365 days a year, the 2013 nonconformance rate was 58.9% and dropped to 38.4% in 2014. FDA did not give them credit for the improvement!

Avoid the Problem

Upon reading this, walk out to the production floor and pick 10 pieces of production equipment. Be sure you include smaller, less obvious pieces because that is where you are more likely to find problems.

Ask the following questions for each of the 10 pieces:

Where is the maintenance scheduled maintained?

Go see it.

Where are the maintenance records maintained?

Review (correctness and completeness) the 7 most recent maintenance records for each of the 10 pieces of equipment

Who is responsible for inspecting the maintenance records?

Get the name of each responsible person

How frequently should the responsible person inspect the maintenance records?

Identify the procedure or work instruction with the requirement

Where are the inspection records maintained?

Go see them

Review (correctness and completeness) the 3 most recent inspection records for each of the 10 pieces of equipment